

# How to Improve Patient Safety

in

## Intensive Care Units

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MASTER'S THESIS

Department of Health Management and Health Economics

Institute of Health and Community

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# Thou shalt not kill.

The sixth commandment

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Improving Patient Safety in Norwegian Intensive Care Units

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## Acknowledgment

The work behind this thesis began already in 2006 when I became interested in the correlation between evidence-based medicine and occurrence of medical errors. In August 2009 I became a student at the “Experience-based Master’s Degree Program in Health Administration” at the Department of Health Management and Health Economics, and already then I knew that my Master thesis would deal with evidence-based medicine, medical errors, quality, and patient safety. However, this thesis has never been completed without input and inspiration from the fruitful curriculum of the department. I would like to thank the leadership of the department and specially Professor Ole Berg, the Norwegian great personality in health administration and management. He generously provided us with the historical background of the medical profession which is quite necessary to comprehend the healthcare in our modern time. I would also like to thank Geir Bukholm (responsible for the Community Medicine part of the program) and his invited lecturers namely Liv H. Rygh, Jon Helgeland, Unni Krogstad, Øystein Flesland, Marianne Tinnå, Signe Flottorp and Øyvind Bjertnes, all employed at the Norwegian Knowledge Centre for the Health Services. The Centre is organized under the Norwegian Directorate of Health but is scientifically and professionally independent and lacks any authority to develop health policy or responsibility to implement policies (<http://www.kunnskapssenteret.no>). My cordially thank goes to Professor John-Arne Røttingen, my supervisor and the Director of Norwegian Knowledge Centre for the Health Services. I was lucky enough and had the privilege of obtaining his comments and using his great knowledge in quality and patient safety. Additionally, he generously gave me the opportunity to co-operate with the Center’s dedicated co-workers in connection with designing and performing the survey performed for this thesis. In this regard I would like to thank Øyvind Bjertnes once again this time for his contribution in designing the questionnaire and Kristin Skutle for her outstanding technical assistance and contribution in performing the survey. It is not an exaggeration that without Norwegian Knowledge Centre for the Health Services and its Director, this thesis would never have become a reality.

Albert Castellheim

## Preface

The general aim of this thesis is to promote the patient safety issue to become a major issue in the Norwegian healthcare system. The rationale behind this is the fact that patient safety has become the most dominating healthcare issue in western countries during the last decade. In the following I will present some pieces of information to make the reading more comprehensive and rewarding for the reader.

The starting point has been trying to understand and explain the processes in the present time healthcare system, like patient safety, on the basis of the historical knowledge from the past. This historical journey begins with Hippocrates, goes through western countries' industrialization, and ends up in our modern time where quality and patient safety has become central system issues. The healthcare quality and patient safety has been discussed from two different perspectives, first a general healthcare perspective and then from a more specific intensive care unit perspective. However, there are occasions where general quality and patient safety discussions do not proceed to their corresponding specific intensive care unit (ICU) discussions.

My first intention throughout the text has been to encourage the reader to compare the patient safety condition in other western countries with that in our country by presenting the facts as the most substantial platform of comparison. My second intention has been trying to stimulate the reader to critically compare the safety issues and how they are handled in other high risk industries with those in healthcare.

The structure of the text is not organized according to only strict boundaries between the concepts, meaning that the same concept may be discussed in different settings with different approaches like "audit" or "evidence-based medicine". In fact, there is a narrative sense of "telling the history", which is thought to make the text more vivid and dynamic and give a broad and holistic view of the concept to the reader.

Regarding the references, as a general rule the reference number has been put directly after the corresponding sentence or paragraph. Furthermore, web references are also treated in this manner consistently, but the difference is that instead of reference number the whole web address is presented. However, besides the general rule of putting the reference number



immediately after the sentences or paragraphs, when appropriate and in some short sections, the reference numbers are collectively placed at the end of the section. The first reason for doing this is to try to offer a continuous text, which is not interrupted repeatedly by reference numbers. The second reason was the wish to create a floating, dynamic, and harmonic text by combining the different concepts presented in the different original references in the same place. However, where the content of the text is crucial (like in “Résumé”) the reference numbers are currently and frequently placed immediately after the corresponding sentences.

Direct citations have been presented in italic and marked with quoting signs. Those direct citations with a longer length have been presented in appendices at the end of the thesis.

At the end I hope the reader finds the reading of this piece of work enjoyable and she/he is inspired by the thoughts presented in it.

## Summary

There is a need for us, Norwegian physicians, to develop our patient safety knowledge, attitude, and practice. The components of this should include the notions that errors are common and many of them are preventable. Moreover, simple techniques can imply substantial impact on preventing errors or reducing their effects. We need a strong leadership directed towards patient safety, and we need to be convinced that our leaders and employers support us in our efforts to improve patient safety.

Norwegian Medical Association stated in December 2006 that the work of patient safety is still in its starting phase in Norwegian healthcare system and included five suggestions for promoting patient safety. These suggestions are in accordance with the results of the extensive literature survey performed in this thesis. The suggestions were constructed by "cooperation, culture, professionalism, regulations, and technology". Co-operation between the medical profession, governmental authorities, and the public is of vital importance to achieve a high quality patient safety policy and practice. Without cooperation it is impossible to promote the culture of patient safety and professionalism. Continuous medical education and continuous professional development are cornerstones of professionalism that should be improved along with a well-defined adherent financing system. Regarding regulations we should take into consideration the experiences from other comparable countries and be open-minded to them. These experiences may include the Danish hospital accreditation program and the program of individual practitioner revalidation in the United Kingdom, both aiming for system changes for promoting patient safety.

In connection with this thesis, we performed a limited survey of perceived concepts of patient safety among the physician-leaders of ICUs in the Norwegian university hospitals as well as those Norwegian physicians who are the members of European Society of Intensive Care Medicine. This survey illustrated that the great majority of physicians believe that it is necessary to improve patient safety in the ICUs. This is also in accordance with the statement from Norwegian Medical Association in 2006: "*there is a lack of systems for nationwide dissemination and implementation of the achieved experiences and knowledge*".

It seems that promoting patient safety is primarily a question of culture and attitudes. It remains to see whether a change of attitudes and culture can be achieved without going through regulations.

# 1. Introduction

Every day there are many patients who are harmed or even die because of medical errors. In the Declaration of Vienna (a statement from European Society of Intensive Care Medicine 2009) it was stated that a significant number of dangerous human errors occur in intensive care units (ICUs). The costs of errors are high, both in terms of human suffering and in economic terms. Patient safety is a vast field of knowledge aiming to prevent errors and harm to the patients. Patient safety is a key indicator of the healthcare quality. Both healthcare organizations and the individual physicians have a responsibility in patient safety and healthcare quality. It has been estimated that one in ten patients in the hospitals in the United Kingdom (UK) experiences an incident which increases the risk of harm which can even lead to death (reference). Half of these incidents are preventable. It is known that system failure explains the majority of these incidents, but there are still concerns about the competence of the physicians.

This thesis will discuss the relative roles of the systems and the practitioners in patient safety and quality of care. Among all the practitioners in healthcare, the focus of this thesis will be on physicians. The role of physicians will be discussed in a historical perspective and especially with respect to the phenomenon called industrialization of medicine. Fast and huge developments of science and technology and consequently the considerable increase in medical knowledge are regarded as the causes of the industrialization of medicine which has changed the way of practicing medicine in many medical domains. With respect to medical specialties the emphasis will be on critical care and intensive care medicine. The role of essential factors influencing patient safety and healthcare quality like the culture of healthcare units including intensive care units (ICUs), financing systems, and leadership will be analyzed. Later, different improvement approaches will be described and finally a survey on patient safety and continuous medical education (CME) will be presented and discussed.

## 2. Medical profession

### History

It is necessary to understand the current culture of medical profession when approaching the issue of patient safety. The history of medical profession, as a profession, constitutes the solid base of its current culture. In this section we shortly discuss the contribution of Hippocrates and his strong influence in building the medical profession.

Hippocrates (460-377 BC) is considered to be the father of the medical profession. He was born on the island of Cos and died at an old age in Larissa. He lived in the 5th century BC, the "golden era" of Greek history and created a famous medical school on Cos around 430 BC. Hippocrates regarded the patient as a whole and promoted a holistic approach in medical science. He proposed a detailed history taking from the patient, evaluation of the symptoms, and performing a meticulous clinical examination by inspection, auscultation, and palpation. He believed the physician's role lies in helping the therapeutic power of nature, which gradually results in the patient's health. Hippocrates took into consideration the existing knowledge of medicine and changed the course of medical practice. He supported the idea that medical treatment must depend on clinical observation and experimentation, and separated medicine from philosophical speculations, superstitions, magic, and religion. He set the grounds for medicine to develop as a systematic science. Hippocrates was deeply concerned about medical ethics and believed that in order to cure a patient the doctor should know him well. The Hippocratic Oath which includes the codes of medical conduct and attitude, has served as a very solid platform of medical profession during the centuries (1).

### Hippocratic Oath

The original version of the Hippocratic Oath translated by J Chadwick and WN Mann in 1950 is as follow:

*"I swear by Apollo the healer, by Aesculapius, by Health and all the powers of healing, and call to witness all the gods and goddesses that I may keep this Oath and Promise to the best of my ability and judgment.*

*I will pay the same respect to my master in the Science as to my parents and share my life with him and pay all my debts to him. I will regard his sons as my brothers and teach them the Science, if they desire to learn it, without fee or contract. I will hand on precepts, lectures and all other learning to my sons, to those of my master and to those pupils duly apprenticed and sworn, and to none other.*

*I will use my power to help the sick to the best of my ability and judgment; I will abstain from harming or wronging any man by it.*

*I will not give a fatal draught to anyone if I am asked, nor will I suggest any such thing. Neither will I give a woman means to procure an abortion.*

*I will be chaste and religious in my life and in my practice.*

*I will not cut, even for the stone, but I will leave such procedures to the practitioners of that craft.*

*Whenever I go into a house, I will go to help the sick and never with the intention of doing harm or injury. I will not abuse my position to indulge in sexual contacts with the bodies of women or of men, whether they be freemen or slaves.*

*Whatever I see or hear, professionally or privately, which ought not to be divulged, I will keep secret and tell no one.*

*If, therefore, I observe this Oath and do not violate it, may I prosper both in my life and in my profession, earning good repute among all men for my time. If I transgress and forswear this oath, may my lot be otherwise.”*

The importance of the Oath was twofold; firstly it constituted a strong profession of the followers of Asclepius, and secondly this profession for the first time in the history was completely dedicated to life and aiming only to cure under all circumstances. The Hippocratic Oath became the essence of all ethical codes and medical professional standards for all years to come (<http://www.bbc.co.uk/dna/h2g2/A1103798>).

Classically, there were only three professions: divinity, medicine, and law. Professional autonomy, which is a quite central concept in professions, includes independency and self-regulation “without undue outside influence”.

## Declaration of Madrid

World Medical Association (WMA) is considered to be the body of the medical profession in the present time. As the global professional body WMA regulates and coordinates the ethical and practical codes of the medical profession in our modern society. “The declaration of Madrid”, produced by WMA, may be regarded as the modern version of the Hippocratic Oath. A survey of “Declaration of Madrid on Professionally-led Regulation”, which in October 2009 was adopted by WMA general assembly, illustrates the very components of the codes of the medical profession.

### ***“WMA Declaration of Madrid on Professionally-led Regulation:***

*The collective action by the medical profession seeking for the benefit of patients, in assuming responsibility for implementing a system of professionally-led regulation will enhance and assure the individual physician's right to treat patients without interference, based on his or her best clinical judgment. Therefore, the WMA urges the national medical associations and all physicians to take the following actions.*

- 1. Physicians have been granted by society a high degree of professional autonomy and clinical independence, whereby they are able to make recommendations based on the best interests of their patients without undue outside influence.*
- 2. As a corollary to the right of professional autonomy and clinical independence, the medical profession has a continuing responsibility to be self-regulating. Ultimate control and decision-making authority must rest with physicians, based on their specific medical training, knowledge, experience and expertise.*
- 3. Physicians in each country are urged to establish, maintain and actively participate in a legitimate system of professionally-led regulation. This dedication is to ultimately assure full clinical independence in patient care decisions.*
- 4. To avoid being influenced by the inherent potential conflicts of interest that will arise from assuming both representational and regulatory duties, National Medical Associations must do their utmost to promote and support the concept of professionally-led regulation amongst their membership and the public.*
- 5. Any system of professionally-led regulation must ensure*
  - a) the quality of the care provided to patients,*
  - b) the competence of the physician providing that care and*
  - c) the professional conduct of physician.**To ensure the patient quality continuing care, physicians must*

*participate actively in the process of Continuing Professional Development in order to update and maintain their clinical knowledge, skills and competence.*

- 6. The professional conduct of physicians must always be within the bounds of the Code of Ethics governing physicians in each country. National Medical Associations must promote professional and ethical conduct among physicians for the benefit of their patients. Ethical violations must be promptly recognized and reported. The physicians who have erred must be appropriately disciplined and where possible be rehabilitated.*
- 7. National Medical Associations are urged to assist each other in coping with new and developing problems, including potential inappropriate threats to professionally-led regulation. The ongoing exchange of information and experiences between National Medical Associations is essential for the benefit of patients.*
- 8. An effective and responsible system of professionally-led regulation by the medical profession in each country must not be self serving or internally protective of the profession, and the process must be fair, reasonable and sufficiently transparent to ensure this. National Medical Associations should assist their members in understanding that self-regulation cannot only be perceived as being protective of physicians, but must maintain the safety, support and confidence of the general public as well as the honour of the profession itself.”*



### 3. Industrialization of medicine

#### History

The industrialization of medicine in recent decades threatens the medical autonomy. Doctors' freedom to choose what they believe to be appropriate management for their patients is increasingly being modified (2). Initially, the driving forces of the industrialization of goods production were science and technology. It was in fact the new equipments that made it possible to transform from the handicraft way of producing goods to the industrial way of doing it. The same is true about the industrialization of medicine that is based on the amazing rate of increasing medical science and technological developments. The new and complicated medical equipments in hospitals need new human resources with new competencies. This process totally differs from the introduction of new technologies and new equipments into traditional industries that normally led to reduced human resources. In the hospitals there is no longer a multi-competent "craftsman" who is in charge and takes the responsibility for the results. Now there are cooperating and organizing in multi-disciplinary teams which stands for the results.

The concept of profession and professional autonomy has strong similarities with the concept of handcraft and handicraft mode of goods production. In this mode the production is done by hand and the craftsman masters the entire process of production and the end result of it. Here the craftsman's skills and individual ability are central factors in production. In contrast, the industrialized medicine is characterized by industrial mode of production that may be summarized by a division of labor between and within work processes and the automatizing of work tasks. The differences between handicraft mode of production and industrial mode of production may be summarized as follow (3) :

## The differences between handicraft and industrial mode of production:

	<i>Handicraft</i>	<i>Industrial</i>
<i>Who is the leader?</i>	<i>The most experienced craftsman</i>	<i>The leader of enterprise</i>
<i>Who owns the methods and procedures?</i>	<i>Craftsman is the owner of methods (individual ownership)</i>	<i>Enterprise owns the procedures</i>
<i>What are the characteristics for product development?</i>	<i>Integrated into the production</i>	<i>Separated as development units</i>
<i>How does the knowledge transfer?</i>	<i>Individual-based (from master to journeyman)</i>	<i>Explicitly product-based (there is a need for those who know the procedures but no need for craftsman)</i>
<i>How does the cooperation occur?</i>	<i>Inter specialty (every craftsman is specialized in his field)</i>	<i>Cross specialty (multi-disciplinary team)</i>
<i>How are the decisions made?</i>	<i>Individual (craftsman finds the solutions when the problems encounter)</i>	<i>Evidence-based</i>
<i>What defines the value of a product?</i>	<i>The procedure (the value is the way of producing the product)</i>	<i>The product itself (Mercedes Benz, Armani)</i>
<i>What characterizes the procedures?</i>	<i>Tailor-made</i>	<i>Standardized</i>

In Norway, the healthcare reform in 2002 was a clear turn towards industrial steering of hospitals. Competition and economic incentives as well as cost effective products and services have been stressed on in “New Public Management”. The industrialization of healthcare was first initiated at the end of 20th century. This process became more visible in the last decade where the roles of patients and physicians were altered. Patients gained a status more similar to customers and should no more be treated as clients or receivers of welfare, while physicians became more like suppliers and less as advisers or guardians. This alteration of roles was formalized in the law of The Rights of

Patients in 2000. Further in 2001, in The Law of Caregivers, the right of the patient as co-decision maker and controller was emphasized. Additionally, the way of financing the hospitals by the government was changed and based on “diagnosis related group” (DRG). DRG is a classification system using some 400 major diagnostic categories that assign patients into different case types. DRG is used to facilitate assessment of the resource utilization and patient case mix. It is also used to determine the hospital reimbursement (4). In this system the price is set for the product itself, similar to the industrial price setting, and not the way the product is produced which is the handicraft way of price setting. Interesting enough, in DRG-systems there is no pay for the costs of development and marketing in contrast to the industrial traditions. In health care settings this corresponds to no pay for the costs of research and teaching which exerts a negative impact on the quality of care in the long run.

## Role of experience in the industrialized medicine

Experience has been quite central in the medical profession as well as in handicraft way of goods production. In these contexts it was not a coincidence that the most experienced craftsman or physician used to also become a leader.

Practicing medicine has always consisted of two components; namely skill and knowledge. Until the amazing acceleration of science and technology, medicine was practiced mostly as an art, an experienced-based art, where skills had a quite dominant position. In a sense experience and skills also contained the knowledge of medicine. This dogma changed parallel to industrialization of medicine and the revolution of science and technology. Now practicing medicine is knowledge-based. However, the relative importance of skills and knowledge in each single domain or discipline of medicine is variable. It is obvious that skills generally still have a dominant importance in surgery-based disciplines while knowledge is of vital importance in all disciplines. A good example of this would be liver transplantation. The surgical part of transplantation needs a long surgical skill and sufficient experience to perform but the patient will not survive without knowledge of medicine to manage her/him until an organ is accessible (which may take years) as well as for instance immunological knowledge which is quite necessary for managing of patient after transplantation.

Unfortunately, experience is still regarded as the central part of practicing medicine of some physicians. This could of course be true, but for a couple of hundreds of years ago. In 2000 a Norwegian physician wrote in *The Journal of the Norwegian Medical Association*: “no one can deny the value of experience, but it has also been said that experience is the most common excuse for the lack of knowledge” (5). In 2005, the central role of experience in the medical profession was seriously challenged. In this year, a systematic review article published in *Annals of Internal Medicine* and concluded that the clinicians get worse with increasing experience (6). The authors, all from Harvard medical school, searched MEDLINE articles in English from 1966 to June 2004 as well as the reference lists of the retrieved articles. The selection criterion was articles providing empirical results about knowledge or a quality-of-care outcome with inclusion of years since graduation or physician age as explanatory variables. The studies were categorized on the basis of the nature of the association between years in practice or age and performance. 52% of the selected 62 articles reported decreasing performance with increasing years in practice for all outcomes assessed, 21% reported decreasing performance with increasing experience for some outcomes but no association for others, 3% reported that performance initially increased with increasing experience, peaked, and then decreased, 21% reported no association, 2% reported increasing performance with increasing years in practice for some outcomes but no association for others; and 2% reported increasing performance with increasing years in practice for all outcomes. The limitation of study, as the authors themselves admitted, was the lack of reliable search terms for physician experience and therefore important reports may have been missed. The authors concluded that *“physicians who have been in practice longer may be at risk for providing lower-quality care. Therefore, this subgroup of physicians may need quality improvement interventions”* (6). “American College of Physicians” and “American Board of Internal Medicine”, two prestigious medical organizations, commented the paper as follows: *“The profession cannot ignore this striking finding and its implications: Practice does not make perfect, but it must be accompanied by ongoing active effort to maintain competence and quality of care”*. This was a milestone in the history of the medical profession; the fact that experience alone may be dangerous.

## Quality in production industries as a consequence of industrialization

In the beginning of the twentieth century the need for a rational working organization in the industrial world was urgent. To meet this need Fredrick Taylor, an American engineer, established the “scientific management theory”. He believed that substitution of “rule-of-thumb” with scientific methods would result in enormous gains in the production of goods. The three most important characteristics of Taylor’s scientific management theory were: the breakdown of the process of work into small moments, the separation of work planning and work performing, and the central inspection and control (7). Taylor’s contribution is the introduction of a systematic and scientific management method; however he is also criticized for the removal of creativity in the work process. Regarding the element of central inspection and control in Taylor’s theory, the large volume of production during 1930s made it impossible to inspect every single product and explain the reasons behind the production of defect products.

During the same period Shewart and his colleagues in the Bell’s laboratories were developing statistical methods for sample control and finding the cause of errors. Their work resulted in development of standards (7). Then until the Second World War the use of statistical methods, establishment of the quality standards, and the internal inspection and control (self-control) were routine. After the war and until 1980s, focus on the production line, quality as the quality of goods, quality as a field for experts, and process steering where dominating quality trends. During 1970s Japan gained exceeding amount of the production market. The Japanese explained their success as a consequence of applying the theories of *Total Quality Control* and *Total Quality Management*. During the 1980s *Total Quality Management* was recognized in the West and was described as user-orientation, process orientation, having focus on the multi-disciplinary form of organizing work, holistic approach, and continuous improvement. In 1990s the theory of *Continuous Quality Improvement* became appreciated as well as process management, and “Plan, Do, Study, Act” (7).

In industry, there have been defined three levels of quality: *conformance quality* which refers to being guided by predetermined standards and specifications, *requirements quality* which refers to meeting total customer requirements, and *quality of kind* which refers to an extraordinary quality that delights the customers by exceeding their expectations. *Conformance quality* is the easiest level to achieve and *quality of kind* the most difficult level. Quality assurance in healthcare (explained later on in this paper) is similar to conformance quality (8).

#### **4. Intensive care medicine and ICU characteristics**

ICU is a clinical micro-system and share similarities with other clinical frontline micro-systems in healthcare organizations. Clinical micro-systems are living and complex systems that have some structures, some patterns of relationships, and some processes to create work and output (9). There are some dissimilarities but many similarities between the industrial mode of production of goods and the mode of work in intensive care units. Dissimilarities are in many cases about the exact description and performing of the work process in industrial production and the existing plans for adverse events. One important similarity is the complexity of work, which necessitates multi-disciplinary way of work organization, cross specialty cooperation, evidence based decision-making and the use of standardized procedures to avoid variability. Intensive care medicine (ICM) or critical care medicine (CCM) is usually defined as the crossroads between science, advanced technology, practical medicine and ethics. The first function of ICM is taking care of acutely ill patients who have life-threatening and potentially reversible organs dysfunction. The second function of ICM is providing intensive monitoring and organ support for elective patients who undergo complex interventional procedures and are at the risk of developing organ dysfunction. ICM is by nature multispecialty and multidisciplinary. Multispecialty in the sense that multiple medical specialties are involved in their specialty's critically ill patients (medicine, surgery, neurosurgery, pediatrics) and multidisciplinary in the sense that multiple categories of caregivers (critical care nurses, pharmacists, nutritionists, social workers, physical therapists -respiratory therapists in North America) are involved in caring for these patients.

ICM is practiced in an ICU, which is a specially equipped hospital ward with specially trained personnel prepared to take care of critically ill patients. The origin of ICUs may be traced back to the postoperative recovery room established in Massachusetts General Hospital in 1873. However, it was poliomyelitis epidemic and the need of long term ventilation of patients in the early 1950s that triggered the development of ICUs in both Europe and the US. The benefits of ICUs were gradually realized and resulted in increased interest in ICUs in the 1970s and early 1980s. During this period the annual usage of ICUs increased 8% in USA and nearly 5% in Canada. The ICUs in different hospitals (university hospitals, regional hospitals, and local hospitals) have different functions offering various types of services with different levels of complexity. The most complex ICUs are university hospital ICUs which should offer all required aspects of intensive care. Hospitals may organize their ICU beds as multiple units divided according to different areas of expertise and managed by a single discipline specialty (medical, surgical, neonatal, neurosurgery, burn, cardiac surgery, or trauma). However, there are good economic and operational arguments for multispecialty ICUs against single specialty ones. The number of ICU beds in a hospital usually ranges from 1 to 4 per 100 hospital beds (10). Multispecialty ICUs, especially if high dependency beds (intermediary beds) are not available in the hospital, would require more beds than single specialty ones. ICUs with less than 4 beds are considered not to be cost-effective, whereas those with 20 beds may be difficult to manage. ICU is an expensive unit in hospital and uses 8% of total hospital budget (14-20% in USA).

In the last four decades the knowledge of ICM has been developed along with the development of ICUs. Intensive care physicians must be experts on this knowledge that includes among others pathophysiology, special management techniques, professionalism, and ethics. The diagnosis and management of critically ill patients in practice is different from other patients and usually require a rapid initial assessment and rapid initiation of treatment before establishing a diagnosis. There is a need for frequent assessment of the patient since the disease process may be rapidly changing. The treatment plans often consist of therapeutic trials with predetermined treatment goals and predetermined responses to possible complications. Critical ill patients are at

higher risk of iatrogenic complications and assessment of developing or potential iatrogenic complications is an important part of the management plan. However, we have made advances to understand the nature of iatrogenic complications better and learned how to avoid them. The best example of this is probably the introduction of lung-protective mechanical ventilation.

Advances in ICM have resulted in increased survival for critically ill patients. Other medical and interventional treatment modalities (malignancies, surgical and other interventional techniques) have also developed and led to increased survival. Additionally, there is also an increasing rate of aging population in the society. These factors have accordingly changed the demographics of the ICU patient population and created new changes like sepsis and multi-organ failure. The prevalence of these serious conditions is increasing while there are only supportive therapies and no causal therapies for them.

There is always a need for improvement of performance and ICUs are no exceptions. There are several process improvement measures and organizational improvement measures, both within and outside ICUs, creating a great potential for improving patient outcomes. These improvement measures which are at least of the same importance as many novel therapeutic interventions, need to be systematically implemented to achieve their potential of improving patient safety. Some of these measures are as follow: the presence of a medical director with specialist training in intensive care medicine, continuous day and night access to intensivist physician (physician with the subspecialty of intensive care medicine or critical care medicine), daily treatment plan, protocolized delivery of mechanical ventilation, sedation protocols, and daily stop of sedation. Success in process optimization requires great leadership, communication, and organizational skills. Quality control and continuous process improvement must be integrated in the daily practice of ICU (10;11).



# 5. Quality in healthcare

## Definitions of quality

There are many proposed definitions for quality of care, and at the same time a lack of an agreed consensus on how to define it. Table 1 presents the currently used healthcare quality definitions in medical literature (12).

Table 1\*: Definitions of quality of care

<i>Author/Organization</i>	<i>Definition</i>
<i>Donabedian (1980)</i>	Quality of care is the kind of care which is expected to maximize an inclusive measure of patient welfare, after one has taken account of the balance of expected gains and losses that attend the process of care in all its parts.
<i>IOM (1990)</i>	Quality of care is the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.
<i>Department of Health (UK) (1997)</i>	Quality of care is: <ul style="list-style-type: none"><li>• doing the right things (what)</li><li>• to the right people (to whom)</li><li>• at the right time (when)</li><li>• and doing things right first time.</li></ul>
<i>Council of Europe (1998)</i>	Quality of care is the degree to which the treatment dispensed increases the patient's chances of achieving the desired results and diminishes the chances of undesirable results, having regard to the current state of knowledge.
<i>WHO (2000)</i>	Quality of care is the level of attainment of health systems' intrinsic goals for health improvement and responsiveness to legitimate expectations of the population.

*Notes:* IOM: Institute of Medicine; WHO: World Health Organization.

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The Institute of Medicine's definition from 1990 indicates that quality is measured as a scale or *degree* rather than a binary system. This definition refers to *health services* and by doing this includes all aspects of care. Further, this definition covers the notion that the desired quality outcomes should be general, despite the fact that quality may be assessed by the perspective of an *individual* or a *population*. This allows that different perspectives like those of professionals, patients, and public to be taken into consideration. This

definition also indicates that the link between quality and outcome is rarely causal (*increase the likelihood*), and that quality of care should be judged relative to *current professional knowledge* (13). In addition to Institute of Medicine, Avedis Donabedian (14) has played a substantial role in increasing awareness of healthcare quality. He comprehended healthcare quality as the product of two factors; the science and technology of healthcare, and the application of that science and technology in actual practice. He proposed that the quality in healthcare could be characterized by several attributes i.e. efficacy, effectiveness, efficiency, optimality, acceptability, legitimacy and equity.

In summer 2010, Norwegian Knowledge Centre for the Health Services published an important report entitled “Conceptual Framework for a National Healthcare Quality Indicator System in Norway - Recommendations” (15). In this report a new definition of quality in Norwegian healthcare system was suggested. The new definition is “quality means the degree to which the activities of healthcare services increase the likelihood of a desirable health-related welfare for individuals and population groups, and the services are performed in accordance with current professional knowledge” (translation by Albert Castellheim).

## Dimensions of quality

Like Donabedian, several authors and organizations have described the concept of quality, by using dimensions of quality, in an attempt to defining it. Table 2 summarizes these attempts.

Table 2\*: Dimensions of quality of care (12):

	<i>Donabedian (1988)</i>	<i>Maxwell (1992)</i>	<i>Department of Health (UK) (1997)</i>	<i>Council of Europe (1998)</i>	<i>IoM (2001)</i>	<i>JCAHO (2006)</i>
<i>Effectiveness</i>	X	X	X	X	X	X
<i>Efficiency</i>	X	X	X	X	X	X
<i>Access</i>	X	X	X	X		X
<i>Safety</i>	X			X	X	X
<i>Equity</i>	X	X	(X)		X	
<i>Appropriateness</i>	X	X		X		X
<i>Timeliness</i>			X		X	X
<i>Acceptability</i>		X		X		
<i>Responsiveness</i>		Respect Choice Information			Respect Patient- centred- ness	
<i>Satisfaction</i>			(X)	X		
<i>Health improvement</i>	X		X			
<i>Continuity</i>					X	
<i>Other</i>		Technical competence Relevance		Efficacy		Availability Prevention/ early detection

*Sources:* Donabedian 1988; Maxwell 1992; Department of Health 1997; Council of Europe 1998; IOM 2001; JCAHO 2006.

*Notes:* IOM: Institute of Medicine; JCAHO: Joint Commission on Accreditation of Healthcare Organizations.

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***Efficacy*** is the ability of the science and technology of healthcare to produce improvements in health when used under the most favorable circumstances.

***Effectiveness*** is the degree to which theoretically available improvements are in reality accomplished.

***Efficiency*** is the ability to lower the costs without decreasing available improvements.

*Optimality* is the balancing of improvements in health against the costs of such improvements.

*Acceptability* is recognition of the wishes, desires and expectations of patients and their families.

*Legitimacy* is compliance to social preferences as expressed in ethical principles, values, norms, traditions, laws, and regulations.

*Equity* is coherence with a principle that determines what is fair in the distribution of healthcare and its benefits among members of the population. Equity is different from equality. Equity is a consideration of fairness where in a given circumstance some individuals within a group with the same medical condition will receive more care based on their different and better ability to benefit the given care.

There is important to note that the definitions of some mentioned concepts like efficiency and effectiveness may vary in different knowledge fields like quality and patient safety, economics, and administration.

## Structure, process, and outcome

According to Donabedian, the overall quality in medicine comprises of three areas; structure, process, and result. The industrial nomenclatures for the same concepts are input, throughput, and output.

**Structure quality** describes the resources available. For instance in an intensive care unit (ICU) it would consist of the design of the unit, rooms, equipments, human resources like nurses and physicians, educational resources and competency, and finally organisation and management resources. Quality standards can be set by national health and regulatory authorities or intensive care societies.

**Process quality** describes all the events during the hospitalization, from admission to discharge, and includes how things are being done (processes). Effectiveness of communication, misunderstandings, omissions, timings, and the use of guidelines are important elements in process quality.

**Outcome quality** describes what the ICU has produced by using its structures and by applying its processes. Important outcome measures are the

following: mortality in the ICU, mortality at hospital discharge and at 6 or 12 months, quality of life and functional status at 6 or 12 months, severity adjusted mortality rates, ICU readmission rate, nosocomial events (nosocomial infections, accidental extubations, decubitus ulcers), number and severity of adverse events and errors, complications, and patient and family satisfaction (16).

As mentioned above communication is an important element in process quality. It has been estimated that 85% of errors across industries result from failures in communication. Impaired communication may occur between patient and healthcare professionals, between family and healthcare professionals, in the shift-to-shift report, between units in case of transfer for instance, and between members of healthcare team. There is a need for physicians to be familiar with communication skills and use them properly. Some of these skills are attentive listening, asking questions, paraphrasing, reflecting, explaining, checking understanding, summarizing, concreteness, and structuring. Unclear verbal or written communication is especially common in connection with medications (17).

## Quality assurance and monitoring clinical performance

Donabedian describes what he calls “the components of quality” and places “the care provided by physicians and other providers” at the center of the components of quality emphasizing its outstanding position in health quality. Care provided by physicians and other providers is comprised of interpersonal and technical aspects. The interpersonal aspect of care deals with patient-practitioner relationship and the technical aspect of it is focused on practitioners’ knowledge, judgment and skills. The knowledge, judgment, and skills of practitioners, and in our case physicians, is one the central themes in this paper.

Donabedian states that one may assure the quality of health (quality assurance) by monitoring clinical performance and improving it when necessary. The necessary steps in this process are as follow: determining what to monitor and priorities in monitoring, selecting approach or approaches to assessing performance, formulating criteria and standards, obtaining the necessary

information, choosing when to monitor and how to monitor, constructing a monitoring system, and bringing about behavior change (18).

## 6. Quality indicators

Quality indicators are surrogates which address the quality issues in an organization. There are different kinds of indicators for assessing different aspects of performance. For instance, indicators used in ICUs (explained in detail further on) may measure medical outcomes (like ICU mortality, hospital mortality, and 30 day mortality) or logistic outcomes (like length of stay in the ICU and length of stay in the hospital). Indicators may measure elements of process quality (like duration of ventilator weaning, off ventilator days, medical decision making, and laboratory use). Further, indicators may also measure patient and family perceived outcomes (patient satisfaction, family satisfaction, and end of life care). There are other indicators measuring among others economic outcomes, staff related issues, and managerial variables (16).

In connection with measuring and evaluating ICU performance we should address structures and processes, ICU factors as well as patient factors, and bear in mind that focusing exclusively on clinical patient-related factors is not sufficient. EURICUS-I, a large multidisciplinary and multicenter study, has shown that non-clinical factors, like organisation and management of ICU, do influence the clinical outcome of intensive care patients (19).

### Quality and safety indicators in ICUs

In this section the structure quality and safety indicators, process quality and safety indicators, and outcome quality and safety indicators in ICU will be discussed in detail.

Structural indicators of quality and safety in ICU, as mentioned above, measure aspects of material and human resources, as well as organizational and technological resources needed to produce high quality patient care. Structure quality and safety indicators may be summarized as below (20-22) :

- I. Organizational structure variable

- II. *Task variables:*
  - Availability of protocols
  - Policy to prevent medication errors
  - Policy to register outcome
- III. *Team variables:*
  - Adequacy of staffing
  - Nurse-to-patient ration
  - Availability of an intensive care practitioner 24 hours a day
  - Pharmacist presence during the ICU rounds
  - Communication or conflicts among teams members
- IV. *Institutional variables:*
  - Process for nursing staff competencies
  - Presence of period of integration of the new healthcare workers
  - Clear task identification
  - Absenteeism, importance of the personnel turn-over

The organizational structure of ICU (ICU model) is an important structure quality variable which refers to how the human resources in ICU are organized. There are three major ICU organizational models; open ICU, closed ICU, and those with intensivist co-management. Open ICU is an ICU in which patients are admitted under the care of another physician than intensivists. The intensivists are available and provide expertise via consultation. Closed ICU is an ICU in which patients admitted to the ICU are transferred to the care of an intensivist assigned to the ICU on a full-time basis. Generally, patients are accepted to the ICU only after evaluation and approval by the intensivist. ICU with intensivist co-management is an open ICU in which all patients receive mandatory consultation from an intensivist. Other physicians collaborate with intensivists in the management of all ICU patients. According the current evidence, a closed intensivist-led model is considered to provide improved outcome at reduced costs.

Process quality and safety indicators in ICU measure the care which is delivered in practice with the available resources and evidence based protocols. Process quality and safety indicators are especially important when specific interventions have been shown to be superior and improve patient care. Unfortunately, the number of supported interventions is very limited, even in case of ICU-specific conditions like sepsis and acute respiratory distress syndrome. This makes it difficult to adopt specific process quality measures as markers of quality of care. However there is strong reason to support

monitoring processes of care which have been shown to improve the performance. Process quality and safety indicators are easiest to use for encouraging change and adherence to evidence-based standards of care.

Examples on the process quality and safety indicators may be:

- I. *Mechanical ventilation*
  - Semi-recumbent position during mechanical ventilation
  - Overinflation of endotracheal balloon
- II. *Sedation*
  - Appropriate sedation
  - Screening weaning of mechanical ventilation
  - Procedure of stopping sedation
  - Daily monitoring of sedation
- III. *Medication*
  - Medication administered to wrong patients
  - Error administering anticoagulant medication
  - Error prescribing anticoagulant medication
  - Error administering vasoactive drugs
  - Error administering insulin
  - Death or serious disability associated with hypoglycaemia
- IV. *Intravenous lines*
  - Screening of removal of central venous catheter
- V. *Management*
  - Appropriate use of prophylaxis against gastro-intestinal haemorrhage in patients with mechanical ventilation
  - Appropriate use of thromboembolism prophylaxis
  - Appropriate use of early enteral nutrition
  - Early management of severe sepsis and septic shock
  - Surgical intervention in traumatic brain injury with subdural and/or epidural brain trauma
  - Monitoring of intracranial pressure in severe traumatic brain injury with pathologic CT findings
  - Delay in surgical treatment
  - Change of route of quinolones
  - Screening of MRSA on admission
  - Pain management in unsedated patients
  - Events during ICU transport
- VI. *Complications*
  - Pneumonia associated with mechanical ventilation
  - Accidental extubation
  - Accidental removal of a central venous catheter
  - Catheter-related bloodstream infections
  - Pneumothorax related to insertion of a central venous catheter



- Death or serious disability associated with intravascular air embolism
- Fall
- Death or serious disability associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood products
- Percentage of infections with resistant organisms (vancomycin-resistant *enterococci*, methicillin-resistant *staphylococcus aureus*)
- Pressure sores

Outcome indicators measure the consequences of healthcare in terms of mortality, complications and sequelae, and quality of care. Examples of outcome indicators are:

- I. ICU mortality rate
- II. Hospital mortality rate
- III. Percentage of ICU patients with ICU length of stay more than 7 days
- IV. Average ICU length of stay
- V. Mean days on mechanical ventilation
- VI. Rate of unplanned re-admissions < 72 hours
- VII. Patient/family satisfaction

Regarding outcome measures of quality we know that by definition the high quality medical care is supposed to result in improved patient outcomes. However, outcome research in critical care is challenging. One reason is that outcome variables typically relies on observational studies and may be influenced by numerous other variables like patient-based variables, disease-based variables, provider-based variables , therapy-based variables, and other variables like socioeconomic variables. Mortality or the probability of death measured at a fix point is the most common outcome variable in ICUs. Recently, there has been a focus on the effects of critical illness on long-term survival and quality of life, but there is insufficient evidence supporting the linkage of specific therapies in ICU with these outcomes. Generally there are several limitations to use outcomes to measure performance of ICU. The outcome measures are usually limited to mortality or length of stay. Risk-adjusted mortality, which is a more adequate variable, also suffers from lack of reliability and validity because of residual confounding and bias due to referral, upcoding of severity, and chance. Other outcomes like medical error rates,

nosocomial infections, patient and family satisfaction, caregiver burnout, and quality of dying are usually not measured routinely (20-22).

## 7. Human errors

### Pattern recognition, heuristics, and cognitive biases

Human error is the most common reason for crash in commercial aviation. The same appears to be true in acute care medicine. In the field of engineering human errors cannot be prevented by merely organizing the activity on the basis of mechanical know-how (skills). There is also a need for a comprehensive strategy that in engineering means teaching situational awareness, improved communication, appropriate task distribution, and optimal teamwork. In aviation these measures collectively are known as Crew Resource Management. Physicians, like engineers, need to have an approach for understanding why errors occur. This is a field that belongs to cognitive psychology. The knowledge on how we humans learn is of great importance in cognitive psychology. An important process in human learning is the concept of pattern recognition that enables us to see connections between apparently varied pieces of information. For instance we consider the diagnosis acute coronary syndrome when we meet an aged patient with chest discomfort, breathlessness, and arm pain. With increasing experience we learn to identify automatically, almost without thinking, according to pattern recognition. The drawback is that decision-making without thinking or with minimal thinking can result in errors. Pattern recognition is necessary for efficient healthcare but it requires that some pieces of information are more emphasized and some others less emphasized. Further we usually assume that the most common explanation is the correct one. This is the rule of Occam's razor that suggests that the simplest solution is usually the correct one (<http://en.wikipedia.org>: Occam's razor). Occam's razor is a rule of thumb or heuristic that refers to experience-based techniques that help in problem solving, learning and discovery.

A rule of thumb or heuristic is an educated guess, an intuitive judgment or simply common sense. Heuristics, in psychology, refer to simple and efficient rules which are either imprinted by evolution or are learned. Heuristics have

been proposed to explain problem-solving and decision-making processes for instance in case of facing complex problems or when there is incomplete information accessible. Heuristics may work sufficiently well under most circumstances, but in certain cases lead to systematic errors or cognitive biases (<http://en.wikipedia.org>: Heuristic).

Cognitive biases are developed mental behavior mechanisms. Some of cognitive biases are adaptive and have been developed to enable faster decisions when faster decisions are of greater value. Others presumably result from a lack of appropriate mental mechanisms or from the misapplication of a mechanism that is appropriate under different circumstances. A list of several cognitive biases is available on Wikipedia (<http://en.wikipedia.org>: List of cognitive biases) (23). Generally, the way humans perceive themselves and their reality is studied by cognitive and behavior sciences which focus on human decision-making, adoption or rejection of rules and guidelines, and human interaction with authorities. Cognitive psychology in contrast to psychoanalysis is based on truly scientific methods and concentrates on mental processes including how people think, perceive, remember, and learn. Cognitive psychology is interested in the ways of acquiring, storing, and processing information and researches on among others how to improve memory, how to increase decision-making accuracy, and how to structure educational activities to enhance learning. Research in cognitive psychology has shown a variety of cognitive biases that are common to all humans and many of them follow predictable and obvious patterns. Some of cognitive biases are as follow:

***Anchoring***: relying too heavily on one piece of information when making decisions

***Bandwagon effect***: doing or believing things because many other people do or believe the same things

***Confirmation bias***: ignoring the information which does not fit with the own beliefs

***Fundamental attribution error***: ascribing behavior to personality rather than social and environmental factors

***Loss aversion***: preferring avoiding losses over acquiring gains

***Omission bias***: preferring a more harmful act of omission to a potentially less harmful act of commission

**Projection:** assuming that other people think as we do

**Selective perception:** where expectations affect perception

Cognitive biases and intentional or non-intentional perception or misperception of one's cognition may be important in linking perception and practice. Then it would not be surprising that not everything that is visible will be perceived in practice and not all practice that is perceived will be truly visible (24).

## Adverse events and errors

An adverse event according to Agency for Healthcare Research and Quality (AHRQ) is *“any injury caused by medical care. Examples are pneumothorax from central venous catheter placement, anaphylaxis to penicillin, postoperative wound infection, and hospital-acquired delirium in elderly patients. Identifying something as an adverse event does not imply error, negligence, or poor quality care. It simply indicates that an undesirable clinical outcome resulted from some aspect of diagnosis or therapy, not an underlying disease process. Thus, pneumothorax from central venous catheter placement counts as an adverse event regardless of insertion technique. Similarly, postoperative wound infections count as adverse events even if the operation proceeded with optimal adherence to sterile procedures, the patient received appropriate antibiotic prophylaxis in the peri-operative setting, and so on”*.

Further, AHRQ defines error as *“an act of commission (doing something wrong) or omission (failing to do the right thing) that leads to an undesirable outcome or significant potential for such an outcome. For instance, ordering a medication for a patient with a documented allergy to that medication would be an act of commission, and failing to prescribe a low-dose unfractionated heparin as venous thromboembolism prophylaxis for a patient after hip replacement surgery would be an error of omission. Errors of omission are more difficult to recognize than errors of commission but likely represent a larger problem”*.

## Errors of omission may characterise not-adhering to clinical research results

Omission bias and the closely related status quo bias are well-described cognitive biases that result from a preference for omission (inaction) and preservation of the status quo. This preference can make decision makers to choose the risks and benefits of the status quo even when the relative risks and benefits of changing the status quo through action are objectively superior. Similarly, decision makers may inappropriately judge harms due to omission as less severe or blameable than harms that result from action. Tendencies toward omission bias may be reinforced by the clinical dictum “first do no harm,” which emphasizes risk avoidance and may serve as a justification for “doing nothing” or “holding course”. In general, critical care decisions are susceptible to the influence of omission and status quo bias (25).

Although no one would question that obvious errors of commission must be prevented whenever possible, errors of omission constitute a far greater safety risk. Errors of omission are more widespread and more difficult to identify. For example, consider the burden of illness related to central venous catheterisation. More than five million patients in the USA have central venous catheters inserted every year. About 15% of patients have complications of the procedure, some of which have the potential for serious harm. Accordingly, optimal management of the central venous catheter should be a major safety priority. Although several effective and affordable catheter strategies do exist for decreasing catheter complications, the application of these strategies is probably inadequate (26).

## 8. Patient safety

### Background

Safety refers to reduction of risk. Patient safety, as illustrated in the table 2, is a dimension of quality. According to Institute of Medicine patient safety is “*freedom from accidental injury due to medical care, or medical errors*”. Patient safety has increasingly been regarded as the key element of quality in the last two decades (12). The process began with Harvard Medical Practice study in 1991 that showed that adverse events occurred in 3.7% of hospitalizations and errors could be related to 27.6% of adverse events (27;28). In 2000 Institute of Medicine published its extremely influential study “*To err is human: building a safer health system*”(29). This study estimated that preventable medical errors are responsible for between 44 000 and 98 000 deaths annually in United States. Subsequently the English National Health Service (NHS) published its pioneering report “*An organisation with a memory*”. This report estimated that each year 85 000 patients (10% of admissions to NHS hospitals) were affected and harmed by adverse events (12). Harm is happening to one in six hospitalized patients in the developed countries, most of them preventable. The rate of harm is much higher in developing countries. In Europe 8 % to 12 % of hospitalized patients experience care-related harm or injury. Patients admitted into ICU are more at risk of harm, partly because of the illness itself and partly because of high complexity and multiple performed interventions in an ICU (30). Lack of patient safety measures make the care unsafe and produce opportunities for medical errors to occur (31).

### Vocabulary

The project “Safety Improvement for Patients in Europe” (SIMPATIE) was one the European Commission’s efforts for improvement of safety in healthcare (<http://www.simpatie.org>). It started in 2005 and was planned to run for two years. The objective of SIMPATIE was “*to establish a common European set of vocabulary, indicators, internal and external instruments for improvement of safety in healthcare*”. The project was divided into 8 “work packages” where work package 4 was “Vocabulary & Indicators”. The aim of this work package

was to formulate *“a set of definitions and a set of system and organization indicators / outcome measures related to patient safety”*. The project leaders stated *“We strongly recommend the vocabulary and vocabulary framework to be made accessible in the European countries. It should be translated into the European languages using a standardized method and adequate implementation strategies developed; health-care organizations, professional and academic bodies and educational institutions should be made aware of the existence of the vocabulary, be encouraged to use it as suggested so that the key elements can be put into everyday practice”*.

The vocabulary was constructed by 24 patient safety terms covering four domains of “detection of risks”, “analysis of risks”, “resulting actions” and “failure mode”. There is a reprint of this vocabulary in appendix 1.

The project leaders further explained that the vocabulary was neither taxonomy nor a classification of adverse events, and referred readers to World Health Organization (WHO) for such works. International Classification for Patient Safety (ICPS) (<http://www.who.int/patientsafety/taxonomy/en/>) is a part of WHO Patient Safety programs. ICPS provides a list of preferred terms and definitions for key concepts that is reprinted below. See appendix 2 for ICPS definitions. WHO explains that ICPS is not a classification but only a conceptual framework for an international classification representing a consensus of international experts on a reasonable understanding of patient safety.

## 9. Evidence-based medicine (EBM)

### What is EBM?

In November and December 1993, the “Evidence-Based Medicine Working Group” published two papers in JAMA (Journal of American Medical Association) entitled “Users’ Guides to the Medical Literature” (32;33). This was an official introduction of EBM to the public.

EBM is not a modern unique event in medical history. Many empiricist, epistemic, and scientific doctors have practiced it during the last 1000 years and managed to improve the quality of care through careful assessment of the available evidence. Rangachari in his paper from 1997 called EBM as “old French wine with a new Canadian label” (34) and illustrated Pierre Louis’ experimental approach with bloodletting in different clinical scenarios in the first half of nineteenth century as an example. The clash between the followers of Louis’ empirical approach versus the Gnostic clinicians’ approach looking to the individual and human variability has exactly been mirrored in the papers from the 1990s. Philosophically EBM is simply the extension of Newton’s and Descartes’ ideas on the importance of observation, method, order, and pattern to exclusion of individuality (2). Hence, the philosophical origins of the modern EBM extend back to the middle of 19th century Paris and earlier (35). EBM was defined by Rosenberg in 1995 as the process of systematically reviewing, appraising and using clinical research findings to aid the delivery of optimum clinical care to patients (36). In 1996 David Sackett defined EBM as:

*“Evidence based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research. By individual clinical expertise we mean the proficiency and judgment that individual clinicians acquire through clinical experience and clinical practice. Increased expertise is reflected in many ways, but especially in more effective and efficient diagnosis and in the more thoughtful identification and compassionate use of individual patients’ predicaments, rights, and preferences in making clinical decisions about their care. By best available external clinical evidence we mean*



*clinically relevant research, often from the basic sciences of medicine, but especially from patient centered clinical research into the accuracy and precision of diagnostic tests (including the clinical examination), the power of prognostic markers, and the efficacy and safety of therapeutic, rehabilitative, and preventive regimens. External clinical evidence both invalidates previously accepted diagnostic tests and treatments and replaces them with new ones that are more powerful, more accurate, more efficacious, and safer. Good doctors use both individual clinical expertise and the best available external evidence, and neither alone is enough” (35).*

The definition given by Sackett is a clinician’s definition of EBM where the elements of “conscientious, explicit and judicious” are markers of clinical expertise and “individual patient” is placed at the center. Another definition, made by Appleby, may be regarded as a manager’s definition: *“the rigorous evaluation of the effectiveness of healthcare interventions, common dissemination of the results of the evaluation and the use of the findings to influence clinical practice”*.

Some of the new trends in EBM are as follow

- The process of assessing the evidence has become more systematic and statistical and in the hands of the statisticians rather than clinicians.
- The results of the analysis are deliberately refined into clinical guidelines.
- Advances in information technology have allowed easier dissemination of the conclusions.
- The process has also looked at structural issues such as whether a higher flow of patients with a specific disease through a unit will produce better results (2).

## **Some of the shortcomings**

Some criticisms of EBM are unjust and based on misunderstanding of what it is. Examples are accusing EBM of being a “cook-book” and disregarding the “individual patient” and “clinical expertise”. However, there are other criticisms which illustrate some limitations of EBM. One such criticism is the quality of evidence. The quality of evidence in EBM may be exceptionally good, but there is also a risk of publication bias favoring interventional studies and

those studies with positive results while disfavoring studies with negative results and qualitative studies. But this limitation is not restricted to the EBM and generally all use of research results bear some degree of risk for publication bias. Another criticism is with respect to meta-analysis which is the most accepted form of summarizing studies. Meta-analysis may include and compare divergent and incompatible studies to be able to conclude in a pre-determined manner. There is no statistical way of resolving the problem of heterogeneity; hence meta-analyses should present their results with utmost carefulness. This carefulness should not be restricted to the results but should also cover the whole process of meta-analysis and generation of guidelines. The rule should be that the same studies should result in identical or very similar meta-analyses and guidelines when different panels of experts perform the process. However, guidelines are needed despite their shortcomings. They are needed because of their role in improving the quality of care. They are also needed because doctors not only may not know what is current best treatment, but may not know that they don't know (2).

## Gap between research findings and clinical practice

There is no guarantee that reliable evidence leads to better decisions. It is also difficult to evaluate the claims that EBM offers an improved method of decision making. There are many factors that influence medical decision making including knowledge and scientific evidence, personal experience, personal biases and values, economic and political considerations, and ethical principles like concern for justice. How clinicians integrate these factors into a final decision is not always clear (37). One of the most consistent findings in healthcare research is the gap between best practice, determined by scientific evidence, and the actual clinical care. Studies in united states and the Nederland suggest that at least 30%-40% of patients do not receive care according to current scientific evidence and 20%-25% of the care provided is not needed or potentially harmful to patients (38). To provide the best care, clinicians should be aware of the results of clinical research and implement them into clinical practice.

In the past decades different approaches have been used to improve clinical practice. One of these approaches has been evidence-based clinical practice

guidelines which appear to be one of the most effective tools for improving the quality of care. Evidence-based clinical practice guidelines generate concrete recommendations to help caregivers providing appropriate care, promote improvement of care processes, reduce unwanted variation, and perhaps help contain costs (39). High quality healthcare needs practice which is consistent with the best evidence (40). Already in 1993, Tony Delamothe, the deputy editor of British Medical Journal, wrote *“imagine a world where every patient received the best known treatment”* and added that *“ignorance, incompetence, poor management, and a sometimes deliberate disregard of established knowledge all get in the way of best practice”* (41). The gap between research findings and clinical practice is not a new phenomenon and has been extensively discussed in the literature. Physicians’ behaviour has been recognized as one of the key elements in sustaining this gap (42;43). Writing practice guidelines is an attempt to correct deviations from recommended medical practice, but the problem remains since the guidelines are not fully implemented (44). Expectedly, there has been a great deal of effort to understand why physicians do not follow clinical practice guidelines (45), how to disseminate evidence effectively (46), and how to change provider behaviour (47).

## Dissemination of evidence

Lack of awareness, lack of familiarity, lack of agreement, lack of self-efficacy (i.e., the belief in one’s ability to perform a behaviour), low expectancy of favourable outcomes, inertia and lack of motivation, as well as perceived external barriers beyond the control of individuals have been identified as significant barriers for physicians to adhere to guidelines. Lack of awareness, motivation, and perceived external factors have been distinguished as particularly important barriers.

How should the clinical research evidence be disseminated and how should the physicians be convinced to follow them? There are at least 6 models of evidence dissemination described below (45). It seems that no single model of dissemination of evidence is capable alone to fill the gap between evidence and clinical practice.

## Six models of evidence dissemination:

**1- Evidence speaks for itself:** It implies that evidence disseminates automatically and consequently changes the clinical practice due to its power. With a couple of exceptions, this model is unsuccessful and in fact browsing journals (with the problems of critically appraising individual trials), attending conferences, and listening to didactic lectures (traditional forms of continuing medical education) has little impact on changing practice.

**2- Evidence as a "ready-to-go" package of knowledge:** This implies packages of high quality evidence with clear and brief bottom lines like meta-analyses, systematic reviews, and practice guidelines which are developed by authoritative groups. Ready-to-go packages have caused the problem of assessing the integrity of these secondary sources of knowledge and have not gained much adherence.

**3- Evidence as an industrial object:** This industrial approach implies the whole field of educational outreach, case reviews by peers, audit and feedback, reminder systems, and clinician decision aids as well as multiple administrative tools and financial incentives. This resource consuming approach, despite important effects in some areas, did not fulfil its initial promise and only increased the proportions of patients receiving optimal care from 6% up to 13%. Additionally physicians felt a sense of loss in autonomy and decision-making.

**4- Evidence within a framework of electronic information systems:** Here computers were supposed to assist in knowledge retrieval and provide automated alerts and prompts. Artificial intelligent systems were to be constructed able to analyse, interpret, anticipate, and advise. However, there has been a great distance between the prototypes and the ordinary clinical and everyday systems. It became clear that the cognitive psychodynamics, technical reliability, and sociological impacts of human-machine interfaces were more problematic than anticipated.

**5- Evidence within a framework of social innovation:** In this model, changing clinical practice with respect to new evidence is seen as a form of social innovation.

**6- Evidence as common property in need of a common language:** Enabling and authorizing non-clinicians (e.g. patients, patient organizations, healthcare administrators and policy makers) to become more aware of and advocate for evidence-based care. Clinicians may need to leave behind their traditionally absolute management of implementing new medical discoveries and accept the

role of certain groups of non-clinicians. Adopting a more universal language of benefit and harm may promote a more common ownership of evidence (45).

## Changing practice; barriers, attitudes and invisible factors

With respect to clinicians' non-adherence to recommended guidelines, the first hindrance is the basic problems with the proposed practice changes. However there are other kinds of hindrances like the clinicians' barriers (impaired knowledge, attitudes, and skills), the invisible influences of opinion leaders, group psychology, influence of peers, social marketing, organisational characteristics, and economic factors (46) .

One may classify the influencing factors to *predisposing factors* (like knowledge and attitudes of the clinicians), *enabling factors* (like capacity and resources) and *reinforcing factors* (like opinions and behaviours of others).

Clinicians' desire to achieve recognition within a social group of like-minded people, belonging to and identifying with them, is an important determinant of clinicians' attitude. This aspect of clinicians' behaviour has been overlooked previously. The social environment of healthcare professionals is governed by norms and customs. These norms may be spoken and clear or unspoken and hidden, and may create morally desirable or undesirable behaviours. Clinician's behaviour is determined by combination of several elements like rational thoughts, profession-based and profession-determined cognition and attitude, and organisational and socio-political factors. Changing practice involves a complex social learning process. The first step of evidence implementation should perhaps be knowledge acquisition on determinants of the clinician's behaviour. The next step is recognition that barriers to guideline adherence include not only individual factors, but also social and organizational factors, each constituted by several different variables.

**Individual factors** (innovation factors [the perceived advantages of innovation in practice and its feasibility, credibility, accessibility, and attractiveness], cognitive, awareness, educational, attitudinal, motivational, and self-efficacy)

**Social factors** (social learning, social network and influence, patient influence, and leadership)

**Organisational and economic factors** (innovativeness of organisation, quality management, complexity, organisational learning, and the economics) (46).

This short description of the barriers and their dynamics that determine the implementation of evidence illustrates the complex and inter-reacting nature of them. There is a need for deeper understanding of the barriers to and incentives for achieving change to bridge the gap between scientific evidence and practice. Below it has been illustrated a typical model of change.

**Important change factors related to individual professionals:**

- **Cognitive** (mechanisms of thinking and deciding; balancing benefits and risks)
- **Educational** (individual learning needs and styles)
- **Attitudinal** (attitudes, perceived behavioural control, self-efficacy, social norms)
- **Motivational** (different motivational stages with different factors/barriers)

**Important factors related to social context:**

- **Social learning** (incentives, feedback, reinforcement, observed behaviour of role models)
- **Social network and influence** (existing values and culture of network, opinion of key people)
- **Patient influence** (perceived patient expectations and behaviour)
- **Leadership** (leadership style, type of power, commitment of leader)

**Important factors related to organisational and economic context:**

- **Innovativeness of organisation** (extent of specialisation, decentralisation, professionalization, functional differentiation)
- **Quality management** (culture, leadership, organisation of processes, customer focus)
- **Complexity** (interactions between parts of a complex system, behavioural patterns)
- **Organisational learning** (capacity and arrangements for continuous learning in organisation)
- **Economics** (reimbursement arrangements, rewards, incentives)

Healthcare professionals work in specific social, organisational, and structural settings involving different factors at different levels supporting or opposing

the change. Research has shown that failure to implement evidence involves factors at different levels including characteristics of professionals and patients, team functioning, influence of colleagues, organisation of care processes, available resources (like time and staffing), policymaking, and leadership. There are change models that focus on individual professionals and aim to make change in their behaviour. This may occur by promoting awareness of innovation, stimulating interest and involvement, creating understanding, developing insight into own routines, developing positive attitude to change, creating positive intentions and decision to change, trying out change in practice, confirming the value of change and its side effects, integrating new practice into routines, and lastly embedding new practice in organisation (48). Barriers to change need to be identified in different healthcare settings to be able to plan and apply a tailored intervention. It has been shown, for more than a decade ago, that tailored interventions can change professional practice (49).

## **10. Strategic management in quality and safety**

The last sections dealt with both “do things right” (efficiency) and “do the right things” (effectiveness). “Insert central venous catheter correctly” (according to the guidelines) is an example of “do things right” (efficiency). “Insert central venous catheters only when it is necessary” is an example of “do the right things” (effectiveness). We discussed the need of filling the gap between research and practice with respect to efficiency and effectiveness. Further, we should remember that if we do wrong things (lack of effectiveness), but perform them well (acceptable or good efficiency), we may measure our performance and easily be impressed by ourselves despite doing wrong things.

These two concepts apply not only for clinical success and in care of individual patients but also in organizational success. In fact, effectiveness and efficiency are of vital importance for strategic management, a managerial responsibility for instance at a micro-system level like ICU. Effectiveness has an external orientation and assesses if the organization is well positioned to fulfil its mission and vision. Efficiency, on the other hand, has an internal orientation and assesses the right use of capital, personnel, and other resources.

It is important to remember that if an organization is doing wrong things (lacking effectiveness), no amount of efficiency will save it from downfall. With economic pressure on healthcare organizations a great deal of emphasis has been placed on efficiency, but effectiveness is the primary and we should understand what we should be doing. Effectiveness requires learning and change but the demands of performance inhibit learning and change (4). Strategic managers should carefully balance the requirements of efficiency and performance with the necessities of effectiveness, learning, and doing the right thing.

## **11. Patient safety in ICU**

*“Making Healthcare Safer: A Critical Analysis of Patient Safety Practices”*, a large piece of patient safety work, was published in July 2001. This report that accomplished by the “Stanford University Evidence-based Practice Center” was an evidence-based review of patient safety with a special focus on hospital activities. It was a mission from Agency for Healthcare Research and Quality (AHRQ) that belongs to “U.S. Department of Health and Human Services”. In this 672 pages review “patient safety practices” is defined as “a type of process or structure whose application reduces the probability of adverse events resulting from exposure to the healthcare system across a range of diseases and procedures”. This definition was based on the concept that a system approach (process or structure) for patient safety would be a much more efficient approach than an approach focused on personnel and person penalty. In the review the authors examined the usefulness of 79 different patient safety measures and described them in 45 chapters. Each chapter contained a standardized structure with the following components: background, practice description, prevalence and severity of the target safety problem, opportunities for impact, study designs and outcomes, evidence for effectiveness of the practice, potential for harm, costs and implementation, and comment. The purpose of analyzing each of these patient safety practices was to try to answer two questions. The first question was whether evidence supports the implementation of a specific practice to improve patient safety, and the second question was whether evidence supports the need for more



research on the measure discussed. In this comprehensive review, the sections and chapters with direct relevance for intensive care units are as follow:

**Section A. Adverse Drug Events (ADEs)**

*Chapter 6. Computerized Physician Order Entry (CPOE) with Clinical Decision Support Systems (CDSSs)*

*Chapter 7. The Clinical Pharmacist's Role in Preventing Adverse Drug Events*

*Chapter 8. Computer Adverse Drug Event (ADE) Detection and Alerts*

*Chapter 9. Protocols for High-Risk Drugs: Reducing Adverse Drug Events Related to Anticoagulants*

*Chapter 10. Unit-Dose Drug Distribution Systems*

*Chapter 11. Automated Medication Dispensing Devices*

**Section B. Infection Control**

*Chapter 12. Practices to Improve Handwashing Compliance*

*Chapter 13. Impact of Barrier Precautions in Reducing the Transmission of Serious Nosocomial Infections*

*Chapter 14. Impact of Changes in Antibiotic Use Practices on Nosocomial Infections and Antimicrobial Resistance - Clostridium Difficile and Vancomycin-resistant Enterococcus (VRE)*

*Chapter 15. Prevention of Nosocomial Urinary Tract Infections*

*Chapter 16. Prevention of Intravascular Catheter-Associated Infections*

*Chapter 17. Prevention of Ventilator-Associated Pneumonia*

**Section C. Surgery, Anesthesia, and Perioperative Medicine**

*Chapter 18. Localizing Care to High-Volume Centers*

*Chapter 20. Prevention of Surgical Site Infections*

*Chapter 21. Ultrasound Guidance of Central Vein Catheterization*

*Chapter 26. Prevention of Falls in Hospitalized and Institutionalized Older People*

*Chapter 28. Prevention of Delirium in Older Hospitalized Patients*

**Section E. General Clinical Topics**

*Chapter 31. Prevention of Venous Thromboembolism*

*Chapter 32. Prevention of Contrast-Induced Nephropathy*

*Chapter 33. Nutritional Support*

*Chapter 34. Prevention of Clinically Significant Gastrointestinal Bleeding in Intensive Care Unit Patients*

*Chapter 37. Pain Management*

**Section F. Organization, Structure, and Culture**

*Chapter 38. "Closed" Intensive Care Units and Other Models of Care for Critically Ill Patients*

*Chapter 39. Nurse Staffing, Models of Care Delivery, and Interventions*

*Chapter 40. Promoting a Culture of Safety*

**Section G. Systems Issues and Human Factors**

*Chapter 41. Human Factors and Medical Devices*

*Chapter 42. Information Transfer*

*Chapter 45. Simulator-Based Training and Patient Safety*

*Chapter 46. Fatigue, Sleepiness, and Medical Errors*

**Section H. Role of the Patient**

*Chapter 48. Procedures For Obtaining Informed Consent*

*Chapter 49. Advance Planning For End-of-Life Care*

In an intensive care unit there are many factors which influence patient safety including organizational characteristics, physician staffing, nurse-staffing levels, nurse-to-patient ratio, collaboration between nurses and physicians, transmission of information between nurses, critical care pharmacists and their participation on physician rounds, inadequate empirical antimicrobial therapy, and volume of work. Other influential factors are volume/outcome and workload/infection relationships, well-being of intensive care nurses as well as human errors (50-65).

Sociedad Española de Medicina Intensiva Crítica y Unidades Coronarias (SEMISYUS) ([www.semicyuc.org](http://www.semicyuc.org)) in its publication from 2005 “Quality indicators in critically ill patients” (66) listed 120 quality indicators for intensive care units; among others “Incidence of barotrauma” (indicator number 13) and “Low tidal volume during invasive mechanical ventilation in acute lung injury (indicator number 26). Further, SEMISYUS considers the existence of basic protocols as a quality indicator (quality indicator number 117). The list of these basic protocols which should at least include evaluation, diagnosis, treatment, and healthcare circuits used are as follow:

1. Criteria for admission and discharge
2. Acute coronary syndrome
3. Management of severe arrhythmias and heart block
4. Traumatic brain injury
5. Sedation and pain management
6. Invasive and noninvasive mechanical ventilation and weaning
7. Severe sepsis and diagnosis of infections in general
8. Withholding and withdrawing life support
9. Appropriate end-of-life care
10. Use of restraints
11. Enteral and parenteral nutrition
12. Dialysis

13. Brain death
14. Acute respiratory distress syndrome
15. Life support
16. Prophylaxis against upper-gastrointestinal bleeding
17. Prophylaxis against deep vein thrombosis

The protocols generally should be updated in a period of 3 to 5 years, and those protocols belonging to the services not provided by the intensive care department should be excluded from the list above.

## **12. Demand for safer care**

There is a demand for patient safety from all stakeholders involved in patient care, i.e. governmental agencies, medical societies, physicians, patients, and healthcare payers (67-72). The Swedish Medical Association (SMA) began a patient safety project in 2008 that lasted two years and was completed at the end of 2009. Chairman of the Swedish Medical Association summarized in "Läkartidningen" (the organ of SMA) the experiences of this project in an article entitled "The work environment affects patient safety" (published in the April 13.th 2010 issue). SMA began this project with a survey on "*what is most important for a patient safe healthcare*". Over a thousand of physicians responded to the survey and the answers could be summed up in four problem areas: competency, time, personnel resources and procedures. This means that physicians pointed out continuous medical education (competency) and structural deficiencies in healthcare organizations (time, personnel resources and procedures) as problem areas. The dynamic relationship between these two factors is apparent; without competent personnel the most suitable organizational structures would be worthless, and without suitable organizational structures even most competent personnel are unable to deliver safe healthcare.

Accordingly, there are two different broad approaches in achieving safer care; the hospital and/or ward approach targeting the system (organizational structure and process), and the individual (professional) approach. Probably the combination of these approaches would be the most optimal one.

## Accreditation; a system-based approach for patient safety

**Accreditation** is a process in which certification of competency, authority, or credibility is presented. **Certification** refers to the confirmation of certain characteristics of an object, person, or organization (Wikipedia).

A common type of certification is professional certification, certifying a person being able to competently complete a job or task. This is usually performed by passing of an examination. Certification may be valid for lifetime or need to be reevaluated after a certain period of time (recertification).

The goal of certification of hospitals and/or wards is system optimization and achieving a higher level of accountability, quality, and patient safety. However, certification itself does not guarantee any quality of end products and services; it only indicates that the formalized processes are being applied. It should be remembered that patient safety in some circumstances may be deficient even in certified healthcare organizations. Further, there are some vital organization structure aspects that hardly can be subjected to an accreditation process and certified, like the way of exerting leadership. It is important to stress that principally the ultimate responsibility for patient safety lies with the leader of organization, and existence or lack of certification does not change it.

Many physicians are skeptical to the notion that accreditation processes and certification of wards and hospitals are for achieving higher levels of quality and patient safety. Research is limited and there is no compelling evidence about the effect of hospital accreditations on the level of quality of care (73). However, accreditation is gaining popularity and there is a tendency for move towards constructing evidence of its effects (74). Danish hospitals are fully engaged in implementing “The Danish Quality Model” (DDKM) by “Institute for Quality and Accreditation in Public Health” or IKAS (<http://www.ikas.dk/>). DDKM is meant to promote collaboration between sectors, create better and more coherent patient flow, prevent errors that cost (quality of) lives and resources, provide continuous quality development, involve and use the knowledge gained through research and experience, and document and highlight the quality of healthcare. DDKM is based on accreditation where a set of quality standards (“accreditation standards”) is developed. All institutions are obliged to meet these standards. Accreditation standards require that each institution has

written guidelines for a wide range of important areas for patient safety and that healthcare professionals know these guidelines and work according to them. Further, institutions should regularly follow up and perform quality control to allow professionals to learn from their mistakes and their successes (<https://www.sundhed.dk/Artikel.aspx?id=71619.1>).

### ***Service quality, audit, and transparency***

The dimensions of healthcare service quality may be summarized to the following three ones; client quality, professional quality, and management quality. Client quality is what clients and practitioners craving from the the healthcare service. Professional quality is whether the service meets the needs and performs necessary techniques and procedures. Management quality is whether resources are used in a most efficient and productive way, within limits and directives set by higher authorities.

Professional audit is one of the main approaches of improving professional quality. Audit has been defined as *“an evaluation of a person, organization, system, process, enterprise, project or product. Audits are performed to ascertain the validity and reliability of information; also to provide an assessment of a system's internal control. The goal of an audit is to express an opinion on the person / organization/system (etc) in question, under evaluation based on work done on a test basis”* (<http://en.wikipedia.org>).

There are four main types of medical audit; internal retrospective, external retrospective, concurrent active, and criterion-based audit. The terms are self-describing. Performing audit needs the establishment of structures and processes for dealing with inter-professional issues. One should select a method of audit that is suited to circumstances of a specific group of professionals. The group should be provided necessary resources for the audit to become meaningful. Management should have an interest in audit processes and outcomes and “market” the need for audit and ask different groups for proposals. Management should determine the progress targets and receive regular reports to review the cost effectiveness of chosen audit method in each professional group to ensure that the audit links with other quality initiatives are suitable (75).

Audit and transparency are two very central concepts of quality. It should be mentioned that both these concepts have been subject to criticism (76;77). The main reason for the criticisms has been the fear that audit, control, and ultimately transparency would be punched in every single aspect of the modern society, building a “big brother society”. Lastly, the method called “audit and feedback” is a means of learning (both individual learning and collective or organisational learning) and aims to improve practice (78).

## CME/CPD; an individual-based approach for patient safety

“Continuing medical education” (CME) may be defined as: *“a distinct and definable activity that supports the professional development of physicians and leads to improved patient outcomes. It encompasses all of the learning experiences that physicians engage in with the conscious intent of regularly and continually improving their performance of professional duties and responsibilities”* (79). The optimized and developed form of CME is “continuing professional development” (CPD). CPD combines the organizational and system factors with self-directed learning and personal development. It covers also other broader aspects of medicine like practice management and ethical decision-making. CPD may be considered as an umbrella for all kinds of interventions, and not just traditional conferences and mailed materials. CPD more easily includes other learning formats such as reminders, audit and feedback, academic detailing, and Web-based guidelines (80). CPD is supposed to occur as near as possible to the practice in contrast to CME which usually is associated with lecture halls and conference rooms long away from the practice. CPD uses the knowledge of how adults learn, that is teacher independent learning and learning by doing. CME may be illustrated as a three dimensional concept where “content”, “setting”, and “format” make the dimensions. Based on this concept, CPD should be regarded as an extension of these three CME dimensions, where the dimension of “content” extends from clinical (CME) to holistic (CPD), the dimension of “setting” extends from educational (CME) to practice (CPD), and the dimension of “format” which extends from lecture (CME) to practice based (CPD) (80).

With respect to CPD, there is a consensus statement entitled “CPD - Improving healthcare quality, Ensuring patient safety” from 2006. This consensus statement (<http://cpme.dyndns.org:591/Adopted/2006/CPDdeclaration.pdf>)

was the result of a European conference entitled “Continuing Professional Development (CPD) - Improving Healthcare”. The Standing Committee of European Doctors, also called Comité Permanent des Médecins Européens (CPME), which is the body of medical profession in European level, participated in this conference. Besides physicians there were also others representatives from national authorities, patients’ organizations, and EU institutions. The conference was held with the EU Presidency and the European Commission protection. The consensus statement was supported strongly by both EU Presidency and the European Commission. The two important aspects of this consensus statement were the followings. Firstly the consensus statement imprinted the concept of quality as a concept belonging to medical profession and as a component for improving healthcare and ensuring patient safety. Secondly the consensus statement initiated the opportunity for cooperation between the medical profession (CPME in this case) and the governmental authorities. The pressure of European public opinion and the public’s demand for cooperation between these two bodies, for improving quality and patient safety, had probably exerted an influential role in creation of this consensus statement. With respect to CPD, CPME, and patient safety there is another document known as “Luxembourg declaration on patient safety” from 2005. These important documents have been adopted by many national medical profession organizations or have influenced them profoundly. These two important documents are reprinted in appendices 3 and 4.

The quality of care is one of the CPME’s concerns: *“CPME aims to promote the highest standards of medical training and medical practice in order to achieve the highest quality of healthcare for all patients in Europe”*. *“To achieve its goals, CPME cooperates proactively with the Institutions of the European Union....”* (<http://www.cpme.be/index.php>). These formulations imply a feeling of democratic liberalism in contrast to for instance “WMA Declaration of Madrid” (discussed previously in this paper) with frequent use of phrases like “right to treat patients without interference”, “high degree of professional autonomy”, “clinical independence”, “legitimate system of professionally-led regulation”, “without undue outside influence” and “threats to professionally-led regulation”. It seems that there are two completely different professional identities behind these formulations where autonomy/independence is placed

opposite to cooperation, and right to treat patients without interference  
opposite to highest quality of healthcare.



Regarding CME and CPD, according to the booklet printed by Swedish Medical Association ([http://www.slf.se/upload/3128/fortbildning\\_webb.pdf](http://www.slf.se/upload/3128/fortbildning_webb.pdf)) CPME and Union Européennes des Médecins Specialists (UEMS) agree in general on the principles which should be applied to CME and CPD. They agree that CME is a fundamental right of every physician, and a responsibility of the profession to meet it and investigate the quality of it. They agree also that quality assurance of the individual physician's CME activities is best performed through a systematic documentation based on a collegial dialogue. CPME and UEMS do not accept compulsory CME points as an adequate method of identifying the physicians' competency and mean that the funding of CME should be an integral part of healthcare service costs.

Anyhow, it should be stressed that CME/CPD educational activities are prerequisites to improving quality and patient safety. They constitute a solid platform where a safer healthcare should be placed on. Hence, there is a great deal of overlapping with respect to CME/CPD educational activities and quality improvement and patient safety measures. These are comprised of mails and printed materials, lectures and conferences, incident reporting, root cause analysis, computerized physician order entry, clinical decision support systems, reminder systems, practice guidelines, critical pathways, opinion leaders, academic detailing, audit and feedback, certification and recertification, and lastly regulation and revalidation. CME/CPD educational activities and quality improvement and patient safety measures involve not only physicians but also patients and patient organizations, taxpayers, governments, payers, and other managerial organizations.

## **13. Public demand for accountability versus autonomy**

“Good Doctors, Safer Patients” was a report printed by the United Kingdom Department of Health in July 2006 (<http://www.dh.gov.uk>). The aim of the report was *“to create a new approach to promoting and assuring good medical practice and protecting patients from bad practice”*. The report that was a comprehensive survey of circumstances regarding patient safety and quality of

care in UK contained 44 detailed recommendations and proposed specific measures to protect patients from harm. A part of these recommendations are reprinted in appendix 5.

The report stressed that poor practice is a reality despite the fact that the vast majority of physicians practice a very high quality medicine. A small proportion of physicians practice at an unacceptable standard which can be due to inadequate training, insufficient support, ill health, lack of motivation, or in rare occasions malice, like the case of Harold Shipman, a general practitioner who killed about 250 of his patients during 1972 and 1998 mostly by overdose of narcotic drugs. In fact the case of Shipman that led to the Shipman inquiry and three other similar inquiries were strong reasons for work resulting to this report where the opinion of public and other stakeholders demanded a radical change. One of the suggested measures in this report was the necessity of introduction of a process of regular physician assessment. The system of medical regulation was revised in the 1970s in UK following a crisis of confidence in the General Medical Council. The new system was however, still firmly based on the principle of self-regulation. While the credibility and trustworthiness of medical self-regulation had been eroded by the above-mentioned high-profile medical scandals, the Bristol inquiry, the inquiry into the failures of the Bristol children's heart surgery service, exploded it.

## Regulation and revalidation in safety-critical industries

Regulation in medicine may be compared by regulation in other safety-critical industries like nuclear, offshore oil, and civil aviation industries that have continuously responded properly to their incidents and have built systems of quality assurance. When a physician achieves independent practice (like a consultant) there is no further formal assessment of knowledge, competence, clinical skills or performance until he or she retires while a pilot would be assessed about 100 times over the same period.

Pilots, oil installation managers, and nuclear power plant desk operators are all regulated. Practitioners are regularly assessed against demanding and objective standards and failure is greeted by corrective action, not sarcasm or guilt. Practitioners are proud of their license to practice and employers appreciate the role of regulation in the wider quality improvement agenda. The striking fact is that in other high-risk industries the burden is on the professional being

regulated (like pilots) to prove their competence. In medicine it is the responsibility of the regulator to disprove the practitioner's competence that is considered quite extraordinary by for instance pilots.

The medical regulation has traditionally been synonymous with "self-regulation". This is a typical feature of the traditional professionalism where the profession owns knowledge and skills and decides the way of providing them to the members.

## **Disintegration of pure self-regulation in UK**

In UK medicine occupied a privileged and relatively protected position until the late 1970s. There was a belief that bad doctors were few and far between, the quality of care was difficult to define and impossible to measure, and the doctor's performance was not the business of colleagues or managers. There was a culture in which information was not transparent or accessible. The scandals of 1980s and 1990s disintegrated the concept of pure self-regulation. However, the Chief Medical Officer, the writer of the report, emphasized that the concept of medical regulation should not be limited to the identification of poor practice. The regulatory system should be able to demonstrate that all practicing doctors reach specified standards, and with doing that, should be conceived as a true guardian of professionalism.

### ***The international trend in medical regulation***

The Health Foundation is an influential and "independent charitable foundation working to improve the quality of healthcare across the UK". As a positive response to the report "Good Doctors, Safer Patients" from Department of Health, The Health Foundation published the report "Professional regulation for high standards" in November 2006 (<http://www.health.org.uk>). Besides UK, the worldwide trend in medical regulation is moving from pure self-regulation to regulation in partnership between the profession and public (table 3).

### ***Linking assessment to competency***

"Good Doctors, Safer Patients" also highlighted that while there are moves towards ongoing assessment of competence, there is no model in which such assessments are explicitly and universally linked with the practitioner's ability

to practice, and subsequently medical regulators should be placed within the wider quality assurance framework. There is no systematic way in which doctors can assess the quality of their practice and identifying the opportunities to improve it, perhaps because currently used methods (in that time in the UK) like annual appraisal, CPD, and clinical audit do not adequately face the related but different tasks of assuring good practice, identifying poor practice, and acting as an instrument for quality improvement. A substantial shift in attitude will be needed to consider medical regulation as enhancing the quality of a physician's practice and the wider medical profession rather than predominantly seeking out and punishing those who perform poorly.

## Public and profession partnership in the rest of Europe

Last year Swedish Medical Association published a booklet entitled "Quality Assured Continuous Education for All Physicians" (Kvalitetssäkrad Fortbildning för Alla Läkare) ([http://www.slf.se/upload/3128/fortbildning\\_webb.pdf](http://www.slf.se/upload/3128/fortbildning_webb.pdf)). The book is in Swedish and the writer of this thesis has performed the translations.

The following statements stand at the "Summary" section of the booklet: *"Knowledge is one of the healthcare's cornerstones, where the quality of care is often settled by the treating physician's competence and skillfulness. For that reason there should be prerequisites in place for the physicians to obtain new knowledge during the whole working life and to improve patients' diagnostic and treatment together with the colleagues"*. In the same booklet there is an outline of different existing revalidation systems in European countries. This outline divides European countries in three different categories depending on their system of voluntary or compulsory participation in CME/CPD and requirement for re-certification.

- 1- The first category consists of those countries with voluntary CME/CPD, i.e. Belgium, Bulgaria, Denmark, Estonia, Finland, Greece (private physicians), Luxembourg, Iceland, Spain, Malta, Portugal, Norway (specialists), and Sweden.
- 2- The second category is consisting of those countries with compulsory participation of physicians in CME/CPD activities, i.e. Cyprus, France, Italy, Norway (general practitioners), Poland, Greece (public employees), Slovenia, Switzerland, Czech Republic, Germany (hospital physicians), Austria, and Hungary.

- 3- The third category consists of those countries with requirement of re-certifying, i.e. Netherlands, United Kingdom, Ireland, Croatia, Rumania, and Slovakia.

This outline gives a rather good overview of the revalidation processes in Europe but it is at the same time quite simplified. Other simplifications are the definitions of “Quality Improvement”, “Quality Assurance”, and “Quality Control”. In the booklet it is stated that these terms “*are used internationally to describe the process of improvement regarding the physician’s continuous education*”. These terms, in fact, stand for other concepts. It is of course quite legitimate to redefine them and use them in different contexts (like CME and CPD), but an historical introduction of the original concepts is perhaps necessary to avoid confusion. The matter of fact is that these terms have originally been used extensively in connection with the quality of care as a whole and not in the context of physician’s continuous education. As mentioned earlier, Avis Donabedian was the first person who used these terms systematically in a whole healthcare quality context.

The booklet’s definitions of these terms are:

**Quality Improvement:** “*all the continuous education that the physician participates in on the basis of his/her own need to maintain and improve his/her competence*”.

**Quality Assurance:** “*quality guarantee of the physician’s continuous education. In Sweden examples of this are systematic documentation, peer inspections, and CME-questionnaires. The aim is to create a reliable follow-up system capable of detecting deviation from continuous learning, to avoid errors, create confidence, and the control of the authorities becomes unnecessary*”.

**Quality Control:** “*authority-steered follow-up of the physician’s continuous education*”.

The incorrect definitions of these terms are a minor problem with this booklet. The major problem is that here, Swedish Medical Association, the body of medical profession in Sweden, illustrates its unwillingness to share the responsibility of continuous education with the authorities. The authorities in

democratic societies, like Sweden, should reasonably be regarded as representatives of the public, and public comprises among others of patients, patient organizations and taxpayers. The question remains if an old-fashioned concept of professional autonomy “without undue outside influence” should be regarded as an appropriate model of professional autonomy in our modern era.

But the question is what the term quality improvement really stands for? The answer is to be found in the third annual report of “The Health Foundation”. The report is entitled “An evaluation of the health Foundation’s engaging with quality initiative”

([http://www.health.org.uk/publications/evaluation\\_reports/ewi\\_3rd\\_evaluation.html](http://www.health.org.uk/publications/evaluation_reports/ewi_3rd_evaluation.html)):

*“Quality improvement involves stepping back from the immediate challenge of delivering care to reflect on the benefits of alternative ways of delivering care and, where appropriate, changing how care is delivered. It will often include an element of ‘learning by doing’ but should always involve an assessment of the resources required and the improvements in quality achieved. It is therefore not just another word for ‘doing a better job’ or ‘working harder’. It is not always (or even often) ‘whole system reform’ but it does involve improving the design of at least one part of the system through which healthcare is delivered. Illustrating the kinds of things this might involve, the scope of the Cochrane Review Group ‘Effective Practice and Organization of Care’ includes case management; revision of professional roles; use of multidisciplinary teams; and formularies and changes in medical record systems and financial interventions. We are aware that not all change is improvement. QI requires a specification of the level at which improvement is anticipated (micro, meso, and macro) and the clinical setting where it is expected to work. It requires some statement of the relationship between the proposed actions and a set of measurable changes that are of benefit to patients and/or public health. And it requires some reduction in the indicators of poor quality such as:*

- I. failure to apply scientific evidence*
- II. provision of inappropriate care*
- III. unjustified variations in practice (eg by practice, time of consultation, age, gender, and geography etc)*
- IV. avoidable patient harm.*

*To be sustainable, it also involves connecting these intended improvements in quality to the preferences and satisfaction of service users, user organizations, and political representatives to maximise the benefits of health interventions. These preferences might reasonably include not only efficacy and effectiveness but also fairness”.*

The Donabedian terms of quality control, quality assurance and quality improvement in intensive care setting may be described as follow (81):

*“Quality control involves inspecting for problems in the ICU service. For example, a statistical sample would be inspected (e.g. the last 25 patients discharged from the ICU) to determine readmissions (also called ‘feed-back control’). Such audits may be undertaken on an occasional or regular basis.*

*Quality assurance encompasses control beyond just inspection. It is a structured approach to preventing quality problems through planned and systematic activities that include: specification, review, monitoring and documentation (‘feed-forward control’). An example of Quality assurance is the regular assessment of ICU lab equipment to show suitable accuracy of the results.*

*Continuous quality improvement promotes continuous improvement through the application of group decision-making methods and statistical tools. A goal of an ICU’s quality improvement programme is to meet and exceed patient and patient family satisfaction by examining and improving systems and work processes.”*

### ***Interpretations of regulation and revalidation***

Back to the UK, according to the “Good Doctors, Safer Patients” regulation is any measure or intervention carried out by (or on behalf of) government, or some other statutory body, that seeks to change the behavior of individuals or groups.

Revalidation is defined as the evaluation of a medical practitioner’s fitness to practice. Revalidation that aims to demonstrate that the competence of doctors is acceptable is attracting increasing interest in Europe, drawing the experiences from USA, Canada, Australia and New Zealand. While accountability, minimal acceptable standards of care, and quality improvement are generally motivations for revalidation, the definitions, mechanisms, and practicing of revalidation varies significantly across member states. CME, aimed to keep the physicians up-to-date, is the most basic form of revalidation. The next step is CPD that includes CME along with the development of personal,

social, and managerial skills. More demanding methods involves peer review, external evaluation, and practice inspection (82). Austria, Germany, and Spain regard CME as a means to promote recertification and quality of care, while Belgium, France and the Netherlands also incorporate peer review. In the UK revalidation includes both re-licensure and re-certification through appraisal and feedback. There are also differences between countries regarding monitoring and enforcement. The regulators of revalidation in many countries are professional medical bodies that may be accountable to government ministries. Insurers may be regulators of revalidation and require physicians contracted with them to fulfill specific requirements. In most cases a combination of stakeholders are responsible for minimal standards and revalidation (82).

Revalidation is generally expected to be transparent and not serving to punish, with efforts focused on professional development. Belgium encourages revalidation, instead for mandating it, by rewarding participating physicians with higher wages. In France there is a legal obligation to participate in CME, but many physicians do not so, most likely because of lack of incentives (neither reward nor punishment) for compliance combined with lack of monitoring. In the UK re-licensure and re-certification (for GPs and specialists) occurs every five years and physicians who fail in either processes would spent a period of time in supervised practice. Depending on the specialty evidence to support recertification come from various sources including clinical audit, knowledge tests, patient feedback, employer appraisal, CPD, or observation of practice. Besides the UK, only Germany and Netherlands have formal revalidation systems in place. Since 2005 Dutch physicians undertake CME and undergo a visit by peers every five years. The visits involve a comprehensive assessment of the practice and adherence to clinical guidelines. The table below summarizes the characteristics of revalidation in some selected European countries (82):



**Table 3: Revalidation of the medical profession in selected European countries**

Data sourced from country questionnaire.

Country	Time frame (years)	Types of revalidation		Compulsatory	Penalty / reward	Lead regulator	Other authorities
		CME/CPD	Peer review				
Austria	3	Yes	Yes	Yes	Legal requirement	Austrian Medical Chamber (PB)	Federal Ministry of Health and Woman (G); Austrian Academy of Physicians
Belgium	3	Yes	Yes	No	Financial incentive (increased salary by about 4%)	Minister of Public Health (G) and INAMI/RIZIV (IF)	N/A
France	5	Yes	Yes (EPP)	Yes	Law suit by Regional Council of the Physicians' Order (not monitored)	National Councils for CME (PB)	Regional Councils for CME (PB); Regional Councils of the Physicians' order (PB); High Health Authority (IA)
Germany	5	Yes	Yes	Yes (GPs and specialists contracted by SHIF)	Non-compliance results in reduced reimbursement; then after two years withdraw of accreditation	Regional Chambers of Physicians (PB)	State Ministry of Health or Social Affairs (G); Regional Associations of SHIF Physicians (PB); Federal Association of SHIF-Physicians (PB)
The Netherlands	5	Yes	Yes (visitation)	Yes (specialists)	Removed from medical registrar	Central College of Specialists (PB)	Central Information Centre for Professional Practitioners in Healthcare (G)
Spain	N/A	Yes (9 of 17 regions)	N/A	No	Varies between regional commissions	Spanish Medical Association (PB)	Ministry of Health and Education(G); Medical Colleges (PB); Commission of Continuing Education of Health Professionals; Accreditation Council for CME (PB)
United Kingdom	5	Yes	Yes (360 degree feedback exercise)	Pending: GPs and specialists	Failure will result in practice supervision	Department of Health (G)	General Medical Council (PB); Royal Colleges (GPs, specialists) (PB)

CMF= Continuing Medical Education; CPD= Continuing Professional Development; EPP= Evaluation of Professional Practices; G= Government; IA; Independent Authority; IF= Insurance Fund; N/A= not applicable; NHS= National Health Service; PB= Professional body; SHIF= Social Health Insurance Fund (With permission from Royal College of Physicians, London)

## 14. Clinical governance and clinical accountability

Clinical governance is the term used by the United Kingdom's National Health Service (NHS). UK's Department of Health defines clinical governance as: *“the system through which NHS organizations are accountable for continuously*

*improving the quality of their services and safeguarding high standards of care, by creating an environment in which clinical excellence will flourish”*

([http://www.dh.gov.uk/en/Publichealth/Patientsafety/Clinicalgovernance/DH\\_114](http://www.dh.gov.uk/en/Publichealth/Patientsafety/Clinicalgovernance/DH_114)).

Clinical accountability, which is used in other healthcare jurisdictions, is similar to clinical governance (81). Clinical governance ensures that there are clear lines of accountability and that there is a comprehensive program of quality improvement systems. The six pillars of clinical governance include education and training, research and development, clinical effectiveness, openness, risk management and clinical audit

(<http://www.medicine.ox.ac.uk/bandolier/painres/download/whatis/WhatisClinGov.pdf>).

In the following there is a short explanation of these concepts:

## 1- Clinical Audit

Audit has been discussed previously in connection with accreditation. In the following section audit will be discussed as a major component in clinical governance. Clinical audit is reviewing of clinical performance, measurement of the performance against agreed standards, and finally refining of the clinical practice. Clinical audit was formally introduced into the NHS in 1993. In 1997 it was incorporated within clinical governance through the White Paper, “The New NHS, Modern, Dependable”, which combined different service improvement processes and established a coherent Clinical Governance framework.

In the paper “Principles for best practice in clinical audit”, the National Institute for Health and Clinical Excellence (NICE) defines clinical audit as: *“a quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change. Aspects of the structure, processes, and outcomes of care are selected and systematically evaluated against explicit criteria. Where indicated, changes are implemented at an individual, team, or service level and further monitoring is used to confirm improvement in healthcare delivery”*.

UK’s Department of Health describes further that: *“Clinical audit and outcomes measurements are quality improvement tools that can help to close the gap between what is known to be the best care and the care that patients are receiving. They aim to ensure that all patients receive the most effective, up*

*to date and appropriate treatments, delivered by clinicians with the right skills and experience. Clinical audit against good practice criteria or standards answers the question - are patients given the best care? Clinical outcomes measurement answers the questions - are they better, and do they feel better?"* (<http://www.rpd-research.org.uk/about.html>).

## 2- Risk management

In the healthcare setting there are risks to the patient, risks to the physicians and other practitioner, and risks to the provider organization. These risks all need to be minimized as part of any quality assurance program.

## 3- Openness

Poor performance likes closed doors. Processes which are open to open public examination are an essential part of quality assurance.

## 4- Research and development

Good professional practice has always sought to change in the light of evidence from research.

## 5- Clinical effectiveness

Clinical effectiveness is a measure of the extent to which a particular intervention works. The measure on its own is useful, but it is enhanced by considering whether the intervention is appropriate and whether it represents value for money.

## 6- Education and *training*

In the modern health service, it is no longer acceptable for any clinician to avoid from continuing education after qualification. Education and training is a pillar in clinical governance and one may use different educational techniques for modifying the behavior of physicians as we will discuss in the next section. As a fact of matter, education is key component in both quality (clinical governance and accountability) and patient safety. Swedish doctors have

considered “competency” as one of four problem areas in patient safety, and competency itself is a result of education and training.

## **15. Educational techniques for modifying the physicians’ behavior towards a higher level of patient safety**

There is publishing a great amount of medical literature each day. Many studies have shown that physicians are not able to keep themselves up-to-date all the time and memorize all the material they read. *Education programs (CMEs), practice guidelines, critical pathways, and clinical decision support systems* are the techniques offering potential solutions to this problem and aim to modify the physicians’ behavior. The methods used to implement these techniques are of key importance in their effectiveness. The most prevalent method traditionally has been use of lectures, conferences, mailings and printed materials, but other methods like *audit and feedback, academic detailing, local opinion leaders, and reminder systems* have also been used. There has also been an opinion about incorporating *sentinel incident reporting* and *root cause analysis* into the educational programs. A long tradition of evaluation of effectiveness of these methods is non-existing (21).

### **CME/CPD**

These educational programs have been described elsewhere in this thesis.

### **Practice Guidelines**

Practice guidelines are defined as “*systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical conditions*”. They are among the most widely used methods of modifying physician behavior and may affect both the process and the outcome of care (21).

### **Critical Pathways**

Critical pathways belongs to those models that streamline work and production processes. Critical pathways have been utilized extensively in several different

business sectors including the construction and automotives industries. It is theorized that the adaptation of pathways to health care, particularly inpatient care, may help ensure the delivery of quality care and decrease the occurrence of medical errors (21).

## Clinical Decision Support Systems

Clinical decision support systems (CDSS) assist the clinician in applying new information to patient care through the analysis of patient-specific clinical variables. Many of these systems are used to enhance diagnostic efforts and include computer-based programs that provide extensive differential diagnoses based on clinical information entered by the clinician (21).

## Audit and feedback

Audit, which is a central and fundamental part of NHS' clinical governance, may be applied to both institutional and individual level.

With respect to assessment of individual practitioner, and apart from clinical governance, audit, and other educational techniques, in the UK it was recently decided that physicians should be revalidated regularly. The reason was to ensure that the physicians' knowledge and skills are up-to-date. Revalidation of physicians is thought to function as a system for providing accountability, maintaining a definite level of the standards of care, and promoting improvements in healthcare quality. General Medical Council in UK (<http://www.gmc-uk.org>) underscores that "Good doctors make the care of their patients their first concern: they are competent, keep their knowledge and skills up to date, establish and maintain good relationships with patients and colleagues, are honest and trustworthy, and act with integrity".

## Academic detailing

Academic detailing or educational outreach involves a personal visit, by a trained person, to healthcare professionals in their own settings. This has also been referred to as university-based educational detailing and public interest detailing. Originally described as a multi-component process where key principles included surveys of practitioners to determine barriers to appropriate practice and the subsequent development of an intervention that was tailored

to address those barriers using simple messages; targeting of practitioners with low compliance; and the delivery of the intervention by a respected person. The intervention often included feedback on existing practice (83).

## Local opinion leaders

Social Learning Theory hypothesizes that individuals perceived as credible, likeable and trustworthy, are likely to be persuasive agents of behavioral change. Such “opinion leaders” may play a key role in assisting individuals to identify the evidence underpinning best practice and to facilitate behavior change. Opinion leaders are those perceived by their colleagues as “educationally influential” (84).

## Sentinel incident reporting

Incident reporting identifies those areas where patient safety and clinical practice can be improved and allows an open and unemotional discussion on errors. The following factors are important for a functioning incident monitoring system: anonymous self reporting, simplified documentation, obligatory participation, inclusion of events without patient damage (near miss), regular and quick evaluation, reporting of deviations to all caregivers, and linkage to management decisions (16). Errors should not only be reported but also be discussed openly and with a focus on solutions (17).

## Root Cause Analysis

This is a retrospective approach to error analysis and is widely applied to investigate major industrial accidents. Root Cause Analysis has its foundations in industrial psychology and human factors engineering. It provides a structured and process-focused framework to approach sentinel event analysis.

## Computerized physician order entry (CPOE)

CPOE is a technological system, which assists the clinician to create a legal and standardized order. CPOE can improve patient safety only with the addition of another technological system called clinical decision support system (CDSS). CDSS in their most fundamental form include basic dosing information and incompatibility guides. More sophisticated CDSS include allergy and interaction checking, duplicate therapy checking, dosing for special populations and organ

function (like pediatrics or geriatrics, renal impairment, liver disease), laboratory monitoring, disease screening (i.e.,  $\beta$ -blockers in asthmatics), and pregnancy warnings. Therefore, CPOE is an approach with a focus on education to assure a correct ordination of medications, rather than depending on a potentially tired and troubled intensive care physician. With respect to technology, ICU is a technology rich environment where there is a perception that additional technologies may enhance safety. CDSS, CPOE, bar-coded medication administration, “smart” infusion pumps and electronic health records are technologies attributed with improving safety. These technologies have been linked to reduction in errors, even though there is little evidence that they reduce harm to the patients. There is also evidence that these technologies can introduce new types of errors, violations, and harm. Generally, the way the technologies are implemented and supported, the interactions between technologies and people determines whether technologies like CPOE will improve or sometimes worsens medication safety (85;86).

### A short summary of effectiveness of these techniques

There are several Cochrane reviews in this field. A recent review illustrated that printed educational materials, when compared to no interventions, have a beneficial effect on process outcomes but not on patient outcomes (87). Another review showed that audit and feedback may help improve performance with a variable effectiveness from small to moderate (78), while local opinion leaders was evaluated to be able to successfully promote evidence-based practice (84). Educational outreach visits have been shown to have small but consistent and important effects on prescribing. Their effects on other types of professional performance vary from small to moderate (83). There has also been shown that multifaceted approaches are more effective than approaches based on single interventions (21).

## 16. Financial incentives and costs in quality and patient safety

### Cost and Quality

The concept of the omnipotence clinician who “knows best” was dominant since the time of Hippocrates until the Second World War. The challenge came from two directions; first, the notion that poor clinical outcomes might reflect faulty investigations, diagnosis or treatment (the quality), and second, the fact that some investigations and treatments are more expensive and often are used inappropriately (the cost). Regarding the quality aspect of the problem some argued that the major problem was trusting in human minds consistently.

The response to these cost and quality problems in United Kingdom was clinical audit as a peer review activity; either in local level or national level. The principles of audit is that the clinicians critically review results of their own work on a regular basis and compare those results with those of others, and if there are lessons to be learned change their practice. In the United States it was used either professional review with mandatory second opinion or professional reviewers to check that the elements of care were within predefined limits. This wave of clinical audit was failed. The problem probably was that there was a conflict between clinical audit as a tool for education and professional development and its use for monitoring performance. The principle of audit was good but the practice of it was bad (2).

The question of cost and quality is still considered to be of great importance in healthcare. There have been attempts to promote the quality of care as well as to cost control and reduction by introducing different incentives in different healthcare financial systems. It has been suggested that payment should be attached to providers' behaviour and that all types of health plans should have strong incentives to improve performance and encourage delivery system change. Performance measurement as well as quality measurement and reporting systems are prerequisites for improving performance. However, focusing on cost and quality separately may be the wrong way of solving either problem (88-94).



## Impact of financial incentives on quality improvements

We know that the use of financial incentives to influence behavior is common in all areas of commerce. There are a good amount of research on and literature about the design and impact of incentives at different levels, i.e. the principal-agent relationship in theoretical economics (examining financial incentives in contracts under different assumptions), employee compensation (compensation with different payment approaches to encourage desired behavior), or consumer responses to targeted incentive programs in marketing literature. Interest in the impact of financial incentives on provider behavior has traditionally been focused on the need to improve efficacy (in publicly funded systems) and a desire to moderate the growth in healthcare costs (in market-based systems). Recently, there has been increased interest in specific relationships between financial incentives aimed at providers and quality of care. However, the amount of research devoted to the impact of financial incentives on the quality of care is limited. The quality of care, as mentioned earlier, is defined by Institute of Medicine as "the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge".

In 2007 a comprehensive review of the literature examining the effect of financial incentives on the quality of care delivered by health care organizations and practitioners was published (Financial incentives, healthcare providers and quality improvements: A review of evidence) (95). The reviewers used an extensive infrastructure of search strategy and involved several credited organizations like Agency for Healthcare Research and Quality (AHRQ), Organization for Economic Co-operation and Development (OECD), and World Health Organization (WHO). The review illustrated that the literature on the influence of financial incentives in provider's quality of care was not fully developed. However, there could apparently be noticed an ongoing change at a relatively rapid pace.

At the same time the science of measuring quality in the healthcare is increasing and financial responsible bodies are intensifying their efforts to measure and reward quality improvement. This will probably generate a significant amount of new research that has at least two tasks; first to

document the relationships between financial incentives and adherence to best practices or changes in patient outcomes, and second contribute to a better understanding of the linkages between financial quality rewards and practitioner behavior.

The findings of “Financial incentives, healthcare providers and quality improvements: A review of evidence” can be summarized in the two sections: 1. Financial incentives directed at improving quality and 2. Secondary impacts on quality of financial incentives directed at reducing utilization and costs. These two sections are reprinted in appendix 6.

## Impact of quality improvements on cost reductions

Poor quality and adverse events are common and costly. In the UK, one in ten hospital patients suffer an adverse event (infection, adverse drug event, surgical complication, and fall) that necessitates extra treatment. Poor quality may be defined as suboptimal care in form of overuse, misuse, and underuse of tests, treatments, and services or ineffective use of them. Failure in communication, transfers, and coordination are other aspects of poor quality. Improvements and interventions, which do cost but make care better, may be defined as changes that result in a better health service for patients.

To increase quality and productivity and decrease waste, health personnel may be organized in project teams and use different methods to change their work and organization. There is strong evidence that changing providers’ behavior to use patient safety practices or validated effective treatments at clinical level will improve patient outcome. There is also evidence that some of these behavior changes save money or increase income for some providers (96). The two important areas connected to improvement are effectiveness and savings. In respect with effectiveness there is evidence for effectiveness of some interventions (like computer physician order entry or prophylaxis before surgery), but there is less evidence for effectiveness or costs of other suggested interventions.

Regarding costs, quality improvement can be costly especially where there is little infrastructure or experience to support improvement. There are also great variations in implementation of interventions. We know that provider’s quality improvement often does not lead to saving because the financial systems does not measure or reward higher quality. On the other hand and

strangely enough, providers may have financial disincentives to make improvements; firstly they bear the intervention costs, secondly they cannot get the investment finance, and thirdly they are financially rewarded for poor quality.

Briefly, improving quality sometimes saves money and sometimes does not. Savings depend on the type of improvement, the cost of it, and who pays the cost of poor quality. Due to limitation of research and lack of evidence we do not know if improving quality saves money or not in majority of cases. But we should not forget that available research, as mentioned above, illustrates that improving quality sometimes saves money, and describes when, where and why it does so. The following equation illustrates the role of different elements in improving the quality of care (96) :

***(Evidence of an effective change) + (Effective implementation method) + (Supportive environment and infrastructure) = Improved quality***

Research may provide information about all these elements to the providers. But a key factor in determining whether providers make savings is the amount of the costs they bear i.e. the costs of poor quality and the costs of intervention solutions. Sometimes providers are paid extra by purchasers to treat the adverse events. Recently, some purchasers in the US shifted the costs of some adverse events to the providers by introducing “never events” which involves exclusion of providers from reimbursement as financial penalty for not achieving certain standards.

Financially it should be made more advantageous for providers to increase quality. In order to do this routine financing systems should be changed and performance measurements should include quality measures. The new financing systems should

- I. ensure that providers bear more of the costs of poor quality, especially where their costs shift to other stakeholders (like in case of delayed transfer and lack of prevention)
- II. measure quality and quality costs in routine service settings
- III. finance local improvement expertise
- IV. spread the investment costs for interventions over time and between providers, purchasers and others

Saving money is not a strong motivation for clinicians to improve quality. Ethical, moral, and professional motives are also important for clinicians, but these alone have not proved sufficient for improving quality.

In summary, there are enough evidence to show which changes we should focus on and how we should implement them. The cost of inaction and not using this knowledge is probably high, both financially and in terms of human suffering (96).

## **17. Changing the practice towards a more patient safe healthcare**

### **Denial of the suboptimal patient safety**

Healthcare is among the most complex systems in the world. Errors in healthcare are not random and are usually predictable. Some errors have their roots in organizations and culture and traditions in healthcare micro-systems. Preventable errors are a major source of mortality and morbidity in hospitals. It seems that consequent and safe application of available medical knowledge would involve far more quality improvement in healthcare than the continuous search for newer and better therapies. Unfortunately, many physicians do not consider medical errors as a key problem in healthcare (16). ICUs are not exceptions. Adverse events are common in ICUs (commonest complications are ventilator procedures or therapeutic errors) and ICU physicians may underestimate these by as much as a factor of 10 (19). Denial of the problem or denial of the problem's gigantic dimensions may be regarded as the most important hindrance for change towards a more patient safe healthcare.

### **System errors and operator errors**

Errors leading to an adverse event and patient harm may represent a system failure (system errors), a practitioner failure (operator errors), or a failure of both (97) .It have been suggested that in complex systems, system errors are the principal responsible factor in dominating majority of adverse events but with the involvement of operator errors in many of them. Operator error may be skill-based, rule based, or knowledge. Knowledge base errors are primarily

due to problems with information, thinking, and remembering. Violation, however, is deliberately doing something wrong, sometime based on a “right argument”. Violations used to be due to problems of motivation or problems within the work environment.

Clinicians generally do not appreciate the notion that system errors play a part in adverse events. If they are involved in an adverse event they feel personally guilty and are often prepared to accept more than their fair share of the blame (operator error) (97).

## Safety in safety-critical and high reliability organizations

Safety-critical organizations, domains, or industries are those that operate in a dynamic and hazardous environment. High reliability organizations are those safety-critical organizations that have substantially succeeded in avoiding errors and catastrophes. All safety-critical organizations rely on humans to perform the tasks, and humans commit errors in a relatively limited number of ways. Thus there are similarities between the kinds of errors that have occurred or occur in these organizations. Inadvertent errors because of for example distraction (slips), errors of the memory (lapses), and errors caused by lack of knowledge (mistakes) are frequent kind of human errors.

Commercial aviation is a high reliability industry. In the 1970s and 1980s it suffered a series of major accidents that cost approximately 10 billion dollars and caused the loss of some 7000 lives. Investigations showed that human factor (pilot error) was the cause of crashes. The airline industry began to understand that it knew very little about the nature of human error. The industry performed a systematic approach to the problem that may be called engineering safety approach.

The characteristics of the engineering safety approach are:

- Mandatory creation and use of standard operating procedures (like protocols and check lists)
- Implementation of safety repetition and duplication measures (like double-checks and time-outs)
- Acknowledgment that the system complexity goes far beyond the ability of any single individual and encouraging teamwork and second opinion
- Continuous updates and the use of best current available information (imperfect research is not an excuse for not to change)

- Errors are described by using system models and subsequently corrective efforts are more focused on “how” instead for “who”
- Near misses represent an opportunity to improve the system especially if freely discussed.
- Enhancing situational awareness and the notion that optimal crisis management begins before the crisis occurs (“flying ahead of the plane” by pilots)

Subsequently, commercial aviation achieved a radical reduction in its fatalities and now there is only 1 fatal crash per 4.5 million take offs. These magnificent results are not comparable with the statistics of healthcare with respect to patient harms.

These measures used by commercial aviation for reducing accidents included:

- I. Standard operation procedures (followed very closely and consistently)
- II. Applying a less steep hierarchy in the organization (which forced for instance pilots to be open to input from the co-pilot)
- III. Use of simulators to develop teamwork
- IV. Auditing

Doctors like pilots do commit the above mentioned errors. The difference is that the pilots are equipped with tools to help them recognize potential and evolving errors. These tools, which are generally lacking in healthcare, either prevent the errors from happening or mitigate their effect once they have occurred.

Another high reliability organization is nuclear-powered aircraft carriers in US navy. The flight deck operations occurring on these carriers are extremely dangerous. The rate of serious accidents in these units, which are now virtually accident-free, has been reduced by 97% compared to some 50 years ago. The tools to achieve these outstanding results include:

- I. Use of standard operating procedures,
- II. Investigating accidents and near accidents
- III. Perform training to avoid accidents and near accidents in future
- IV. Institution of a culture of confidence and trust
- V. Regular staff training in technical skills and in the role of human factors in errors
- VI. Excess in hardware personnel and procedures
- VII. Use of simple safety systems,

- VIII. Open management and a balanced hierarchy where appropriate
- IX. Personnel and process auditing

The common feature of high reliability organizations may be summarized as follow: preoccupation with failure, compliance and adaptability, operation audits (analysis of operations), institution of a safety culture with a total determination to achieve consistently safe operations. In this culture individuals feel comfortable to draw the attention to potential hazards or actual failures without fear of sanctions from management.

Humans have limited memory capacity and limited ability to perform several tasks simultaneously. Additionally stress and fatigue increase the rate of errors and cognitive biases (like anchoring bias and tunnel vision bias). These are some of the reasons why it is impossible to prevent operator error completely. Hence, the establishment of protection strategies is necessary. A protection strategy may include among others the systems for defending, detecting, and reversing as well as designing the future preventive methods (23;97).

## Swiss-cheese model

Protection against error may be resembled as layers of defense shields.

These defense layers or barriers against the occurrence of errors include among others trained personnel, good communication routines, reliable technology, appropriate administration and leadership, adequate checking routines, existence of procedures and a safety culture in unit. The barriers together construct a nearly impermeable shield against errors. Despite the defense shield errors still occurs but hopefully through the correct function of the defense barriers they should be stopped in their way to produce harm. There may be weaknesses in the barrier layers making it possible for an error to pass through and cause harm. The weaknesses may be resembled as holes in a Swiss-cheese slice (barrier layers). If an error succeeds to pass a barrier (through the hole in the barrier) and proceed, it will hopefully be stopped at the next barrier. However, if there are several barrier holes lined up in front of each other there exists an opportunity for an error to pass through all the defense layers and produce harm. Hence, it is essential to establish intact and functioning error barriers to avoid harm (98).

## Communication failure

The term “error chain” describes the sequence of events that lead to an accident. The rings in the error chain may be regarded to be the same as holes in the barrier layers in Swiss-cheese model. Breaking the error chain is quite essential in avoiding harm. High reliability organizations train their Personnel to break the error chain by targeting its weakest point. The weaker points of error chain are:

- 1- Communication failures
- 2- Poor checking behaviors
- 3- Inadequate or inconsistent procedures
- 4- Interruptions
- 5- Changes of plan

Communication failure is an important component in the error chain and may reflect the problems of both healthcare system and individual practitioner’s (the operator’s) behavior and attitude. There is a general lack of awareness about the extent of communication failures between clinicians and the very significant adverse effects that these communication failures exert on patient outcomes.

Communication failures within and between teams in safety-critical organizations can be divided into the following categories:

- I. Absent message (a total failure to communicate)
- II. Content problems (missing or incomplete data) or inappropriate tone
- III. Addressing problems (speaking to the wrong person)
- IV. Wrong communication medium (telling something to a colleague rather than writing it down to the patient’s notes)
- V. Inappropriate time (distracting a colleague with a less urgent communication)
- VI. System failures (inadequate communication channels, lack of communication skills and training)

Communication failure was in fact one of the important shortcomings in the “Bristol case”. Bristol case was the tragic circumstances around the death of 30



children who underwent heart surgery at Bristol Royal Infirmary between 1991 and 1995. The children died as a result of substandard care. The caregivers who were well intentioned and well trained still could produce harm because of working in a culture that lacks insight into its own shortcomings. The final report of “Bristol Royal Infirmary Inquiry” (<http://www.bristol-inquiry.org.uk/>) states that: *“The story of the pediatric cardiac surgical service in Bristol is not an account of bad people. Nor it is an account of people who did not care, nor of people who willfully harmed patients. It is an account of people who cared greatly about human suffering, and were dedicated and well motivated. Sadly, some lacked insight and their behavior was flawed. Many failed to communicate with each other, and to work together effectively for the interests of their patients. There was a lack of leadership, and teamwork”. Further “an imbalance of power, with too much control in the hands of few individuals”.* Hence human errors may occur, despite the caregivers’ good intentions, as a result of a defect care. The first victims of human errors are those patients (and their families) who suffer harm, and second victims are those doctors and nurses who are often set up to be the final and visible link in an error chain. For these practitioners the burden of knowing that they have harmed a patient may be substantial. The enormous economic costs of errors is also a burden which should be carried by the taxpayers who may be regarded as the third victims of errors in healthcare (97).

## Role of leadership in Systemic changes and building a safer ICU

After the publication of the report *“Crossing the quality chasm: a new health system for the 21st century”*, published by Institute of Medicine in 2001, it has been widely accepted that the major cause of adverse events is system deficiencies and not the behaviour of individual professionals.

Research has demonstrated undoubtedly that “good healthcare management” has a positive impact on clinical and safety performance in ICUs. One of the studies illustrating this was the paper “The performance of intensive care units: does good management make a difference?” written by Shortell and colleagues and published in 1994. The paper, which was based on data from 18000 patients in 42 ICUs, illustrated that superior organizational practices were related to four characteristics: a patient-centered culture, strong medical and

nursing leadership, effective communication and co-ordination, open and collaborative approaches to problem-solving and conflict management. Research has also shown that ICU staffing by trained ICU physicians leads to better patient outcome (81).

Intelligent systemic changes are necessary to make improvements in patient safety work. Improvements best can be achieved by systemic application of a broad array of changes in process and organization, and with supervision, training, simulation, and teamwork. The role of leadership is vital. Leadership should define the safety vision and align organizational quality and safety goals, identify current situation and its difficulties. Leadership should allocate resources and provide organisational support, staff focus, and education and training. Leadership should also support error reporting systems, disclosure and truth around medical errors and try to establish patient and family partnership for safety (9). Knowing that quality is a multidimensional construct, it is unlikely that a single approach would be effective. There is a need for a combination of different approaches and developing appropriate systems for patient care both in ICU and other wards in the hospitals (99). With respect to the relative roles of structure/system versus individual practitioner, and as it was mentioned earlier, leadership is a part of the structure and in fact the most important part of it but this does not imply that the performance of the individual practitioner should be ignored (31). The General Medical Council has described recertification (called revalidation in the United Kingdom and Canada) as “one element of the quality framework which aims to address two distinct but complementary purposes; ensuring patient safety and improving the quality of patient care” (100).

The old understanding of patient safety and healthcare quality consisted of an essential operator-centred element. According to this understanding the operator has the total responsibility when errors occurred. In this school the operator was the scapegoat and the relevance of structure and system were totally forgotten. This concept has been changed over the time and now the relative roles of operator and system in patient safety and quality have largely been balanced in many countries. However, recently a challenging theory has been emerged nearly claiming that systems bear the whole responsibility of suboptimal care (85).

## Organizational culture and information processing

According to the World Health Organization (WHO) patient safety includes three complementary actions: preventing adverse events, diminishing their effects when they occur, and making them visible. Making them visible perhaps should be the first step, as without the knowledge provided by data the problems cannot be identified and the impact of preventive measures cannot be evaluated (101). Leadership is the key element in all these three actions. Patient safety does not only refer to prevention of error. If this was the case then patient safety had gained a reactive rather than proactive and comprehensive characteristic. Patient safety means the assurance that every patient will receive medical care that is timely, appropriate, and evidence-based. This means that patient safety include both absence of error and the reliable use and safe practice of processes in ICU. A combination of human factors and system factors (like workload) are causes of critical events. Development of a safety culture with open communication of problems at all levels, and aiming to overcome the culture of blame and shame and create a new attitude toward learning, are ICU leaders' distinct responsibilities (102). In order to influence the behaviour of ICU staff it is necessary to build a culture of safety in which healthcare personnel perceive safety as a high priority goal. Organizational culture is the norms, values, beliefs, and assumptions that are shared by the members of an organization. Organization climate is shared perceptions on the part of employees regarding formal and informal policies, procedures, and practices concerning certain aspects of the work environment such as service, safety, and quality. The terms "culture" and "climate" are usually used interchangeably. Patient safety climate may be defined as shared perceptions of medical team members regarding the importance of patient safety in their unit. There are a number of tools and surveys to measure patient safety climate. The measuring surveys should be specific for each professional group (for example physicians and nurses) and examine only the phenomenon of patient safety and nothing else (103).

The ICU culture is also consists of beliefs, values, faith, attitudes, norms, and assumptions. These may be expressed in form of how people work together, how they communicate, how they adopt to challenges, and how they react to errors. According to the article "A typology of organisational cultures" written

by R. Westrum and published in “Quality and Safety in Health Care” December 2004, there are three types of organizational cultures based on how the leaders of these organizations handle the information. The following table illustrates these three kinds of organizational cultures (104).

Table 4: How organizations process information

	Pathological culture	Bureaucratic culture	Generative culture
Organization	Power oriented	Rule oriented	Performance oriented
cooperation	low	Modest	High
Messengers	shot	neglected	trained
Responsibilities	shirked	Narrow	Risks are shared
Bridging	discouraged	tolerated	encouraged
Failure results in	scapegoating	justice	inquiry
Novelty	crushed	leads to problems	implemented

With permission from: Westrum R. A typology of organisational cultures. Qual Saf Health Care 2004 Dec;13 Suppl 2:ii22-ii27

The three organizational cultures may be described as “pathological or power-oriented”, “bureaucratic or rule-oriented”, and “generative or performance-oriented”. The way of cooperation and treating messengers, responsibility, bridging, failure, and novelty is different in these three organisational cultures. There are many other aspects of organization culture that are not illustrated by this table, like education and training, structure, and styles of problem solving. Furthermore, there are effective organizations that are not generative. The performance of these organizations is based on other features, like a brilliant algorithm or a charismatic leader. Ultimately, it is the goal of an organization, which may be or may not be patient safety, determines the level of patient safety in that organization . This means that performance oriented organizations are not necessarily the best in patient safety, but they tend to be more creative, open, and solution-oriented which in turn make their processes to be more patient safe.

## Components of a safety culture

The components of a safety culture include openness and fairness, constant and active awareness of the potential for adverse events to happen, encouraging people to speak up about their mistakes, and willingness of staff to learn from the mistakes as well as their willingness to put things right.

Error reporting, use of check lists, teamwork, and right communication are thought to be those elements of ICU culture which may be of special importance in patient safety. However, it is not always easy to establish a solid link between these elements and improved patient outcome despite improved process outcome. Furthermore, a rigorous reporting work may show increased adverse events while “*standardized mortality rate*” decreases. The explanation of this phenomenon is not easy but perhaps the kind of events that is reported may play a role. We know that the majority of adverse events have little or no influence on clinical course of patients and some of the events may be detected early so that contra-active measures can be applied (104;105).

## 18. Résumé of the literature survey

Patient safety is one of the biggest healthcare problems today (106). There are international data indicating that clinicians have poor compliance with evidence-based guidelines where consistent use of these guidelines increases quality and patient safety. The current situation is that only approximately 50% of patients receive recommended therapies (107). Translating evidence into clinical practice has been challenging. Now there has been developed an explicit model for a collaborative transition of knowledge into practice (108). A flowchart of this method has been illustrated in appendix 7.

We know that the explanation of physicians' behavior and their poor guideline compliance is not an easy task. This may be the reason why there have been developed approximately 13 different current explanation models. However, there are many other barriers than the behavior of the clinicians and their compliance to the guidelines. Generally, barriers or factors to guideline compliance may be divided into four categories namely clinician -, system -, guideline -, and implementation factors (107). System factors (like non-compliance) are the crucial variables in occurrence of errors and accidents. System may be defined as the sum of the structure, process, and culture in the unit. The important **system** factors include **task factors** (e.g. availability of protocols and test results), **team factors** (e.g. care -, crisis - and hand-over communication, seeking help, supervision, team structure and leadership), **environment** (e.g. physical environment, staffing levels, work load, skills mix, administrative and managerial support, availability and maintenance of equipment), and **organizational factors** (e.g. the culture of unit, communication, teamwork) (107;109). With this background it would be predictable that uni-factorial interventions like education alone might not be the solution of compliance with evidence-based guidelines and there is a need for multi-factorial interventions (107).

These **multi-factorial interventions** should first of all eliminate the preventable harm resulting from failure to standardizing care and failure to use evidence-based guidelines. Accordingly, professionalism should be strengthened meaning that evidence should be translated into practice (108) and should be implemented. There certainly would be barriers to implementation of evidence

where necessitating the use of a systematic and practical tool to identify and eliminate them. Professor Pronovost has described one such a tool called “Barriers Identification and Mitigation (BIM) Tool” (110) (appendix 8). It should be stressed that a tool like BIM would operate most optimally in the context of a larger and more extensive patient safety program like “Comprehensive Unit-Based Safety Program (CUSP)” (111). There exists also a web-based version of CUSP (112). The use of checklists is of paramount importance for securing the process of translation of evidence to practice as well as its implementation (113;114). In fact the use of checklist was one of the main pillars in the developing CUSP (111).

Culture is of central importance for any comprehensive patient safety initiative to be successful. Changing the culture and instituting a new culture of patient safety, not only in the front line institutions like university hospitals but also across the whole healthcare system and at the patient and practitioner level, is a demanding process. A survey of current culture in the unit should be the first step in the course of changing the culture towards a culture of patient safety. For this reason there have been developed culture survey questionnaires with approved validity and reliability (115)

(<http://www.ahrq.gov/qual/patientsafetyculture/hospscanform.pdf>).

The survey of current culture should preferably be incorporated in a more comprehensive patient safety program, like CUSP. In fact the first step in CUSP is performing a culture survey. In other words, CUSP safeguards the right approach to both culture and professionalism in a patient safety initiative.

*“The Agency for Healthcare Research and Quality (AHRQ) announced in October 2009 that a program called the Comprehensive Unit-based Safety Program (CUSP), which successfully reduced central line-associated blood stream infections in intensive care units, will expand to all 50 States and additional hospitals in States already participating in the CUSP, extend to other settings in addition to intensive care units, and broaden its focus to address other types of health care-associated infections”.*

(<http://www.ahrq.gov/qual/haicusp.htm>) ([www.patientsafetygroup.org/program/index.cfm](http://www.patientsafetygroup.org/program/index.cfm))

A flowchart of CUSP has been demonstrated in appendix 9 to facilitate the understanding of the steps involved in the program.

Expectedly, dysfunctional systems, sometimes created by non-competent providers or administrators, make it difficult to act correctly.

System thinking, however, combined with the notion that “most errors are committed by good, hardworking people trying to do the right thing” has built the platform for “no blame” culture. Now, this culture has begun to be questioned and the need for accountability for failure is gaining some grounds. The need for a “just culture” which differentiates blameworthy from blameless acts has been declared (116).

Promoting quality and patient safety in general may necessitate the implementation of a global, versatile, and comprehensive system, much alike that of clinical governance from NHS. Moreover, the measures for promoting patient safety may be divided in two categories; measures at the unit level and measures at national level. At the unit level (micro-level) there is a need for strengthening professionalism as described earlier in this section. In brief, we need to implement more specific programs for translation and implementation of evidence, for identification and mitigation of evidence implementation barriers (like BIM), and for comprehensive patient safety initiatives (like CUSP initially developed for ICUs). Regarding the national level, first it should be stressed that we in the western countries suffer from insufficient training in quality and patient safety depending to our collective failure to comprehend the delivery of health care as a science (117;118). Hence, long term measures in national level should include investigation in the science of quality and patient safety, revising the quality and safety governance in our hospitals, and integrating the roles within the hospitals and medical faculties (117). Short term measures in national level may first include system approaches (like for instance accreditation of hospitals, departments, and units), and then a practitioner approach (like obligatory revalidation). The profession, authorities, and the public should cooperate regarding the type, extend, and comprehensiveness of revalidation (CME/ CPD, Peer review, or both), as well as its financing, organizational forms, and involved penalties or rewards.



## 19. The history and present status of quality and patient safety in Norway

In this section the work performed within the healthcare quality and patient safety in Norway will shortly be introduced. Norwegian Medical Association (NMA) at the end of 2006 published a document entitled “The Norwegian Medical Association’s Policy of Patient Safety” (called “PPS-document” further on in this thesis) ([http://www.legeforeningen.no/asset/34520/1/34520\\_1.doc](http://www.legeforeningen.no/asset/34520/1/34520_1.doc)). PPS-document included a comprehensive list of quality and patient safety initiatives taken by both NMA and Norwegian healthcare authorities up to 2007. PPS-document, which has kept its importance until now, is a quite comprehensive document and has been used as one the main information sources in this section. Briefly, NMA established early three quality assurance funds that have played an essential role in promoting quality and patient safety during the last two decades. Quality assurance fund (QAF) I was established in 1991 with an orientation towards primary health care and private specialist practice. QAF II was established in 1992 and aimed to support the projects in the specialist healthcare. QAF III was established in 1997 and financed the quality development of laboratory services in primary care that is the NOKLUS project (Norwegian quality improvement of laboratory services outside the hospital). NMA, through its competency and funds, has performed a number of important patient safety projects. QAFs have provided support to hundreds of projects and the NMA's annual "Quality Days", a two-day seminars gathering healthcare professionals, managers, administrators, and representatives for information exchange. In 1997, NMA established cooperation with leading international patient safety organizations, like Institute for Healthcare Improvement (IHI) in Boston, and since then has actively participated in promoting patient safety. In 1998, NMA began to implement Norwegian "Breakthrough Projects" in large parts of the healthcare system in cooperation and co-financing with healthcare authorities. Breakthrough method was innovated in 1995 by IHI and since then has continuously been improved giving rise to “Breakthrough Series” (<http://www.ihl.org/NR/rdonlyres/3F1925B7-6C47-48ED-AA83-C85DBABB664D/0/TheBreakthroughSeriespaper.pdf>). The aim of Norwegian breakthrough projects was to increase the quality of care by targeting systems

as well as systematic implementation of quality improvement measures. Norwegian ICM and some Norwegian ICUs became early involved in patient safety projects. In fact, ICM was one of the included areas in the breakthrough projects. An example of a breakthrough project in ICU is the project of systematic assessment and adjustment of the depth of sedation in mechanically ventilated patients. This project led to a shorter length of mechanical ventilation in ICU patients (119;120). Driving force of these and other quality and patient safety activities was NMA's quality improvement committee during the years 1992 - 2005. During this period a great deal of work was performed. PPS-document, however, underlines that ***"there is a lack of systems for nationwide dissemination and implementation of the achieved experiences and knowledge"***.

In general, patient safety has long been a focus of attention among the senior members of anesthesiology and intensive care medicine in Norway. This is reflected in different publications such as a publication from 1991 discussing quality assurance of medical equipments (121) and two publications from 1990,s discussing human errors and errors in ICUs (122;123). Focus on quality and patient safety is also reflected in the establishment of quality registers and patient safety databases. A database for registration of adverse events in anesthesia was established in St. Olav's Hospital in Trondheim in 1985. A similar database for systematic registration of adverse events in ICU was constituted in 1993 in Haukeland University Hospital in Bergen. Furthermore, Norwegian Intensive Register (NIR) was also established in Haukeland University Hospital in Bergen in 1999. The national quality registers, with few exceptions, started by enthusiastic clinicians often under the auspices of the specialty associations in the NMA and many of them received financial support from the QAF II. Financing, management and responsibility for some of the registers have gradually been moved to regional health administrators. Today, there are 13 central "health registers" like cancer register, cause-of-death register, and birth register. There are no quality data in these registers. Additionally, there are approximately fifty medical quality registers that include quality data but they are administered by different operators. In Health Conference in 2008, it was stressed that we should go for national systems with many high quality registers, like Denmark and Sweden.

Norwegian health authorities have also played a crucial role in improving

healthcare quality and patient safety in Norway. Legislations and regulations belong the main tools of improvement for authorities. Legislations like the need for “Justifiability” in practice (aiming to protect the patients from “unnecessary” risk for damage), requirement of implementation of internal control systems, and requirement of reporting of adverse effects have been important steps in promoting quality and safety. The Norwegian Board of Health Supervision performs the audit of patient-related activities as another important measure of promoting quality and patient safety.

The Ministry of Health and Care Services in 2003 ordered a report on patient safety. In that report Professor Peter Hjort introduced a comprehensive overview of the problem areas and suggested a number of specific measures, like the establishment of a reporting system to an independent national center without disciplinary authority. Norwegian Directorate of Health has also focused on patient safety through, among others, its comprehensive publications (circulars, national guidelines, guides, reports, recommendations, statutory regulations, evaluations, hearings and so on) and through following up the work of national quality indicators in healthcare. Norwegian Directorate of Health in 2005 published “National Strategy for Quality Improvement in the Social- and Health Services” for the coming ten years was (124). In this extensive document the necessity of working with multiple approaches as well as different measures at different levels to ensure the quality of services was specified. These levels include community and system levels, organizational and institutional levels, and the levels of the individual practitioners and users. In the section “The strategy’s approach to improvement” the measures Norwegian authorities currently use to improve the quality of services was described. These measures include regulations, education and authorization of personnel, financing, audit, prioritization of resources, as well as research, summary of current knowledge, and technology assessment for improvement of the scientific basis of the medical practice. “Services with good academic standards” and “delivery in a good and humane way” are two pervasive elements in this strategy document. Further, there have been described those principles that should be the basis for all improvement efforts. These principles include the existence of measures that can document continuous change as well as the necessity of anchoring the improvement efforts to the management and leadership and including the practitioners and users. According to this

strategy improving quality goes through strengthening the users, strengthening the practitioners, improving the management and organization, strengthening the knowledge of improvement during the primary educations, and monitoring and evaluating the services. Moreover, there have been described detailed measures to be taken to achieve each of these objectives; **“further development of systems for patient safety”** being one of the measures.

Norwegian health authorities have also been aware of the importance of quality registers and quality indicators and according PPS-document they have supported actively establishing of the quality registers for years. However, PPS-document in 2006 declared that the quality indicators in that time had a character of being more like quantity indicators. The authorities have continued the substantial work with quality indicators which has resulted in two valuable publications (125;126) .

In summary it is clear that both the Norwegian health authorities and NMA have a sound and solid understanding of quality and patient safety, all in accordance with the literature survey presented in this thesis. They have absorbed the international knowledge of patient safety and in turn contributed to production of such knowledge; like the importance of teamwork and use of checklists (127-131) or more ICU-specific knowledge in quality and patient safety (132-134). Further, they have initiated and carried out a great many quality and patient safety activities. The achievements have not been few, which may naturally raise a great sense of satisfaction. The question is if we should be satisfied with this satisfaction?

We know that in our country we still miss a great many of our patients because of adverse events. A calculated number for this is up to 2000 lives each year ([http://test.tidsskriftet.no/index.php?seks\\_id=1790214](http://test.tidsskriftet.no/index.php?seks_id=1790214)) which is an alarming number. It was only for three years ago the PPS-document was published and the situation today should not be very different from then. In the following I record in italic some short sections of PPS-document (all translations have been performed by Albert Castellheim). These statements may constitute a platform for future work in quality and patient safety in our country.

*“In Norwegian healthcare system the work of patient safety is still in its starting phase”.*

*“Norwegian Board of Health Supervision commends and appreciates the good*

*thinking around specific adverse events in different medical communities, but criticizes the healthcare administrators and physician-leaders for the lack of prioritization of patient safety. We know that the "system thinking" and "process" is not included in medical education implying the notion that such knowledge is relatively poorly developed within the profession. Physicians have had limited tradition of interdisciplinarity in thinking and in practical work".*

*"Patient safety work in Norway must be developed".*

*"Patient safety should be on the agenda and be relevant for physician leaders and representatives, at scientific meetings and in The Journal of Norwegian Medical Association".*

*"Hospital owners and managers have shown a limited degree of interest in working with safety at patient level. Moreover, educational institutions have not taken any specific measures (to educate healthcare personnel) at collage level or university level. Stavanger University Hospital is an exception".*

At the end of the PPS-document there are five suggestions regarding the methods to promote patient safety: *"Promoting patient safety includes five main areas: **cooperation, culture, professionalism, regulatory, and technology**. There is potential for improvement in all areas. Work with the patient safety is complex where all the stakeholders are interdependent and all the elements affect each other".* These suggestions are also totally in accordance with the results of the literature review presented in the previous section in this thesis. Some short reflections on these suggestions:

In connection with **cooperation** it is necessary to stress that a common language, understanding, and cooperation between the stakeholders of healthcare are essential and should initially be secured. For instance, a field that needs a higher level of common language and cooperation is the field of health and quality registers. There is a need for common understanding regarding the necessity of these registers and their content, and cooperation regarding how to initiate, organize, and manage them. In the document "National Strategy for Quality Improvement in the Social- and Health services"

published by Norwegian Directorate of Health in 2005, the following goal was stated clearly: “ Support and further develop professional quality registers; locally, regionally and nationally”. In 2008 the Ministry of Health and Care Services initiated the national health registry project to coordinate and modernize the existing national medical quality registers and the central health registers. The project led to the development of the important document *“Good health registers - Better health; Strategy for the modernization and coordination of the central health records and medical quality registers 2010-2020”* with action plans for 2010-2011 ([www.nhrp.no](http://www.nhrp.no)). Unfortunately, there seems to be disagreement about the basic concepts of the registers that may make obstacles for cooperation in this regard

([http://www.tidsskriftet.no/index.php?seks\\_id=1958579](http://www.tidsskriftet.no/index.php?seks_id=1958579))

([http://www.tidsskriftet.no/?seks\\_id=1976006](http://www.tidsskriftet.no/?seks_id=1976006)).

Further, without reaching an acceptable and necessary level of cooperation it would be impossible to work with **culture**, the second suggestion. The central importance of culture in patient safety was extensively discussed in the last section, *Résumé* of the literature survey. In fact, the existence of a culture of patient safety will automatically imply the need of an acceptable level of **professionalism** aiming to increase patient safety through secure deliver of evidence-based medicine.

The next suggestion is **regulation** that is used as a steering system for improving quality and patient safety by Norwegian health authorities, like other health authorities. An important matter concerning specific regulations is their form, content, appropriateness, and timeliness. Regulations normally should be based on an accepted cultural platform to be able to be successfully implemented. Certification of hospitals and wards, and reevaluation of physicians may be the main areas where regulations may lead to improvements. According to IHI, still half of all care given to the patients is unscientific (<http://www.ihl.org/IHI/Results/WhitePapers/TheBreakthroughSeriesIHIsCollaborativeModelforAchieving+BreakthroughImprovement.htm>). In this regard one of the goals should be institution of an effective educational system that would strengthen professionalism and reduce the rate of given unscientific care. We know that our current system of CME/CPD has difficulties to meet this goal ([http://www.legeforeningen.no/asset/49386/1/49386\\_1.pdf](http://www.legeforeningen.no/asset/49386/1/49386_1.pdf)). On this background one may think of regulation on revalidation as one the appropriate measures to

ensure that physicians are up-to-date and compliant to the guidelines. Anyhow, there seems to be a need for discussion between the healthcare stakeholders regarding revalidation and the future form of CME/CPD, its financing and administrating. Do we need regulations to secure the delivery of scientific care and do regulations alone secure the delivery of scientific care? Regardless the form of CME/CPD, with or without regulation, my personal impression is that any measure that would reduce the number of unnecessary deaths due to unscientific care would broadly be accepted in our country.

In summary, in Norway there have been done much in the field of quality and patient safety but much more remains to be done.

## 20. The survey on patient safety and CME

We know that errors happen frequently in the ICUs (123;135-137) and at the same time ICU physicians have the best intentions to care for their patients. We were interested in the ICU physicians' perceived roles of ICU system factors in patient safety (like CME/CPD, evidence-based protocols, and leadership) as well as the roles of attitudes and culture of the units. We know that leadership is a system factor and has the highest level of responsibility in every organization, including healthcare organizations. This responsibility is total and includes every aspect of organizational structure, process, and outcome. Further, this responsibility is time unlimited meaning that it is valid all round the clock every day. Hence, ICU leaders and their attitudes are major determinants of patient safety issues (perception of the concept of patient safety and taking measures for increased patient safety). The main aim of the study was to determine whether the ICU physicians and ICU leaders are of the opinion that there is necessary to increase the patient safety level in these units. Exploration of their opinion about all other major factors in patient safety (like CME/CPD) was regarded as secondary aims of the study.

### Subjects and methods

A questionnaire constituted by 23 questions was send as an e-mail link to two study groups (appendix 10). The first study group was the "leader group" and the second study group was the Norwegian members of The European Society of Intensive Care Medicine (ESICM).

The leader group was itself comprised of three categories: first the leaders of the ICUs in all five university hospitals (seven ICUs) in Norway. An ICU leader was defined as either an administrative physician-leader or as an academic leader (professors and assistant professors). In Norway there are five university hospitals. ICUs in Norway are usually staffed and run by anesthesiologists and serve as organizational units belonging to the departments of anesthesiology. The second category of leaders who received the questionnaire was the leaders of these mother departments of anesthesiology. The third category of leaders who received the questionnaire was a limited number of peers who in the past have functioned as either administrative or academic leaders and currently are



regarded to exert some significant degree of influence on ICUs. In Norwegian university hospitals there are limited numbers of ICUs, which do not belong to the departments of anesthesiology. The leaders of these ICUs did not receive the questionnaire as well as those leaders who are not physicians. Totally 29 leaders received the questionnaire. The response time was between 11 May and 14th June. During this time the non-responders received two reminders. The total number of responders was 14 (48%).

The second study group, the Norwegian members of ESICM, was thought to be the representatives of the physician staff in ICUs. However, the membership in ESICM is open for all clinicians including physicians, nurses, physiotherapists, nutritionists, and clinical pharmacists. However, there are reasons to believe that the absolute majority of the Norwegian ESICM members are physicians. The questionnaire was sent to this group (67 clinicians). Three clinicians were excluded on their own demand (one guest physician who had moved back to her native country, one non-physician practitioner who meant she was not the right person to answer the questions, and an ICU leader who had received and responded to the questionnaire previously). Hence, the total number of receivers was 64. The response time was between 2nd June and 18th June 2010. The number of responders was 24 (37.5%). Compared to the first group, this group had two additional questions to answer in the questionnaire. The first question was about if the responder works in a university hospital (62.5% answered that they work in a university hospital). The second question was about if the responder had a leader function without defining what the leader function was (33% answered that they had a leader function).

## Results

### *Numeric presentation of parts of data*

A complete and detailed numeric presentation of data is included in appendix 10. Here we present some tables illustrating parts of these data.

*Question (Q)1-Do you think that the patient safety level is acceptable in your department?*

	Leaders	ESICM
Not at all	0.0	0.0
To a small extent	0.0	8.3
To some extent	14.3	8.3
To a great extent	50.0	70.8
To a very large extent	35.7	12.5
Do not know / not applicable	0.0	0.0

86% of leader responders (LR) and 83% of ESICM member responders (ER) believe that the patient safety level is acceptable in their departments to a great extent or very large extent.

*Q2- To what extent do you think there are medical errors in your department?*

	Leaders	ESICM
Not at all	0.0	0.0
To a small extent	57.1	41.7
To some extent	42.9	54.2
To a great extent	0.0	4.2
To a very large extent	0.0	0.0
Do not know / not applicable	0.0	0.0

100% of LR and 96% of ER believe that medical errors occur either to a small or some extent in their departments.

*Q3- What kind of mistakes do you think that doctors in your department make most frequently? Put only one tick.*

Q3- Kind of errors	Leaders	ESICM
Commission	0.0	4.2
Both	57.1	20.8
Omission	35.7	54.2
Do not know / not applicable	7.1	20.8

*Q20- If you are going to improve patient safety in your department, which department-based measure do you choose to take (if none of these are implemented)? Choose two options.*

Q20- Department-based measure	Leaders	ESICM
Reporting	71.4	8.3
Root cause analysis	64.3	70.8
Clinical procedures	28.6	50.0
IT-based solutions	7.1	8.3
Audit and feedback	7.1	25.0
Structure changes	28.6	25.0
Do not know / not applicable	0.0	4.2

*Q21- If you are going to improve patient safety in your department through increasing competency of physician staff, what kind of CME do you choose as the most appropriate? Choose only one option.*

	Leaders	ESICM
Self-steering model	25	0.0
Profession- steering model	50	90.5
Regulation	25	9.5

*Q22- Altogether, do you think it is necessary to improve patient safety in your department?*

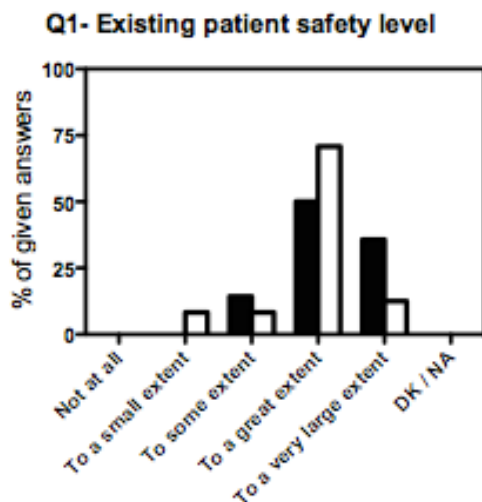
	Leaders	ESICM
Not at all	0.0	0.0
To a small extent	14.3	13.0
To some extent	57.1	60.9
To a great extent	21.4	26.1
To a very large extent	7.1	0.0
Do not know / not applicable	0.0	0.0

Table following table illustrates parts of data in connection with the answer option “to a very large extend” in different questions:

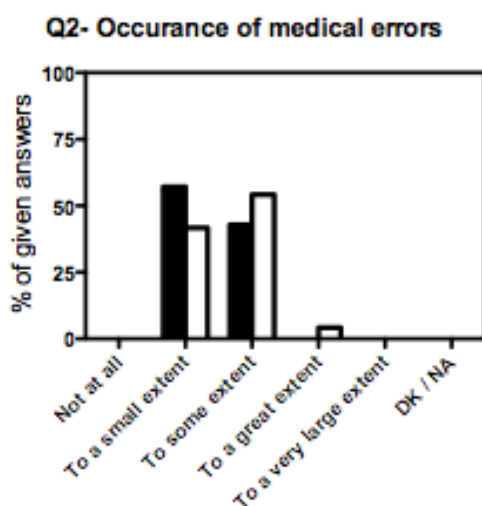
	Leaders %	ESICM %
to a very large extent		
Q1- patient safety level is acceptable	35.7	12.5
Q4- leadership performance is important	35.7	34.8
Q6- explicit clinical procedures are important	50.0	37.5
Q7- colleagues' attitudes are important	28.6	43.5
Q8- motivation is important	28.6	29.2
Q9- theoretical knowledge is important	21.4	37.5
Q10- practical skills are important	21.4	41.7
Q11- ethical awareness is important	21.4	20.8
Q12- reporting of adverse events promotes good patient safety	50.0	58.3
Q13- root cause analysis is important	35.7	47.8
Q14- IT-based solutions are important	21.4	20.8
Q15- external audit and feedback are important	7.1	20.8
Q16- clinical experience alone is sufficient	0	0
Q17- self-steering model of CME (like “LEIF”) is important	7.1	0
Q18- profession-steering of CME (like GPs in Norway) is important	7.1	12.5
Q19- regulation model of CME is important	21.4	4.2
Q22- it is necessary to improve patient safety in your department	7.1	0

## The graphic presentation of the results

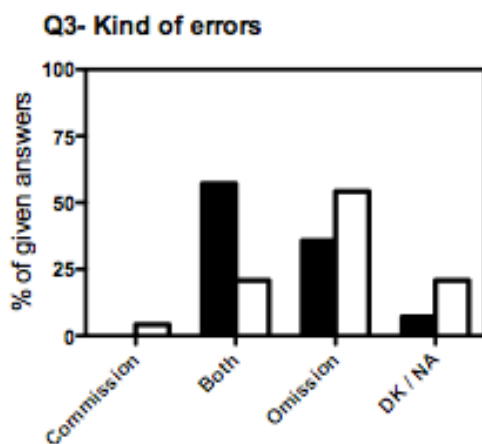
In the following the complete data have been demonstrated graphically. The reason is offering the readers an easy overview of all the data.



Q1- Do you think that the patient safety level is acceptable in your department?



Q2- To what extent do you think that there's medical errors in your department?



Q3- What kind of mistakes do you think that doctors in your department make most frequently? Put only one tick.

Leaders  
 ESICM members

DK / NA = Do not know / not applicable



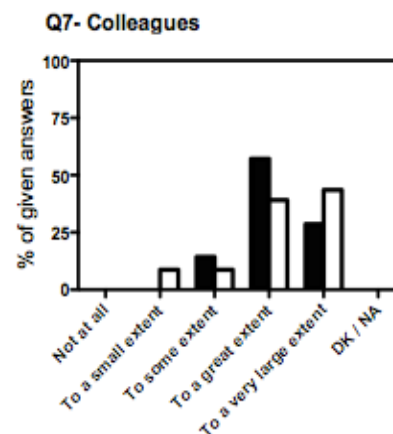
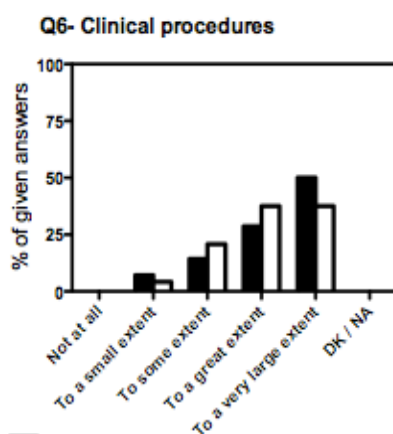
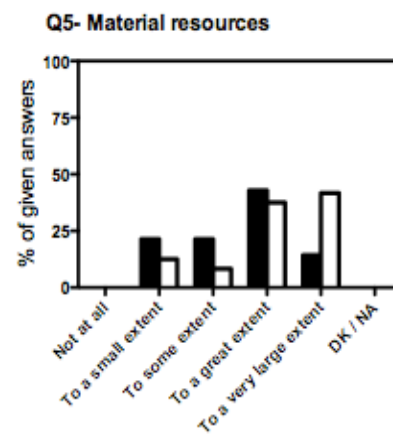
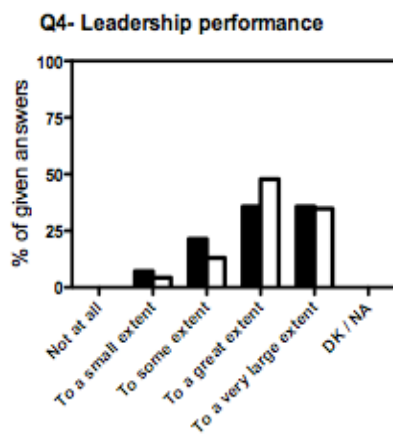
To what extent do you think

Q4- Leadership performance in your department is important for patient safety?

Q5- Material resources and the treatment capacity in your department is important for patient safety?

Q6- Explicit clinical procedures in your department are important for patient safety?

Q7- Colleagues' attitudes to the introduction of new procedures or treatments are important for patient safety?



Leaders  
 ESICM members  
 DK / NA = Do not know / not applicable

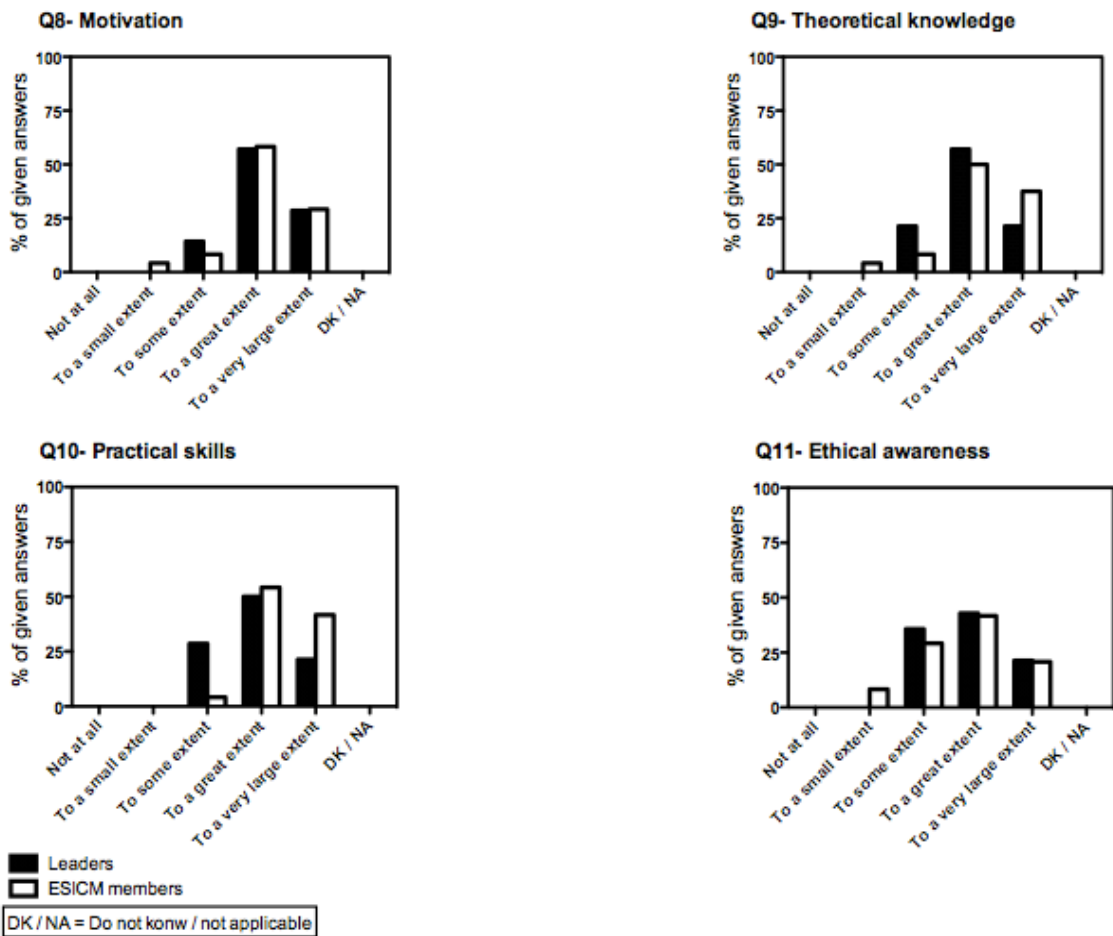
To what extent do you think doctor's

Q8- Motivation is important for patient safety in your department?

Q9- Theoretical knowledge is important for patient safety in your department?

Q10- Practical skills are important for patient safety in your department?

Q11- To what extent do you think doctor's ethical awareness is important for patient safety in your department?



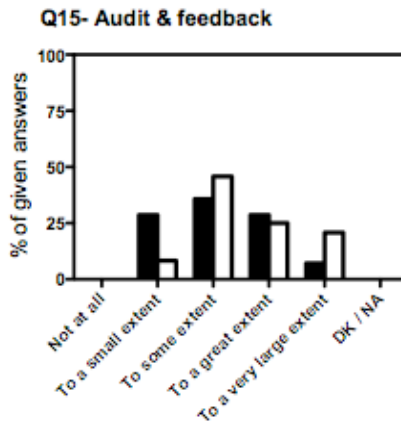
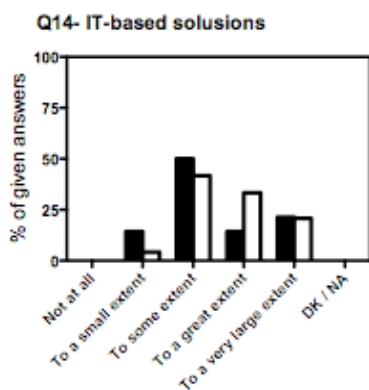
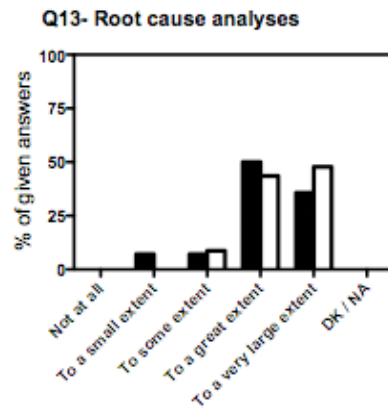
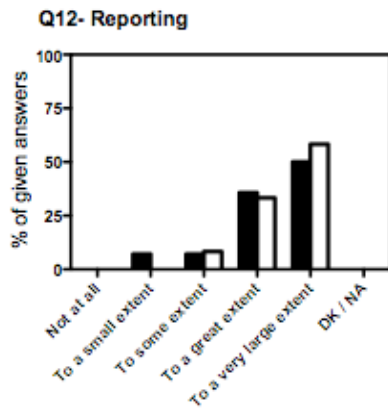
To what extent do you think

Q12- Physicians' reporting of adverse events (without risk of sanctions) is important to promote good patient safety in the intensive care units in general?

Q13- Root cause analysis based on the reporting of adverse events is important for patient safety in the intensive care units in general?

Q14- IT-based solutions (for example in the drug administration / reminders / support for clinical decisions) are important for patient safety in the intensive care units in general?

Q15- External audit and feedback are important for patient safety in the intensive care units in general?



Leaders  
 ESICM members  
 DK / NA = Do not know / not applicable



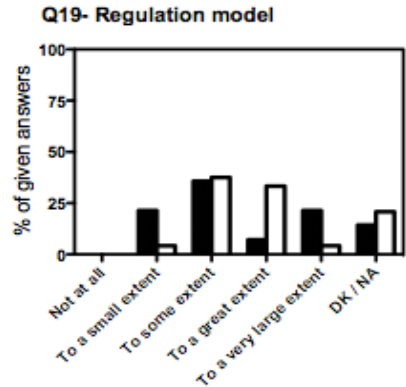
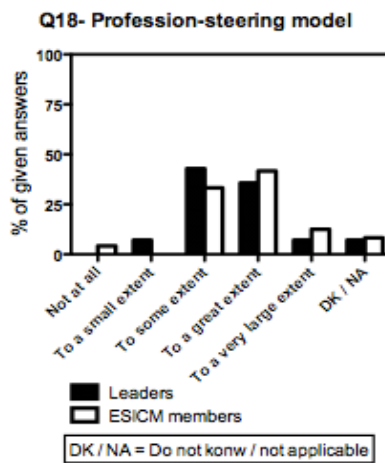
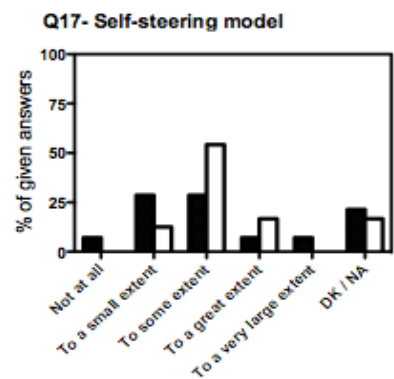
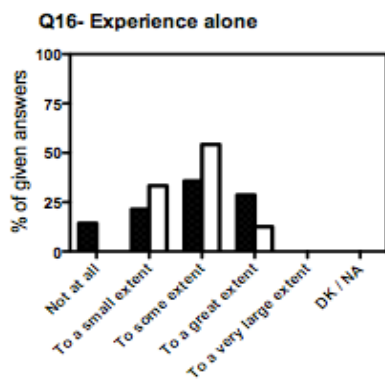
To what extent do you think

Q16- Clinical experience alone is sufficient to achieve high degree of patient safety?

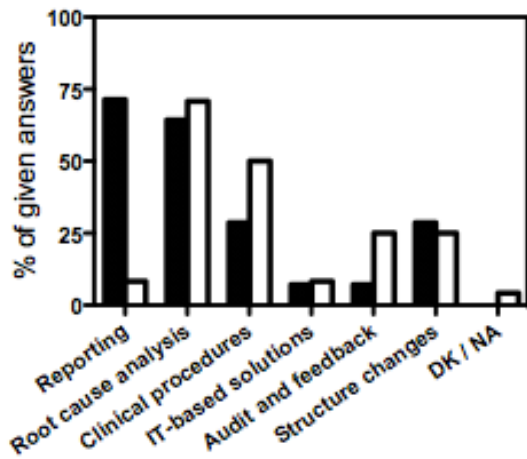
Q17- Self-steering model (for example “LEIF” program from The Norwegian Medical Association) is important to achieve high degree of patient safety?

Q18- Profession-steering model of CME (for example, GPs in Norway) is important to achieve high degree of patient safety?

Q19- Regulation model of CME is important to achieve high degree of patient safety?

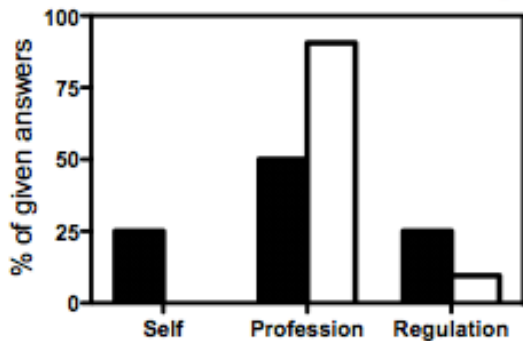


**Q20- Department-based measure**



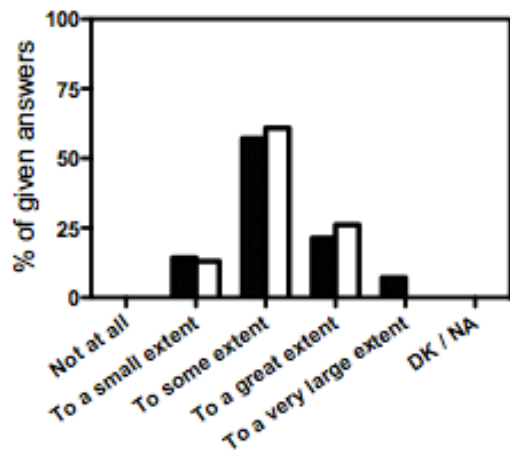
Q20- If you are going to improve patient safety in your department, which department-based measure do you choose to take (if none of these are implemented)? Choose two options.

**Q21- Preferred kind of CME Steering**



Q21- If you are going to improve patient safety in your department through increasing competency of physician staff, what kind of CME do you choose as the most appropriate? Choose only one option.

**Q22- Necessity of improving patient safety**



Q22- Altogether, do you think it is necessary to improve patient safety in your department?

Leaders  
 ESICM members

DK / NA = Do not know / not applicable

## Discussion

In this section we will discuss shortly a limited number of the results and their implications. A more extended discussion of the results are planned to be performed in the future when we publish this study in an international journal.

First of all it should be noted that the groups were alike and there was no statistical significant difference between the two groups in any question. This may reflect a common and collectively homogenous perceived understanding in the two groups regarding patient safety and education issues. The drawback of the survey, like other surveys of this kind, is the uncertainty of the answers and if they really reflect the real answer to the questions. Questionnaires like this are usually answered during work stress without time for deeper reflections. The responder usually chooses that answer which looks like more reasonable according to the first impression. The more adequate and reliable tool for studies like this study (investigating perceptions and attitudes), is probably deep interviews with limited number of well-chosen subjects.

The first questions in the questionnaire, concerning the perceived levels of patient safety and proportions of errors consider awareness of patient safety issues in general. The first question deals with the perceived current level of patient safety (*do you think that the patient safety level is acceptable in your department*). 86% of leader responders (LR) and 73% of ESICM-member responders (79.5% in average) think that the level of patient safety is, either to a great extent or to a very large extent, acceptable. This is an overwhelming high level of conviction. Accordingly, the second question (*to what extent do you think there are medical errors in your department?*) was answered by 49% of the LR and ER in average as the medical errors occur only to a small extent.

This initial part of the questionnaire and its first questions is complemented by the last part of the questionnaire where in question 22 the responders are asked if altogether, they think it is necessary to improve patient safety in their department. 84% percent of the LR and ER in average answered they think so either to a great extend or to a very great extend.

The first part of the questionnaire may demonstrate that we are overconfident in that we do the right things and we do them right as well as our lack of knowledge regarding patient safety literature and movement. If we assume that the difference between the Norwegian healthcare outcomes and those

outcomes in USA or England is not significant then it will be legitimate to adopt the results of the reports like “*To err is human*” and “*An organisation with a memory*” to Norwegian conditions. This adoption would demonstrate a striking number of deaths as a result of preventable errors and perhaps make us less overconfident.

In addition, there is a discrepancy between the answers to the question 1 and 22 which may be explained by the fact that many physicians think that the level of patient safety is good/very good but at the same time they are interested in to further improve it. Another explanation may be that the responders really think they are good/very good initially, but during the time they spend answering the questions they changed their minds and become interested in improving patient safety. This may occur as the responders are confronted with the different aspects of patient safety as well as more or less crucial factors influencing it. With this explanation the 10-15 minutes of answering the questionnaire may be regarded as a well rewarding educational time in patient safety. And if so, perhaps the most striking finding in our study was that there is a lack of patient safety awareness and education in Norwegian ICUs. Anyhow, one may simply emphasize only on the answer to the question 22 and formulate the statement that nearly 85% of the LR and ER think it is necessary to improve patient safety in their ICUs. This is a clear signal to the profession, authorities, and leaders in the hospitals. I have previously (in the section “*Résumé of the literature survey*”) outlined my personal views, regarding how to increase patient safety in Norway. I think these views deserve repetition:

*The situation in Norway cannot significantly be different from other western countries and the appropriate measures to promote patient safety should be similar as those described here.*

*A versatile and comprehensive system, much alike that of clinical governance from NHS, should be applied in Norwegian healthcare system by cooperation between the profession and authorities.*

*At the unit level (micro-level), we need to implement more specific programs like BIM and CUSP for ICUs.*

*And at the national level, Norway like US and other western countries should learn that the delivery of health care is a science. We suffer from insufficient training in quality and safety depending to our collective failure to*

*comprehend the delivery of health care as a science (117;118). Hence, at a national level we need to implement the following long-term measures; investing in quality and safety science, revising quality and safety governance in our hospitals (first university hospitals), and integrating the roles within the hospitals and medical faculties (117). In short term, we need to have a system approach first (like accreditation of hospitals, departments, and units) and a practitioner approach afterwards (compulsatory revalidation). The profession, authorities, and the public should cooperate regarding types of this revalidation (CME/ CPD, Peer review, or both), its regulators and involved penalty or rewards.*

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## 21. Appendices

### Appendix 1: SIMPATIE vocabulary

#### 1- DETECTION OF RISK

- **Patient Safety:** *The continuous identification, analysis and management of patient-related risks and incidents in order to make patient care safer and minimizing harm to patients. Safety emerges from interaction of the components of the system. Improving safety depends on learning how safety emerges from such interactions.*
- **Adverse Event:** *An unintended and undesired occurrence in the healthcare process because of the performance or lack of it of a healthcare provider and/or the healthcare system.*
- **Please note:** *In this vocabulary adverse events are considered as preventable (Please see Diagram 1) although realizing, that the clinical distinction between preventable and non preventable events is rather academic.*
- **Actual Event:** *An adverse event, which causes harm*
- **Near Miss (sub-event):** *An adverse event, with the capacity to cause harm but which does not have adverse consequences, because of for instance timely and appropriate identification and correction of potential consequences for the patient.*
- **Complication:** *An unintended and undesired outcome which develops as a consequence of intervention of an already present illness. It may be non preventable under the given circumstances.*
- **Please note the related definition of term “Adverse Outcome”.**
- **Sentinel Event:** *Sentinel reflects the seriousness of the injury and the likelihood that investigation of an event will reveal serious problems in current policies or procedures. Such occurrences signal the need for immediate investigation and response.*
- **Critical Incident:** *Occurrences, which are significant or pivotal, in either a desirable or an undesirable way. Significant or pivotal means that there was significant potential for harm (or actual harm), but also that the event has the potential to reveal important hazards in the organization. In other words, these incidents, whether near misses or events in which significant harm occurred, provide valuable opportunities to learn about individual and organizational factors that can be remedied to prevent similar incidents in the future.*



- **Complaint:** Each expression of resentment or discontent with the practice, operation or conduct of a healthcare provider made by a potential user or a user of the healthcare services or someone acting on their behalf.
- **Reporting System:** A system which is designed to contain reports on adverse events. On the basis of reports analysis and communication of known causes and risk situations is possible. The system can contain reports on human and technical errors as well as organizational circumstances, which affects the occurrence of adverse events in the healthcare process. Reporting systems include input from all stakeholders - providers and service users.
- **Professional Standard:** The standard of performance in particular circumstances taking into account recent insights and evidence-based norms and a standard of practice to be expected of a comparable experienced and qualified prudent practitioner in equal circumstances
- Please note the related definition of term “Negligence”.

## 2- ANALYSIS OF RISK

- **Harm:** Negative consequence experienced by a patient leading to; death, a permanent or temporary impairment of physical, mental or social function or a more intense or prolonged treatment
- **Adverse Outcome:** An unintended and undesired occurrence in the healthcare process, which causes harm to the patient
- Please note related definition of term “Complication”.
- **Risk:** The probability or chance that something undesirable will happen. A measure of the probability and severity of potential harm
- **Calculated Risk:** A deliberately and consciously taken risk in which the benefits of a treatment are deemed to offset/countervail the possible burden of serious harm
- **Barrier:** Protect people and structures from adverse events
- **Situational Awareness:** Refers to the degree to which one’s perception of a situation matches reality

## 3- RESULTING ACTIONS

- **Risk Management:** Identifying, assessing, analyzing, understanding, and acting on risk issues in order to reach an optimal balance of risk, benefits and costs
- **Error Management:** An approach to manage the aftermath of an error with the goal of reducing future errors, avoiding negative consequences and dealing quickly with consequences once they occur

- **Action Plan:** An Action Plan can be the result of analysis of adverse events. The Action Plan addresses system and process deficiencies; improvement strategies are developed and implemented
- **Culture of Safety:** An integrated pattern of individual and organizational behavior, based upon shared beliefs and values that continuously seeks to minimize patient harm, which may result from the processes of care delivery
- **Human Factor:** Refers to the study of human abilities, behaviors and characteristics as they affect the design and suggested intended operation of equipment, systems, and jobs. The field concerns itself with considerations of the strengths and weaknesses of human behavior, physical and mental abilities and how these affect the systems design.

#### **4- FAILURE MODE**

- **Error:** Preventable event leading to an adverse outcome being either an act of commission (doing something wrong) or omission (failing to do the right thing) that leads to an undesirable outcome or having significant potential for such an outcome
- **Situational Factor:** The factor in a process, which activates an error in the system
- **Negligence:** Care provided failed to meet the standard of care reasonably expected of a reasonably prudent and careful practitioner qualified to care for the patient in question
- Please note the related definition of term “Professional standard”.

## Appendix 2: ICPS definitions

- **Classification:** an arrangement of concepts into classes and their subdivisions, linked so as to express the semantic relationships between them
- **Concept:** a bearer or embodiment of meaning
- **Class:** a group or set of like things
- **Semantic relationship:** the way in which things (such as classes or concepts) are associated with each other on the basis of their meaning
- **Patient:** a person who is a recipient of healthcare
- **Healthcare:** services received by individuals or communities to promote, maintain, monitor or restore health
- **Health:** a state of complete physical, mental and social wellbeing and not merely the absence of disease or infirmity
- **Safety:** the reduction of risk of unnecessary harm to an acceptable minimum
- **Hazard:** a circumstance, agent or action with the potential to cause harm
- **Circumstance:** a situation or factor that may influence an event, agent or person(s)
- **Event:** something that happens to or involves a patient
- **Agent:** a substance, object or system which acts to produce change
- **Patient Safety:** the reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum
- **Healthcare-associated harm:** harm arising from or associated with plans or actions taken during the provision of healthcare, rather than an underlying disease or injury
- **Patient safety incident:** an event or circumstance which could have resulted, or did result, in unnecessary harm to a patient
- **Error:** failure to carry out a planned action as intended or application of an incorrect plan
- **Violation:** deliberate deviation from an operating procedure, standard or rule
- **Risk:** the probability that an incident will occur
- **Reportable circumstance:** a situation in which there was significant potential for harm, but no incident occurred
- **Near miss:** an incident which did not reach the patient
- **No harm incident:** an incident which reached a patient but no discernable harm resulted



- **Harmful incident (adverse event):** an incident that resulted in harm to a patient
- **Harm:** impairment of structure or function of the body and/or any deleterious effect arising there from. Harm includes disease, injury, suffering, disability and death
- **Disease:** a physiological or psychological dysfunction
- **Injury:** damage to tissues caused by an agent or event
- **Suffering:** the experience of anything subjectively unpleasant
- **Disability:** any type of impairment of body structure or function, activity limitation and/or restriction of participation in society, associated with past or present harm
- **Contributing factor:** a circumstance, action or influence which is thought to have played a part in the origin or development of an incident or to increase the risk of an incident
- **Incident type:** a descriptive term for a category made up of incidents of a common nature, grouped because of shared, agreed features
- **Patient characteristics:** selected attributes of a patient
- **Attributes:** qualities, properties or features of someone or something
- **Incident characteristics:** selected attributes of an incident
- **Adverse reaction:** unexpected harm resulting from a justified action where the correct process was followed for the context in which the event occurred
- **Side effect:** a known effect, other than that primarily intended, related to the pharmacological properties of a medication
- **Preventable:** accepted by the community as avoidable in the particular set of circumstances
- **Detection:** an action or circumstance that results in the discovery of an incident
- **Mitigating factor:** an action or circumstance that prevents or moderates the progression of an incident towards harming a patient
- **Patient outcome:** the impact upon a patient which is wholly or partially attributable to an incident
- **Degree of harm:** the severity and duration of harm, and any treatment implications, that results from an incident
- **Organizational outcome:** the impact upon an organization which is wholly or partially attributable to an incident
- **Ameliorating action:** an action taken or circumstances altered to make better or compensate any harm after an incident

- **Actions taken to reduce risk:** actions taken to reduce, manage or control any future harm, or probability of harm, associated with an incident
- **Resilience:** The degree to which a system continuously prevents, detects, mitigates or ameliorates hazards or incidents.
- **Accountable:** being held responsible
- **Quality:** the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge
- **System failure:** a fault, breakdown or dysfunction within an organization's operational methods, processes or infrastructure
- **System improvement:** the result or outcome of the culture, processes, and structures that are directed towards the prevention of system failure and the improvement of safety and quality
- **Root cause analysis:** a systematic iterative process whereby the factors that contribute to an incident are identified by reconstructing the sequence of events and repeatedly asking why? Until the underlying root causes have been elucidated

WHO explains that ICPS is not a classification but only a conceptual framework for an international classification representing a consensus of international experts on a reasonable understanding of patient safety.

# Appendix 3: Luxembourg Consensus statement

## Continuing Professional Development Improving Healthcare Quality, Ensuring Patient safety Luxembourg, 14 December 2006

 <p><b>CPD Improving Healthcare</b> Luxembourg, 14 December 2006</p> <p><b>CONTINUING PROFESSIONAL DEVELOPMENT IMPROVING HEALTHCARE QUALITY, ENSURING PATIENT SAFETY</b></p> <p><b>CONSENSUS STATEMENT</b></p> <p>Within our lifetimes major advances in Medicine have been, and continue to be made. The implementation of these is dependent on doctors learning how new techniques, therapies and clinical concepts can improve the quality and safety of care they provide for patients. Since its establishment the medical profession has recognised the importance of education, noting this as a core feature of its professionalism and a fundamental ethical principle.</p> <p>In this new century – characterised by an accelerating pace of change, increasing complexity, an unprecedented growth in information, and ever-increasing societal expectations – it is essential that doctors are supported in their continuing education, from medical school to retirement. Supported in this way, and entrusted with this responsibility, doctors will be more able to apply the beneficial effects of education, thus developing and improving their clinical performance.</p> <p>In addition to contributing to improvements in the care of individual patients, CPD also plays an important part in improving the quality of healthcare systems. This is through increasing doctors' awareness of the need for, and how to achieve improved healthcare. By virtue of their clinical and managerial responsibilities, doctors are well-placed to implement beneficial changes to the quality, efficiency and effectiveness of healthcare.</p> <p>While primarily directed at CPD for doctors, the principles of this statement are applicable in the context of the multi-disciplinary and multi-professional nature of modern healthcare and can also apply to other health professions.</p> <ol style="list-style-type: none"><li>1) Continuing Professional Development (CPD) can be defined as the educational means by which doctors ensure that they maintain and improve their medical competence and clinical performance. As such CPD incorporates and goes beyond Continuing Medical Education (CME).</li><li>2) It is an ethical and professional responsibility of every practising doctor to ensure that the medical care they provide for patients is safe and based on valid scientific evidence. In order to achieve this, every doctor must engage actively in CPD appropriate to their medical practice.</li><li>3) Ultimately it is patients who benefit from the involvement of their doctor(s) in CPD – through the improved quality and safety of medical care. Patients also benefit from the greater availability of medical educational material, by being more able to learn about their own health, illness and treatment. This knowledge would be even further improved by enhancing the role of doctors in information for and communication with their patients.</li><li>4) Irrespective of the nature of the healthcare system – whether employer-based, direct-paying, or insurance-remunerated – resources must be allocated to ensure that doctors are able to take part in CPD. Resources to support CPD include: educational activities; access to information technology; time for doctors to engage in education; peer support for a 'learning culture'; and, financial resources and an educational structure to support these.</li></ol> <p>1/2</p>	 <p><b>CPD Improving Healthcare</b> Luxembourg, 14 December 2006</p> <p><b>CONSENSUS STATEMENT</b></p> <ol style="list-style-type: none"><li>5) Doctors are very familiar with learning, but learn in individual ways; recognition must be given to this. Doctors should be supported in being able to use the learning methods that they prefer, based on an assessment of their learning needs, and educational opportunities must be sufficiently varied to provide for this. However, doctors should also be encouraged to develop new ways of learning, and to learn how to make the most of new technologies that can assist with medical education.</li><li>6) Every practising doctor must maintain those components of CPD that apply for all doctors, such as good communication, team-working, learning from audit and research. Similarly, each doctor must engage in 'specialised' aspects of CPD, which are specific for each speciality, or sub-speciality, and are relevant to their individual area of medical practice.</li><li>7) Specific attention must be given to the doctor's work environment, to ensure that this is supportive of learning 'on the job'. This will encourage doctors to reflect on, and learn from issues directly applicable to their clinical practice. As important members of healthcare teams, doctors should also be encouraged to support multi-disciplinary, and multi-professional team learning where that is relevant to the care of patients.</li><li>8) Doctors also should take part in medical educational activities outside the workplace, such as learning through reading, e-learning activities, small group learning, and clinical conferences. These support the development of learning with reference to externally-set educational standards.</li><li>9) It is important to ensure that learning also occurs when there may have been problems related to medical care. Accordingly, learning should be linked to clinical audit, patient and colleague feedback, and clinical/critical incident reporting systems, thus ensuring that these contribute to a culture of improving quality and safety.</li><li>10) Doctors should reflect on what they have learned and on how this can be applied in their clinical practice. Every doctor, preferably in a peer dialogue, should regularly review the outcomes of their CPD, and consider what areas need to be addressed before the next review. To assist with this, doctors should keep a record of their CPD activities, ideally emphasising what they have learned. In addition to being supportive of good education, a system such as this – based on peer review of CPD goals set and achieved – also provides the basis for accountable self-regulation.</li><li>11) In order to ensure that doctors can know that they are taking part in formal CPD activities that fulfil appropriately high quality standards, a quality assurance system, based on accreditation of CPD events and validation of providers, must be enforced. While usually these are national systems, in the case of the European Accreditation Council for CME (EACCME) accreditation can also be confirmed for international meetings.</li><li>12) There must be appropriate regulation of formal CPD activities. All providers of formal CPD activities must adhere to policies – usually national – that ensure such CPD will be free of any form of bias. There must be a clear declaration by organisers and lecturers of any potential or actual conflict of interest, and transparency regarding the funding of educational activities.</li></ol> <p>2/2</p>
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*Within our lifetimes major advances in Medicine have been, and continue to be made. The implementation of these is dependent on doctors learning how new techniques, therapies and clinical concepts can improve the quality and safety of care they provide for patients. Since its establishment the medical profession has recognised the importance of education, noting this as a core feature of its professionalism and a fundamental ethical principle.*

*In this new century - characterised by an accelerating pace of change, increasing complexity, an unprecedented growth in information, and ever-increasing societal expectations - it is essential that doctors are supported in their continuing education, from medical school to retirement. Supported in this way, and entrusted with this responsibility, doctors will be more able to apply the beneficial effects of education, thus developing and improving their clinical performance.*

*In addition to contributing to improvements in the care of individual patients, CPD also plays an important part in improving the quality of healthcare systems. This is through increasing doctors' awareness of the need for, and how to achieve improved healthcare. By virtue of their clinical and managerial responsibilities, doctors are well-placed to implement beneficial changes to the quality, efficiency and effectiveness of healthcare.*

*While primarily directed at CPD for doctors, the principles of this statement are applicable in the context of the multi-disciplinary and multi-professional nature of modern healthcare and can also apply to other health professions.*

*1) Continuing Professional Development (CPD) can be defined as the educational means by which doctors ensure that they maintain and improve their medical competence and clinical performance. As such CPD incorporates and goes beyond Continuing Medical Education (CME).*

*2) It is an ethical and professional responsibility of every practising doctor to ensure that the medical care they provide for patients is safe and based on valid scientific evidence. In order to achieve this, every doctor must engage actively in CPD appropriate to their medical practice.*

*3) Ultimately it is patients who benefit from the involvement of their doctor(s) in CPD – through the improved quality and safety of medical care. Patients also benefit from the greater availability of medical educational material, by being more able to learn about their own health, illness and treatment. This knowledge would be even further improved by enhancing the role of doctors in information for and communication with their patients.*

*4) Irrespective of the nature of the healthcare system – whether employer-based, direct-paying, or insurance-remunerated – resources must be allocated to ensure that doctors are able to take part in CPD. Resources to support CPD include: educational activities; access to information technology; time for doctors to engage in education; peer support for a “learning culture”, and; financial resources and an educational structure to support these.*

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*10) Doctors should reflect on what they have learned and on how this can be applied in their clinical practice. Every doctor, preferably in a peer dialogue, should regularly review the outcomes of their CPD, and consider what areas need to be addressed before the next review. To assist with this, doctors should keep a record of their CPD activities, ideally emphasising what they have learned. In addition to being supportive of good education, a system such as this - based on peer review of CPD goals set and achieved - also provides the basis for accountable self-regulation.*



*11) In order to ensure that doctors can know that they are taking part in formal CPD activities that fulfil appropriately high quality standards, a quality assurance system, based on accreditation of CPD events and validation of providers, must be enforced. While usually these are national systems, in the case of the European Accreditation Council for CME (EACCME) accreditation can also be confirmed for international meetings.*

*12) There must be appropriate regulation of formal CPD activities. All providers of formal CPD activities must adhere to policies - usually national - that ensure such CPD will be free of any form of bias. There must be a clear declaration by organisers and lecturers of any potential or actual conflict of interest, and **transparency** regarding the funding of educational activities.*



# Appendix 4: Luxembourg Declaration on Patient Safety

## Patient Safety - Making it Happen! Luxembourg , 5 April 2005

 <p><b>Patient Safety – Making it Happen!</b></p> <p><b>Luxembourg Declaration on Patient Safety</b></p> <p>Access to high quality healthcare is a key human right recognised and valued by the European Union, its Institutions and the citizens of Europe. Accordingly, patients have a right to expect that every effort is made to ensure their safety as users of all health services.</p> <p><b>Background:</b></p> <p>The health sector is a high-risk area because adverse events, arising from treatment rather than disease, can lead to death, serious damage, complications and patient suffering. Although many hospitals and healthcare settings have procedures in place to ensure patient safety, the health care sector still lags behind other industries and services that have introduced systematic safety processes.</p> <p>A number of investigations from all over the world have underlined the need for and the possibility of reducing the number of adverse events in the health sector. Current data show that almost half of all preventable adverse events are a consequence of medication errors.</p> <p>Accordingly, tools must be introduced aimed at reducing the number and consequences of adverse events. The health sector should be designed in a way that errors and adverse events are prevented, detected or contained so that serious errors are avoided and compliance with safety procedures is enhanced.</p> <p>As a result of the work done in this field by many players and institutions and the evidence gathered, it is now clear that the first step that needs to be taken should be to establish a culture of patient safety throughout the entire health system. Risk management must be introduced as a routine instrument within the running of the entire health sector. A precondition for risk management is an open and trusting working environment with a culture that focuses on learning from near misses and adverse events as opposed to concentrating on "blame and shame" and subsequent punishment.</p> <p>Health sector induced harms to patients imposes a heavy burden on society. Investment in patient safety therefore has the potential to generate savings in expenditure coupled with its obvious benefit to patients.</p> <p>Focus on patient safety leads to savings in treating patients exposed to adverse events and the consequential improved use of financial resources. In addition, savings are achieved in administrative costs associated with compulsory and applications for compensation. Most importantly, patient safety contributes to an increase in quality of life. In order to achieve this, the culture of safety can be improved significantly in various ways.</p> <p>In light of the above, the conference recommends that "Patient Safety" has a significant place high on the political agenda of the EU, nationally in the EU Member States and locally in the health care sector.</p> <p><b>The conference recommends: the EU Institutions:</b></p> <ul style="list-style-type: none"><li>◆ To establish an EU forum with participation by relevant stakeholders to discuss European and national activities regarding patient safety.</li><li>◆ To work in alliance with WHO Alliance towards a common understanding on patient safety issues, and to establish an "EU solution bank" with "best practice" examples and standards.</li></ul> <p>Luxembourg , 5 April 2005</p>	 <p><b>Patient Safety – Making it Happen!</b></p> <ul style="list-style-type: none"><li>◆ To create the possibility of support mechanisms for national initiatives regarding patient safety projects, acknowledging that patient safety is in the programme of DG Health and Consumer Protection</li><li>◆ To ensure that EU regulations with regard to medical goods and related services are designed with patient safety in mind.</li><li>◆ To encourage the development of international standards for the safety and performance of medical technology.</li><li>◆ To ensure that the European regulatory framework protects the privacy and confidentiality of patient records in the best interests of the patient, while at the same time ensuring that relevant patient information is readily available to health care professionals.</li></ul> <p><b>The conference recommends to the National Authorities:</b></p> <ul style="list-style-type: none"><li>◆ To provide patients with full and free access to their personal health information whilst ensuring data accuracy and that patients fully understood their treatment. It is acknowledged that "informed patients" are well positioned to safeguard their own health.</li><li>◆ To consider the benefits of a national voluntary confidential reporting systems of adverse events and near misses.</li><li>◆ To work towards the introduction of risk management routines, for example, by developing guidelines and indicators as a part of a quality assessment systems in the health care sector.</li><li>◆ To optimise the use of new technologies, for example, by introducing electronic patient records. Such records would include the personal medical profile and decision-making support programs for health professionals with a view to reducing medication errors and increasing compliance rates.</li><li>◆ To establish national fora, with participation by relevant stakeholders, to discuss patient safety and national activities.</li><li>◆ To safeguard working conditions for all health care professions and to ensure that policies on recruitment and retention are linked to patient safety.</li><li>◆ To recognize and support the user training provided by medical devices, tools and appliances manufacturers thereby ensuring the safe use of new medical technology and surgical techniques.</li><li>◆ To include patient safety in the standard training of health professionals combined with integrated methods and procedures that are embedded in a culture of continuous learning and improvement.</li><li>◆ To ensure that national regulatory framework protects the privacy and confidentiality of patient records in the best interests of the patient, while at the same time ensuring that relevant patient information is readily available to health care professionals.</li><li>◆ To create a culture that focuses on learning from near misses and adverse events as opposed to concentrating on "blame and shame" and subsequent punishment.</li></ul> <p><b>The conference recommends to health care providers:</b></p> <ul style="list-style-type: none"><li>◆ To facilitate a collaborative care approach between health professionals and health care providers, aimed at enhancing patient safety.</li><li>◆ To implement work place projects focusing on patient safety and to establish an open culture to deal with errors and omissions more effectively.</li><li>◆ To initiate a co-operation between patients/relatives and health care professionals in order that patients/relatives are aware of near misses and adverse events.</li></ul> <p>Luxembourg , 5 April 2005</p>
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*Access to high quality healthcare is a key human right recognised and valued by the European Union, its Institutions and the citizens of Europe. Accordingly, patients have a right to expect that every effort is made to ensure their safety as users of all health services.*

### **Background:**

*The health sector is a high-risk area because adverse events, arising from treatment rather than disease, can lead to death, serious damage, complications and patient suffering. Although many hospitals and healthcare settings have procedures in place to ensure patient safety, the healthcare sector still lags behind other industries and services that have introduced systematic safety processes.*

*A number of investigations from all over the world have underlined the need for and the possibility of reducing the number of adverse events in the health sector. Current data show that almost half of all preventable adverse events are a consequence of medication errors.*

*Accordingly, tools must be introduced aimed at reducing the number and consequences of adverse events. The health sector should be designed in a way that errors and adverse events are prevented,*

*detected or contained so that serious errors are avoided and compliance with safety procedures is enhanced.*

*As a result of the work done in this field by many players and institutions and the evidence gathered, it is now clear that the first step that needs to be taken should be to establish a culture of patient safety throughout the entire health system. Risk management must be introduced as a routine instrument within the running of the entire health sector. A precondition for risk management is an open and trusting working environment with a culture that focuses on learning from near misses and adverse events as opposed to concentrating on “blame and shame” and subsequent punishment.*

*Health sector induced harm to patients imposes a heavy burden on society. Investment in patient safety therefore has the potential to generate savings in expenditure coupled with an obvious benefit to patients.*

*Focus on patient safety leads to savings in treating patients exposed to adverse events and the consequential improved use of financial resources. In addition, savings are achieved in administration costs associated with complaints and applications for compensation. Most importantly, patient safety contributes to an increase in quality of life. In order to achieve this, the culture of safety can be improved significantly in various ways.*

*In light of the above, the conference recommends that “Patient Safety” has a significant place high on the political agenda of the EU, nationally in the EU Member States and locally in the healthcare sector.*

***The conference recommends the EU Institutions:***

- ❖ To establish an EU forum with participation by relevant stakeholders to discuss European and national activities regarding patient safety.*
- ❖ To work in alliance with WHO Alliance towards a common understanding on patient safety issues, and to establish an “EU solution bank” with “best practice” examples and standards.*
- ❖ To create the possibility of support mechanisms for national initiatives regarding patient safety projects, acknowledging that patient safety is in the programme of DG Health and Consumer Protection*
- ❖ To ensure that EU regulations with regard to medical goods and related services are designed with patient safety in mind.*
- ❖ To encourage the development of international standards for the safety and performance of medical technology.*
- ❖ To ensure that the European regulatory framework protects the privacy and confidentiality of patient records in the best interests of the patient, while at the same time ensuring that*

*relevant patient information is readily available to healthcare professionals.*

***The conference recommends to the National Authorities:***

- ❖ To provide patients with full and free access to their personal health information whilst ensuring data accuracy and that patients fully understand their treatment. It is acknowledged that “informed patients” are well positioned to safeguard their own health.*
- ❖ To consider the benefits of a national voluntary confidential reporting systems of adverse events and near misses.*
- ❖ To work towards the introduction of risk management routines, for example, by developing guidelines and indicators as a part of a quality assessment system in the healthcare sector.*
- ❖ To optimize the use of new technologies, for example, by introducing electronic patient records. Such records would include the personal medical profile and decision-making support programs for health professionals with a view to reducing medication errors and increasing compliance rates.*
- ❖ To establish national fora, with participation by relevant stakeholders, to discuss patient safety and national activities.*
- ❖ To safeguard working conditions for all healthcare professions and to ensure that policies on recruitment and retention are linked to patient safety.*
- ❖ To recognize and support the user training provided by medical devices, tools and appliances manufacturers thereby ensuring the safe use of new medical technology and surgical techniques.*
- ❖ To include patient safety in the standard training of health professionals combined with integrated methods and procedures that are embedded in a culture of continuous learning and improvement.*
- ❖ To ensure that national regulatory framework protects the privacy and confidentiality of patient records in the best interests of the patient, while at the same time ensuring that relevant patient information is readily available to healthcare professionals.*
- ❖ To create a culture that focuses on learning from near misses and adverse events as opposed to concentrating on “blame and shame” and subsequent punishment.*

***The conference recommends to healthcare providers:***

- ❖ To facilitate a collaborative care approach between health professionals and healthcare providers, aimed at enhancing patient safety.*

- ❖ *To implement work place projects focusing on patient safety and to establish an open culture to deal with errors and omissions more effectively.*
- ❖ *To initiate a co-operation between patients/relatives and healthcare professionals in order that patients/relatives are aware of near misses and adverse events.*

List of supporting organizations to the Luxembourg Declaration on Patient Safety:

European Commission, DG Health and Consumer Protection, Luxembourg Presidency (first half of 2005), Presidency of the United Kingdom, European Association of Senior Hospital Physicians (AEMH), Standing Committee of European Doctors (CPME), European Federation of Pharmaceutical Industries and Associations (EFPIA), European Health Management Association (EHMA), European Health Telematics Association (EHTEL), European Patients' Forum (EPF), European Society for Quality in Healthcare (ESQH), European Medical Technology Industry Association (Eucomed), European Hospital and Healthcare Federation (HOPE), Standing Committee of Nurses of the European Union (PCN), Pharmaceutical Group of the European Union (PGEU), European Diagnostic Manufacturers Association (EDMA), Dutch Institute for Healthcare Improvement (CBO), Danish Society for Patient Safety (DSFP), European Association for Medical Device Reprocessing (EAMDR), Austrian Association of Hospital Pharmacists (AAHP), European Association of Hospital Pharmacists (EAHP)

## Appendix 5: “Good Doctors, Safer Patients”

### **Change recommendations**

- I. “design a strong, effective interface between local healthcare systems for assuring good clinical governance and patient safety, and the system of regulating the practice of individual doctors;*
- II. establish clearer and more rigorous public accountability for the performance of the systems intended to promote and assure good practice and protect patients from bad practice;*
- III. introduce a system of regular assessment of doctors’ practice which overcomes the weaknesses of the current revalidation proposals, is valued by the medical profession, is trusted by the public, is effective and is sustainable in the long term;*
- IV. create for generic and specialist domains of medical practice clear standards that are valid, reliable, capable of assessment and transparent to the public, professionals and employers;*
- V. develop good methods of assessment that: measure a doctor’s performance against a predetermined standard; assess knowledge, skills and task performance; are relevant to the day-to-day work that a doctor undertakes; represent value for money, and create the opportunity for a doctor to develop and improve;*
- VI. reduce the climate of blame, retribution and disciplinary action that usually attends poor medical performance, and introduce stronger elements of prevention and earlier recognition of problems, retraining and rehabilitation;*
- VII. eliminate situations where poor practice is not recognised and acted upon because of adverse organisational culture, weak local clinical governance, poor employment practice, variable standards for judging performance, doctors being between jobs, or locations or situations where it is unclear whose responsibility it is to take action;*
- VIII. reshape the role, structure and functions of the General Medical Council to focus it on the core activities of investigating serious complaints (rather than adjudicating on them), maintaining the medical and specialist registers, and overseeing the system of quality assurance of standards of practice whilst devolving more assessment and decision making to a local level;*
- IX. ensure a stronger interface between complaints about clinical services and complaints about doctors;*
- X. give educational and standard-setting bodies a more formal role in medical regulation.”*

## **Action recommendations**

- I. the creation of a clear, unambiguous and operationalised standard to define a good doctor, and its adoption into the contracts of all doctors*
- II. measures to reduce the risk of poorly performing doctors falling through the net, especially since the expansion in the diversity of roles, working patterns and practice settings*
- III. steps to further the consistency with which medical education is managed across undergraduate and postgraduate curricula;*
- IV. improve access for the public to timely and meaningful information about doctors, coupled with measures to ensure that such information is handled intelligently*

## Appendix 6: Financial incentives and quality

### **1. Financial incentives directed at improving quality**

- I. The findings from studies on the effect of payer initiatives that reward providers for quality improvements or the attainment of quality benchmarks are mixed. Relatively few significant impacts are reported, and it is often the case that payer programmes include quality improvement components in addition to incentive payments, making it difficult to assess the independent effect of the financial incentives.*
- II. Very little research has been done on the impact of direct payments to hospitals to improve quality. The published research to date in this area is too limited to draw conclusions with confidence.*
- III. Though relatively more attention has been paid to preventive services, there is limited evidence that targeted interventions employing financial incentives to improve the delivery of preventive services are effective. The few studies in this area with strong research designs find small, if any, effects of payments to providers that are intended to improve quality.*
- IV. The accumulated body of research described in this chapter is not yet sufficient to assess the relative significance of identified barriers to the effective design and implementation of pay-for-performance initiatives. There are large pay-for-performance programmes underway in the US and the UK with more evaluations likely to appear in the peer-reviewed literature in the near future. Because of the variation in the way these programmes have been designed and implemented, synthesizing their findings to provide useful guidance for decision-makers will be challenging. It will be especially important to have comprehensive reporting of results in future studies (not limiting results to a subset of quality measures rewarded by payers), accompanied by complete descriptions of study context and possible confounding factors. In the meantime, policy-makers can support, and learn from, process evaluations of ongoing pay-for-performance efforts with particular attention to accurate documentation of costs as well as continued tracking of outcomes.*

### **2. Secondary impacts on quality of financial incentives directed at reducing utilization and costs**

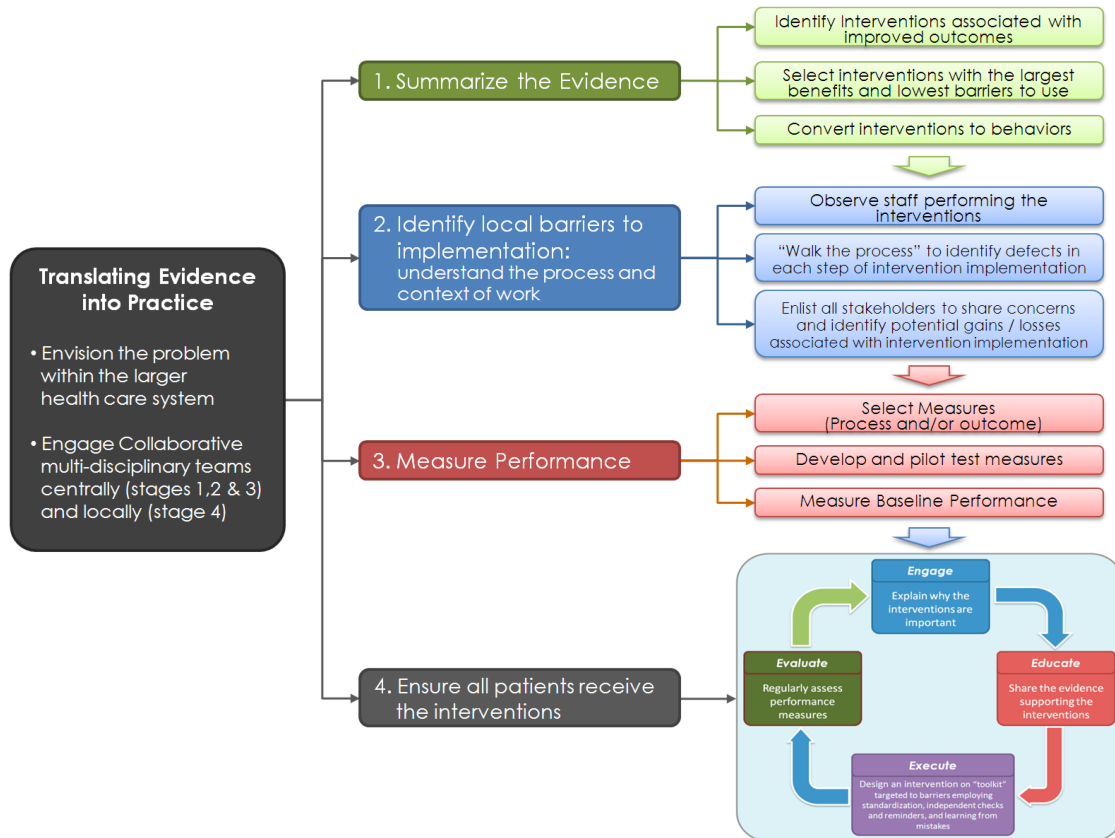
- I. The evidence regarding the secondary impacts of financial incentives on quality of care is not compelling. There are several possible explanations. First, the incentives studied were designed, for the most part, to reduce utilization of services. Generally, the hypothetical link between service reduction and quality in the studies is not clear, especially where utilization may have been excessive prior to the introduction of different payment arrangements. Second, the literature reports results for a wide range of quality and outcome measures, making it difficult to detect patterns in the findings. The most commonly used outcome measure - mortality - may not be sensitive to the relatively modest changes in financial incentives found in many studies. Also, mortality can be influenced by a host of factors,*

*many unrelated to medical care, making it difficult to isolate the marginal effects of financial incentives.*

- II. How incentives are transmitted to the level at which decisions about treatment are actually made is not clear in most studies. Typically, information is lacking concerning other efforts to address quality via the health plan, hospital, and physician practice or government agencies. It seems likely that these efforts would interact with financial incentives for providers to influence quality of care. Most studies do not control for these quality management efforts when drawing conclusions about the impact of financial incentives.*
- III. The use of multiple quality of care and patient outcome indicators in a single research study enables a richer interpretation of findings. However, when results are conflicting in these situations, no clear overall picture of the impact of incentives emerges. Also, it is not clear in most of these studies if the authors adjusted their statistical tests to account for the multiple comparisons undertaken in their analyses.*
- IV. The exact nature of provider payment arrangements often is not clearly described in the studies. This is true in particular for comparisons of quality of care under different insurance arrangements. Because the relationships between payment arrangements and quality are likely to be more subtle than the links between payment and service utilization, the absence of a description of provider payment incentives makes interpretation of findings even more difficult.*
- V. Many of the studies were cross-sectional in design. There may have been considerable variability in provider quality of care, irrespective of financial incentives, that made it difficult for researchers to detect the influence of financial incentives on quality without access to adequate control variables.*



## Appendix 7: A collaborative model of translating evidence into practice



## Appendix 8: Steps of Barrier Identification and Mitigation (BIM) Tool

### Step 1. Assemble the interdisciplinary team

The team should be composed of frontline care practitioners (physicians, nurses, technicians), administrators, and human factors and quality improvement specialists.

### Step 2. Identify barriers

This step includes three methods of data collection that can be performed in parallel. Each investigator collects data independently using these collection methods and records both the barriers and possible corrective actions on Table 3. This step may take 2-6 hours.

**Method 1:** Observe the process: Observe staff attempting to use the guideline and record

Steps skipped

Work-arounds (other process steps)

Why it is difficult to comply

Factors that support compliance (i.e. guideline facilitators)

**Method 2:** Ask about the process: Ask staff through interviews or short questionnaires whether they

Are aware of the guideline

Agree with the guideline (i.e., Do staff think that the guideline is appropriate for their patients?)

Have any suggestions to improve compliance with guideline

**Method 3:** Walk the process

Try to comply with the guideline using simulation or, if appropriate, under real circumstances.

Continue collecting data until no new barriers are identified upon new data collection and a comprehensive understanding of current practices used and barriers to guideline compliance is achieved

### Step 3. Summarize barriers (table 3)

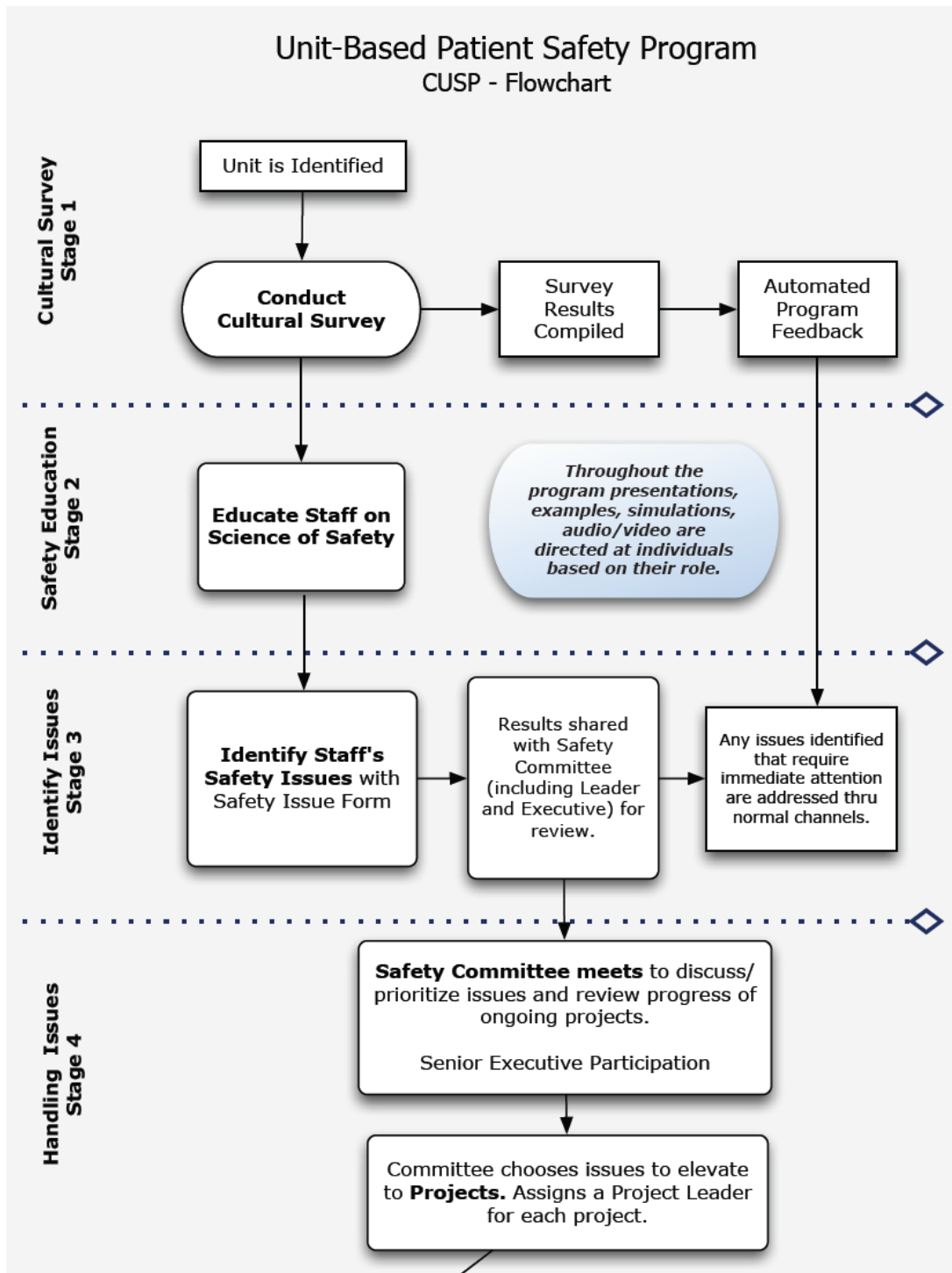
A team member compiles the data collected by several investigators on Table 3.

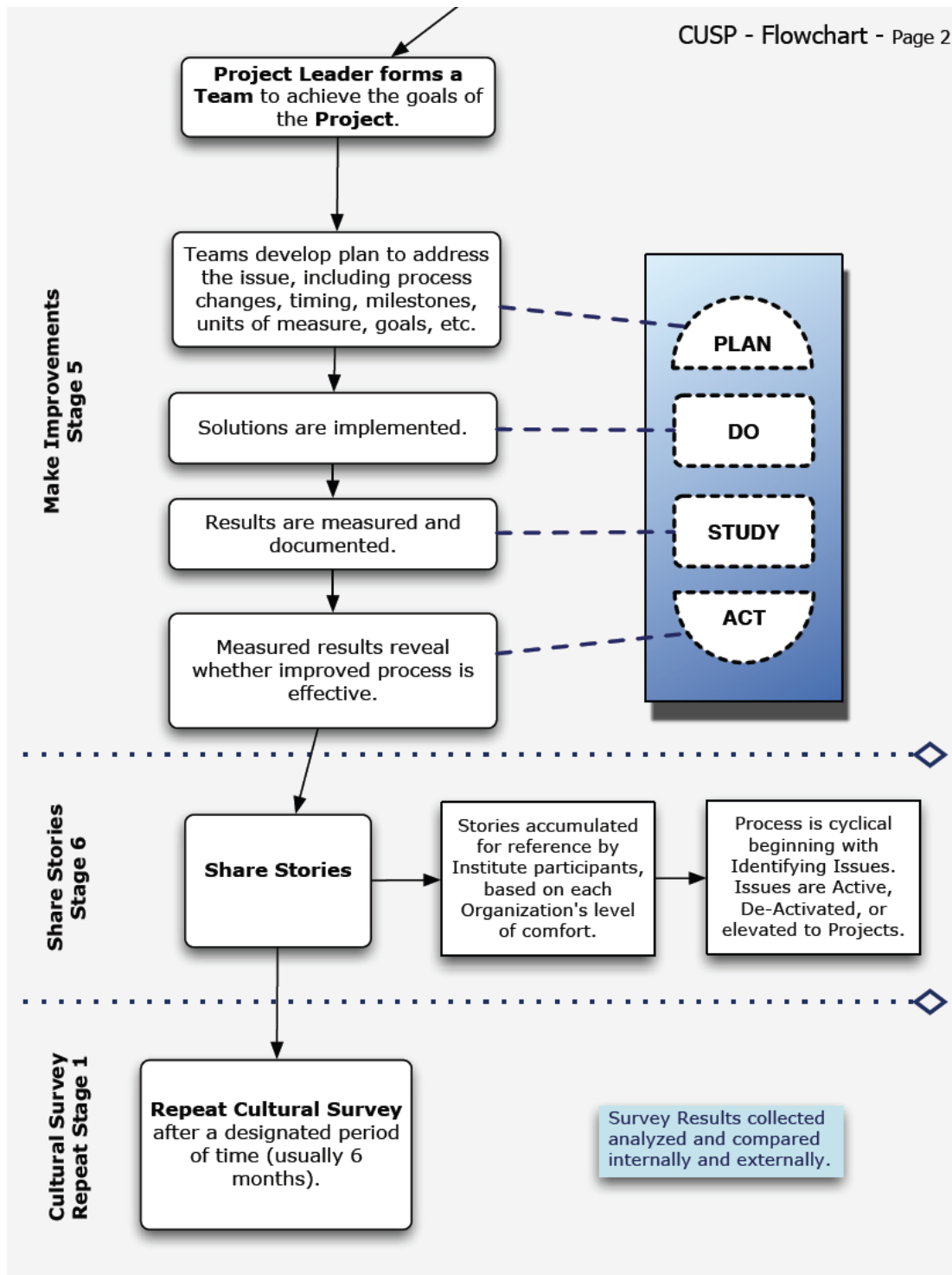
### Step 4. Prioritize barriers (Table 4)

The interdisciplinary team reviews and discusses the barrier summary. The team prioritized barriers based on two criteria:

1. Likelihood: probability of experiencing a barrier
2. Severity: probability that barrier will lead to noncompliance

# Appendix 9: Comprehensive Unit-based Patient Safety Program (CUSP)





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## Appendix 10: The survey

### *The introduction e-mail*

Dear colleague!

First, we thank you for being willing to dedicate time to answer our current poll. The questionnaire, which is answered anonymously, seeks to shed light on whether there is any relationship between patient safety and the department's characteristics and doctors' continuous medical education. The questionnaire consists of 23 questions (taking about ten minutes to complete it) and may have implications for how the patient safety work and continuing education should be arranged in the future.

The questionnaire has been sent to all academic and administrative managers in the intensive care units at university hospitals. It has also been sent to other defined decision-makers at the same units. This means that there are approximately 30 people who received the questionnaire and each response is thus very valuable. The short-term goal of this study is to determine the status with regard to the relationship between patient safety and factors related to the departments and physicians, including doctors' continuous medical education.

The information will be analyzed and initially used in a master's thesis which deals with this topic. The long-term goal is - through dialogue and cooperation - to help develop the Norwegian intensive care units to the most knowledgeable and patient secure in Europe. The first requirement in order to achieve this is precisely the belief that one can be the best. Furthermore, it requires of course, hard work and clear goals and means. We hope that our study may contribute to discussions in the academic community and inspire a common effort for such an improvement.

Sincerely,

Albert Castellheim, MD, PhD  
Chief senior consultant

John-Arne Røttingen  
Professor, MD, PhD  
Director of Norwegian Knowledge  
Centre for the Health Services

## ***The questionnaire***

### **I. Patient safety and errors in the intensive care unit**

**1- Do you think that the patient safety level is acceptable in your department?**

- 1 Not at all
- 2 To a small extent
- 3 To some extent
- 4 To a great extent
- 5 To a very large extent
- 6 Do not know / not applicable

There are two types of medical errors; “error of commission” which means that things that should not happen, happen anyway (like amputation of the wrong leg), while “error of omission” means that things which should happen, do not happen (like the lack of insulin administration when blood glucose is high).

**2- To what extent do you think that there's medical errors in your department?**

- 1 Not at all
- 2 To a small extent
- 3 To some extent
- 4 To a great extent
- 5 To a very large extent
- 6 Do not know / not applicable

**3- What kind of mistakes do you think that doctors in your department make most frequently? Put only one tick.**

- 1 Error of commission
- 2 Both types of errors occur approximately at the same frequency
- 3 Error of omission
- 4 Do not know / not applicable

## II. System and structural factors that may affect patient safety

System and structural factors may be of great importance for quality and patient safety. Organizational structure includes leadership, personal and material resources, capacity and treatment procedures as well as the department's culture which consists of its "history" plus a number of other factors. These factors consist of both individual-dependent factors (as motivation and competence) and social-dependent factors (such as colleagues' views, cooperation)

To what extent do you think

4- Leadership performance in your department is important for patient safety?

- 1 Not at all
- 2 To a small extent
- 3 To some extent
- 4 To a great extent
- 5 To a very large extent
- 6 Do not know / not applicable

5- Material resources and the treatment capacity in your department is important for patient safety?

- 1 Not at all
- 2 To a small extent
- 3 To some extent
- 4 To a great extent
- 5 To a very large extent
- 6 Do not know / not applicable

6- Explicit clinical procedures in your department are important for patient safety?

- 1 Not at all
- 2 To a small extent
- 3 To some extent
- 4 To a great extent
- 5 To a very large extent
- 6 Do not know / not applicable

7- Colleagues' attitudes to the introduction of new procedures or treatments are important for patient safety?

- 1 Not at all
- 2 To a small extent
- 3 To some extent
- 4 To a great extent
- 5 To a very large extent
- 6 Do not know / not applicable

## III. Physician factors that may affect patient safety

There are several physician factors that may affect patient safety. In the following there are several questions regarding your views about the importance of these factors to maintain or improve patient safety.

To what extent do you think doctor's

8- Motivation is important for patient safety in your department?

- 1 Not at all
- 2 To a small extent
- 3 To some extent
- 4 To a great extent
- 5 To a very large extent
- 6 Do not know / not applicable

9- Theoretical knowledge is important for patient safety in your department?

- 1 Not at all
- 2 To a small extent
- 3 To some extent
- 4 To a great extent
- 5 To a very large extent
- 6 Do not know / not applicable

10- Practical skills are important for patient safety in your department?

- 1 Not at all
- 2 To a small extent
- 3 To some extent
- 4 To a great extent
- 5 To a very large extent
- 6 Do not know / not applicable

11- To what extent do you think doctor's ethical awareness is important for patient safety in your department?

- 1 Not at all
- 2 To a small extent
- 3 To some extent
- 4 To a great extent
- 5 To a very large extent
- 6 Do not know / not applicable

#### IV. Department-based patient safety

In the following we have listed five quality and patient safety measures at department level. The questions deal with your views about the importance of these measures in the intensive care units in general.

To what extent do you think

12- Physicians' reporting of adverse events (without risk of sanctions) is important to promote good patient safety in the intensive care units in general?



- 1 Not at all
- 2 To a small extent
- 3 To some extent
- 4 To a great extent
- 5 To a very large extent
- 6 Do not know / not applicable

13-Root cause analysis based on the reporting of adverse events is important for patient safety in the intensive care units in general?

- 1 Not at all
- 2 To a small extent
- 3 To some extent
- 4 To a great extent
- 5 To a very large extent
- 6 Do not know / not applicable

14-IT-based solutions (for example in the drug administration / reminders / support for clinical decisions) are important for patient safety in the intensive care units in general?

- 1 Not at all
- 2 To a small extent
- 3 To some extent
- 4 To a great extent
- 5 To a very large extent
- 6 Do not know / not applicable

15-External audit and feedback are important for patient safety in the intensive care units in general?

- 1 Not at all
- 2 To a small extent
- 3 To some extent
- 4 To a great extent
- 5 To a very large extent
- 6 Do not know / not applicable

#### V. Knowledge, experience and continuous medical education

There is disagreement about how to organize the continuous medical education (CME) for specialists. There have been proposed several models like "self-steering model" in which physicians self manage their own CME, and "profession-steering model" where the profession (for example through The Norwegian Medical Association) manages CME. According to this model the physician completes a profession- approved mandatory program required for applying recertification and getting recertified periodically (for example, GPs in Norway). The mandatory program may consist of participation in approved courses and other activities like participation in colleague-based small groups. The third CME model is the "regulation model". This model is similar to profession-steering model in that there are mandatory requirements for CME and need for periodic recertification, but in addition, it requires some kind of audit or control before recertification can take place. It also includes a

completion program for those who cannot meet audit requirements and cannot be recertified immediately. Regulation model is usually practiced in form of a partnership between the state and the profession, like England.

In the following there are several questions about your views on the importance of various CME models on patient safety.

To what extent do you think

16-Clinical experience alone is sufficient to achieve high degree of patient safety?

- 1 Not at all
- 2 To a small extent
- 3 To some extent
- 4 To a great extent
- 5 To a very large extent
- 6 Do not know / not applicable

17-Self-steering model (for example “LEIF” program from The Norwegian Medical Association) is important to achieve high degree of patient safety?

- 1 Not at all
- 2 To a small extent
- 3 To some extent
- 4 To a great extent
- 5 To a very large extent
- 6 Do not know / not applicable

18-Profession-steering model of CME (for example, GPs in Norway) is important to achieve high degree of patient safety?

- 1 Not at all
- 2 To a small extent
- 3 To some extent
- 4 To a great extent
- 5 To a very large extent
- 6 Do not know / not applicable

19-Regulation model of CME is important to achieve high degree of patient safety?

- 1 Not at all
- 2 To a small extent
- 3 To some extent
- 4 To a great extent
- 5 To a very large extent
- 6 Do not know / not applicable

## VI. Measures and the need of action

20-If you are going to improve patient safety in your department, which department-based measure do you choose to take (if none of these are implemented)? Choose two options.

- Reporting of adverse events
- Root cause analysis based on reporting of adverse events
- Clinical procedures
- IT-based solutions
- External audit and feedback
- Structure changes (changes in organization, management, culture, cooperation and partnership forms)
- Not applicable

21-If you are going to improve patient safety in your department through increasing competency of physician staff, what kind of CME do you choose as the most appropriate? Choose only one option.

- Self-steering model
- Profession-steering model
- Regulation model

22-Altogether, do you think it is necessary to improve patient safety in your department?

- 1 Not at all
- 2 To a small extent
- 3 To some extent
- 4 To a great extent
- 5 To a very large extent
- 6 Do not know / not applicable

23-Comments and reflections:

## ***The numeric presentation of the results***

***1-Do you think that the patient safety level is acceptable in your department?***

<b>1 Existing patient safety level</b>	<b>Leaders</b>	<b>ESICM</b>
Not at all	0.0	0.0
To a small extent	0.0	8.3
To some extent	14.3	8.3
To a great extent	50.0	70.8
To a very large extent	35.7	12.5
Do not know / not applicable	0.0	0.0

***2- To what extent do you think there are medical errors in your department?***

<b>2 Occurance of medical errors</b>	<b>Leaders</b>	<b>ESICM</b>
Not at all	0.0	0.0
To a small extent	57.1	41.7
To some extent	42.9	54.2
To a great extent	0.0	4.2
To a very large extent	0.0	0.0
Do not know / not applicable	0.0	0.0

***3- What kind of mistakes do you think that doctors in your department make most frequently? Put only one tick.***

<b>3 Kind of errors</b>	<b>Leaders</b>	<b>ESICM</b>
Commission	0.0	4.2
Both	57.1	20.8
Omission	35.7	54.2
Do not know / not applicable	7.1	20.8

***4- To what extent do you think that leadership performance in your department is important for patient safety?***

<b>4 Leadership performance</b>	<b>Leaders</b>	<b>ESICM</b>
Not at all	0.0	0.0
To a small extent	7.1	4.3

To some extent	21.4	13.0
To a great extent	35.7	47.8
To a very large extent	35.7	34.8
Do not know / not applicable	0.0	0.0

**5- To what extent do you think that material resources and the treatment capacity in your department are important for patient safety?**

5 Material resources	Leaders	ESICM
Not at all	0.0	0.0
To a small extent	21.4	12.5
To some extent	21.4	8.3
To a great extent	42.9	37.5
To a very large extent	14.3	41.7
Do not know / not applicable	0.0	0.0

**6- To what extent do you think that explicit clinical procedures in your department are important for patient safety?**

6 Clinical procedures	Leaders	ESICM
Not at all	0.0	0.0
To a small extent	7.1	4.2
To some extent	14.3	20.8
To a great extent	28.6	37.5
To a very large extent	50.0	37.5
Do not know / not applicable	0.0	0.0

**7- To what extent do you think that colleagues' attitudes to the introduction of new procedures or treatments are important for patient safety?**

7 Colleagues attitudes	Leaders	ESICM
Not at all	0.0	0.0
To a small extent	0.0	8.7
To some extent	14.3	8.7
To a great extent	57.1	39.1
To a very large extent	28.6	43.5
Do not know / not applicable	0.0	0.0

**8- To what extent do you think that physician's motivation is important for patient safety in your department?**

8 Motivation	Leaders	ESICM
Not at all	0.0	0.0

To a small extent	0.0	4.2
To some extent	14.3	8.3
To a great extent	57.1	58.3
To a very large extent	28.6	29.2
Do not know / not applicable	0.0	0.0

*9- To what extent do you think that physician's theoretical knowledge is important for patient safety in your department?*

9 Theoretical knowledge	Leaders	ESICM
Not at all	0.0	0.0
To a small extent	0.0	4.2
To some extent	21.4	8.3
To a great extent	57.1	50.0
To a very large extent	21.4	37.5
Do not know / not applicable	0.0	0.0

*10- To what extent do you think that physician's practical skills are important for patient safety in your department?*

10 Practical skills	Leaders	ESICM
Not at all	0.0	0.0
To a small extent	0.0	0.0
To some extent	28.6	4.2
To a great extent	50.0	54.2
To a very large extent	21.4	41.7
Do not know / not applicable	0.0	0.0

*11- To what extent do you think that physician's ethical awareness is important for patient safety in your department?*

11 Ethical awareness	Leaders	ESICM
Not at all	0.0	0.0
To a small extent	0.0	8.3
To some extent	35.7	29.2
To a great extent	42.9	41.7
To a very large extent	21.4	20.8
Do not know / not applicable	0.0	0.0

*12- To what extent do you think physicians' reporting of adverse events (without risk of sanctions) is important to promote good patient safety in the intensive care units in general?*

12 Reporting	Leaders	ESICM
Not at all	0.0	0.0
To a small extent	7.1	0.0
To some extent	7.1	8.3
To a great extent	35.7	33.3
To a very large extent	50.0	58.3
Do not know / not applicable	0.0	0.0

*13- To what extent do you think root cause analysis based on the reporting of adverse events is important for patient safety in the intensive care units in general?*

13 Root cause analyses	Leaders	ESICM
Not at all	0.0	0.0
To a small extent	7.1	0.0
To some extent	7.1	8.7
To a great extent	50.0	43.5
To a very large extent	35.7	47.8
Do not know / not applicable	0.0	0.0

*14- To what extent do you think IT-based solutions (for example in the drug administration / reminders / support for clinical decisions) are important for patient safety in the intensive care units in general?*

14 IT-based solutions	Leaders	ESICM
Not at all	0.0	0.0
To a small extent	14.3	4.2
To some extent	50.0	41.7
To a great extent	14.3	33.3
To a very large extent	21.4	20.8
Do not know / not applicable	0.0	0.0

*15- To what extent do you think external audit and feedback are important for patient safety in the intensive care units in general?*

15 Audit & feedback	Leaders	ESICM
Not at all	0.0	0.0
To a small extent	28.6	8.3
To some extent	35.7	45.8
To a great extent	28.6	25.0
To a very large extent	7.1	20.8
Do not know / not applicable	0.0	0.0

**16- To what extent do you think clinical experience alone is sufficient to achieve high degree of patient safety?**

16 Experience alone	Leaders	ESICM
Not at all	14.3	0.0
To a small extent	21.4	33.3
To some extent	35.7	54.2
To a great extent	28.6	12.5
To a very large extent	0.0	0.0
Do not know / not applicable	0.0	0.0

**17- To what extent do you think self-steering model (for example “LEIF” program from The Norwegian Medical Association) is important to achieve high degree of patient safety?**

17 Self-steering model	Leaders	ESICM
Not at all	7.1	0.0
To a small extent	28.6	12.5
To some extent	28.6	54.2
To a great extent	7.1	16.7
To a very large extent	7.1	0.0
Do not know / not applicable	21.4	16.7

**18- To what extent do you think profession-steering model of CME (for example, GPs in Norway) is important to high degree of patient safety?**

18 Profession-steering model	Leaders	ESICM
Not at all	0.0	4.2
To a small extent	7.1	0.0
To some extent	42.9	33.3
To a great extent	35.7	41.7
To a very large extent	7.1	12.5
Do not know / not applicable	7.1	8.3

**19- To what extent do you think regulation model of CME is important to high degree of patient safety?**

19 Regulation model	Leaders	ESICM
Not at all	0.0	0.0
To a small extent	21.4	4.2
To some extent	35.7	37.5
To a great extent	7.1	33.3
To a very large extent	21.4	4.2
Do not know / not applicable	14.3	20.8



*20- If you are going to improve patient safety in your department, which department-based measure do you choose to take (if none of these are implemented)? Choose two options.*

20 Department-based measure	Leaders	ESICM
Reporting	71.4	8.3
Root cause analysis	64.3	70.8
Clinical procedures	28.6	50.0
IT-based solutions	7.1	8.3
Audit and feedback	7.1	25.0
Structure changes	28.6	25.0
Do not know / not applicable	0.0	4.2

*21- If you are going to improve patient safety in your department through increasing competency of physician staff, what kind of CME do you choose as the most appropriate? Choose only one option.*

21 Preferred kind of CME	Leaders	ESICM
Self	25	0.0
Profession	50	90.5
Regulation	25	9.5

*22- Altogether, do you think it is necessary to improve patient safety in your department?*

22 Necessity of improving patient safety	Leaders	ESICM
Not at all	0.0	0.0
To a small extent	14.3	13.0
To some extent	57.1	60.9
To a great extent	21.4	26.1
To a very large extent	7.1	0.0
Do not know / not applicable	0.0	0.0

## Appendix 11: Some useful websites

### **ACCME**

<http://education.accme.org/>

### **Accreditation Canada**

<http://www.accreditation.ca/en/default.aspx>

### **ACMQ - American College of Medical Quality**

<http://www.acmq.org/>

### **AHRQ - Agency for Healthcare Research and Quality - Glossary of Terms**

<http://effectivehealthcare.ahrq.gov/index.cfm/glossary-of-terms/>

### **AHRQ - Agency for Healthcare Research and Quality - Patient Safety network**

<http://www.psnet.ahrq.gov/resource.aspx?resourceID=3601>

### **AMA - Continuing Medical Education**

<http://www.ama-assn.org/ama/pub/education-careers/continuing-medical-education.shtml>

### **AMA - Physician Consortium for Performance Improvement (PCPI)**

<http://www.ama-assn.org/ama/pub/physician-resources/clinical-practice-improvement/clinical-quality/physician-consortium-performance-improvement.shtml>

### **American College of Medical Quality**

<http://www.acmq.org/>

### **BMJ Group**

<http://group.bmj.com/>

### **Comite Permanent Des Medecins Europeens - CPME - Standing Committee Of European Doctors**

<http://www.cpme.be/index.php>

### **Comprehensive Unit-Based Safety Program (CUSP)**

[http://www.hopkinsmedicine.org/innovation\\_quality\\_patient\\_care/services/consulting/patient\\_safety\\_cusp.html](http://www.hopkinsmedicine.org/innovation_quality_patient_care/services/consulting/patient_safety_cusp.html)

<http://www.innovations.ahrq.gov/content.aspx?id=1769>

<http://www.hpoe.org/topic-areas/sub-topic2.shtml#five>

<http://www.onthecuspstophai.org/>

[http://www.cha.com/index.php?option=com\\_content&task=view&id=977&Itemid=235](http://www.cha.com/index.php?option=com_content&task=view&id=977&Itemid=235)

### **Danish Public Health**

<https://www.sundhed.dk>

### **Department of Health\_UK**

<http://www.dh.gov.uk/en/index.htm>

**DIUS : Further Education - Review of the future role of FE Colleges**  
<http://www.dcsf.gov.uk/furthereducation/index.cfm?fuseaction=content.view&CategoryID=20>

**European Commission proposal on Patient Safety**  
<http://www.esqh.net/Members/noel/nieuws/news20090615173140/view>

**European Commission, Public Health**  
[http://ec.europa.eu/health/index\\_en.htm](http://ec.europa.eu/health/index_en.htm)

**European Network for Health Technology Assessment**  
<http://www.eunethta.net/>

**European Observatory on Health Systems and Policies**  
<http://www.euro.who.int/observatory>

**European Society for quality in healthcare**  
[http://www.esqh.net/www/about/view?portal\\_status\\_title=About%20us](http://www.esqh.net/www/about/view?portal_status_title=About%20us)

**European Union Network for Patient Safety (EUNetPaS)**  
<http://www.eunetpas.eu/>

**General Medical Council  
Guidance on Continuous Professional Development**  
[http://www.gmc-uk.org/education/continuing\\_professional\\_development/cpd\\_guidance.asp](http://www.gmc-uk.org/education/continuing_professional_development/cpd_guidance.asp)

**Good doctors, safer patients: Proposals to strengthen the system to assure and improve the performance of doctors and to protect the safety of patients : Department of Health - Publications**  
[http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_4137232](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4137232)

**Health-EU - The Public Health Portal of the European Union - Patient Safety**  
[http://ec.europa.eu/health-eu/care\\_for\\_me/patient\\_safety/index\\_en.htm](http://ec.europa.eu/health-eu/care_for_me/patient_safety/index_en.htm)

**Health-EU - The Public Health Portal of the European Union - Quality Assurance**  
[http://ec.europa.eu/health-eu/care\\_for\\_me/quality\\_assurance/index\\_en.htm](http://ec.europa.eu/health-eu/care_for_me/quality_assurance/index_en.htm)

**Helsebiblioteket - Kvalitetsforbedring**  
**Kvalitetsforbedring er et ledelsesansvar!**  
<http://www.helsebiblioteket.no/kvalitetsforbedring>

**healthfinder.gov - Your Source for Reliable Health Information**  
<http://www.healthfinder.gov/>

**High Reliability Versus High Autonomy: Dryden, Murphy and Patient Safety**  
<http://www.chspr.ubc.ca/node/429>

**High Reliability Management**

<http://www.highreliabilitymanagement.org/>

**IAPO - International Alliance of Patients' Organizations - World Alliance for Patient Safety**

<http://www.patientsorganizations.org/showarticle.pl?id=576;n=37201>

**ICH - Interoperability Clearinghouse - Glossary of Terms**

<http://www.ichnet.org/glossary.htm>

**IHI - Institute for Healthcare Improvement**

<http://www.ihl.org/ihl>

**International Forum on Quality & Safety in Healthcare**

<http://internationalforum.bmj.com/>

**Institute for Quality and Accreditation in Public Health in Denmark**

<http://www.ikas.dk/>

**International Society for Quality in Health Care.**

<http://www.isqua.org/>

**Intern journ for quality in health care**

<http://intqhc.oxfordjournals.org/current.dtl>

**Johns Hopkins Anesthesiology & Critical Care Medicine**

<http://www.hopkinsmedicine.org/anesthesiology/>

**Kvalitetsforbedring - Helsebiblioteket.no**

<http://www.helsebiblioteket.no/kvalitetsforbedring>

**London Health Science Center\_ Adult Critical Care**

<http://www.lhsc.on.ca/critcare/icu/>

**Mayo School of Continuous Professional Development**

<http://www.mayo.edu/cme/>

**Nasjonalt råd for kvalitet og prioritering i helsetjenesten**

<http://195.159.251.11/Hjem>

**National Quality Measures Clearingshous**

<http://www.qualitymeasures.ahrq.gov/resources/glossary.aspx>

**New South Wales Government**

<http://www.gcio.nsw.gov.au/>

**NICE - National Institute for Health and Clinical Excellence**

<http://www.nice.org.uk/>

**NHS Scotland - Clinical Governance**

<http://www.clinicalgovernance.scot.nhs.uk/>

**NHS**

National Patient Safety Agency - National Reporting and Learning Service  
<http://www.nrls.npsa.nhs.uk/home/>

Royal College of Physicians - Continuous Professional Development  
<http://www.rcplondon.ac.uk/education/cpd/Pages/cpd.aspx>

UEMS - European Union of Medical Specialists  
<http://www.uems.net/>

PMETB: Home  
<http://www.pmetb.org.uk/>

Quality and Mayo Clinic  
<http://www.mayoclinic.org/quality/>

Quality and Safety in Health Care (QSHC)  
<http://qshc.bmj.com/>

Quality Tips  
[http://www.learnicu.org/Quality\\_and\\_Safety/Quality/Pages/Quality\\_Tips.aspx?token=B6BF1E62-705D-4318-9CBB-92FFE836F494](http://www.learnicu.org/Quality_and_Safety/Quality/Pages/Quality_Tips.aspx?token=B6BF1E62-705D-4318-9CBB-92FFE836F494)

Revalidation BMJ  
[http://careers.bmj.com/careers/advice/article-search.html?action=browseByTopic&categoryId=1008&utm\\_campaign=7119312&utm\\_content=42013439382&utm\\_medium=email&utm\\_source=Emailvision](http://careers.bmj.com/careers/advice/article-search.html?action=browseByTopic&categoryId=1008&utm_campaign=7119312&utm_content=42013439382&utm_medium=email&utm_source=Emailvision)

Royal College of Physicians  
<http://www.rcplondon.ac.uk/Pages/index.aspx>

SIMPATIE\_Safety Improvement for Patients in Europe  
<http://www.simpatie.org/Main>

Society of Critical Care Medicine - Quality corner  
[http://www.sccm.org/Professional\\_Development/QualityCorner/Pages/default.aspx](http://www.sccm.org/Professional_Development/QualityCorner/Pages/default.aspx)

The Health Foundation  
<http://www.health.org.uk/>

The Shipman Inquiry  
<http://www.the-shipman-inquiry.org.uk/home.asp>

Scottish Safer Patient Programme  
<http://www.ihl.org/IHI/Programs/StrategicInitiatives/ScottishPatientSafetyProgramme.htm>

The Cheshire and Mersey Critical Care Network  
<http://www.warrington-pct.nhs.uk/>

The Health Foundation's Safer Patients Network

<http://www.ihl.org/IHI/Programs/StrategicInitiatives/SaferPatientsNetwork.htm>

**U.S. Department of Health & Human Services - AHRQ - Agency for Health Research and Quality - Making Health Care Safer A Critical Analysis of Patient Safety Practices**

<http://www.ahrq.gov/clinic/ptsafety/>

**WHO - World Health Organization - Patient Safety**

<http://www.who.int/patientsafety/en/>