

Work Package 5 – Improving patient safety through External auditing

Final report

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Summary: *The French Haute Autorité de Santé (HAS, formally ANAES) is in charge of the WP5 of the SIMPATIE Project. The report is divided into 5 main sections. Section 1 defines the context and definition of external auditing. Section 2 describes the objectives and the change in focus over time. Section 3 gives an overview of the types of auditing strategies. This section also includes the discussion of barriers to achieve the goals. Section 4 focuses on the decision process after auditing. The last and fifth section tentatively classifies the various European countries attitudes and specificities regarding external auditing, and then debates on the pros and cons of a series of strategies for European harmonisation of external auditing ranging from the easiest to the most ambitious.*

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0. SUMMARY OF THE SIMPATIE'S GLOBAL CONTRACT

This report has been produced as part of the European SIMPATIE project [Safety IMprovement for PATients In Europe].

SIMPATIE is a 2-year project funded by DG SANCO which started in July 2005 (T0). Its aim is to help provide the European community with a unified, transparent methodology to improve patient safety. It is understood that the methodology and tool kit proposed is applicable to the promotion of patient safety in the setting of health care organisations. Its application to other health care settings has not been assessed here.

Seven partners are working on the project: *Stichting Kwaliteitsinstituut voor de Gezondheidszorg* (CBO, the Netherlands) the Council of Europe (COE, France), the Standing Committee of European Doctors (CPME, Belgium), *HAS* (formerly *ANAES*), the Long-term medical conditions alliance (LMCA, UK), the European Society for Quality in Healthcare (ESQH, Ireland) and the Standing Committee of Hospitals of the European Union (HOPE, Belgium).

The project is divided into 8 parts (Work Packages).

- WP1: project management. Leader CBO, Holland, duration 2 years
- WP2: mapping exercise to review practice in Europe. Leader ESQH, Ireland, duration 19 months
- WP3: review, standardisation and dissemination of existing recommendations on safety and quality of care and preventing adverse events. Leader COE, France, duration 2 months
- WP4: creation of a glossary of definitions of terms to be used in relation to patient safety and drawing up a list of indicators and standardised outcome measures (clinical and administrative). Leader ESQH, Ireland, duration 8 months (start date T0+8 of the project).
- **WP5: definition of a set of instruments and recommendations to improve patient safety through external auditing, and a patient safety toolkit. Leader HAS (formerly ANAES), France, duration 8 months (starting date T0+8 of the project, March 2006 - December 2006)**
- WP6: recommendations to improve organisational and clinical governance aspects of patient safety. Leader CBO, Netherlands, duration 8 months (start date T0+8 of the project)
- WP7: strategy to develop a common policy using the results of WP 2–6. Leader CPME, Netherlands, duration 5 months (start date T0+17 of the project)
- WP8: promotion of results. Leader CBO, 2 months (starting date T0+22 of the project)

WP 5 is coordinated by HAS and is the subject of this interim report.

00 . PRELIMINARY NOTE

The scope and the purpose of the report

There is a large range of external evaluation mechanisms that play a role in patient safety. For the purpose of this report, however, it was decided to focus essentially on models that were applicable to health care organisations and whose objectives were to assess organisations as a whole. It was felt that this was necessary for the sake of coherence and for the identification of evolutions and trends.

This report deals with external evaluation mechanisms in terms of patient safety. It should be clearly understood that there are other issues and dimensions of quality that external evaluation models, such as accreditation, are organised to address and appreciate. These include respect for patients' rights and responsiveness to patients, continuity and appropriateness of care, capacity and competency of the organisation and health care professionals, efficacy and effectiveness of care. Nevertheless, most external evaluation organisations believe that 40 to 50% of their standards address patient safety issues.

The aim of this report is to give a succinct overview of the trends and issues in terms of external evaluation models for patient safety that will be helpful to health care professionals and decision makers from member states of the European Community. The identification of common principles and tools that can be used within various member states should lead to the sharing of information in terms of patient safety and may contribute to the definition of strategies for European harmonisation.

Cross-references and writing strategy of the report

A number of documents have been published recently in connection with actions to be carried out by public or private bodies to monitor healthcare policy and health care organisations (HCOs), and these documents can be used as a reference.

The existence of these very recent reports and articles inevitably affects the content of this report:

- There is no point in reproducing in detail an existing, particularly well-produced list of references that details key concepts in external auditing. The most important points in these texts have been summarised in this report and readers can find more details in the source documents referred to in the text.
- Rather, the aim of this document is to produce a summary of work already done and ideas already developed and to reinterpret points which could be an obstacle to dissemination of these concepts throughout Europe.

The published documents can be divided into two groups:

- The first group of texts, which we will call "METHODODOLOGICAL", focuses on the mechanisms of external auditing, with particular emphasis on accreditation. It might appear to be a direct response to WP5 but, in fact, it is inadequate for implementing a consistent common policy at European level (it is more an aggregation of methods).

The Charles Shaw article of 2004 is an updated, simplified summary that covers all the technical points and which could be used as a base document for the SIMPATIE project. HAS' French accreditation manual provides a good framework for national practice. Particular attention is drawn to the upstream work by the Australian Council on the limitations of accreditation.

- Klazinga N. Re-engineering trust: adoption and adaptation of four external quality assurance models in Western European health care systems. *Int J Quality in Health Care* 2000; 12: 183-9
 - Donahue KT, van Ostenberg P. Joint Commission International accreditation: relationship to four models of evaluation. *Int J Quality Health Care* 2000; 12: 243-6
 - HAS-ANAES. Manuel d'accréditation des établissements de santé, 2003, available at <http://www.anaes.fr/> or <http://www.has-sante.fr/>
 - HAS-ANAES. Accreditation manual for health care organisations. Second accreditation procedure, September 2004
 - Joint Commission on Accreditation of Healthcare Organizations. Comprehensive accreditation manual for hospitals: the official handbook, 2004, available also at <http://www.jointcommission.org/>.
 - Canadian Council on Health Services accreditation, available at <http://www.cchsa-ccass.ca/>
 - Øvretveit J, Gustafson D. Qual. Saf. Evaluation of quality improvement programs, *Health Care*, 2002 11, 270-275
 - Shaw C. External assessment of healthcare, *BMJ* 2001, 322:851-854
 - Shaw C. Toolkit for accreditation programs. Some issues in the design and redesign of external health care assessment and improvement systems, International Society for Quality in Health Care, 2004
 - Shaw C. Accreditation in European healthcare. *Joint Commission Journal on Quality and Patient Safety* 2006, 32(5):276-87
 - Standards setting and accreditation systems in health, Australian Council for Safety and Quality in Healthcare, 2003, www.aqc.org.au
 - World Alliance for Patient Safety available at www.who.int/patientsafety.
- The second group of texts, which we will call "STRATEGIC", focuses on the strategies to be implemented to improve patient safety. Auditing is only one aspect, and an almost marginal one, of what this group addresses. But these texts are important for SIMPATIE as they provide a more global perspective on external auditing goals. Here again, reading the three documents listed below will provide a full inventory of the current situation.
 - Seven Steps to Patient Safety. National Patient Safety Agency, 2004, found at www.npsa.nhs.uk/sevensteps
 - Øvretveit J. Which interventions are effective for improving patient safety: a review of research evidence. Stockholm: Karolinska Institute, Medical Management centre, 2005
 - Carthey J, Woodward S, Lewis R. Safety Management Systems, high reliability organisations and resilience engineering: Implications for strategies to improve patient safety (draft), NPSA, 2006
 - Patient Safety Goals and Required Organizational Practices, August 2006, Canadian Council on Health Services accreditation, available at <http://www.cchsa-ccass.ca/>

More punctual quotations are made along the text when needed.

1. CONTEXT AND DEFINITION OF EXTERNAL AUDITING

1.1 Context: A growing need for mandatory auditing systems

There is a growing public demand on European countries' governments for a better medical service. This demand combines with a global demand for additional transparency and pay-for-performance medical systems.

Many studies also point to the public dependency on the closest neighbouring medical establishment. The public has often few or no opportunity to select the best establishment, and the demand is clearly to have a standardised level of good and safe care in each establishment wherever it is located¹. This standard of safe care is expected to cross borders as the mobility of patients increases.

Politicians may well lose elections if this national standard of care is not attained. The consequence is clearly a move towards more standardised and mandatory auditing processes, to the detriment of optional and voluntary programs.

Another consequence is that such a progressive shift towards mandatory systems and greater accountability, if generalized, could result in an alignment of external auditing to minimum standards.

In this context, one of the challenges is to structure external evaluation models that will foster improvement as well as accountability and will mobilise all organisations whatever their level of quality towards objectives of excellence.

The growing need for European harmonization, which is the very reason of the SIMPATIE project, is particularly sensitive to this aspect, and will probably accelerate the move to a **minimum mandatory common platform for auditing**; conversely, the development of new advanced and costly patient safety initiatives could be considered in the next decade of much lower priority compared to this need of a common basic platform within and among EC countries.

1.2 Definition of external auditing

- covers all auditing actions related to delivery of care
- is carried out by staff who do not belong to the health care organisation being audited (although the process is necessarily connected to internal evaluation, both processes ideally converge on a similar set of safety goals and indicators and feed one another)
- strives to provide an objective assessment of the quality of services delivered by the HCO against the most up to date standards
- identifies weak points to be improved by a specific deadline
- contributes to transparency and quality in the health care system through information and external recognition
- and by this, ensures user confidence in the health system and in the care delivered. Beyond local improvement, it is expected that the external auditing process will

¹ Schneider E., Lieberman. Publicly disclosed information about the quality of health care : response of the US public, *Qual. Saf. Health Care*, 2001, 10: 96-103

induce system-wide changes involving multiple HCOs, and on a national scale in case of national programs.²

1.3 The three key steps of external auditing

A comprehensive approach of external auditing is based on a thorough description of three milestones:

- The first point is to make the objectives of the auditing process as pertinent and as clear as possible.
- The second point concerns methods to evaluate the achievement of objectives. The portfolio of methods should be described at various levels of granularity from general principles to detailed tools.
- The third point focuses on how to deal with the results and how to make decisions, and on the follow-up by corrective and maintenance actions.

These three points organize the sections of this report.

² For the record, the Version 2 of the French accreditation Manual defines these aims as follows (Manual, V2, pp[11]): the purpose of accreditation is to ensure continuous improvement in the safety and quality of patient care delivered to patients in HCOs [...] Accreditation reflects two international trends: 1) a professional procedure for promoting continuous quality improvement (CQI) based on health industry standards and an external peer assessment, and 2) an assessment of the level of quality achieved in the context of increasing compulsory public accountability concerning the quality of healthcare services.

2. OBJECTIVES FOR EXTERNAL AUDITING AND PROGRESSIVE CHANGES IN FOCUS

2.1 The four families of objectives for external auditing

Four aims are usually identified to achieve this overall objective of auditing quality and safety of care. These four aims are not necessarily covered in the same level of detail by all external audits. The first objective is to assess the means, programs and actions implemented in the promotion of patient safety. The second is to assess the organisation actual performance in terms of patient safety. A third objective is to have an assessment process that is cost effective. Lastly, the model should promote coordination of internal and external evaluation activities in order to diminish redundancy and increase efficiency.

2.1.1. Assessment of the resources available and the proper use of a toolkit of good safety practices:

- This refers to the actual use of the tools rather than to the results obtained from them (next point in this paragraph). The following factors are worth mentioning (list not exhaustive) :
 - a) Tools related to specific risks that monitor the implementation of :
 - at-risk subsystems in the HCO's hotel systems infrastructure : building protection systems (fire, flooding, etc.), quality monitoring systems for perishable or hazardous products and foodstuffs (food and health products, water, medicines)
 - at-risk subsystems in the HCO's clinical infrastructure : calibration of measuring instruments, systems to monitor medical devices and healthcare products, such as medicines, waste products, care environment and water, to assess patient records (traceability of prescriptions and of communication between health professionals, etc.) information systems, emergency plans to deal with exceptional risks, and patient rights
 - clear medical and treatment standards for clinical risk management in the HCO (for example, the prevention of care-related risks such as risks of thromboembolism, poor pain control, loss of autonomy in geriatrics by the application of management protocols)
 - b) Elements related to risk management initiatives:
 - Incident reporting systems for all forms of incidents, with a range of associated tools for managing and learning from these situations (and the proper use of these tools) (vigilance systems, voluntary reporting systems at departmental or HCO level, patient satisfaction questionnaires, systems for taking account of patients' views, failure mode, root cause analyses or other forms of risk analysis, walkrounds, computerised monitoring systems, data recovery based on SSPI data, etc.)
 - Risk management structure, organisation chart or definition of responsibilities within the hospital, possibly with a senior member of staff allocated to it
 - Active policies for disseminating a culture of safety within the HCO : dissemination of information, feedback on morbidity and mortality to professionals and other staff, involvement of top management, different campaigns, patient information and education, etc.

- Use of the tools listed above is of course also assessed in terms of the HCO's human resources policy, dedicated job functions or time made available for these types of action, associated financial support, and further training in relation to these objectives.

2 1.2. Assessment of the HCO's own performance in safety of care

- This involves assessing an HCO's performance in the field of patient safety in an external monitoring program
- This quantitative assessment is based on the regular monitoring of safety initiatives (declaration of adverse events, declaration in the different vigilance systems, number of complaints) and the use of rate-based risk indicators (analysis of satisfaction questionnaires, clinical or organisational audits)

This will involve eventually measuring the appropriate use of a policy or program and the measurement of context of care often termed safety culture. The evaluation of institutional resilience (see for example Carthey, de Leval, Reason, 2001) by means of questionnaire and indicators may permit going beyond the classic focus on the medical staff, focusing on the high level management strategies to concretely arbitrate the politics in favour to safety³.

2.1.3. Assessment of the best cost-efficacy ratio for the initiative

There are two aspects to this:

- (i) the cost-efficacy of the action itself in relation to patient safety. The concept of safety measure cost must be taken into account to remain realistic. It may result in different forms of compromise depending on how rich the country is, so ensuring the best compromise in favour of the user, taking account of resources and of what is available at local and national levels. This point is often regarded as a goal not fully achieved (Ovretveit & Gufstason, 2002; Shaw, 2001, 2004, *opus quoted*), but it becomes major once there is the possibility of international implementation in countries with different levels of revenues and health systems. Problems may arise with product-based improvement plans (prion control, endoscope protection) or more strategic plans (which require more human and material resources than a country can provide)

(ii) the cost-efficacy of the external audit to demonstrate the system's validity. From the clinical specialist's point of view, the auditing system can rapidly take up too much time and resources (to the detriment of their clinical work), or consume an excessive amount of resources in absolute terms⁴. The USA is often cited as a country with a very high global healthcare cost, and a very high cost of self-assessment, which is seen as excessive.⁵

³ Carthey, J., de Leval, M., Reason, J. Institutional resilience in healthcare, QSHC, 2001, 10:29-32

⁴ Standards setting and accreditation systems in health: Australian Council page 6: It should not be assumed that the higher the standards set by standard-setting agencies the better compliance would be. Whenever a standard is set, some organisations will decide that the costs of compliance exceed the costs of non-compliance (see also Ayres & Braithwaite, Responsive regulation [*sic*], Transcending the deregulation debate, Oxford University Press, 1992, 20-21)

⁵ B K Frogner and G F Anderson, Multinational Comparisons of Health Systems, The Commonwealth Fund, April 2006

G F Anderson, B K Frogner, R A Johns, U E Reinhardt. Health Care Spending and Use of Information Technology in OECD Countries, Health Affairs, May/June 2006, 25(3):819-31

A Five-Nation Hospital Survey : Commonalities, Differences, and Discontinuities, D Blumenthal, C Vogeli, L Alexander et al., The Commonwealth Fund, May 2004

Pronovost PJ, Miller MR, Wachter RM. Tracking progress in patient safety. An elusive target. JAMA, 2006, 296, 696-699

2.1.4. Coordination of internal and external audit approaches

- There are an increasing number of both internal and external audits of the healthcare system. What can be seen as an advantage can rapidly become a consumer of time and money, with reduced efficacy
- The cost of duplication and the search for efficiency represent incentives to define goals more clearly, and to make the different approaches more mutually complementary
 - In particular, there is a need to make the quality and safety processes more complementary. The quality process emphasises traceability, stability, improvement and efficacy of a care process, while the safety initiative emphasises superficial and root causes of care process destabilisation, and avoiding accidents by developing, as and when required, barriers for prevention and mechanisms of recovery or attenuation
 - Reactions to a local event (reactive governance) and long-term safety policy (proactive governance) also need to be more complementary
- A nation, a healthcare system or even an HCO may use a number of approaches, requiring a high level of mutual coordination of external audits as well as coordination with internal audits, in order to become effective and comprehensible to the public. Coordination is itself a sub-objective of auditing

2.2. Patient safety initiative targets, development of initiatives

2.2.1 A progressive change in focus

Whatever process is chosen to carry out external audit, the published data trace four phases of development of the content of safety audits. These phases often overlap to various degrees in different auditing programs.

- a) The oldest movement, which started before the 1990s, corresponds to the **physical safety of goods and individuals** :
- safety of technical areas in hospitals (firebreaks, electricity (circuit breakers and emergency supply), water (Legionella), etc),
 - measuring systems (equipment calibration, critical equipment maintenance, biomedical vigilance in the wider sense),
 - processes of storage and physical transformation of consumables (food, medicines, etc.).

This area can be well covered by ISO standards and by quality assurance. It could almost be regarded as outside the scope of patient safety or safety of care as it is so basic. However, it remains important both because it is a prerequisite and because it involves quality professionals, who are often not doctors, and whose role gradually extends into other areas more specific to safety of care.

- b) The second movement, dating from the end of the 1990s or the beginning of the 2000s, focuses on **clinical prevention standards (clinical governance)**. These include good care practice (keeping a care record, traceability of medical orders, prophylaxis against infection, prophylaxis against thrombosis, early treatment of myocardial infarction, blood management, various forms of prophylaxis). Producing sets of standards, and reinforced voluntary and compulsory feedback systems (such as vigilance systems) are the two classical approaches used. A quality improvement initiative is often the key initiative to measure progress made.

Accreditation is well suited to this movement, which is mainly carried out by medical staff⁶.

c) The third movement introduces the **concept of dynamic interfaces, informing patients and patient participation, and transparency**. It includes:

- Patient and drug flow circuits, management of the interfaces within the hospital and between hospitals, monitoring of care and consistency of discharge prescribing (reconciliation) – shared care networks
- Quality and maintenance / management of skills of those involved (nurses and doctors)
- Information for patients, transparency, participation by the patient in their own care and in the reporting of problems.

Few external audit tools make it possible to really ensure that these dynamic points are functioning well. A quality initiative is pushed to its limits. Peer reviews (skills of those involved), audits and inspections (occasional tests) are probably to be recommended. In theory, accreditation could have a role, but the sets of standards are not complete, and the real situation is difficult to verify⁷.

d) Finally, the last movement, the most recent and one which is still being constructed, concentrates on **global management of safety, a systemic approach, and the culture of safety**

- Global management of medical safety is currently being deployed in a number of countries, notably the United Kingdom⁸, and is based on four areas of action :
 - Commitment by top management, in particular mentioning the importance of a senior member of staff responsible for patient safety at the highest level in the HCO⁹
 - A proactive approach to risk, which does not confine itself to reacting to superficial causes identified in feedback as causing problems (the ‘react to what happened’ approach), but analyses and attacks the root causes of risks in the system
 - A sophisticated and multifaceted feedback system
 - An approach focusing on the responsibility and action of the actors, from top management to front-line staff, with particular emphasis on resilience strategies (robustness to destabilisation of the system, strategies of sacrifices between competing and contradictory goals, and crisis management)¹⁰.

⁶ see for example :

- the ANAES 1996 report “Mise en place d’un programme d’amélioration de la qualité dans un établissement de santé”, [“Implementing a quality improvement programme”], published in French only ;

- or the AHRQ 2001 report, “Making Health Care Safer. A Critical Analysis of Patient Safety Practices”. AHRQ Publication No. 01-E057., available at <http://www.ahrq.gov/clinic/ptsafety/summary.htm>

⁷ National Quality Forum (USA). Recommended Safety Interventions, 2003, www.qualityforum.org ; and Seven Steps to Patient Safety. National Patient Safety Agency (UK), 2004, www.npsa.nhs.uk/sevensteps

⁸ Cartney J. Safety management systems, HRO and resilience engineering : implications for strategies to improve patient safety. National Patient Safety Agency, June 2006

⁹ Reason J, Carthey J, de Leval M. Diagnosing vulnerable system syndrome: an essential prerequisite to effective risk management, Qual. Saf. Healthcare, 2001, 10:21-25

¹⁰ Hollnagel E, Woods D, Levison N. Resilience engineering: concepts and precepts, Aldershot, England: Ashgate, 2006: 238-256

2.2.2 Auditing the medical staff's competence is traditionally outside the scope of external auditing, but... credentialing and privileging may represent an alternative solution

The external processing is not supposed to control the competences of the individual health care professionals. However, several countries including USA, Australia and Canada are asking the HCOs to demonstrate

- first that their staffs have the proper level of competence for the types of cares and medical protocols delivered in the HCO (concept of privileging),
- second that actions are actively taken to maintain these specific competences via appropriate training and tutoring. For example, these privileges and credentials are part of the JCAHO accreditation program.

These credentials are provided by the HCOs and differ from the accreditation of post MD medical training programs (like the work done by the *US ACGME-Accreditation Council for Graduate Medical Education*) and from voluntary or mandatory doctors' accreditation programs (like the new French Program of *Accreditation des médecins et des équipes médicales* made by HAS – dating July 2006).

3. EXTERNAL AUDITING METHODS

3.1 Models of external evaluation : variety and convergences

There are numerous methods usable for external evaluation of HCOs. The ExpeRT (External Peer Review Technique) project¹¹, funded by EU, showed that methods of developing and assessing organisational standards range from the medical speciality driven ‘visitation/visitation’ (the Netherlands and UK), through traditional accreditation (developed in North America, Australia, UK, Spain, The Netherlands, Finland, Italy, France, Portugal, Sweden, Bulgaria, Poland, Germany, and Switzerland) and European Quality Awards (Scandinavian nations, The Netherlands, Spain) to industrial certification ISO standards (Germany, UK, Switzerland, and Spain).

The multiplication of methods, often coexistent in the same country, does not facilitate a global and consistent safety process in Europe. Although a process of convergence is expected, the main barriers to adopt a unique method for external evaluation remain cultural (the cost of evaluation -who pays: private or public-, the bureaucratic tendencies to too much focus on public perception and local efficiency compared with attention to medical effectiveness, and the impact of various national systems of responsibility and accountability).

Nevertheless, all the models share a minimum set of common features such as:

- use of standards,
- external evaluation by auditors who are variably trained, polyvalent or specialized, and who may or may not be peers,
- on site visit to check compliance (at different degrees : meetings, documents analysis, direct observation),
- decision committee,
- report with mention of axes to be improved,
- need for external recognition
- a process of dissemination whether public or restricted to professionals
- defined cycle-duration inter procedures,
- little based-evidence regarding their impact on effectiveness on health system performance and especially on patient safety improvement.

3.2 The families of methods

■ Accreditation:

- + : By far the most usual method for external auditing in HCOs. Programs are being set up more frequently in Europe than anywhere else. Originally aimed to promote continuous healthcare quality improvement, HCO accreditation is gradually changing to a tool of regulation and public accountability. It may be voluntary or compulsory depending on the country, but the tendency is clearly to move to more mandatory systems; public recognition is an essential component; external auditing by independent peers covers all fields; the standards checklist sent out in advance has a high educational value; it is developed specifically for the healthcare system. In Europe, France, Denmark

¹¹ Heidemann, E. Moving to global standards for accreditation processes: the ExPeRT project in a larger context, *Int. Journal for Safety in Health Care*, 2000, 12 (3):227-230

and Ireland in particular are very committed to the process, but this is far from the case for all European countries. According to the literature, the accreditation system aims to guarantee and report on both the enforcement of minimum standards and the level of achievement regarding quality or security objectives striving for excellence (this last point is made particularly explicit in the ISQUA guide). The accreditation may cover all aspects of patient safety. The process relies on HCO self assessment (Grading), visit on site by surveyors/peers, surveyor's report, and certification committee decision. The evaluation frequency is based on a 3-4 year-cycle except in case of follow up focused visit. Results are moving from confidential to public.

- - : The system is cumbersome to implement and often ambitious in terms of human resource utilisation ; the fact that, in many of its demands, it exceeds the bounds of minimum standards (e.g. in France) means that priorities are less clearly defined ; it may lead to excessive work in meetings and not enough in the form of continuous audit (to the point that the US and UK authorities suggest carrying out unannounced visits); priorities for improvement are not always clear ; the consistency and credibility of follow-up actions applied to HCOs which do not perform adequately or fail accreditation are not always visible.

■ **ISO 9001 certification (International Organization for Standardization)**

- + : Systems of practice standards, originally designed for industry, mainly focusing on the Quality management system, Management responsibility, and Resource management, easy to apply to parts of the medical system where tasks and products are clearly defined, and a quality system is already in place with measurable objectives (laboratory testing, pharmacy, radiology, patient feedback and complaints, results of audits, etc.). The certification is voluntary. Each centre can formulate the requirements for the practices and processes that are developed in their quality manual. Evaluation are yearly based and are made on site by auditor specialized in the targeted domain with a final supervision of a certification committee. The audit report mentions the strong points and progress axes. Results are generally kept confidential to public.
- - : Attempts at application to medical care are still very limited, and the rationale for applications in the field of patient safety has been even less well demonstrated; however, its applications in the UK and in Northern Europe are examples to consider (ISO 9000 in healthcare, a guide to implementation, BSI management, 2001, www.bsiamericas.com).
- Note: The French accreditation manual contains a summary (Introduction, p 13) of the differences between accreditation and certification: “The process of accrediting an HCO is different from a certification process. Accreditation is an external assessment system specific to HCOs that has been implemented internationally. It is carried out by peers and uses specific standards. It assesses not only the HCO's quality management system*, but also specific aspects of healthcare organisation and professional practice appraisal. ISO 9001 certification is not specific to HCOs. Certification focuses on the implementation of a quality management system*.

■ **Audit by professional peers (Peer review, Dutch *visitatie*):**

- + : A collegian approach focused on audits of professionals practices and training courses. It is characterized by evaluation between colleagues, confidentiality, and tolerance of the realistic constraints of the job. The

Netherlands are the leading promoters of this method. The evaluation frequency is usually based on a 5 year-cycle plus annual self assessments. Results are generally kept confidential to public.

- - : Subjectivity of the approach; attempts at application to medical care and to patient safety have not been very convincing.

■ **The Quality Management Model (Malcolm Baldrige type)**

- + : Voluntary classical quality-related approach, now well-tested, allowing self-assessment or external audit against stated quality goals and standards (see also Australian Business Excellence Model, www.aqc.org.au/). The fields of intervention are management systems first, then clinical outcome, patient and staff satisfaction. In order to achieve continuous quality improvement, a recognised quality management system is required. CQI involves a systematic approach to the improvement of problem solving, and requires commitment from individuals. The evaluation is on request and results in the delivery of excellence awards. Results are generally kept confidential to public.
- - : Once again, the problem is applying this approach to the field of healthcare, and in particular to patient safety. However, it should be noted that the revised version of the European Foundation for Quality Management (EFQM) 1999 standards includes a much wider field of application, particularly in the area of client satisfaction and the organisation of care. The organisations can choose the processes and areas to be covered.

■ **Indicators monitoring**

- +: Some external auditing strategies now consist essentially in a continuous monitoring and control of a set of mutually accepted list of indicators, transmitted by the medical establishment to the auditing body on regular basis. The choice of indicators is based on the type of activity, the results of reporting systems, and in-service experience. The method is reputed to motivate the medical staff (move your dot), to save considerable resources on the two sides (no or very rare visits, limited paper and pencil demonstrations, event and situation-driven selection of a limited sub-set of relevant indicators). This method is closely related to self assessment methods. Lately, some accreditation systems include in their requirements the reporting of specific indicators.
- -: The auditing process is limited to the selected indicators. This selected approach may hide new problems and new deficiencies. Essential aspects of patient safety are not adequately measured by the indicators available at present.

■ **Inspections of healthcare services**

- + : often, but not exclusively, a reaction to problems raised in the public arena ; may allow rapid diagnosis and resolution of those problems with major decisions to protect patients' interests. Another type of inspection is a routine inspection, but with the focus almost always on the immediacy of the risk.
- - : often limited to a retrospective and reactive view ; an intervention coming late in a process of deterioration often leading to a standardized response to a problem, with a scapegoat effect, and few lessons for the organisation.

■ Evaluations done by patients

- +: Patients survey provides an alternative approach to the evaluation of the quality of care¹². Inpatients can identify adverse events affecting their care. Many patient-identified events are not captured by the hospital incident reporting system or recorded in the medical record.
- -: Methods are not yet standardized; gathering reliable data is a problem; patients are good in identifying problems but not as good on reporting on them. Moreover, the medical staff – including the auditors- is chronically distrusting the value of patient reports, hence not extracting all proper lessons from these surveys. A substantial cultural change is required for an optimal use in the auditing process¹³

■ ReCertification, registration and licensing:

- + : compulsory / voluntary for staff, or physicians. Some of these programs focus on professional involved in high risk-practices, guaranteeing that they have a particular skill. France has just invested in this type of programme.
- - : indirectly concerns patient safety (necessary condition but not sufficient).

3.3 Barriers to implementation and points for discussion irrespective of audit method

• Voluntary versus compulsory audit

- There is a lot of debate on whether an audit should be a free choice or imposed to some extent. The response seems to be mainly related to a country's political system, but there is doubtless a cultural dimension as well. However, the previous section has clearly pointed to the growing development of mandatory systems in all Western countries.
- If the process of auditing becomes mandatory for all medical establishments, the number of auditors will have to increase in a similar proportion. The human resources cost of external auditing may rapidly become exponential. For example, France has 800 accreditation surveyors to accreditate all 2900 HCOs in the country.
- As mentioned above, the compulsory nature of the process automatically drags the objectives towards minimum standards able to be applicable to most establishments.

• Profile of surveyors

- In most programs, auditors are peers who have little exposure and practice in auditing and for whom surveying represents an auxiliary and occasional job.
- There is also a need to guarantee the independence of judgment that may restrict the number of available candidates. Some countries have recruited foreign surveyors

12) Weingart S, Pagovitch O, Sands D, Li J, Aronson M, Davis R, Bates D, Phillips R. What can hospitalized patients tell us about adverse events? Learning from patient-reported incidents, *J Gen Int Med*, 20, p 830, September 2005
Davies E, Cleary PD. Hearing the patient's voice? Factors affecting the use of patient survey data in quality improvement. *Qual Saf Health Care* 2005, 14(6), 428–32 .

¹³ Davies E. Cleary P. D. Hearing the Patient's Voice? Factors Affecting the Use of Patient Survey Data in Quality Improvement. *Qual Saf Health Care* 2005; 14(6):428–32
Weingart, S., Pagovitch, O., Sands, D., Li, J., Aronson, M., Davis, R., Bates, D., Phillips, R., What Can Hospitalized Patients Tell Us About Adverse Events? Learning from Patient-Reported Incidents, *J Gen Int Med*, 2005, 20 : 830

(the Irish use Canadian and Australian experts). Others recruit surveyors from structures relatively close to the HCO (a body representing health insurance funds, an inter-hospital group organisation, etc).

- More needs and less specialized resources may lead to wider eligibility criteria for surveyors, thus resulting in a huge disparity of these surveyors and an instability of results. The disparity of judgment and the disputes among experts grows with the number of experts, the previous professional experience, the reduction of training, and the use of qualitative indicators.
- Conversely, the disparity may represent a rich mix of experience, particularly adapted to the diversity of the activities of HCOs.

Finally, four suggestions may reduce conflicts:

- First, maintain a high level of standardization by *ab-initio* and recurrent training of surveyors with concrete testing on scenarios.
- Second, keep the number of surveyors reasonably low. While surveying by peers in current hospital practice helps insure clinical relevance, there are organisations who are turning to more experienced surveyors who will audit on a regular basis.
- Third, use teams of experts with a good mix of competences and trades, and not isolated surveyor; make these teams rotating in order to express a 'law of requisite diversity of opinion'. An important reproducibility factor is the team consensus.
- Fourth, supervise and accompany the debriefing when the external auditing process reveals an important non compliance to requirements.

- **Audit frequency and procedure**

- Most methods are based on periodic audits notified in advance, for which (significant) preparatory work is carried out by the HCO being audited. The preparation is often considered to be a particularly valuable opportunity for acquiring a culture of safety.
- But increasingly, in spite of the initial advantages of scheduled surveys (with the preparation itself constituting a 'learning system'), disadvantages become apparent in a system involving too much preparation (artificiality, concern for the image presented rather than the reality); this is particularly true for accreditation. Several systems now recommend moving on to unscheduled external auditing (JCAHO 2006, Health Care Commission (UK), Australian Council for Health Standards).
- A number of bodies (JCAHO, HCC) have suggested or practised a mixture of (i) periodic self-assessments (a sector currently developing rapidly, which includes the benefits of a learning system and the acquisition of a culture of safety) and (ii) unscheduled external audits for validation, sometimes even limited to a few HCOs chosen at random (HCC).

- **Maximum versus minimum requirements : setting the objectives**

- A number of authors have emphasised the risk of working to optimum standards: they are generally very hard to achieve, and the level of complexity and cost involved is such that in the end, the optimum standard may be adhered to less than an actually achievable minimum standard (Australian Council for Safety and Quality in Health Care, 2003 ; Ovretveit, 2005).
- The absence of mutually-agreed standards often makes the work of external audit difficult or open to criticism.

- Demonstration of scientific proof of the efficacy of actions undertaken for patients (burden of proof), balanced by the cost and simplicity of implementation, guides the drafting of external audit standards (the first to be implemented are the most effective and the easiest to put in place and to monitor and the least expensive) (Ovretveit, 2005, pp 22-25).
- But the more systemic aspects in the longer term (e.g. promoting an organisation and culture within an HCO), although recognised by the literature in the field as essential for achieving and maintaining a high level of safety, are difficult to impose as they are not supported by scientific proof.
- Too many standards can be just as harmful as having no agreed standards; a battery of rules, especially when they differ from the HCO's or country's economic and cultural model, create strong pressure to violate them. The Australian reference document on accreditation considers that having too many standards is one of the greatest risks of an accreditation as it may lead to a 'paper policy' with a high level of virtual safety going hand in hand with a very high number of violations in the real world^{14 15}.
- The economic conditions of the countries and HCOs concerned are not sufficiently taken account of in the range of requirements. This is particularly the case in Europe, and is a very sensitive issue for the SIMPATIE project (safety is known to be closely related to a country's GDP).

At the European Level, a reasonable platform for action should inevitably adopt an achievable standard for all countries. Such a minimum platform could include

- A series of patient safety goals, supposed to be revised and improved on periodic cycles.
- And a set of standards for external evaluation that have the following properties
 - An objective to be attained
 - Realistic/economic
 - Pertinent : Evidence-based or consensus-based
 - Recognized by professionals and the public
 - Evolving by close linkage between the processes of definition of standards and feedback on their utilisation by HCOs and surveyors
 - Measurable by mean of easy-to-gather, easy-to-compare safety indicators

- **Comparative and public audit results**

- Publishing the results to give the public confidence is problematical. Publicity about risk is poorly managed, and often poorly interpreted; there can be both too much and too little publicity.
- Many studies and guidelines emphasise the benefit of a clear decision on the quality observed, and of credible corrective follow-up actions addressing all weak points.
- But the actual publishing of these weak points is controversial. The accepted wisdom is that a culture of safety is built in a 'blame-free' setting. If this is the case, insisting that faults in the system are publicised will make a system purely reactive and defensive, and the harmful effect will be greater than the anticipated benefit

¹⁴ Ayres I, Braithwaite, J. *Responsive regulation-Transcending the deregulation debate*. Oxford: Oxford University Press, 1992.)

¹⁵ Amalberti, R., Vincent, C., Auroy, Y., de Saint Maurice, G., (2006) Framework models of migrations and violations: a consumer guide, *Quality and Safety in Healthcare*, 2006;15(suppl_1):i66-i71

(there is a very interesting discussion of this in the Australian Council’s 2003 publication, “Standard setting and accreditation systems in healthcare”).

- However, the recent French experience of publishing on the web site the full details of the second round of accreditation has apparently not been detrimental to public confidence, and has not provoked a new legal pressure on the medical system.

• **Role of self-assessment**

Most accreditation programs include a self evaluation made prior to the visit of surveyors (this is for example the case of the French accreditation program). This self evaluation has numerous objectives. First, the process of evaluation is by itself an educational process for the medical staff; it can clarify safety objectives, encourages installing or updating reporting systems and dedicated protocols possibly using external assistance; in any case it may facilitate the development of a safety culture. Second, many complex indicators are not directly accessible within the time frame of the visit by surveyors; the self assessment, less constrained in time, may serve to feed these series of missing indicators for the final evaluation. Third and not least, self-assessment permits the HCOs to make corrections prior to the external auditing process and to demonstrate the ability of the HCO to react and improve.

As mentioned before (3.3 § Audit frequency & procedure), some accreditation programs go beyond the use of self evaluation as a pre visit, considering that a joint negotiated selection of objectives between authorities and HCO, followed by self-evaluation and communication of results to the external agency may replace the external auditing process. External controls by surveyors may then take place randomly with a much lower pace.

• **The development of indicators and performance measurements**

A very wide range of indicators can be used.

Only indicators that focus on immediate deficiencies of patient care are easy to compare and doubtless to standardise.

A good review of the literature is provided by the WP4, with a special value of the section on the evaluation of patient safety culture.

These are the five families of safety indicators recognised as generally accepted and published by OECD (Quality indicator project,2006¹⁶)

1.	Hospital acquired infections	Ventilator pneumonia Wound infection Infection due to medical care Decubitus ulcer
2.	Operative and post-operative complications	Complications of anaesthesia Postoperative hip fracture Postoperative pulmonary embolism or deep vein thrombosis Post operative sepsis Technical difficulty with procedure

¹⁶ OECD Quality Indicator Project: The Patient Safety Expert Panel, 2006, <http://www.oecd.org/dataoecd>

3.	Sentinel events	Transfusion reaction Wrong blood type Wrong-site surgery Foreign body left in during procedure Medical equipment-related adverse event Medication errors
4.	Obstetrics	Birth trauma injury to neonate Obstetric trauma vaginal delivery Obstetric trauma caesarean section Problems with childbirth
5.	Other care-related adverse events	Patient falls In-hospital hip fracture or fall

The indicators can be strategically prioritized and used for developing a solid method for evaluating and improving patient safety strategies.

- **IHI’s Whole System Measures Tool Kit** : IHI’s Pursuing Perfection and IMPACT Network aim is to make fundamental improvements in the performance of participating health systems. The changes in the design of these systems are expected to improve major outcomes identified in the IOM’s Chasm Report so that care is more safe, effective, patient-centered, timely, efficient and equitable. Version 2.0 recommends the following ten measures:
 - Adverse Events - inpatient and outpatient
 - Work Days Lost
 - Hospital Standardized Mortality Ratio (HSMR)
 - Unadjusted Raw Mortality
 - Functional outcomes
 - 30 Day readmission
 - Patient Satisfaction – inpatient and outpatient
 - Patient Days spent in the Hospital during the last six months of life
 - Days to 3rd Next Available Appointment – primary care and specialty care
 - Health Care Costs per Capita for Region

The indicators focusing on safety culture are distinctly less consistent between countries, and over time. Another disadvantage is that they are much harder to collect objectively.

However, there is growing tendency to evaluate the culture. A series of in-depth reviews of existing and validated methods has been recently published by Pronovost & Sexton, 2005; Kho, Carbone, Lucas & al, 2005; and Sexton, Thomas, Helmreich and al, 2004¹⁷.

- **The integration of strategies to imbed specific consensual or evidenced-based professional practices**

Beyond the utilization of well established indicators for internal improvement, Agencies are setting up global programs for HCOs to embed safe and well evidenced professional practices. These include the implementation of Patient safety solutions and the measurement of system wide indicators of process and outcome.

¹⁷ Pronovost, P. Sexton, B. Assessing Safety culture : guidelines and recommendations, QSHC, 2005 14: 231-233
 Kho, M. Carbone, JM, Lucas, J. & al, Safety culture climate survey, reliability of results from a multicenter ICU survey, QSHC, 2005, 14 273-8
 Sexton, JB, Thomas, EJ, Helmreich, R., et al, Frontline assessments of healthcare culture: safety culture questionnaire norms and psychometric properties, 2004, available at <http://www.utpatientsafety.org>

- The US JCAHO proposes for 2007 a National Patient Safety Goals made of 15 goals (Improve the accuracy of patient identification, improve the effectiveness of communication among caregivers, improve the safety of using medications, reduce the risk of healthcare associated infection, accurately and completely reconcile medications across the continuum of care, reduce the risk of patient harm resulting from falls, reduce the risk of surgical fires, reduce the risk of influenza and pneumococcal disease in institutionalized adults, etc).
- The JCAHO's is also recommending the promotion of **Patient Tracer Methodology** aiming at adopting a whole and systemic approach of all aspects of patient safety¹⁸ including:
 - Priority focus areas identified by priority focus process
 - Traces patients through entire inpatient experience
 - Patient records are selected in several departments. Surveyors trace the analytical procedures
 - Supporting activities reviewed:
 - Diagnostic related activities (i.e.: evaluation of needs, ordering, specimen collection , preservation, transportation, etc.),
 - Care administration activities (i.e. Procedure written, approved, implemented, specimen analysis, assuring competence of staff, etc.),
 - and Post-analytical processes (i.e.: review of results prior to reporting, assuring an acceptable process for correcting erroneous results, etc.)
 - Instrument calibration and maintenance
 - Multiple patients followed
 - Issues may be identified in one or more steps of a process or in interfaces between processes
(numerous consultancies are available to follow the process¹⁹).
- The Canadian Council for Health Services Accreditation (CCHSA) adopted in 2004 a global plan to implement Canadian's Patient Safety Goals and Required Organizational Practices that came into effect in January 2007 after an experimentation of one year in 2006.. The outcome is the creation of **five Patient Safety areas** (culture, communication, medications, workforce, infection control), **six Patient/Client Safety Goals, and 21 Required Organizational Practices (ROPs)**
- **The World Health Organization (WHO) Collaborating Centre on Patient Safety (Solutions), the World Alliance for Patient Safety are presently working on the definition of safety solutions** :: these include look-alike, sound-alike medications, patient identification, communication during hand-overs, prevention of wrong site/wrong procedure/wrong person surgical errors, prevention of continuity of medication errors or medication reconciliation, prevention of high concentration drug errors and promotion of effective hand hygiene practices.
- Some clusters of indicators have been successfully developed by the Institute for Healthcare Improvement in Boston (IHI) and may serve safety self assessment by means of **triggers tools**²⁰. These triggers based on an risk-related aggregation of

¹⁸ Steffens, K. Suvey process and patient tracer activity, IFCC/AACC 2005 Annual meeting, Quality issues in POCT: 3rd annual POC coordinators forum, July 28

¹⁹ See for example <http://www.jcrinc.com/consulting.asp>

²⁰ Resar, R. Rosich, J., Classen, D., Methodology and rationale for the measurement of harm with trigger tools, *Qual. Saf. Health Care*, 2003, 12, 39-45

Rozich JD, Haraden CR, Resar RK. Adverse drug event trigger tool: a practical methodology for measuring medication related harm. *Qual Saf Health Care* 2003; 12: 194-200

indicators (in most cases related to **bundles** of best practices) permit rapid identification of adverse events through simplified chart review.

4. ABOUT DECISIONS AND AFTER AUDIT FOLLOW-UP ACTIONS

This section deals with the key step in auditing which is the less harmonized across different countries and programs.

Most Western countries recognize the need for delivering three types of conclusion after an external auditing process, according to the result of the audit :

- Type 1: The auditing process is satisfactory and the HCO is fully accredited with or recommendations and with an agreement on priorities to be pursued and on actions to maintain quality and safety initiatives
- Type 2: The auditing process concludes that the medical establishment is not at major risk for patients, although, in some critical areas, it does not comply with standards and additional specific efforts are required. The medical establishment must comply with these critical points within a defined period of time (to be mutually agreed according to the changes to be made). The compliance is re-evaluated by auditors at the end of the agreed period. The auditing process is recognized as fully successful when the corrections have been made.
- Type 3: The auditing process concludes that the establishment is at major risk for patients. In that case, the logic should ask for immediate closing. A mutually agreed plan for improvement can be also defined with the selective closing of some activities and wards.

There is little evidence in the literature on the uniformity of application of these three types of conclusion. There is a potential for a wide variation in the applications of follow up actions among European countries, because of the variable cultural, economic and political contexts and because of the variable practice of the auditors who propose the inclusion of a partially non compliant establishment into conclusions of type 2 or type 3. It appears that type 3 decisions are extremely rare, both to avoid social consequences associated with closing, and as a consequence of a strategy to keep the HCO enlisted into the auditing program and to promote a positive attitude fostering improvement. Conversely, type 2 decisions are very frequent.

It is essential that the corrective actions be perceived as credible in regards to the risk detected in the organisation in order to build trust into the auditing program (Australian Council for safety and Quality, 2003).

This section needs much further work for a potential standardisation among EC countries, including debates on cultures.

5. TOWARDS AN EUROPEAN HARMONIZATION OF EXTERNAL AUDITING

4.1 Contrasts in European approaches to external audit

The table here below shows the stage of accomplishment of the accreditation programs in the EC countries (to be completed by the information gathered under WP 2 and by the inclusion of other other families of auditing methods used in European countries).

Accreditation	Program (Shaw, 2004, Accreditation toolkit)	Total
Active program	COMPULSORY France, Germany, Italy (regional), VOLUNTARY: Ireland, Bulgaria, Netherlands, Poland, Portugal, Spain, Switzerland (two), UK (three)	11
In development	Bosnia (RS, FBiH), Croatia, Czech Republic, Denmark (two), Finland, Hungary, Kyrgyzstan, Latvia, Lithuania, Malta, Slovakia	11
No national program	Albania, Armenia, Austria, Belgium, Cyprus, Estonia, Kazakhstan, Luxembourg, Sweden, Turkey, Yugoslavia	11

4.2 A tentative classification of European attitudes in managing external auditing

Some global characteristics are related to countries' policies. It is roughly possible to divide the European attitudes in three tiers from North to South of Europe.

- The countries of Northern Europe, which tend to have a small number of citizens with a high income, encourage a very wide distribution of facilities to monitor their medical systems. (i) Certification methods (ISO) are commonly used. (ii) These countries are much more interested than countries in Southern Europe in assessing the general primary care sector (particularly in Finland). (iii) Monitoring is based much more on voluntary external continuous audit (accreditation, certification, peer review) supervised by the State. They are pushing for the voluntary adoption of high standards. Paradoxically, these countries have few rules (based on minimum standards), but they assess relatively severely, with full transparency for the public, and with fairly strong professional obligations and sanctions. Public satisfaction for the medical system is generally high because of the global quality of care, the commitment of the politicians, and of the extent of the social coverage (little or no out-of-pocket financing of the healthcare systems).
- The countries of Southern Europe have more rules (accreditation is compulsory in France and Italy), are more directive and more focused on public HCOs and hospitals. Their desire to promote excellent practice leads them to be more demanding in terms of rules (an approach which is differs significantly from the intention of accreditation), but there is a certain tolerance and numerous derogations in terms of practical implementation (Roman legal tradition). These countries make a lot of rules, but audit less. If audit results are negative, there are fewer places for sanctions (compared to Northern countries) unless a crisis occurs, but, in such a case, a special additional

mechanism will be required (general inspection). The public satisfaction is generally high, first because of the good financial coverage, and because of the trust in the government to make decisions on healthcare management that are beneficial for citizens.

- The central tiers of Western EC countries (UK, Germany, Austria, Netherlands...) often fall between these two approaches. They adopt almost all the tools and strategies (peer review, accreditation, quality, certain ISO standards). For example in UK, initiatives are based on the many recommendations and guides provided by the National Patient Safety Agency (with a distinctly higher level of inducement than in France), with an objective of minimum standards to be adopted by all. Performance assessment is currently stronger than in France, with an emphasis on cost effectiveness and safety management at top management level. However, the public satisfaction tends to be less than in Northern and Southern countries, especially in UK. Note that the public satisfaction is likely to be based on a social perception and not necessarily relate to an objective reality.
- The Eastern countries are increasingly visible but are still dealing with economic problems and trying to reconcile ambition (Western European model) and social realism.

In summary, politically-driven systems induce a more hierarchical culture and the adoption of very strict but frequently unrealistic rules ; the aim is to encourage excellent practice, while accepting that the current situation falls short of the desired quality level. Conversely, the less hierarchical states pragmatically adopt guaranteed minimum standards and delegate the supervision and monitoring of the system to private bodies.

There are many methods, all of them leading to apparently positive results according to a large consensus of opinions from both the auditors and the health care professionals. It is then difficult to recommend a specific method of external assessment for HCOs. While there is evidence that individuals practices have a strong impact on patient safety, there are few studies of the impact of hospital wide assessment programs. The MARQuIS program (Method of Assessing Response to Quality Improvement Strategies) running in parallel to the SIMPATie program, has an objective to assess and compare the different National quality strategies, and may provide comparative data .

4.3 Feasibility of harmonization: from the easiest to the most demanding.

In view of the above, a European external audit platform will necessarily be either very minimalist (lowest common denominator), or will consist of a number of alternative paths, depending on the political models. It may be based on goals or methods. It is easier to harmonise goals than methods.

The following table suggests the different available solutions from the easiest and minimalist, to the most sophisticated, but potentially difficult to harmonize. The total of the port folio of solutions could also be interpreted as a tentative map road for implementation of harmonization within EC countries during the next decades.

	Objectives	External audit methods
<p>Minimum tool platform (lowest common denominator)</p>	<p>Encouragement to use the tool</p> <p>Improve patient safety by imposing minimum standards :</p> <ul style="list-style-type: none"> • on facility safety • on product safety (foodstuffs and healthcare products) • on the adoption of good care practices in relation to safety (prophylaxis, etc.) 	<p>Feasible: Identify common indicators Develop and apply a culture of quality assurance Publish common European standards for good basic practice</p> <p>More difficult: Impose the choice of an audit tool</p>
<p>Minimum performance platform</p>	<p>Monitor performance</p> <p>Improve patient safety by imposing a minimum performance level</p> <ul style="list-style-type: none"> • work on transparency • work on the care circuit • work on the system's actual performance (errors, adverse events) 	<p>Feasible: Encourage the use of common performance indicators, and list these indicators</p> <p>More difficult: Determine a minimum performance standard by medical sector Come to an agreement on a standardised strategy in the event of conformity / non-conformity (European, national, regional?)</p>
<p>Common minimum system platform</p> <p>Common systemic approach, align healthcare systems</p>	<p>Align safety cultures</p> <p>Improve patient safety by standardising healthcare systems</p> <p>Develop safety and organisational governance standards</p>	<p>Already difficult Cross audits between countries, reinforced benchmark strategy List the differences, be aware of these differences, and make public information on the advantages and drawbacks of each model</p> <p>Very difficult Strong political voices Financial constraints</p> <p>Leads to the idea of an Agency</p>

6. Conclusions and proposed actions

This reports attempts to identify the evolution and trends and the basic principles of external evaluation models in terms of the promotion of patient safety. These conclusions do not necessarily apply to external evaluation models of health care organisations when they address issues and dimensions of quality that do not directly relate to patient safety.

1) Adopting a minimum set of requirements or adopting core standards, practices and performance indicators for patient safety

Adopting a minimum safety platform with a minimum set of mandatory requirements and a corresponding surveillance system is a true challenge. The medical community must make significant effort to elaborate minimum thresholds for acceptable standards and not to continue designing high cost and ultra best practices. There is now evidence in the literature that simple measures that are not costly can show significant benefits (e.g. education, adopting a safe organisation of care, reporting, hand washing, phlebitis preventive protocols, etc.). This is an opportunity to involve new member countries while mobilising more advanced countries where very up to date practices may be pursued at the expense of basic ones that have been shown to have a large impact on the safety of patients and that rely less on technology than on individual and group practices.

This is a strong argument for the definition of specific safety priorities and for the organisation of external evaluation models around more targeted objectives. This does not imply that sustained quality improvement becomes a secondary goal but that the quest for excellence must build on a minimum platform accessible to all.

There is a strong trend towards the development of mandatory programs of external evaluation of health care organisations in response to the need for accountability to the public and to their representatives the politicians and in response to the need for equity of access to safe care. As programs become mandatory, the objectives tend to become minimal standards applicable to most organisations that should take into account the organisation's and the country economic and cultural situation to avoid a strong pressure to violation leading to a paper policy and virtual safety.

This same trend leads to the development of programs which aim increasingly at national coverage and at the improvement of patient safety throughout a health system. A national approach has the added advantage of representing an opportunity for coordination of external evaluation activities to increase efficiency and decrease work load.

This implies the integration of specific strategies to identify and embed safe and well-evidenced professional practices such as national patient safety goals, required organisational practices, patient safety solutions and evidence-based bundles of care applicable to high risk situations.

Recommendations :

External evaluation programs should integrate specific strategies to identify and embed patient safety objectives and well evidenced professional practices

Standards should take into account the HCO's or the country's economic and cultural situation to avoid a strong pressure to violation leading to a paper policy and virtual safety

There are advantages to a national approach to external evaluation including an improvement strategy for patient safety applicable throughout the health care system and a response to a strong demand for coordination of external evaluation activities to increase efficiency and diminish workload

2) Assessment of dynamic interfaces, resiliency and patient safety culture

There has been a change in focus in terms of targets for external evaluation of safety. From the physical safety of goods and individuals, to a focus on clinical standards and clinical governance, to the assessment of dynamic interfaces at all steps of the care pathway within the hospital and within shared care networks involving professionals and patients and, finally, concentrating on a systemic global approach associating commitment by top management, a proactive approach to risk and an emphasis on the responsibility of actors, on resilience strategies, on an open patient safety culture and on effective competence maintenance and development activities.

There is mounting evidence that leadership and mobilisation are key to implementation of safe practices and to the creation of an open and proactive safety culture. The external evaluation of dynamic interfaces, patient participation, safety culture and commitment of management and leadership are new frontiers in terms of external evaluation models that should be further researched.

External evaluation programs should be considered learning systems at the health care organisation level. Self-assessment will contribute to this objective leading to a global diagnosis, and to the identification of opportunities for improvement. Furthermore, the implementation of corrective actions prior to the survey will demonstrate to the external evaluation organisation the capacity of the hospital to effectively improve.

Recommendations :

- Methods should be developed to better assess recent trends such as dynamic interfaces, patient involvement, resiliency, safety culture and leadership

- External evaluation programs should be considered learning systems at the health care organisation level. Self-assessment will contribute to this objective

- **These programs do not assess the competence of individual professionals directly but may ask hospitals to demonstrate that they have effective competence maintenance and development activities, notably in the field of patient safety**

3) Measurements are essential to any improvement strategy

Indicators should focus on different aspects of safe care that are easy to compare and standardise. Indicators for outcomes, processes, structure and context are available and will help to create a composite image of patient safety.

See the report of Work Package 4 on safety indicators

4) The external assessment process must be credible

The credibility of the external evaluation will depend on the strength of the three essential steps of these models.

Safety objectives must be clear and follow the current trends of evolution in the field of patient safety. They must integrate the expectations and opinions of all stakeholders. They must be recognised as essential by the health care professionals.

Credibility will depend on the methods to assess the achievement of the objectives. This raises the issues of reproducibility and competence of surveyors, of the ways to validate the objectivity of data through varied concrete approaches such as the patient tracer methodology, of audit frequency and of unscheduled surveys.

Credibility will also depend on the quality of the decision process and on follow-up actions such targeted surveys relative to specific deficiencies. The publication of the results will contribute to the credibility of the process in the eyes of the professionals and patients.

Recommendations :

- **Safety objectives must be consensual and clearly defined and should follow the current trends of evolution in the field of patient safety**
- **Surveyors should function as teams representing a mix of competences insuring a multifaceted approach, credibility, independence and consensus**
- **It is essential that corrective actions be perceived as credible in regards to the risk detected in the organisation in order to build trust into the auditing program**
- **The extent of publication of the results is debated :**
 - The right to information of patients is recognised
 - Publication is a strong motivation to change
 - The information must be understandable to all stakeholders, including patients, and allow for national or regional comparison
 - The “accepted wisdom” amongst health professionals and health providers is that a safety culture is built in a “blame-free” setting and that publication may lead to the non disclosure and non correction of faults. However, feedback from patients suggests that more work is needed on agreeing an

understanding of what these terms mean in practice and balancing the desire to encourage reporting with the ethical and professional requirement that patients or their families be fully informed of incidents affecting them
-There must be a clear understanding by all of what is confidential and what can be published

5) Towards strategies of European harmonisation

Recommendations :

- **Make existing information available to member states on :**
 - programs of external evaluation applicable to HCOs
 - on hospital quality based on the results of these programs

- **Adopt common general goals and principles for external evaluation (on the model of those of the International Accreditation Program of ISQua) as well as a portfolio of common methods**

- **Incorporate into those principles European requirements on patient safety as they are being adopted**

- **Further harmonisation will be harder to achieve :**
 - Common standards :
 - Easy : Physical standards
 - Relatively Easy : Clinical governance
 - Hard : Organisation and system approach
 - Monitoring of performance
 - Common processes of evaluation
 - Common logics of decision