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SIMPATIE Final Report

Safety Improvement for Patients in Europe

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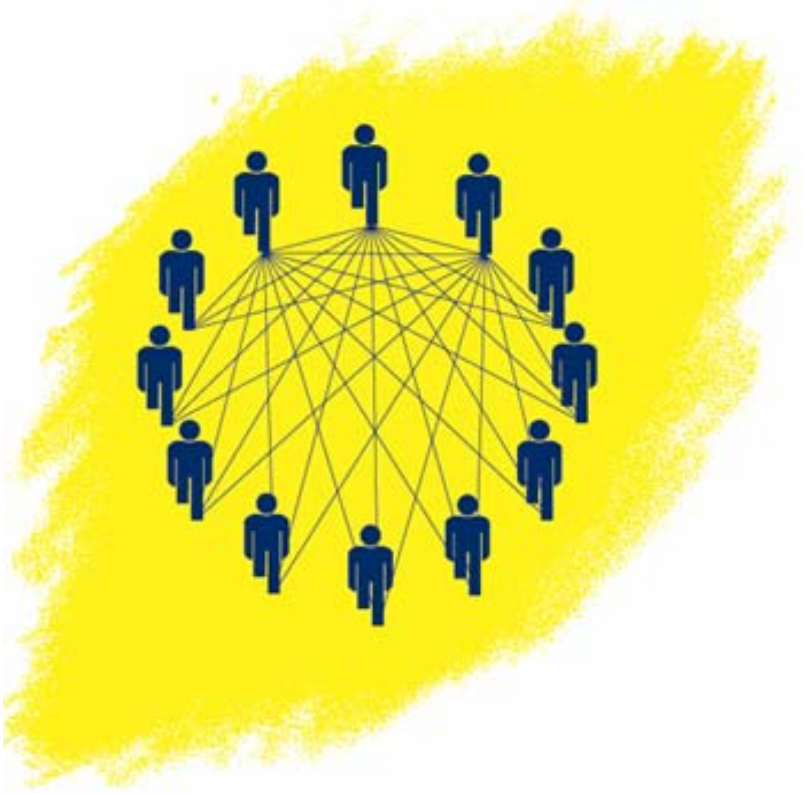

SIMPATIE Project

Final Report

SAFETY IMPROVEMENT FOR PATIENTS IN EUROPE

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Partners in the SIMPATIE project are:

- CoE Council of Europe
- CPME Standing Committee of European Doctors
- HOPE European Hospital and Healthcare Federation
- ESQH European Society for Quality in Healthcare
- HAS Haut Autorité de Santé (former ANAES)
- LMCA Long Term Medical Conditions Alliance
- AvMA Action Against Medical Accidents
- CBO Dutch Institute for Healthcare Improvement, lead partner

Please visit our project website at www.simpatie.org

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1. Introduction

Patient safety: the hidden problem in our health care system. Health care has as its mission to cure and to relief suffering the best we can according to the "state of the art"-scientific knowledge, realizing that our "object of care" is a fellow human being. All professionals and managers agree to this mission with their whole heart.
But, at the same time we harm patients unintentionally by the way we organize and deliver care: professional by over- and under use (and sometimes misuse) of effective care, organisational by making healthcare too complicated and fragmented and relational by forgetting that our patient is a human being with insecurities, feelings and specific needs.
The IOM-report "To err is human" (USA, 1999) did highlight this "hidden" problem in a comprehensive, not blaming way with the intention to create a culture of learning and improvement in stead of the usual "naming, blaming and shaming".
This report has effected a big impact in many countries. The confronting facts about the lack of patient safety in our healthcare system have been confirmed in many countrywide research projects since. What we still consider acceptable in our healthcare system would be totally unacceptable in other industries. That's one of the reasons we can learn a lot from the approach and results to assure safety in airline industries, oil companies, nuclear power plants, etc.
In many countries numerous initiatives have been taken – both national and within healthcare institutions – to promote patient safety. The results are inspiring to continue on this road.
Patient safety management is a clear distinguishable, but inseparable part of our quality management system, that should be part of our normal management and leadership systems, both professional and managerial.

While noting the artificiality of separating safety from quality in general, patient safety can also be considered in terms of three levels of analysis. At health system level, patient safety schemes include national incident reporting systems; the use of standards to minimise harm to patients; professional liability arrangements; public availability of information relating to patient safety incidents; the existence of health inspectorates, national patient safety campaigns, and enhanced training of professionals. At the organizational level, patient safety schemes cover instruments such as no fault/no blame schemes; analysis of incidents; safety interventions; process redesign and support provided by risk or patient safety managers. At the clinical level, actions to improve patient safety include attention to clinical guidelines; team training and professional peer review schemes. In the SIMPATIE project a variety of actions were taken to explore the three levels in various ways. In the next chapter a brief overview will be given of the methodologies used in the project. This will be followed by the WP summaries including their Conclusions and Recommendations.

2. Methodology

The different tasks set out in the various WPs required the use of a varied number of methodological instruments to conduct the work laid out in the project. By using the networks of the European NGOs participating (ESQH, HOPE, CPME) a network was established of more than a hundred contacts in most Member States to conduct the mapping exercise by a developed questionnaire and also establish a good practice compendium(WP2). For the work done by the Council of Europe to produce it's Recommendation (WP3) the CoE compiled an expert group to formulate a draft to reach the required policy consensus by Member States.
For the development of indicators and a vocabulary (WP4) extensive desk research was done by the ESQH-office for Quality Indicators in Aarhus (Dk) on existing activities in this area

(CoE, OECD, WHO, etc.). In parallel a rating instrument was developed for the indicators and tested and an international expert group was established to conduct the rating and develop a vocabulary on which consensus was reached.
By using the expertise of HAS (WP5) desk research was conducted to develop an overview of models used for external evaluation and on the strategies to be implemented to improve patient safety. Before publishing the WP5 report drafts were discussed with the partners of the Simpatie project and with the Council of the International Accreditation Program of the International Society for Quality in Healthcare. The report was reviewed by a panel of five internationally recognised experts in the field of patient safety.
Building on work done by CBO in The Netherlands an international expert group was established to elaborate on their work to produce a toolbox for improving safety in health care organisations(WP6).
By organising a consensus conference (WP7) -for which CPME was the lead partner- in September 2006 the consortium and building on the preliminary results of the different WPs a wide range of recommendations were developed on international, national and local/individual professional level. Over 200 experts attended the conference and were able to comment on the preliminary findings.
Aided by the advice requested from a professional communications company a dissemination policy was developed that addresses the various levels of expertise/interest in the topic of patient safety (WP8).
Throughout the project HOPE as well as LMCA/AvMA, not leading a separate WP, participated in the various activities in the project and commented on draft work from their perspective.

3. General objectives of the Simpatie Project

The project aims to facilitate free movement of people and services by developing EU-wide commonality and transparency in methodology on patient safety in healthcare institutions. It is multidisciplinary and includes input from patient representatives.

The objective of this project is to use Europe-wide networks of organizations, experts, professionals and other stakeholders to establish, within two years, a common European set of vocabulary, indicators, internal and external instruments for improvement of safety in health care. The set will be disseminated to parties involved.

- A mapping exercise across a minimum of 20 member and accession states will describe and make accesible status of activity and strategic planning on PS. A data base with standardised format will be developed which is sustainable i.e. has the potential to be updated regularly and cheaply. Data for benchmarking good practice will be an additional output.
- A working group of experts will develop a common vocabulary,outcome indicators and internal and external instruments for improvement in PS, based on a CoE framework. Current activities of WHO and OECD will assist in this process.
- A third work stream will utilise material from the other two to develop a consensus approach to health strategy on PS .
- The final work stream concentrates on dissemination using established professional,institutional and patient networks.

Mobility across EU is a benefit to citizens, able to obtain healthcare outside of their state, but represents at the same time a challenge in relation to the quality of the services provided. Health care payers need to be assured that care purchased across borders is at least as good and as safe as at home. Patients have the right to expect safe care across the Union.
There is still a lack of European consensus on the best way to monitor most key patient safety issues. In addition, methodology and interventions for improving safety are diverse and partially not validated. There is a clear need for a concerted European approach.

4. Project coordination and Management (WP 1)

Lead Partner: CBO

Objectives
Use Europe-wide network of experts, professionals and other stakeholders to establish information, quality tools and common strategy.

Deliverables
Project progress reports to the Commission
Final report

Deliverables fulifilled
Interim report has been submitted to SANCO halfway through the project as contractually required. (D1-1)
Final report finished and submitted. (D1-2)

From the start of the project a project secretariat and steering group to manage the project were established. The Steering group consisted of representatives of all partners and were responsible for guiding all project activities. Lead partner CBO was the link with the Commission for the project.
The Steering group has met regulary, using tele-conferencing and face-to-face meetings where convenient and needed. It coordinated execution of work packages and production of deliverables.
A project secretariat was established at CBO and was responsible for administrative and financial management. Through joint CBO / ESQH office in Brussels contact was maintained with other relevant European organizations and actions.
Project partners HOPE and LMCA were not leading a separate Work Package in the project but on a continuous basis cooperating constructively with the other partners in the project from their own expertise.
In addition, the secretariat developed, the PR strategy for the project, in a way that will assure targeted provision of relevant information both to general and professional public. Part of the strategy has been developed by a professional PR company and consolidated with the partners. Also, the website designed for the project includes a protected area accessible for project partners used for project management and coordinated by CBO.

4.1 Patient involvement

During the first phase of the project LMCA announced that it had requested one of its members to cooperate with LMCA in the consortium, all partners agreed with Action Against Medical Accidents (AvMA) to work with partners representing the patient view. Further details of their participation are given in Chapter 11.

4.2 Note on policy interest/ relevance

The project has raised considerable interest from the start on a European policy level. Already in September 2005 the consortium was invited by WHO/Europe to have a joint workshop on patient safety. The report of this meeting is attached to this report as Annex 15.

On request of DG Research input was provided for the topic of patient safety during the development of FP7.

Within the EU, Member States are working together in the High Level Group Working Group on Patient Safety (HLG WGPS). The progress of the project has been presented several times to the WG. The last time this happened was in December 2006 in Paris where all project partners were involved in a discussion with the WGPS how to take up the recommendations and findings of the project. At the headquarters of the Haut Autorité de Santé (HAS) the WGPS and project partners met in an effort in to develop a project proposal called European Network on Patient Safety (EUNetPas), to be submitted to SANCO in Spring 2007. SANCO staff was present at the meeting as well. The work done in SIMPATIE should form the basis of some of the work envisaged there.

SIMPATIE has also contributed to policies of the EC by providing their data to and cooperating with WHO Europe/European Observatory on Health Systems. They had been commissioned in December 2006 by DGSANCO to produce a report by using secondary research on a number of recently finished and still ongoing projects in the area of –among others- quality and patient safety. Aim is to provide Commission services with data that can be used in their efforts to establish a Community framework for safe, high-quality and efficient health services.

5. Mapping exercise (WP 2)

Lead Partner: ESQH

Objectives
To establish systematic knowledge repository on patient safety related to legislation, regulation and actions in EU states.

Deliverables
Web based knowledge resource on patient safety activities and practice
Overview report
Best practice compendium (web-based).

Deliverables fulfilled
Responses from 20 of the then 25 EU states were specified as a criterion in the original agreement. Data was obtained from 23 states.
The report is published on the project website (D2-1,2).
A best-practice compendium is available on the project website (D2-3).

5.1. Methodology

At the start of the project two international groups were set up, the experts' network and the reference group. The experts' group constituted individuals who acted as contact points in each country and who agreed to help with collection of data via their in-country contacts. Through this arrangement, taking into account the identification of country experts within Question 5 of the survey instrument, it has been possible to create a network of more than 100 experts (nominated by their peers) across 23 countries. This group also provided the basis for rapid collection of good practice examples during November and December of 2006. CPME and HOPE, two of the consortium partners, were particularly helpful in supplementing country data with information from their members. AvMA, delegated by LMCA advised on all patient issues. The experts' group was therefore to an extent drawn together by serendipity, and because one agreed aim was to mobilise both networks and opinions outside those already involved and researched, a reference group was set up in parallel.
The reference group consisted of people from different countries and were represented the different professional and special interest stakeholders that the data was to be of service to. Therefore this group was recruited from patient safety experts, academics, healthcare policy makers and managers, clinicians, those representing the interest of patients, professional organisations, specialist healthcare risk managers, lawyers, commentators, quality improvement specialists, regulators and educationalists. The group maintained contact and had occasional face-to-face meetings throughout the duration of the project.
At the first meeting an initial framework for the data collection was developed. It catalogued the potential interest areas for the different parties who might utilise the end product of the Simpatie mapping exercise once the project was completed. As the survey instrument developed it was shared between the Simpatie partners and the reference group and pilot tested to check clarity, usability, completeness and fitness for purpose. The instrument was in English and invited responses in English only, although attached documents in the language of the particular country were welcomed.
Although based on principles derived from previous quality mapping, e.g. the CASPE/BIOMED2 survey of External peer review in Europe (ExPeRT project), it is evident

that the format of the questionnaire stems primarily from consensus between selected experts, rather than from scientific research. Nevertheless feedback from respondents suggests no major omissions in the span of the questions.
The data to be collected was thus summarised in question form into a survey instrument with twenty-one different questions, and within these in excess of one hundred different data items to be collected. Most were questions of fact, but some were of opinion. Some sought further information on resources, or to steer towards the direction of further work covering a particular issue. In all, the survey instrument aimed to establish a comprehensive and wide-ranging insight into progress with patient safety initiatives in the respondent countries.

5.2 Description of work

A panel of country contacts was set up at the beginning of the project and was modified and expanded during the course of the project. Project partners, particularly HOPE and CPME were very helpful in making links with individuals who were sources of information. Additional information was obtained for half the respondent countries as a means of validating the original data and for a further quarter, countries adopted a consensus approach to provide internal validation.Good practice examples were obtained by asking a network of experts (between one and six for each respondent country) to nominate examples. The network was obtained by expanding the original panel of country experts by inclusion of experts identified through responses to Q.5 of the questionnaire, so that a total of 100 or so experts were approached, resulting in the collection of 61 examples during a period of one month.

5.3 Role of the patient in the activities and recommendations

Apart from patient-focused questions such as Q.17 it is fair to say that patient organizations only contribute perhaps 5% of the total data.
Nevertheless, through nomination by the patient organization LMCA, Peter Walsh, CEO of AvMA (Action against medical accidents) was advisor on patient related issues throughout the project.
From a patient's perspective in particular with regard to the data collected in this WP the following issues are recommended for further study:

- the types of administrative systems of awarding compensation which are in existence (the so called 'no fault' or 'no-blame' systems in Q 8) and the identification of good practice which can be replicated across Member States;
- a common definition of what constitutes a good 'patient safety culture' and in particular the implications for this of the differing approaches amongst Member States of disclosing or not disclosing to patients or their families information on incidents affecting them (see discussion of Q 9)
- ways in which patients' organizations with a specific interest in patient safety can be supported to play an active role in patient safety work both at the national level and across the European Union (given the responses to Q17 and the importance placed on involving patients).

5.4 Main conclusions and recommendations

Conclusion 1) While patient safety is recognised as a health quality priority across Europe, inevitably there is wide variation in the level of implementation of appropriate mechanisms for improvement.

Conclusion 2) There was a positive response to the mapping exercise from the majority of those approached and overall there is evidence of substantial expertise and good practice, scattered across Europe.

Conclusion 3) Unless some funding is found to allow sustainability of the databases they will rapidly become obsolete. Equally, the network of contacts having now been set up (with potential for further expansion), the cost of refining survey tools and managing the databases in the medium term is relatively small compared to the initial outlay. This then offers excellent value for money as an investment and would actively support the policy direction associated with a European network for patient safety. For example, the network of contacts set in place includes competent authorities for some countries but also provides a means to establish competent authorities for some countries that have not yet identified them.

Conclusion 4) The completion of the mapping exercise and good practice compendium provides a foundation for more focused investigation of specific elements within the general overview. As examples, two particular issues involving measurement are highlighted which could provide the basis for further study; whether there is transfer of expertise across country boundaries as a result of collaborative projects and whether direct benefit to citizens, as customers of healthcare services, can be identified as an outcome of such collaborative efforts.
The full report of WP2 can be found on the project website (www.simpatie.org).

6. Promotion of Recommendation on Patient Safety by the Council of Europe (WP 3)

Lead Partner: CoE

Objectives
The CoE Recommendation on Prevention of Adverse Events is used as a framework for development of toolbox for improving patient safety. The framework should enable translation in a practical and usable tool for the work floor.

Deliverables
Adaptation of Recommendation published by the CoE to form framework for toolbox development.
Web based discussion forum for feedback on Recommendation

Deliverables fulfilled
WP4 and WP5 in particular have used the WP3 work as a basis for their activities
A facility has been created on the project website where an interactive communication has been set up about the CoE Recommendation (D3-1,2).

At the moment the SIMPATIE project was submitted to DGSANCO a Council of Europe Recommendation on "management of safety and quality in health care – prevention of adverse events in health care, a system approach", was scheduled to be agreed on by the Council's Committee of Ministers in November 2004. However, after this initial time frame, the Committee of Ministers linked this Recommendation with three other health related Recommendations. Despite minor changes to the final text, due to this linking the final Recommendation has to date (April 2006) still not been published and is now scheduled for July 2006.

These developments caused the consortium to resort to work with the present draft Recommendation as input for later Work Packages. The web based discussion forum for feed-back on the Recommendation been established following the official publication of the Recommendation by the Council of Europe.

6.1 Recommendation Rec(2006)7 of the Committee of Ministers to member states on management of patient safety and prevention of adverse events in health care

(Adopted by the Committee of Ministers on 24 May 2006 at the 965th meeting of the Ministers' Deputies)

The Committee of Ministers, under the terms of Article 15.*b* of the Statute of the Council of Europe,

Considering that the aim of the Council of Europe is to achieve a greater unity between its members and that this aim may be pursued in particular by the adoption of common rules in the health field;

Considering that access to safe health care is the basic right of every citizen in all member states;

Recognising that although error is inherent in all fields of human activity, it is however possible to learn from mistakes and to prevent their reoccurrence and that health-care providers and organisations that have achieved a high level of safety have the capacity to acknowledge errors and learn from them;

Considering that patients should participate in decisions about their health care, and recognising that those working in health-care systems should provide them with adequate and clear information about potential risks and their consequences, in order to obtain their informed consent to treatment;

Recalling that Article 2 of the Council of Europe's Convention on Human Rights and Biomedicine (ETS No. 164) establishes the primacy of the human being over the sole interest of society or science, and recalling its Article 3 on the equitable access to health care of appropriate quality;

Considering that the methodology for the development and implementation of patient-safety policies crosses national boundaries and that their evaluation requires substantial resources and expertise and should be shared;

Recalling its Recommendations Nos. R (97) 5 on the protection of medical data, R (97) 17 on the development and implementation of quality improvement systems (QIS) in health care, and R (2000) 5 on the development of structures for citizen and patient participation in the decision-making process affecting health care, and its Resolution ResAP(2001)2 concerning the pharmacist's role in the framework of health security, which explicitly suggests working in partnership with other health professionals;

Noting the relevance of the World Health Organisation (WHO) "Health for All" targets for the European Region (target 2) and of its policy documents on improving health and quality of life and having regard to its Health Assembly Resolution 55.18 (2002) on "Quality of care: patient safety", which recognises the need to promote patient safety as a fundamental principle of all health systems;

Considering that patient safety is the underpinning philosophy of quality improvement and that all possible measures should therefore be taken to organise and promote patient-safety education and quality of health-care education;

Considering that the same principles of patient safety apply equally to primary, secondary and tertiary care and to all health professions as well as to health promotion, prevention, diagnosis, treatment, rehabilitation, and other aspects of health care;

Recognising the need to promote open co-ordination of national and international regulations concerning research on patient safety,

Recommends that governments of member states, according to their competencies:

i. ensure that patient safety is the cornerstone of all relevant health policies, in particular policies to improve quality;

ii. develop a coherent and comprehensive patient-safety policy framework which:

a. promotes a culture of safety at all levels of health care;
b. takes a proactive and preventive approach in designing health systems for patient safety;
c. makes patient safety a leadership and management priority;
d. emphasises the importance of learning from patient-safety incidents;

iii. promote the development of a reporting system for patient-safety incidents in order to enhance patient safety by learning from such incidents; this system should:

a. be non-punitive and fair in purpose;
b. be independent of other regulatory processes;
c. be designed in such a way as to encourage health-care providers and health-care personnel to report safety incidents (for instance, wherever possible, reporting should be voluntary, anonymous and confidential);
d. set out a system for collecting and analysing reports of adverse events locally and, when the need arises, aggregated at a regional or national level, with the aim of improving patient safety; for this purpose, resources must be specifically allocated;
e. involve both private and public sectors;
f. facilitate the involvement of patients, their relatives and all other informal caregivers in all aspects of activities relating to patient safety, including reporting of patient-safety incidents;

iv. review the role of other existing data sources, such as patient complaints and compensation systems, clinical databases and monitoring systems as a complementary source of information on patient safety;
v. promote the development of educational programmes for all relevant health-care personnel, including managers, to improve the understanding of clinical decision making, safety, risk management and appropriate approaches in the case of a patient-safety incident;

vi. develop reliable and valid indicators of patient safety for various health-care settings that can be used to identify safety problems, evaluate the effectiveness of interventions aimed at improving safety, and facilitate international comparisons;

vii. co-operate internationally to build a platform for the mutual exchange of experience and knowledge of all aspects of health-care safety, including:

a. the proactive design of safe health-care systems;
b. the reporting of patient-safety incidents, and learning from the incidents and from the reporting;
c. methods to standardise health-care processes;
d. methods of risk identification and management;
e. the development of standardised patient-safety indicators;
f. the development of a standard nomenclature/taxonomy for patient safety and safety of care processes;
g. methods of involving patients and caregivers in order to improve safety;
h. the content of training programmes and methods to implement a safety culture to influence people’s attitudes (both patients and personnel);

viii. promote research on patient safety;

ix. produce regular reports on actions taken nationally to improve patient safety;

x. to this end, whenever feasible, carry out the measures presented in the appendix to this recommendation;

xi. translate this document and develop adequate local implementation strategies; health-care organisations, professional bodies and educational institutions should be made aware of the existence of this recommendation and be encouraged to follow the methods suggested so that the key elements can be put into everyday practice.

The Appendix to this Recommendation can be found on the project website (www.simpatie.org).

7. Developing indicators/outcome measures and vocabulary (WP4)

Lead Partner: ESQH

Objectives

The objective of this work package was the development of a vocabulary and an internal indicator set for patient safety that is to be a part of a final project toolbox for improving patient safety.

Results to be achieved

The results to be achieved by the work package were:

- Defining a vocabulary related to patient safety, considering language, health care system organisation and economy and cultural issues across Europe (described in another report)
- Establishing a set of indicators / outcome measures that can be used in efforts to improve patient safety both at the system and organisation level
- Developing a brief rating assessment instrument for external application to provisional outputs

Deliverables fulfilled

The work package delivers:

- A set of definitions of terms related to patient safety and a framework to illustrate the core terms of the vocabulary (D4-1).
- A set of indicators for use in efforts to improve patient safety (D4-2).
- A brief rating assessment instrument for external application to provisional outputs (D4-2).

7.1 Methodology

An expert group consisting of European representatives of project partners, stakeholders and external experts was established for the achievement of the aims of WP4. The expert group met in February 2006 with the purpose of introducing to SImPatIE and WP4. A detailed work plan for WP4 was established and tasks were assigned.

Prior to the meeting of the expert group an extensive literature search was initiated using the search terms: “Patient safety”, “Vocabulary”, “Glossary”, “Taxonomy” and “Indicator”. PubMed http://scholar.google.dk/ were searched. The literature search was repeated and extended in the process of the work and finalised towards the end of 2006. It was based on a review of similar studies and carried out by the Danish ESQH-office.

A literature review was carried out by the by the Danish ESQH-office in order to identify all relevant sources for the description of concepts and terminology related to patient safety, and to descriptions of indicators. The review included work by the Council of Europe, European Comminities, Organisation for Economic Co-operation and Development (OECD), Agency for Healthcare Research and Quality (AHRQ), Eropean Community Health Indicator Monitoring, The Nordic Indicator Group etc. It was decided to take all identified available material – European and international - into account in the development of the indicators. Details of the literature/background sources related to the development of the PSIs are given later. A full reference list can be found at the end of the report.

Selecting and defining terms, and clarifying the concepts were done in a formalised consensus process in a sub-group to the expert group, interacting with the expert group. The work was executed using telephone conferences and mail correspondence, the sub-group meat once in the developmental process to deepen the work. The final draft of the vocabulary was sent to the expert group and two patients' representative for comments. Comments were discussed in a telephone conference of the subgroup, alterations were made accordingly and the vocabulary finalised.
The patient safety indicators were derived through a formalised consensus process based on literature review, targeted information gathering and expert consultation, taking into account previous work done by the project partners and international quality and patient safety organisations.
We developed the Stepwise Assessment Framework Approach to select, characterise and evaluate both new PSIs and indicators from existing programmes. The framework was based on the definition of the term "patient safety indicator" and the vocabulary framework followed by a charaterisation and an evaluation of the PSI. Indicators were characterised using the developed "Schemes for Characterisation of Indicators". Eight experts from six nations evaluated the PSIs on a scale ranging from 1 to 9 for "Relevance", "Validity and Reliability" and "Feasibility". Statistics for each dimension of the indicator formed the basis of recommendations in four categories from "recommended used throughout EU" to "not recommendable for implementation in EU". Five Institution-Wide PSIs were commented by a patient representative taking into account for experiences gathered by the organisation "Action against Medical Accidents".

7.2 Description of the work

A set of 24 definitions of patient safety terms and a framework illustrating the connection of the five core terms of the vocabulary are available for use in a cross European context. The vocabulary is aimed at professionals, e.g. risk managers, administrators, project managers and others working with patient safety. The vocabulary covers the domains: "Detection of Risks", "Analysis of Risks", "Resulting Actions" and "Failure Mode". The vocabulary is available in English language via simpatie.org. The vocabulary is aimed at professionals e.g. risk managers, administrators and others working with patient safety.
A "Brief Assessment Instrument" was developed and presented as part of the Stepwise Assessment Indicator Framework Approach. "The Brief Assessment Instrument" is suitable for use with other measures than PSIs.
All together 42 PSI were described and evaluated: 28 existing known indicators, mainly originating from AHRQ and OECD and 14 new SimPatIE PSIs. Description of the PSIs can be found on www.simpatie.org. The PSIs are relating to risk reduction and harm reduction and covering the dimentions; process and outcome. The PSIs are devided into subsets: "Institution Wide Measures", "Specific Measures" and "Theme Related Measures" covering the themes: "infection control", "surgical complications", "medication errors", "Obstetrics" and "Fall". The PSIs cover a wide spectrum ranging from surveillance of cultural assessment to measurement of standardised mortality rates. The consensus process was successfully completed leading to a recommendation of nine of 12 new SimPatIE PSIs whereas 16 of 30 PSIs from existing programmes were recommended for implementation in parts or throughout EU.
To coordinate between the work of WP4 and the other work packages at least one representative of the ESQH-office in Aarhus continuously took part in telephone conferences, overall project meetings, steering group meetings, and congresses.

7.3 Patients and hospitals perspectives

Patients perspectives were represented in work of WP4 in different ways; the organisation "Action against Medical Accidents" (AvMA), an independent English charity promoting better patient safety and justice for people who have been adversely affected by a medical accident were represented in the over all project meetings. A range of international and national patient interest groups and organisation representatives participated the SImPatIE Consensus Conference in Luxembourg.

Two patients' representatives reviewed and commented the vocabulary, and one patient representative reviewed and commented on five PSIs.

The organisation HOPE and a patient representative commented on a draft of the two reports on the vocabulary and the PSIs and the characterisation of the PSIs.

7.4 Main conclusions and recommendations

The vocabulary provides a basis of achieving greater unity of patient safety work in Europe - especially it serves as a basis for applying patient safety evaluation tools of the toolbox of SimPatIE WP4 and WP5. The vocabulary is explicitly neither a taxonomy nor a classification of adverse events. For such works we refer to the International Patient Safety Event Classification by the World Health Organisation.

We strongly recommend the vocabulary and the vocabulary framework made accessible in the European countries. It should be translated into the European languages using a standardised method and adequate implementation strategies developed; health-care organisations, professional and scientific bodies and educational institutions should be made aware of the existence of the vocabulary, be encouraged to use it suggested so that the key elements can be put into everyday practice.

The consensus process of the WP4 expert group was successfully completed leading to a recommendation of nine out of 12 new SimPatIE PSIs whereas 16 of 30 PSIs from existing programmes were recommended for implementation in parts or throughout EU. The PSIs from existing programmes have all been clinically applied.

The 42 established PSIs present a set of possible measures of patient safety. The themes and areas covered by this set are not intended to be exhaustive in the development of patient safety. E.g. within the area of measures of medication errors no indicators for "sound-alike" and "look-alike" medications are established. Though we find it highly relevant to work with these themes to improve safety, more suitable methods than PSIs can be found, and we support work in progress by project partners. The PSI concerning patients understanding of their medication at discharge from hospital can be seen as a supplement to medication reconciliation, which is part of the High 5s Initiative. In this context we recommend the continuous use of PSIs supplemented by other measures and initiatives to improve safety. Each institution must carefully plan, develop, and evaluate patient safety.
Due to patient safety cultural differences, which includes aspects of organisational and clinical culture and sub cultures e.g. related to specialities and professions as well as cultural differences related to national, regional and local aspects we do not recommend a common "package" of PSIs for implementation in EU. Prior to embarking on actual patient-safety

assessment activities using the PSIs, a systematic strategy should be established at an institutional or regional level to measure, report, and use information. Implementing the PSIs must be based upon thorough assessment of suitable data, considerations of interpretation and use, and publication of result, especially considering that patients should participate in decisions about their health care, while recognising that health-care workers should provide patients and potential patients with adequate and clear information about potential risks and consequences.

In connections with the rating of the dimension; "Feasibility" of each PSI the expert group discussed aspects such as data availability, the quality and features of administrative data present available, resources available, organisation of data collection in individual EU countries, legal systems concerning data collection individual data etc., these aspects are not systematically deepened and uncovered by WP4 for EU, but we found common traits leading to questions, which need to be followed up upon, if one wants to use the PSIs for comparison over time or even benchmarking building up European Patient-Safety-Indicator-Database. Some of these questions need to be taken carefully into account when planning to use the PSIs for comparison over time – some are more relevant if on wants to consider benchmarking. The questions uncovered in need of further investigation are:

- How is the quality of administrative data – does it match the definitions of the PSIs? Are further definitions needed to make the PSIs suitable for use?
- How do cultural differences (e.g. opinions, perceptions, attitudes, beliefs, values, norms, assumptions and expectations) concerning adverse events and errors among clinicians, hospital management, policy makers and planners etc. influence the decision of embarking on systematic collection of personal data for the sake of using PSIs to develop patient safety?
- What resources are needed in individual hospitals/nations of Europe to embark on using the PSIs for comparison or even for benchmarking?
- How is the data collection organised (centralised/decentralised)?
- Do individual hospitals/nations have informatics and reliable systems?
- How the availability of administrative data is – is it sufficient in its currents form?
- How do individual national legal systems allow data collection – especially with regard to data related to individuals?
- Not all European countries work with ICD-10 or DRG coding, how can this be handle for the PSIs where this coding applies in case of benchmarking?

In the work process of WP4 we uncovered that several member states work with different PSIs. We discussed the use of the PSIs and we believe that several of the used PSIs are suitable for spreading and using in Europe to a larger extend than what we found is the case to day, thus we recommend a common European Patient-Safety-Indicator-Library containing information on indicators relevant for developing and monitoring patient safety. Such a European Patient-Safety-Indicator-Library must as a minimum be:

- well organised and coordinated across member states
- elaborated
- continuously up dated

to be useful and fulfil its purpose of cross nation knowledge sharing and cooperation.

A literature review show, that monitoring and developing patient safety is impossible without the use of patient safety indicators to assess effectiveness, efficacy and effect of interventions. Thus comparison using PSIs is highly recommendable and necessary, all though the use of the recommended 28 PSIs implies methodological problems as the feasibility and quality of indicator data are varied along a number of dimensions across institutions and nations in Europe we estimate, that a subset of the indicators are usable in each EU country. Developing PSIs is an ongoing process in it self.

Additional work concerning homogeneous and comparable data and investigation of indicator sensitivity and specificity remains necessary prior to embarking on actual patient safety assessment activities using most of the PSIs for Europe wide common development here by supplying clinicians, risk managers, policymakers, and researchers with ongoing, comprehensive, and reliable data on patient safety. The methodology requires sophisticated resources in terms of informatics and reliable system wide patient identification and data processing. We strongly recommend that future projects on patient safety monitoring follow up and investigates these aspects to develop assessment of effectiveness, efficacy and effect of interventions.

The full report of WP4 can be found on the project website (www.simpatie.org).

8. Improving patient safety through external auditing (WP5)

Lead Partner: HAS

Objectives
The objective of this work package was the definition of a set of instruments and recommendations to improve patient safety through external evaluation

Results to be achieved
The results to be achieved were:
- To define a set of instruments that can be used to increase patient safety through external evaluation
- To develop recommendations on external evaluation of health services with regard to patient safety

Deliverables fulfilled (D5-1,2)
The work package delivers the following information:
- A description of the evolving context within member states and a definition of external evaluation
- A description of the objectives of external evaluation models in terms of patient safety and of the change in focus over time.
- An overview of the types of auditing strategies. This section also includes the discussion of barriers to achieve the goals.
- A focus on the decision process after external evaluation.
- The last and fifth section tentatively classifies the various European countries attitudes and specificities regarding external evaluation, and debates on the pros and cons of a series of strategies for European harmonisation of external evaluation ranging from the easiest to the most ambitious.

8.1 Methodology
The literature review concerned two main types of documents. The first group focus on models of external evaluation from a methodological point of view. The many recent documents were analysed. The second group of texts focus on the strategies to be implemented to improve patient safety. These texts are important in that they provide a global perspective on trends in patient safety and on the evolving goals of external auditing indicating strengths and areas for development and research. The review included work by the main organisations involved in external evaluation in North America, Australia and Europe.
The content of the report was discussed at different steps with the partners of the Simpatie project and with the Council of the International Accreditation Program of the International Society for Quality in Healthcare. The report was reviewed by a panel of five internationally recognised experts in the field of patient safety.

8.2 Description of the work
There was a preliminary consultation amongst the partners of the project to define the scope and perimeter of the work package, e.g. the promotion of patient safety within the healthcare organisations and not in other care settings, or the study of organisation-wide external

evaluation programs rather than external evaluation mechanisms limited to specific safety issues.
Participation in various teleconferences and meetings between partners of the project. Cooperation notably with partners responsible for work packages 4 and 6. A member of work package 5 acted as an expert for work package 4 on safety vocabulary and indicators and participated in their meetings and teleconferences. There was a meeting in Paris in June 2006 of the leaders of work packages 4, 5 and 6.
Participation in the Consensus conference held in Luxembourg on September 18 and 19 where the views of various stakeholders on the preliminary productions of the work package were presented and discussed.
Comments of the stakeholders and of the panel of international expert were integrated.

8.3 Main conclusions and recommendations

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 mimimum 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. More research is needed in the European Union on these issues often grouped under the concept of patient safety culture

- 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

The full report of WP5 can be found on the project website (www.simpatie.org).

9. Improving patient safety in health care organisations (WP 6)

Lead Partner: CBO

Objectives
Recommendations for internal evaluation of health services, including a set of instruments that can be used for improvement, are defined with regard to patient safety.

Deliverables
Publication: Improving patient safety in health care organizations
Web based resource of information on approaches to increase patient safety within health care organizations.

Deliverables fulfilled
A book has been published containing instruments for improvement of patient safety (D6-1).
A summarized version of the book is available on the website (D6-2).

9.1 Description of work

This Compendium (WP6) was designed to define a set of instruments that can be used to increase patient safety in health care organizations and to develop recommendations on internal audit mechanisms on patient safety for health care organizations. The objective was to develop a toolkit for patient safety in healthcare organizations. The development process was divided in two phases
Phase 1 started out with a Dutch expert group of 20 people, mostly medical specialists as the editorial committee for developing a compendium of instruments on patient safety. They were recruited based on their extensive experience in daily practice and their expertise on patient safety.

An introductory part sketching safety environment for health care organizations and a description of selected instruments have been developed. The methodology used by the expert group consisted of extensive desk research on international publications on a number of instruments improving patient safety. This lead to a compendium of instruments on patient safety developed with an overview of around 20 instruments that organisations can use in their setting, in particular in hospitals.
The format for the description of the instruments consists of;
a description of the instrument itself;
how and when to use it;
the experiences and results achieved;
the advantages and disadvantages of its use;
an overview of the researched literature.
The Compendium has been published as a book in Dutch and edited and translated in English

Phase 2 of the development process dealt with the international consultation. The English translation was submitted to project partners for comments and additions and also additional international experts were invited to contribute.

The present Compendium structure consists of two parts
Part 1. Introduction to the topic of patient safety in chapters 1 - 5
1. What is patient safety?
2. Patient safety from an international perspective
3. Why are hospitals not as safe as we would like them to be?
4. The epidemiology of medical errors: do we know what we are measuring?
5. The safety management system, the approach at the organisation level

Part 2. Description of instruments Ch 6 – 21
In the second part a number of instruments are described in a generic way. This has been done to make application of the described instruments possible across the EU regardless of national/cultural differences.
The instruments described can be divided into four categories;
1. Tools for analysis of incidents or risks on a prospective
2. Tools for analysis of incidents or risks on a retrospective basis
3. Intervention approaches at the system or organizational level
4. Intervention approaches at the process or professional level

9.2 Recommendations

1. To use a selection of these evidence based instruments as most appropriate to local circumstances. To that purpose we offer in the Compendium a selection of instruments including examples of its use as a basic set of best practices or possible training modules.

2. The EC should facilitate and promote further cooperation on developing and implementation of instruments to be used by healthcare providers and organizations.

A summarized report of WP6 can be found on the project website (www.simpatie.org).

10. Strategy Exercise (WP7)

Results to be achieved
Aim of WP7 'the strategy exercise' is to reach expert consensus on a strategy for patient safety that incorporates the information of previous work packages (WP2-6) and to develop a Strategy Framework that can be modified to fit individual health care systems and organizations but that contains agreed components.

Several tasks of previous work packages have served as a foundation for the Strategy Framework:

- Overview of actions to improve patient safety at the Community level. (WP2)
- Recommendation on patient safety for governments. (WP3)
- Toolbox for improving patient safety in health care organizations. (WP4-6)

Deliverables Fulfilled

- Consensus Conference 'Building a strategy for patient safety in Europe' (D7-1).
- Strategy Framework (D7-2).
- Web based resource (D7-3, described by WP8).
- Dissemination plan (D7-4, described by WP8).

10.1 Methodology

The Consensus Conference has been organized by CPME in close cooperation with CBO, the Council of Europe, ESQH, HAS, HOPE, LMCA and A*v*MA.

Delegates of a European wide network attended the conference on 18-19 September 2006, representing the European Commission, national governments, organizations, experts, medical professionals, patients and other stakeholders involved in the project.

The WP's preliminary results and contiguous issues where presented and discussed.
The debate was realised, making use of plenary presentations and discussions. Analysis of the strategy framework was organized in two intensive workshops:

1. on patient safety at the national and European level
2. on patient safety at the provider level

Rapporteurs of the workshops proposed consensus conclusions accordingly.
Reportage of the event resulted in a basis for the subsequent Strategy Framework conclusions and recommendations.

Distribution of the provisional conference conclusions and contribution of all participants assured the consensus and a common consent among the stakeholders.

10.2 Description of work

The Consensus Conference built on CPME's activities in 2005 that have been related but not financially supported from the project, namely:

- Organization of the patient safety conference "Making it happen" in Luxembourg, 4-5 April 2005.
- The development of the "Stakeholder's position paper on patient safety". This position paper was finalised in November 2005 and presented during the UK Patient Safety Summit on 28-30 November 2005.

Building on previously mentioned CPME activities the project team embarked on integrating project results and building expert consensus on main recommendations. The work encompassed various preparatory teleconferences and meetings to set stock on the progress of the different WP's and to set the conference agenda jointly. Besides it was decided on what experts to invite for the event.

Over 200 experts were invited to the conference, including experts from the SIMPATIE project, national authorities, EU institutions (incl. EC and EP), international organizations, academia, patient safety organizations/societies, organizations representing patients, healthcare professionals, industry and other NGOs and stakeholders. The selection of invitees was based on their expertise and previous involvement in Patient Safety activities. The conference was promoted via personal invitation, the SIMPATIE and CPME websites and online media.

On 18-19 September 2006 the Consensus Conference took place in Luxembourg, consulting the 65 participants to reach consensus for a patient safety strategy resulting in a set of conclusions.

After distribution of the provisional version of the Strategy Framework among the Conference participants and project partners, a final version could be prepared based on the conference conclusions.

The conference results and recommendations where disseminated by means of Strategy Framework and additional conference materials were made available on the SIMPATIE website. The conference conclusions were published on the DG SANCO EU Health Portal as well.

10.3 Role of the patient in the activities

A wide range of International and National patient interest groups and organisation representatives have been invited to the Consensus Conference.
Both the patient interest organisations LMCA and A*v*MA had the opportunity to give feedback in WP7 owing to their role in the SIMPATIE project.

10.4 Conclusions

(Below a summary is given of the recommendations of the strategic framework comprising the main conclusions of WP7)

Towards a strategic approach to patient safety

Patient Safety Network
The conference participants applauded the initiative of the High Level Group on Patient Safety to move to set up a patient safety network in Europe involving all Member States.
It was agreed that such a network would have an important role as a coordinating body in Europe, to share knowledge and solutions between the Member States and stakeholders; e.g. by introducing a solutions bank on a European level.

Involvement
As it was also agreed that the voice of the patients was paramount in the process, it was stressed that patient safety activities must involve all relevant stakeholders, especially patients, patient organizations, acute and long term health care providers, healthcare professionals, patient safety organisations and insurers. The role of a possible involvement of the media as a further stakeholder in the process was briefly discussed.

National platforms
It is further recommended that national platforms should be introduced to reach a harmonization on national level and to adapt proposed approaches to the different national and local systems. Annual reports by the Ministries of Health were suggested as an additional method to actively involve the Member States in the process by maintaining the profile of patient safety at a national level. To ensure the comparability of results the need for a clear vocabulary and a common inventory of patient safety indicators, e.g. as presented by the SIMPATIE consortium, was stressed by the participants.

Creating a culture of safety
Regarding reporting and risk management systems, discussions mainly focused on their scope and format, including the relevance of insurance schemes to provide compensation, and the meaning of open-and-fair systems in practice. The importance of adequate competencies, state-of-the-art education, appropriate human resources and a real culture of safety were mentioned as prerequisites for patient safety on national and local levels.

Feasibility
The value of investment in patient safety should therefore be highlighted for Member States and healthcare providers, thus demonstrating that there is a sound business case for introducing patient safety interventions to healthcare organizations.

A common set of indicators and instruments for internal and external evaluation would contribute to producing the necessary economic evidence. However the tools must be practical and easy to implement within healthcare organisations.

Clinical Governance and team approach
It was also noted that the issue of clinical governance needs to be included in the process, especially to give hospital managers a framework for the tools to improve patient safety within their organizations.
Improved multidisciplinary team work among healthcare professionals is seen as a potential solution to the growing demand for cost-effectiveness leading to an increasing volume of treatment.

Perspectives

In general the conference affirmed the relevance of and willingness for a change in culture, a fact that was expressed by the general feeling of impatience and the desire for action, notwithstanding the recognition for the need for further discussion on a European level. Given awareness and the necessity for action being generally recognized, the logical next step would be the development and implementation of the right tools to ensure patient safety at all levels.

Based on the project contributors, as well as the different views expressed during and after the conference, a strategy framework document has been prepared, which will be published in December 2006. All comments on the draft strategy framework presented and discussed in Luxembourg submitted within the given deadline (1 October 2006) were included in the updated version.
The full report of WP7 can be found on the project website (www.simpatie.org).

11. Patient perspectives on Simpatie project

The Simpatie project has sought to ensure that the perspective of patients is included in its work by first of all including a well-established patients' organisation - Longterm Medical Conditions Alliance (LMCA) as a project partner. It has also been the intention that each work package seek out patient perspectives in its work. LMCA is a UK umbrella charity for other patients' charities in the UK dealing with long-term conditions. In order to ensure a more specialist focus on patient safety, LMCA made arrangements for one of its member organisations, Action against Medical Accidents (AvMA) to provide the main patient input to the project's work. AvMA is a UK charity specifically working on patient safety and also support and justice for patients who have been affected by medical accidents.

Where possible, each work package has made arrangements for patient perspectives to be taken into account in its work. In addition, either AvMA or LMCA has been involved in all of the project meetings. AvMA has scrutinised each of the work package reports, and provided input to ensure that the reports reflect a patient perspective as well as professionals'. A presentation on patient perspectives on the project's work was provided at the stakeholder conference in Luxembourg, to which various patients' organisations were invited. AvMA and LMCA have also used their own networks to inform patients' groups about the project and take soundings on key issues. AvMA is in contact with a number of patients' organisations with a specific interest in patient safety in various member States. Meetings and liaison has also taken place with the European Patients Forum. AvMA also contributed a chapter to the compendium of good practice publication, covering tools involving and/or empowering patients.

In practice, it has sometimes been difficult to ensure meaningful ongoing patient involvement in all of the project's work. Not all of the 'expert groups' used by the different work packages involved patients. Whilst AvMA/LMCA provided a 'safety net' by which they were at least able to comment on and suggest changes to each of the work package reports and the overall recommendations, a lesson for the future would be to build in patient representation in all the work at an earlier stage. It can be quite difficult to 'pull back' professionally-led processes of work at the later stage to consider issues from a patient perspective. This is one reason why it was felt important to provide this section to discuss not only the methodology used for getting patient input, but to make some overall observations.

The biggest issues which have arisen during the course of the project involving potentially conflicting views between the professional/healthcare provider perspective and that of the patients, are around issues of 'culture'. Whilst both patients/patients' groups and other stakeholders by and large fully support the statements made in the Council of Europe recommendations and the Luxembourg Declaration on Patient Safety with regard to patient safety culture, it became apparent during the project that these statements can be interpreted very differently. The Council of Europe recommendations use the phrases 'open and fair' and 'no-blame' culture, as well as 'patient safety culture' without defining them. To some extent the project partners, and the 'experts' with whom they have worked, have all started with their own interpretation of such terms and assumptions about the desirability, or otherwise, of policies or interventions which are seen to be conducive to the respective cultural position. For example, one tension that has arisen is over the phrase 'no-blame' culture, and the assumption that such a culture is a 'good thing'. In some member States, notably the UK, 'no-blame' culture has been replaced in the context of discussing a good 'patient safety culture' because it is seen to imply a lack of accountability – that blame will not be

apportioned even where it is justified. Whilst it can be argued that this phrase was never intended to imply such absence of accountability, and was actually intended to describe a culture which was less focussed on applying individual blame when errors/accidents occur, it still has those connotations. In the UK, 'open and fair' now tends to be the preferred terminology because it suggests there will be openness and honesty about incidents rather than protecting health professionals from 'blame'/accountability at all costs. Also, because it conveys the desire that if people are to be held to account, that this must be fair and proportionate.

Two practical areas where differences in interpretation of what constitute important ingredients of a 'patient safety culture' arise are 'no-fault compensation' and confidential reporting systems. 'No fault compensation' schemes were assumed by some of the project partners to be a 'good thing' – part of a good patient safety culture which shifts away from individual blame to systems approach, and which is fair to injured patients by awarding them some compensation in certain circumstances. This was the reasoning behind work package 2 asking the question whether 'no-fault compensation' schemes existed in the various member States. The trouble is, no-one has properly defined what a so-called 'no fault compensation' scheme is, and the discussion or debate has not been had as to whether such an arrangement is necessarily consistent with an open and fair culture, particularly from the patients' perspective. For example, in the experience of AvMA and many of the patients/patients' organisations with which it works, the very concept of 'no fault compensation' is illogical.

For example, for many patients the establishment of where the fault lies in respect of a medical accident is actually more important than obtaining compensation. Being given some money without a full acknowledgement of the gravity of the fault which led to the unnecessary injury can add insult to injury. However, where 'no fault compensation' relates to the ability to obtain compensation without the necessity of going through lengthy legal action, thereby saving cost and stress for all sides, is usually seen by everyone as a good thing. In this context 'no fault' refers to taking away the need to establish 'fault' or 'negligence' to the standard required by the courts. In other words an 'administrative' system of justice for victims of medical accidents as an alternative to the judicial one. Most patients' groups, including AvMA, would agree that the availability of such an alternative is a good thing in the context of developing an open and fair patient safety culture, provided that the system applied is robust enough to be fair and credible. For example, factors to be taken into consideration when considering an alternative 'administrative' system are:

- is the patient allowed specialist representation within the scheme to enable them to be empowered in the process of establishing eligibility for compensation?
- Is the patient entitled to the same level of compensation in the scheme as they would have been in a legal resolution of the case, or is compensation capped at a certain level regardless of the injury and losses incurred?

In other words, this is a complex issue. Whilst there are undoubtedly potential benefits in having an alternative system to the legal system for compensating patients, there are a number of factors to take into consideration in determining the acceptability of a system. The term 'no fault compensation' without further explanation or an agreed definition
can be misleading and unhelpful.

With reporting systems, whilst there is wide consensus by all stakeholders that reporting systems, including the potential to report incidents anonymously, are a good thing and an important part of any patient safety system. There is also consensus that no-one making a report should be admonished or punished because of the act of making the report. However, an area which is more contentious is the extent to which information which is reported through such a system is protected from use for the purposes of helping an individual find out the truth about what has happened to them, to obtain redress or compensation, or to ensure that patients are protected from health professionals whose fitness to practise might be in question. The Council of Europe recommendations include patients/their families being fully informed of details of errors or omissions which may have caused harm. There is wide consensus that this is an ethical and professional requirement. However, an emphasis on anonymous or confidential reporting of patient safety incidents is perceived by patients and patients' groups sometimes as implying that not informing patients of such incidents is in reality condoned. In other words, it is acceptable not to inform a patient/family of an incident which has caused harm if a report is made about the incident which can help the system learn lessons. The implication is that this is the only way in which reports will be obtained – that health professionals will not report incidents if they fear that there may be repercussions for them. These notions have serious implications for public confidence in health professionals and health systems, for ethical standards in the health professions, and for the viability of what we call a 'patient safety culture'. Whilst the Council of Europe recommendations and the systems employed by some of the member States say both that patients/families should be fully informed and there should be a confidential/anonymous reporting system, these can be perceived by patients as contradictory. For example, if patients are fully informed anyway, what can be the justification for withholding from them information which is obtained via the reporting system? Whilst it is accepted that some health professionals, as in any walk of life, will feel unable to be open and honest, and it is better to receive some information, even if anonymous, about patient safety incidents rather than none. However, giving mixed messages about the need to be open and honest with patients, and about the ethical standards which can be expected of health professionals can be profoundly damaging to patient/public confidence. Without patients, it is not possible to have a 'patient safety culture'. To put it in the words of Sir Liam Donaldson, 'to err is human; to cover up is unforgivable'.

11.1 Conclusions/Recommendations

1. Patient Involvement/Empowerment in Patient Safety
   The experience of the project itself and the results from the mapping exercise demonstrate that much more needs to be done to facilitate the involvement of patients in patient safety work. Resources should be made available specifically to enable the participation of patients and patients' groups at the national and European level.

2. Compensation Systems
   More work is required in establishing the nature, the advantages and disadvantages of compensation schemes used in various member States as an alternative to legal action. This could lead to recommended good practice for member States to consider adopting.

3. Reporting of Incidents
   There needs to be more open debate about the desirability or otherwise of confidentiality/anonymity and the protection of individuals reporting incidents through official reporting systems. In particular, more work is needed on the impact that the

availability of such a mechanism has on the full reporting of incidents to patients/families, and on patient/public confidence. Research should be conducted on how the requirement to report incidents to patients/families can be enforced, whilst allowing for confidential/anonymous reporting by those unable to meet the normal ethical standards expected of health professionals.

12. Dissemination (WP 8)

Lead Partner: CBO

Objectives
Results are disseminated to the wider public and involved parties.

Deliverables
Dissemination targets as defined in strategy (dissemination plan) deliverable D7.4
Deliverables fulfilled:
By subcontracting to a professional public relations company input was received through which the consortium has compiled a Dissemination plan. This WP has also contributed to deliverables listed in WP7, the web based resource and this Dissemination plan. (D8)

During the first year of the project a website has been set up to inform the public on the project and to be able to disseminate the results of the project (www.simpatie.org). The website contains general information on the project. Results of the project can be shown on the site.

During the negotiation phase of the project DGSANCO requested to incorporate in the final project plan a dissemination plan for the project after its finish. The preparations to establish the dissemination plan were set up. Terms of Reference have been developed and two professional communication companies were invited to submit a proposal to develop a communication plan for the Simpatie project based on the terms of reference that were sent to them. The company selected provided input for the dissemination plan that subsequently has been developed by partners.

Five broad target groups have been identified;
1. Policy makers
2. NGOs
3. Broad (lay) public
4. Quality professional community
5. Scientific community

These groups have been specified in more detail and the possible ways of communication with these groups and the various types of deliverables/messages have also been identified.

In the course of the project the Consortium has adapted the publication strategy focusing on web based dissemination and build up of a first rate web site that could serve as a platform for patient safety activities in the future. In addition, previously mentioned activities of consortium partners like for instance ESQH, CPME and HOPE and their already established websites, newsletters etc. for their constituents have been used.
The full report of WP8 can be found on the project website (www.simpatie.org).

13. Conclusions

1. Going back to the general objectives of the project we can conclude that the main goals have been achieved. Namely; to use Europe-wide networks of organizations, experts, professionals and other stakeholders:
   The project consortium included representatives of European organisations of providers, hospitals and professionals, quality experts, patient representatives and a direct link to policy level through the Council of Europe.
   In addition national expertise centres for quality of care in France, Denmark and The Netherlands have been involved, together this presents a Europe wide network that has enabled successful project activities.

2. Within the project period of two years, a common European set of vocabulary, indicators, internal and external instruments for improvement of safety in health care have been established: Through expert groups and project teams, involved in different WPs, sets of instruments, indicators and a vocabulary have been developed and validated through an international expert consensus conference.

3. The set will be disseminated to parties involved:
   The previously mentioned consensus conference has also formulated a strategic framework for patient safety together with all the underlying documents. These have been made available to a broad healthcare community in Europe through the project website, publication of a book and extensive input on policy level throughout the duration of the project.

4. Finally, project findings as well as the established network and infrastructure have been used as a basis for a potential follow up on synchronised European activities on Community level involving many stakeholders as well as all Member States