Public Health

Interim Report SIMPATIE Project

SAFETY IMPROVEMENT FOR PATIENTS IN EUROPE
REPORTING PERIOD FEB 2005 - FEB 2006
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Contact:
Dutch Institute for Healthcare Improvement CBO
Projectleader / Project Coordinator
Benno van Beek MSc.
PO Box 20064
3502 LB Utrecht
The Netherlands
Tel.: +31 30 2843 989
Fax: +31 30 294 36 44
Email; b.vanbeek@cbo.nl

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
- CBO Dutch Institute for Healthcare Improvement, lead partner

Content

Summary
From the start of the project a project secretariat and Steering Group have been established. Lead partner CBO is 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.

A project secretariat has been established at CBO and is responsible for administrative and financial management. Through joint CBO / ESQH office in Brussels contact is maintained with other relevant European organizations and actions. A project website has been developed.

A reference and expert group have been established to support the mapping exercise in which an extensive questionnaire has been developed and data collection is on-going. In September 2005 a joint SIMPATIE/WHO Europe meeting was organised in Copenhagen.

The publication scheduled early in the project of the Council of Europe's Recommendation on Patient Safety has been postponed by the Council's Committee of Ministers. Partners have resorted to the draft Recommendation as part of the input for their activities in later stages of the project. The originally planned web based activities after publication are now scheduled for the second year of the project.

Following an extensive literature review on patient safety indicators an expert group has been established for development of a vocabulary of about 30 definitions of patient safety terms. The vocabulary framework will form a basis for developing the indicators. Schemes for classification and evaluation of a limited set of indicators have been developed relating to risk reduction and harm reduction and covering the three dimensions; process, structure and outcome.

A literature review has been carried out reg. existing mechanisms of external evaluation. Following this an indicative survey has been developed aimed at the identification of the respective roles of existing external evaluation mechanisms in addressing five majors risks; pressure sores, falls, surgical complications, medication errors, nosocomial infections.

After extensive desk research by a group of experts a compendium of about twenty instruments to improve patient safety have been developed. This will be finalised in year two and may serve as a toolkit in healthcare organisations.

A start has been made with the development of a Strategy Framework that will incorporate the aforementioned activities. This will include a consensus conference in September 2006 on strategy for patient safety, a publication as well as a dissemination plan.

Project indicators

Output indicators title *(e.g. Distribution of leaflets:)*	Target value to achieve *(e.g. 200 copies:)*	Status 2006
All deliverables to be assessed against project plan	keep to time (see T5.2)	
Review and monitor quality of data base content	Random sampling on basis agreed by steering committee	2 x in 2006
Consensus on vocabulary. Test by circulation to critical group (use of rating scale prepared as output D4.3).	50% response from 50 experts in 20 countries	Ongoing
Outcome indicators - submit to OECD Patient safety indicator group (already exists) for review (using rating instrument D4.3)	get response by M22	NA
External evaluation - seek response from International Accreditation forum e.g. ALPHA (as above, using rating instrument D4.3).	get response by M22	NA
Internal audit report - seek quick response from International expert group as above, with whom links already exists e.g.EFQM (also using D4.3)	get response by M22	NA
Project: SImPatiE.		
Strategy report to be evaluated at next European meeting (iterative process)	within 12 months of project end	NA
Dissemination criteria	Will be developed as part of dissemination plan Deliverable D7.4	ToR developed

Activity indicators

Indicator title (e.g. Coordination meetings:)	Target value to achieve (e.g. Number of meetings:)	Status 2006
WP1 (for details refer to T6-1 to 8) minutes of steering group with action points	Updated two monthly for duration of project	Minutes
WP2 Regular reports on progress to steering group during collection phase (M2-19) timely delivery of literature review, interim & final report	Two monthly reports to schedule T5.2	From April- Febr as planned
WP4,5 and 6 report to steering group on progress. Esqh officer organises one expert seminar and delivery of final report to schedule	Two- monthly reports To schedule T5.2	Since Oct operational
WP7 Group reports to steering group. Consensus conference organised by ESQH officer Final report delivered to time Patient centred version of report initiated promptly	2 reports To schedule T5.2 To schedule T5.2 Version by M23	NA
WP8 Discuss with Commission necessity of translation of reports into other Community languages. CBO organises demonstration of IT sites	Meet with representative from DGSANCO	1 meeting

1. Introduction

Patient Safety is now recognised internationally as a health quality issue. There is good evidence of the level of harm to citizens and the cost to both healthcare providers and to society of what amounts to preventable harm in delivering healthcare.

In recent years the issue of patient mobility, stimulated by a number of European Court of Justice rulings together with system incompatability problems raised in the context of cross-border contracting have stimulated debate. Discussion fora and evidence presented during the High Level Process of Reflection (HLPR) on Patient Mobility in 2OO2/3 have contributed to the Work Plan 2004 for the first time specifying the topic of patient safety.

In response to the recommendations given by the the HLPR in its final report[1], the Commission issued a Communication regarding the reflection process in March 2004[2]. Following up on one of the recommendations, the Commission in cooperation with Member States established the High Level Group on Health Services and Medical Care[3](HLG). In May 2005 the HLG Working Group on Patient Safety met for the first time. The WG was established after the decision that this topic was equally important to discuss in this forum as the other topics debated by the HLG.

Already in 2002 the Council of Europe established an Expert Committee to advise the Council on a Recommendation on Patient Safety. As the Council of Europe decided to participate in the SIMPATIE during the preparations of the project proposal, we will discuss their actions later in the report.

A third institution active in the field in of patient safety is the Organisation for Economic Cooperation and Development (OECD). The OECD Health Care Quality Indicator (HCQI) Project was started in 2001. The long-term objective of the HCQI Project is to develop a set of indicators that can be used to raise questions for further investigation concerning quality of health care across countries. It was envisioned that the indicators that were finally recommended for inclusion in the HCQI measure set would be scientifically sound, important at a clinical and policy level and feasible to collect in that data would be available and could be made comparable across countries. It was also envisioned that the indicators would not enable any judgement to be made on the overall performance of whole health systems. In essence, they should be used as the

[1] http://europa.eu.int/comm/health/ph_overview/Documents/key01_mobility_en.pdf

[2] See: COM (2004) 301, final.

[3] http://europa.eu.int/comm/health/ph_overview/co_operation/mobility/high_level_hsmc_en.htm

basis for investigation to understand why differences exist and what can be done to reduce those differences and improve care in all countries[45].

On a global level WHO Geneva launched in October 2004, the World Alliance for Patient Safety in response to a World Health Assembly Resolution (2002) urging WHO and Member States to pay the closest possible attention to the problem of patient safety. The Alliance raises awareness and political commitment to improve the safety of care and facilitates the development of patient safety policy and practice in all WHO Member States. Each year, the Alliance delivers a number of programmes covering systemic and technical aspects to improve patient safety around the world[6].

During the preparation of SIMPATIE project proposal these activities were taken into account in effort to prevent any overlap between these activities and to create an overview of these actions during the project period which started mid-February 2005. We have experienced during the project period so far a lot of attention by policy maker and will continue our efforts in informing them as well as the wider audience to the best of our abilities, in particular by having our results on the project website (www.simpatie.org) when they become available. In addition a number of direct communication channels have been created with relevant policy and advisory bodies, this includes presenting the project and/or an update of the project to the HLG and the Working Party on Health Systems. Besides this the project has been presented on a joint conference with WHO Europe and has DG Research been informed during an informal about relevant patient safety issues assisting in the development of the 7th Framework Programme.

[4] http://www.oecd.org/dataoecd/1/34/36262514.pdf
[5] http://www.oecd.org/dataoecd/1/36/36262363.pdf
[6] http://www.who.int/patientsafety/en/

2. Objectives of the SIMPATIE Project
2.1 Project objectives

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.

3. Project activities:

3.1 Project coordination and Management (Work package 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

From the start of the project a project secretariat and steering group to manage the project have been established. The Steering group consist of representatives of all partners and is responsible for guiding all project activities. Lead partner CBO is 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 coordinates execution of work packages and production of deliverables.

A project secretariat has been established at CBO and is responsible for administrative and financial management. Through joint CBO / ESQH office in Brussels contact is maintained with other relevant European organizations and actions.

Project partners HOPE and LMCA are not in lead of a separate Work Package in the project but are on a continuous basis cooperating constructively with the other partners in the project from their own expertise.

In addition, the secretariat will develop, coordinate and execute the PR strategy for the project, in a way that will assure targeted provision of relevant information both to general and professional public. The strategy will be developed by a professional PR staff and consolidated with the partners and the Commission.

An internal reporting system has been established and an internal communication system through the closed part of the website. This lead to development of the progress report.

In addition financial management structures have been established with distribution of the first advance payment and financial reporting prepared.

3.2 Mapping exercise (Work package 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
Published overview report
Best practice compendium (web-based).

The main goal of the mapping exercise is to develop a systematic overview of activities related to patient safety in a maximum of 20 EU countries. This information will be made accessible through web based communication. The activities relate to creation of a systematic, easily accessible, knowledge repository related to legislation, regulation and actions in EU states directed towards improvement of patient safety. To achieve this a number of methodologies have been used;

- The information from the Council of Europe's Recommendation in relation to information collected through country framework reports has been used as a source of government information
- the format is being used to collect information from respectively healthcare organisations, professional bodies, patient organizations.
- a data base format has been developed and is in its final stages of implementation to enter the data on the website

To assist this work two separate groups have been established at the start of the project, a reference group and a group of special advisors.
A multi-disciplinary reference group, which acts to help formulate the detail of what would be useful to collect. The reference group members are a mixture of individuals with differing perspectives on patient safety and from different European countries. They include -among others- care managers, doctors, lawyers, (chief) executives in specialist healthcare quality organisations, safety managers in healthcare and industry, policymakers, scientists. The purpose of the reference group is to help ensure that the research addresses the right issues and asks the right questions. The initial format for the questionnaire was developed, and after a number of revisions organised into four tranches of research for better data collection. This was done in collaboration with the reference group. Data was collected in an interactive process, and during the reporting period the research questions were the focus of the work. The research questions were framed, drafted and tested with the reference group at a meeting which was held in London in November 2005.

A network of special advisors, one from each of the twenty countries targeted by the research has also been established. The special advisors are providing information about the systems relating to patient safety within their country, to be a second opinion to help interpret the significance of information collected and generally to promote the research.
A special advisor is an expert in his/her country in the field of patient safety. They have an overview of what is happening on the several issues, for example patient safety systems, standards, accreditation, regulation, etcetera. Special advisors also are knowledgeable about the institutions which specialise in patient safety and patient safety experts in their country.

An extensive questionnaire has been developed and sent out to the experts in all participating countries. Data collection is still on-going after which analysis of the data will take place [7].

A website www.simpatie.org has been set up and a framework has been developed to enter the information in the database. Work is ongoing to fill the database following responses from the experts. The questions developed are being send to the experts on a regular basis in batches over the project period in order for the experts to respond to them.

During a meeting with WHO Europe staff in April the goals of the project were discussed and explained. WHO Europe informed us about their work on a Patient Safety questionnaire that they were about to launch. To prevent any overlap the project representative commented on the draft questionnaire. It appeared that the work by the two initiatives were complementary to each other. An initial agreement was made that the project could have a look at the draft WHO data coming in from Member States. Afterwards we were informed by WHO/Europe that the data will not be provided to the project before official publishing. Publication has not taken place during the reporting period, we hope to be able to use the data in the second stage of the project.

A combined SIMPATIE/WHO Europe meeting was organised in Copenhagen in September. This meeting was attended by some 60 experts from across Europe and resulted in a joint report that was published in January 2006 by WHO/Europe. It should be noted here that this event was not scheduled in the project proposal but was regarded as mutually beneficial to both the SIMPATIE partners as well as WHO/Europe. The activity did contribute to dissemination of information about the project.

[7] See Annex2

3.3 Promotion of Recommendation on Patient Safety by the Council of Europe (Work Package 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

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 could for this reason not yet be achieved as it is not yet published. However, given the present schedule for publication this might still be possible within the project time frame.

3.4 Toolbox Developing indicators/outcome measures and vocabulary (Work Package 4)

Lead Partner: ESQH

Objectives:

A vocabulary (set of definitions) and a set of system and organization indicators / outcome measures related to patient safety is formulated.

Deliverables:

Publication on vocabulary and indicators / outcome measures for safety
Web based knowledge resource on terminology and indicators for safety
Assessment tool for use by external experts to validate outputs of WP4,5 and 6

The Danish ESQH office (Aarhus) for quality indicators established an international expert group –for which the office will act as secretariat- which met for the first time in January this year to decide on the detailed workplan for this WP. This included preliminary decisions for the development of the vocabulary and preliminary patient safety indicators.

Literature review
Prior to the meeting of the expert group an extensive literature search was initiated including work by the CoE, EC, OECD, AHRQ, Nordic Indicator Group etc. The literature review was done by the secretariat in order to identify all relevant sources for the description of concepts and terminology related to patient safety and indicators. This literature search is based on a review of similar studies and carried out by a medical employee of the secretariat.

Development of a vocabulary related to patient safety.
The vocabulary on patient safety and terminologies and concepts is developed in a formalized consensus process in a sub-group to the Expert Group. This sub-group is supported by the secretariat. A vocabulary of about 30 definitions of patient safety terms covering the domains: “Detection of risks”, “Analysis of risks” and “Resulting actions” is in process. The vocabulary framework will form a basis for developing the indicators.

Development of patient safety indicators/outcome measures
In the development of patient safety indicators/outcome measures all nationwide and international patient safety indicator programs will be included in the literature evaluation.
The patient safety indicators are derived through a Delphi consensus process.
In cooperation with the expert group schemes for classification and evaluation of indicators have been developed. And a definition of the term “patient safety indicator” (PSI) has been agreed upon by the expert group.
It has been decided to develop indicators relating to risk reduction and harm reduction and covering the three dimentions; process, structure and outcome.
The indicators will be divided into three sets dependent on whether they 1) are immediately workable throughout the European health care systems 2) are workable in part of Europe 3) will be ready for implementation after some time

The process to develop the indicators has started. To structure this process schemes have been developed for classification and evaluation (Annex 3 and 4) of a limited set of indicators in cooperation with the expert group. Work on WP5 is taken into account in developing indicators covering: nosocomial infections, pressure sores, falls, surgical complication and medication error.

3.5 Toolbox Improving Patient Safety through external audit (Work Package 5)

Lead Partner: Haute Autorité de Santé (HAS)Objectives:
Recommendations for external evaluation of health services, including selected instruments that can be used for improvement, are defined with regard to patient safety.

Deliverables:
Publication: Using external evaluation to increase patient safety
Web based resource of information on external evaluation of health services for improving patient safety

WP5 has been divided in three tasks. The first one is to perform an analysis of mechanisms of external evaluation; the second to develop a toolkit that can be used for external evaluation of patient safety and the third to develop recommendations and describe instruments for external evaluation that could be used for the European Community and Member State level.

Project leaders are assigned to each task. A committee of national experts is to be convened after completion of a preliminary report related to the first task. Particular attention will be paid to the relationships with the other work packages, notably work packages 4 and 6.

First Task of WP5
The completion of the first task, consisting in the analysis of mechanisms of external evaluation has followed two approaches, one based on literature, one based on hospitals survey.

Approach 1: The commonalities and differences of existing mechanisms of external evaluation.
This work will address issues of inspection and authorization processes standards-based activities (accreditation-like), monitoring performance activities / benchmarking, system-wide learning through adverse events, cost effectiveness. The search is based on literature and Web sources.

A first version of a document was produced that describes the main objectives today of external evaluation mechanisms, presents an overview of the different methods, summarises the evolutions from 1990 to 2000, from 2000 to 2003 and from 2003 to present, discusses the limits of external evaluation and the criteria for success (accompanied by a bibliography):

Definition and Objectives :

To evaluate the utilization and control of the tools and resources in safety management
To evaluate performance in relation to patient safety
To evaluate the best compromise for cost efficiency for the patient
To coordinate the approaches of internal and external audits
To promote improvement
To inform and promote accountability

Methods of external evaluation:

ISO certification
The Malcolm Bridge model
Peer review specialty approaches
Accreditation
Inspections of health services
Recertification of competences

Common evolutions of these mechanisms (four phases) :

Physical security, security of apparatus and measurement systems
Clinical standards and vigilance systems
Dynamic interfaces, patient participation, transparency
Systemic approaches and culture for patient safety

Critics and limits of external evaluation
Criterias for success
The European picture relative to external evaluation
Lessons for a European ptatform

Other issues will be addressed such as the role of publication of the results, the place of indicators, the interplay between autonomy for the professional and control to limit practice variation in relation to evidence-based medicine, the link between levels of achievement and allocations of resources or other ways of recognizing value.
This version must be enlarged to define the implications of this overview on the different steps of an external evaluation procedure, i.e. creating a tool box. It should be as it is already a good basis for discussion between partners.

Approach 2: The management of majors risks in a number of countries.

This work will be based on a survey aimed at the identification of the respective roles of existing external mechanisms in addressing five majors risks (pressure sores, falls, surgical complications, medication errors, nosocomial infections). The survey will be non exhaustive but indicative and will question professionals

of healthcare organizations to identify which are the most visible mechanisms of external evaluation in their respective countries. The survey is to be completed by the end of March 2006 and should lead to the production of a users' guide for the mechanisms described in the first approach. Ten hospitals have been contacted in seven countries. The initial response was considered as insufficient so they were contacted again and the sample has been enlarged. The survey should lead to the production of a users' guide for the mechanisms described in the first approach.

3.6 Web based resource of information (toolkit) on approaches to increase patient safety within health care organisations (Work Package 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.

Method used for Work package 6:

Stage 1: A group of more than 20 experts was formed, among them medical specialists, that constituted the editorial committee for developing a compendium of instruments on patient safety. The experts were recruited based on their extensive experience in daily practice and/or their expertise on patient safety. This group started by developing a model for the Dutch situation and at a later stage adapted this model to make it suitable for the international context.

Stage 2: For the purpose of developing a compendium of instruments an extensive desk research has been carried out to research international publications on a number of instruments improving patient safety such as; root cause analysis, move your dot, health failure mode effect analysis, breakthrough approach, bundles, etc. Based on the gathered information the group of experts developed a compendium of instruments on patient safety with an overview of around 20 instruments that organisations can use to improve patient safety in their setting. This compendium has been published as a book in the Netherlands At the moment agreement has been reached with the publisher about the translation of the collected information on instruments into English. The table of content of the compendium -to serve as a toolkit for healthcare organisations- has already been circulated to the Simpatie partners to give them an indication of what to expect (Annex 5).

Stage 3: As soon as this stage of the work package is finished, the translated compendium will be circulated to the partners in the Simpatie project. They will be asked for best practice examples in their respective countries to be included in the compendium as illustrations. This will make it into a valuable instrument and toolkit for organisations wishing to improve patient safety.

Stage 4: Dissemination through a project publication / book and web site where information will be made available.

3.7 Strategy exercise (Work Package 7)
Lead Partner: CPME
Objectives:
Development of a Strategy Framework that will incorporate tasks of WP2-6 i.e.:

- Overview of actions to improve patient safety at the Community level.
- Recommendation on patient safety for governments.
- Toolbox for improving patient safety in health care organizations.

Deliverables

- Consensus conference on strategy for Patient Safety
- Framework strategy – publication
- Web based resource
- Dissemination plan

The activities in WP7 during the period February 15th 2005 – February 15th 2006 were mainly focused on 2 areas:

- Mapping exercise
- Preparation of the development of the consensus conference

Mapping exercise
CPME has contributed to the Mapping exercise (WP2) by providing information obtained through the European National Medical Associations. National Medical Associations were asked to give information on National actions and programs on Patient safety in their respective country. Over a period of 6 months (July 2005 – December 2006), 11 countries have replied, namely: Austria, Hungary, Denmark, Germany, Norway, Israel, Belgium, Slovakia, Switzerland, Estonia and Poland. The information was compiled and forwarded to ESQH for the mapping exercise.

Development of the Consensus Conference

The underlying principle of SIMPATIE project is to find European consensus on the best way to monitor patient safety issues and on methodology and interventions regarding patient safety, with feasible, measurable, short- and long-term goals. The Framework Strategy that will be developed will take into account the work done already by other organizations, like the WHO and the OECD, and build on existing initiatives.

In September 2006 a consensus conference will be held in order to discuss and finalize the Strategy Framework on Patient Safety. The target groups of the Conference will be partner organizations, experts, EU institutions, EU Presidency, national authorities etc. The project partners have agreed on the date of the conference to be 18-19 September 2006.

This consensus conference will build on CPME's activities in 2005 that have been related but not financially supported from the project, namely organization of the PS conference "Making it happen" and the development of the "Stakeholder's position paper on patient safety". These activities included a number of other partners than the SIMPATIE partners and have been executed in their own right. However, given the relevance of these actions for the project activities a brief summary is provided in this report;

European 'Patient Safety – Making it happen!' Conference in Luxembourg, 4-5 April 2005

On 4-5 April 2005 major EU health stakeholders representing patients, health care professionals, EU and national authorities, met in Luxembourg at the first EU conference on patient safety. The Conference "Patient Safety – Making it happen – The European perspective" was held under the auspices of the Luxembourg EU Presidency and the European Commission, with CPME being the main organizer of the event. The conference focussed on patient safety interests and challenges at EU level, on facilitating the exchange of best practices and experiences and sustaining and strengthening the political momentum. Speakers included: Mr. Di Bartolomeo (Minister of Health and Social Security Luxembourg), Mr. Kyprianou (Commissioner for Health and Consumer Protection), Dr. Bagian (Director of the US Veterans Affairs National Centre for Patient Safety - USA), Dr. Schellekens (CEO of the Dutch Institute for Healthcare Improvement), Sir Liam Donaldson (Chief Medical Officer of the United Kingdom and chair of the WHO World Alliance on Patient Safety) and others.

On the second day of the conference there were three different parallel sessions. The first parallel session dealt with therapies, medicines and communication in

primary healthcare. The second one addressed the question of developing a national framework for patient safety. And the last session discussed the issue of how to ensure patient safety in hospitals.A panel discussion where the audience could discuss with the speakers followed. Finally a discussion on the draft Luxembourg declaration on patient safety that was circulated took place among the attendees of the conference and the final version was agreed upon.
After the conference the declaration was presented in a press conference by the Luxembourg Minister of Health, Mr. Di Bartolomeo, the Director of Public Health at DG SANCO Mr. Sauer and the CPME President, Dr. Bernhard Grewin. With the Luxembourg Declaration the conference and the group of organizing stakeholders have put a starting point to more widespread political attention to the subject of patient safety.

Stakeholders' Position Paper on Patient Safety
Since June 2005 and after the Patient Safety Conference, 11 EU health stakeholders (Eucomed, EHTEL, EHMA, EFN, ESQH, CPME, HOPE, EFPIA, AEMH, EPF, PGEU, Danish Society for Patient Safety) had been working on a common position paper on Patient Safety under coordination of CPME. This position paper was finalised in November 2005 and presented during the UK Patient Safety Summit on 28-30 November 2005.

The paper was built upon the Luxemburg Declaration on Patient Safety, the work of the High Level Group Working Group on Patient Safety, the Council of Europe, the WHO Alliance for Patient Safety, and European projects on Patient Safety like SImPatIE and MARQuIS Projects. It is a call for action for all parties concerned with the issue of patient safety at European level, the level of national authorities as well as at the level of local/individual healthcare providers.

Beside the above mentioned the organizational activities for the consensus conference has started. At present the activities related to the organization of the conference are as follows:

- Securing a venue for the conference (probably in European Commission premises)
- Drafting the Conference programme
- Preparing the list of possible speakers

3.8 Dissemination (Work Package 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

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. So far, the results that can be shown are those of the mapping exercise (wp2). The collected data are listed on the website and are added on a continuous basis, as the mapping follows a sequential procedure by sending a couple of questions to the country experts at a time.

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 have been set up. Early February two professional communication companies have been 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 terms of reference can be found in Annex6.

The company that will be selected will develop the dissemination plan that will be presented to the European Commission together with the results of the project. They will use the terms of reference as a basis and consult several key project partners as well as SANCO experts -through the project coordinator- to be able to develop the plan. Especially coordination is required with the two other initiatives of dissemination, the conference for patient parties that will be organised by LMCA and the consensus conference of work package 7, led by CPME.

4. Financial statement over the period Feb 2005 - Feb 2006

(confidential data not published)

5. Annexes

Annex WP2 questionnaire

QUESTIONNAIRE

1. STANDARD DEFINITION OF PATIENT SAFETY USED IN YOUR COUNTRY

The Council of Europe (CoE) has been working on a glossary of terms relating to patient safety. We would like to find out whether there is a standard recognised definition of patient safety being used in your country and if so, how does it match the definitions the CoE are considering. The CoE definitions (see also attachment by mail) of patient safety are:

Translation:

- *French : sécurité des patients*
- *Spanish : seguridad clínica*
- *German : patientensicherheit*

Definitions being considered by the CoE:

- ***patient safety** : freedom from accidental injuries during the course of medical care; activities to avoid, prevent, or correct adverse outcomes which may result from the delivery of health care. (IOM, 2000; AHA&HRET&ISMP, 2002)*
- ***patient safety** : the identification, analysis and management of patient-related risks and incidents, in order to make patient care safer and minimise harm to patients. (IOM, NPSA, 2004)*

QUESTION 1: Does your country have a recognised definition on patient safety? (The definition should be recognised by some official authority rather than a definition used by custom and practice)	
A. In your native language? If yes, could you send us your definition?	☐ Yes → see attachment ☐ No → go to next question
B. Is this definition, as mentioned in <A> translated in other languages?	☐ Yes → see attachment ○ French ○ Spanish ○ German ○ Other: …… ☐ No
C. What is the national authority which has recognised this definition?	Name: Website address:
D. Do you consider there are significant differences between your country's definition and those being considered by the Council of Europe?	☐ Yes → see remarks below ☐ No
E. Question 1: remarks and additional information	

2. NATIONAL AGENCIES / BODIES and/or INSTITUTIONS

A. Which national agencies/institutions in your country specialise in patient safety or are responsible for reducing the number of patient safety incidents? Could you give us their contact details?
B. Is their role principally or only partly related to patient safety?
C. In which areas of patient safety do they operate? eg, adverse events data collection, the environment of care, medical devices, etc

In this question we ask you to provide us with the contact details of the organisations and your view on their areas of expertise. You can use the framework below. Please explain any abbreviations you may use.

In particular, please comment on the format of this question – for example, would additional categories for expertise be useful? If so, what would be useful to add?

1. Organisation name: Website:	☐ Principal role is patient safety ☐ Patient safety accounts for only part of their role
Address, postcode, place, telephone number etc.	Expertise: ☐ infection control ☐ medicines management ☐ adverse events/near miss reporting ☐ adverse events reduction ☐ issuing risk alerts ☐ environment of care ☐ safe medical devices use ☐ implementing standards relating to patient safety ☐ training for better patient safety ☐ mobilising patient/consumer input to safer care ☐ awareness raising on patient safety ☐ others (please state) …….. ☐ ALL OF THE ABOVE

Question 2: Any further remarks or information you feel useful to add

3. TAXONOMY FOR PATIENT SAFETY

QUESTION 2: Does your country have a taxonomy to classify incidents or adverse events relating to patient safety:	
A. In your native language?	☐ Yes → see attachment ☐ No
B. Translated into another language?	☐ Yes → see attachment ○ French ○ Spanish ○ German ○ Other: …… ☐ No
Comments re: Question 3:	

4. STANDARDS AND/OR GUIDELINES

Does your country have patient safety standards and/or guidelines? If so, can you supply us with copies of them?

A. Which subjects are covered by the standards/guidelines? For example: medication, blood, infection, medical devices, clinical etc.
B. If the standards/guidelines are written in your own native language, do you also have translations into other languages?
C. At what level are the guidelines developed? For example: national, local, by specialised institutions, by groups of professionals, by patient organisations.

In this question would like you to give information for each standard/guideline, which your country wants to share. For the internet site we could consider to translate guidelines from the native language to the English language.
To some questions you have the possibility of more answers.

Guideline 1 → see attachment ……..		
Relating to: □ Medication □ Blood □ Infection □ Medical devices □ Clinical □ Other: …….	Language: □ Native language □ Translated into: ……..	Developed: □ At national level □ At local level □ By specialised institutions □ By groups of professionals □ By patient organisations

Guideline 2 → see attachment ……..		
Relating to: □ Medication □ Blood □ Infection □ Medical devices □ Clinical □ Other: …….	Language: □ Native language □ Translated into: ……..	Developed: □ At national level □ At local level □ By specialised institutions □ By groups of professionals □ By patient organisations

Guideline 3 → see attachment ……..		
Relating to: □ Medication □ Blood □ Infection □ Medical devices □ Clinical □ Other: …….	Language: □ Native language □ Translated into: ……..	Developed: □ At national level □ At local level □ By specialised institutions □ By groups of professionals □ By patient organisations

Guideline 4 → see attachment ……..		
Relating to: □ Medication □ Blood □ Infection □ Medical devices □ Clinical □ Other: …….	Language: □ Native language □ Translated into: ……..	Developed: □ At national level □ At local level □ By specialised institutions □ By groups of professionals □ By patient organisations

5. EXPERTS

Within national health services there are often a number of professionals with a high level of expertise in their field. Some of these individuals promote the need to improve quality of services and reduce risks associated with treatment. We are interested in learning more from these experts and from their published work.

Expert Name 1:	Area of expertise:
Address, postcode, telephone number etc.	Additional info:
Publication title:	
□ Attached □ Book / journal □ Web page □ Other	Publisher / Issue / Web address:
Comments:	

Expert Name 2:	Area of expertise:
Address, postcode, telephone number etc.	Additional info:
Publication title:	
□ Attached □ Book / journal □ Web page □ Other	Publisher / Issue / Web address:
Comments:	

Expert Name 3:	Area of expertise:
Address, postcode, telephone number etc.	Additional info:
Publication title:	
□ Attached □ Book / journal □ Web page □ Other	Publisher / Issue / Web address:
Comments:	

6. REPORTING SYSTEMS FOR PATIENT SAFETY INCIDENTS

Does your country have a system for reporting patient safety incidents? Please provide details of any system by answering these questions.	
Does your country have a reporting system?	☐ Yes ☐ No
Name and brief description of system:	☐ Description and details attached
Characteristics of the reporting system(s) please identify all that apply: ☐ Paper–based forms ☐ Software application / database ☐ Internet-based reporting ☐ Single national system ☐ Multiple local systems ☐ Government involvement ☐ Published statistics available to the public ☐ System to allow reporting by patients ☐ System to allow reporting by medical professionals	
Contact details of the manager of the reporting system Name: Address: Postcode Telephone number: Email:	
Comments re: Question 6:	

7. AWARENESS OF INTERNATIONAL HEALTHCARE RISK MANAGEMENT

Has your country reviewed healthcare risk management practice in other countries and, if so, what conclusions have you drawn from this?	
Review of international practice:	□ No review □ Informally □ Formally □ Review attached
Level(s) at which the study was focussed:	□ National □ Regional □ Local □ Specialist level / area: ……..
Countries where systems have been reviewed / studied:	
□ Australia □ Austria □ Belgium □ Denmark □ France □ Germany □ Italy	□ Norway □ Sweden □ Switzerland □ Spain □ USA □ United Kingdom □ Other(s):……
Contact details of the person who conducted the review(s) Name: Address: Postcode: Telephone number: Email:	
Conclusions:	
Comments re: Question 7:	

8. IDENTIFICATION AND CLASSIFICATION OF ROOT CAUSES

The analysis of adverse events related to patient safety has real benefits if the underlying causes can be identified and remedied thus reducing or eliminating further events.

Examples[1] of Root Causes would be:

- Diagnosis did not account for all the known symptoms
- Staff undertook work outside their grade/expertise/experience
- Guideline followed was incorrect or inadequate
- Supervision sought but not available
- System of referral to another service/specialty/team member
- Workload exceeds capacity of planned staffing levels
- Fault with the process for identifying patients

Does your country investigate and classify the root causes of patient safety incidents? Can you provide details of any classification system in use?	
In your native language?	☐ Yes → see attachment ☐ No
Translated into another language?	☐ Yes → see attachment ○ French ○ Spanish ○ German ○ Other: …… ☐ No
Comments re: Question 8:	

1. Provided by DATIX Limited (www.datix.co.uk)

9. COMMERCIAL ORGANISATIONS PROVIDING PRODUCTS OR SERVICES RELATED TO PATIENT SAFETY OR HEALTHCARE RISK MANAGEMENT

An indicator of the level of activity in the fields of patient safety and healthcare risk management is the involvement of commercial organisations. Please identify commercial organisations active in your country.

Organisation 1 Name: Address: Postcode: Telephone: Website:	Product(s) / service(s): □ Incident reporting software □ Claims management software □ Consulting services □ Training □ ICT □ Other ……
Comments re Organisation 1:	

Organisation 2 Name: Address: Postcode: Telephone: Website:	Product(s) / service(s): □ Incident reporting software □ Claims management software □ Consulting services □ Training □ ICT □ Other ……
Comments re Organisation 2:	

Organisation 3 Name: Address: Postcode: Telephone: Website:	Product(s) / service(s): □ Incident reporting software □ Claims management software □ Consulting services □ Training □ ICT □ Other ……
Comments re Organisation 3:	

10. LEGISLATION RELATED TO PATIENT SAFETY

Has your government passed legislation related to patient safety or risk management in healthcare? Please provide details of any system by answering these questions.
Legislation: □ To establish an authority responsible for patient safety □ To enable the payment of claims resulting from clinical negligence □ To create standards for healthcare practice □ To enable inspections against standards and enforce penalties for non-compliance □ To enforce reporting of patient safety incidents □ Giving the public rights to, and freedom of, information relating to patient safety
Please attach any relevant documentation or provide links to resources on the internet:
Comments re: Question 10:

QUESTION 11 – LIABILITY ARRANGEMENTS

a) Is there a medical defence organisation based in your country? Yes/No

b) Do clinicians use medical defence organisations based in other countries? Yes/No

If yes, please provide details……..

c) Are there any other malpractice protection schemes? Yes/No

If yes, please provide details……..

d) Who are the premiums usually paid by?
    a. Individual clinicians Yes/No
    b. Employer Yes/No
    c. State Yes/No

QUESTION 12

Is there a national whistleblowing policy? Yes/No

If yes, please provide details……..

QUESTION 13 - Professional patient safety membership organisations

a) Does your country have a professional/membership society for healthcare risk/patient safety managers/specialists? Yes/No

If yes, please provide name and contact details of organisation……..

b) If yes, are there any entry requirements? Yes/No

If yes, please provide details……..

QUESTION 14 – HEALTHCARE RISK MANAGEMENT QUALIFICATIONS

a) Are there professional healthcare risk management qualifications available in your country? Yes/No

b) If yes, please provide examples and the contact details of the providing organisations……..

1. QUALIFICATION	2. ORGANISATION & CONTACT DETAILS

QUESTION 15

Are healthcare organisations required to have a risk management or patient safety manager? Yes/No

If yes, please provide details……..

QUESTION 16

Is patient safety a required part of training in respect of:

a) Medical undergraduates Yes/No

If yes, please provide details……..

b) Medical postgraduates Yes No/

If yes, please provide details……..

c) Nursing Yes/No

If yes, please provide details……..

d) Other clinical staff Yes/No

If yes, please provide details……..

e) Healthcare Managers Yes/No

If yes, please provide details……..

QUESTION 17

Are there any patient organisations the main focus of whose mission is patient safety? Yes/No.

If yes, please provide details……..

3. QUESTION 18 – NATIONAL PATIENT SAFETY CAMPAIGNS

Within the past three years, have there been any national patient safety campaigns –

a) Addressed to healthcare professionals? Yes/No
If yes, please provide details……..

b) Addressed to healthcare managers Yes/No
If yes, please provide details……..

c) Addressed to healthcare purchasers Yes/No
If yes, please provide details……..

d) Addressed to patients or the public Yes/No
If yes, please provide details……..

QUESTION 19

Are there any professional peer review systems with the aim of reducing healthcare mishaps? Yes/No

If yes, please provide details……..

QUESTION 20

In your opinion, is there a role for European bodies in respect of the following?

Issue	Yes	No	If yes, which body	What should that body be doing?
a) Patient safety generally				
b) Reduction of medication errors				
c) Wrong site surgery				
d) Sharing information about incompetent/dismissed clinicians				
e) Setting patient safety standards				
f) Improving patient safety information to professionals				
g) Improving patient safety information to the patients or the public				
h) Reducing blood borne infections				
i) Reducing hospital acquired infections				
j) Suicide prevention in care settings				
k) Reducing falls in				

care settings				
l) Reducing falls in the community				
m) Other – please state				

QUESTION 21

Are the following resources freely available in the native language for healthcare professionals, managers and policy makers?

Resource	**Yes**	**If no, would this be helpful?**
a) Institute of Medicine Report "To err is human"		
b) Building a Safer NHS		
c) Seven steps to patient safety		
d)NPSA Risk Alerts		
e) Joint Commission Risk Alerts		
f) Details of the IHI "Saving 100,000 lives" campaign		
g) Danish Patient Safety Law		
a) Examples of patient safety standards from other countries? (give examples)		
b) Any other resources? Please provide examples		

ANNEX2 WP2 Responses received to questionnaires

Country	Special advisor	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12	Q13	Q14	Q15	Q16	Q17	Q18	Q19	Q20	Q21
Austria	Maria Woschitz-Merkač	1	1	1	1	1	1	1	1													
Belgium	agnes jaquery																					
Bulgaria	Lidia Mladenova Georgieva																					
Croatia	Ana Stavljenic-Rukavina						1	1	1	1	1											
Czech republic	Ales Bourek	1	1	1	1	1	1	1	1													
Denmark	Beth Lilja+	1	1																			
Estonia	Laine Peedu																					
Finland	Pirjo Pennanen	1	1	1	1	1																
France	Philippe Michel	1	1			1	1	1	1													
Germany	Annette Riesenberg																					
Greece	Anastasius Moumtzoglou	1	1	1	1	1	1	1	1													
Hungary	Peter Makai	1	1	1	1	1	1	1	1													
Ireland	Cornelia Stuart	1	1	1	1	1	1	1	1													
Italy	Piera Poletti	1	1	1	1	1																
Lithuania	palmira morkuniene	1	1	1	1	1	1	1	1	1	1											
Luxembourg	Raymond Lies																					
Malta	John Cachia																					
Netherlands	Susanne Smorenburg	1	1	1	1	1																
Poland	Halina Kutaj-Wasikowska	1	1																			
Portugal	Rui Miguel Loureiro																					
Serbia	Viktorija Cucic	1	1	1	1	1	1	1	1	1	1											
Spain	Susana Lorenzo																					
Sweden	Kaj Essinger	1	1																			
Turkey	Hasan Kus	1	1																			
United Kingdom	Susan Burnett	1	1	1	1	1	1	1	1													
Total		16	16	11	11	12	10	10	10	3	3											

ANNEX 3 WP4

Scheme for classification of patient safety indicators, ver 2.	
Dimension of classification	**Description**
Title	
Sheet no.	
Description	Provides a concise statement of the specific aspects of patient safety, the patient population, providers, setting(s) of care, and time period that the measure addresses.
Indicator category	Specifies whether the indicator is: 1. **Specific** relating to e.g. o Surgical complication o Pressure sores Or: 2. **General** e.g. "safety culture"
Source(s)	Identifies the complete bibliographic source(s)/reference(s) for the measures
Evidence Supporting the Criterion of Patient Safety	Describes the type(s) of supporting evidence appropriate for the measure domain.
Data definitions	Describes the data definition in detail
Denominator Description	Provides the *general* specifications of any clinical component that is the basis for inclusions and exclusions in the denominator.
Numerator Description	Provides the *general* specifications of any clinical component that is the basis for inclusions and exclusions in the numerator.
Data Source	Identifies the data source(s) necessary to implement the measure
Care Setting	Classifies the settings for which the measure applies
Professionals Responsible for Health Care	Classifies the professional(s) who is/are responsible for health care
Lowest Level of Health Care Delivery Addressed	Classifies the lowest level of health care delivery to which the measure (in its current use) applies
Level of Determination of Patient Safety	Identifies the level at which safety can be assessed (i.e., at the individual patient level or the aggregate patient level).
Allowance for Patient Factors	Identifies the type of analytic considerations made for the measure based on patient factors or characteristics (e.g., High-risk/vulnerable subgroups, Other subgroups [e.g., age cohort], Case-mix adjustment, Paired data at the patient level, Risk adjustment).
Stratification by Vulnerable Populations	Describes the populations vulnerable to health care patient safety problems that are separately identified for sampling
Standard of Comparison	Classifies the type and time frame of the comparison according to whether the comparison is external (at a given point-in-time or of a time trend), internal, or to a prescriptive standard.
Extent of Measure Testing	Describes the extent of testing of the measure including reliability and/or validity testing.

Scoring	Identifies the method used to score the measure (e.g., Categorical, Continuous Variable, Count, Frequency Distribution, Non-weighted Score/Composite/Scale, Rate, Ratio, Weighted Score/Composite/Scale).

ANNEX 4 WP4
Scheme for Evaluation of Patient Safety Indicators, Ver. 2

Indicator scoring matrix		
Dimension	**Definition**	**Score**
Relevance/appropriateness	Does the indicator cover areas of significance (severity and frequency) in terms of patient safety within its specified domain (population and/or organization)?	1-3 Low degree of usefulness 4-6 Medium degree of usefulness 7-9 High degree of usefulness
Validity	Is the indicator satisfactory in terms of: - construct validity (evidence based) - Internal consistency - Exhaustiveness/exclusiveness - Reliability	1-3 Low degree of usefulness 4-6 Medium degree of usefulness 7-9 High degree
Practicability	Availability of data – the burden of data collection	1-3 Low degree of usefulness 4-6 Medium degree of usefulness 7-9 High degree

Example of scoring sheet					
		Scores			
Indicator	Classification no.	Relevance/appropriateness	Validity	Practicability	**Additional comments/overall evaluation of indicator**
Name	Number	Score from 1-9	Score from 1-9	Score from 1-9	(free text)

Annex 5 WP 6
Draft toolkit on approaches to increase patient safety within health care organisations.

1. Development and implementation of a safety management system
   1.1. Introduction
   1.2. Hospital and safety management
   1.3. Example 1: improving medication safety
   1.4. The SPAR-management system (Structural Patient Risks)
   1.5. Implementation and investment
   1.6. Conclusion

2. Move your dot: example of improving patient safety
   2.1. Introduction
   2.2. Applications of mortality
      2.2.1. Eye-opener
         2.2.1.1. Determining the Hospital Standardised Mortality Ratios (HSMR)
         2.2.1.2. Mortality analysis and reduction at the hospital level
      2.2.2. What to do with these number? / The numbers, and then?
      2.2.3. The ‘Move Your Dot’ method
   2.3. Research ‘Plot your dot…’
      2.3.1. Explanation of the methodology
      2.3.2. Data collection
      2.3.3. Analysis
   2.4. Examine your DOT: results
      2.4.1. General data
      2.4.2. The four items
      2.4.3. Reporting of patient incidents
      2.4.4. Fall incidents
   2.5. Recommendations
      2.5.1. Internal organisation
      2.5.2. Care process
         2.5.2.1. Reduction medication faults
         2.5.2.2. Fall incidents: registration, prevention and intervention
         2.5.2.3. Medication policy and the elderly
      2.5.3. Efficient
      2.5.4. In time
      2.5.5. Effective
   2.6. Conclusion

3. Trigger tool and analysis of patient records: instrument to detect adverse events

15. Rapid Response teams
    - 15.1. Description of the instrument
    - 15.2. How and when to use the instrument?
    - 15.3. Experiences and results
    - 15.4. Advantages and disadvantages

16. Methods to improve communication with the Time-Out procedure
    - 16.1. Introduction
    - 16.2. Description of the Time-Out procedure
    - 16.3. How and when to use the instrument?
    - 16.4. Experiences and results
    - 16.5. Prerequisites

Annex 6 WP 8
Terms of reference Communication plan

TERMS OF REFERENCE

Communication Plan

Simpatie project

Table of contents :

4. SUMMARY OF THE PROJECT

4.1. Title

Safety Improvement For Patients In Europe (S.IM.PAT.IE)

Priority area:	HI 2004
Action:	1.6 Co-operation between member states
Duration (months):	24
Starting date	15-2-2005

4.2. Abstract

Patient Safety is now recognised internationally as a health quality issue. There is good evidence of the level of harm to citizens and the cost to both healthcare providers and to society of what amounts to preventable harm in delivering healthcare. The cost is such, it can be argued, that eventually it will be recognised as an issue for public health within the Health Threats priority area.

Community action in health policy has been limited to the field of public health for legal reasons. Recent patient mobility (and some related judgements of the ECoJ) together with system incompatability problems raised in the context of cross-border contracting have stimulated debate.

Discussion fora and evidence presented during the HLRP in 2OO2/3 have contributed to the Work Plan 2004 for the first time specifying patient safety (see 2.1.6 cooperation between member states:priority 1).

The Simpatie 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.

A mapping exercise across a minimum of 20 member and accession states will determine the status of activity and strategic planning on patient safety. 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.

In parallel a working group of experts will develop a common vocabulary,outcome indicators and internal and external instruments for improvement in patient safety, 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 in patient safety. The final work stream concentrates on dissemination using established professional,institutional and patient networks.

4.3. General objectives

Mobility across the 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.

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.

4.4. Specific objectives

1. To establish systematic knowledge repository on patient safety related to legislation, regulation and actions in EU states. (wp 2)

2- The CoE recommendation on Prevention of Adverse Events is translated into a practical and usable tool for the work floor. (wp 3)

3- A vocabulary (set of definitions) and a set of system and organization indicators / outcome measures related to patient safety is formulated. (wp 4)

4- Recommendations for external evaluation of health services, including selected instruments that can be used for improvement, are defined with regard to patient safety. (wp5)

5- 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. (wp 6)

6- There is an expert consensus on recommendations and instruments, described in above mentioned objectives (2-5). (wp 7)

7- Results are disseminated to the wider public and involved parties. (wp 8)

Specific objective 7 on dissemination of the results of the project to the wider public and all involved parties will be dealt with in the communication plan that will be developed based on these terms of reference. The issue of internal project communication lies outside the scope of this communication plan, which deals specifically with the external communication of the project.

What to communicate?

The Simpatie project generates four distinctive information bundles that can be communicated. These are:

1. Project methodology - methodological approach and techniques, for example:
    a. design of the project
    b. research approach to identify tool boxes
    c. approach to establish a consensus strategy
    d. etc.
2. By-products of the project - rapports and knowledge generated in the course of project activities, for example
    a. the database on patient safety activities
    b. DRAFT Toolbox 1: Vocabulary & Indicators on patient safety
    c. DRAFT Toolbox 2: External tools for safety improvement
    d. DRAFT Toolbox 3: Internal tools for safety improvement (internal audit)
    e. Strategy exercise: dissemination of interim project conclusions to participants in the strategy exercise who will draw up the final advise for the EU, DG SANCO, on a stategy for patient safety through consensus.
3. Project's results and recommendation – these are final products of the project, for example:
    a. the database on patient safety activities
    b. Final Toolbox 1: Vocabulary & Indicators on patient safety
    c. Final Toolbox 2: External tools for safety improvement
    d. Final Toolbox 3: Internal tools for safety improvement (internal audit)
    e. Expert advise on patient safety strategy: recommendations to EU, national governments and health care organizations established through a consensus approach with relevant stakeholders.
4. Project management information
    a. As mentioned before this issue lies outside the scope of this communication strategy, which deals with the external communication of the project.

The emphasis of the communication strategy is on point 3: the dissemination of the final products of the project. Within this set of final products the most important message that has to be communicated is the result of the consensus procedure to establish an expert advise on a European strategy on patient safety. This strategy will be developed through a thorough discussion with key stakeholders on patient safety and will incorporate the most useful tools in practice from the toolboxes 1 till 3.

5. TARGET GROUPS

Project communication can roughly be divided in communication at national and international level. Roughly as, especially in the English language publications, this distinction is not always clear with many national journals having in fact an international audience. On the other hand strategy and structure described, although primarily intended for international communication, is to a large extent applicable to national communication as well (one can replace European doctors or hospital association with national).

The emphasis of the communication strategy will be on the international communication and the relation to the mass media. National communication will have to follow logically from the international communication activities.

An attempt is being made to structure the target audience of the Simpatie project in a limited number of groups. These groups are being defined by anticipated similar interest in relation to project information, and by same means of communication that can be used to reach them. The are:

A. Policy makers in health care and related areas
    - International organizations: WHO, CoE, WB
    - European Union: DG Sanco, DG Social Affairs, DG Research
    - National Ministries of health (including various departments and services like inspectorate)
B. NGO's (representing parties) relevant for health care:
    - Providers associations: CPME (doctors), EFN (nurses), HOPE (hospitals)
    - Financing authorities: AIM, EuRaPCo
    - Patients: EPF, IAPO
    - General and other: EHMA (management), EOQ (quality)
C. Broad (lay) public
D. Quality professional community
    - Institutes: accreditation (JCAHO, CCHA, etc..), quality general (IHI, Innovation Agency, Quality department Swedish County Councils ect..)
    - Quality professionals: working in hospitals and other places
E. Scientific community
    - Universities, other research centers, researcher
F. Project participants and relations
    - Beside partners, reference group and national experts, all other relations of these groups that may be interested

Communication works best on `need to know ' basis: provide information that one needs to know, and the information will be well accepted. This pertains not only the quality / subject of information (all listed above do have an interest in patient safety, albeit from different aspects), but also the quantity (some need to know all the details, others just general information).

6. COMMUNICATION INSTRUMENTS

The following communication instruments are at the disposal of the Simpatie project :

- the project's website: www.simpatie.org
- web-based database:
  - information on patient safety activities throughout Europe
  - public forum
- official EU reports, the project's deliverables (all in English):
  - 2 annual reports: 500 each
  - 1 final report: 500
  - WP 3 report – Council of Europe report: 250
  - WP 2&4 report – ESQH (mapping&indicators toolbox 1): 250 each
  - WP 5 report – HAS (external instruments toolbox 2): 250
  - WP 6 report – CBO (internal instruments toolbox 3): 250
  - WP 7 report – CPME (strategy exercise): 250
- Project brochures/folders: 4500
- Publications in scientific journals

7. ASSIGNMENT

We are looking for advise on the communication strategy for the Simpatie project and ask for the development of a communication plan for this project.

The communication plan that we want to see developed based on these terms of reference will deal with the dissemination of the results of the project at the international level to the wider public and all target groups mentioned before.
The communication plan should cover the issues:

- How to organise this communication with the instruments at our disposal?
- How to communicate with and involve the mass media?
- What aspects are interesting to communicate to the broad public and the other target groups?

Within the communication plan the most important message that has to be communicated is the expert strategy on patient safety which was established through a consensus approach. This expert strategy incorporates the most useful tools from the toolboxes 1 till 3 and contains recommendations on patient safety at the EU level, national level and the level of healthcare organizations.

8. PROCEDURE

The procedure on the communication plan is outlined below:

a. You are invited to return this invitation to bring out an offer in two separate envelopes:
   - one offer containing the proposal on content
   - one offer containing the financial picture

   Please write your offer in English and return it to the CBO before the end of February.

b. The CBO will react to your offer before the 15th of March.

c. The development of the communication plan takes a two-step approach as well:

   i. A concept of the plan will be send to CBO for their comments at the end of April.
   ii. CBO reacts within 2 weeks. The final plan will be send to CBO at the end of May.

For questions on these terms of reference you can contact:

Jeroen Jurriëns
Junior Advisor at CBO
P.O. Box 20064
3502 LB Utrecht
The Netherlands
Phone: +31 (0)30 2845708
Fax: +31 (0)30 2943644
E-mail: j.jurriens@cbo.nl