



Luxembourg  
18 – 19 September 2006

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## CONFERENCE REPORT

### 'Building a Strategy for Patient Safety in Europe'

Luxembourg, 18-19 September 2006

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## Conference Report

### Introduction

On 18 and 19 September 65 European participants met in Luxembourg to discuss the preliminary results of the SIMPATIE project and to draw first conclusions for patient safety in Europe. Among these participants were representatives of the European Commission, national governments, organizations, experts, medical professionals, patients and other stakeholders involved in the project.

### Organisation

The Consensus Conference has been organized by the Standing Committee of European Doctors (CPME) in close cooperation with the Dutch Institute for Healthcare Improvement (CBO), the Council of Europe (COE), the European Society for Quality in Healthcare (ESQH), Haute Autorité de Santé (HAS), the European Hospital and Healthcare Federation (HOPE), the Long Term Medical Conditions Alliance (LMCA) and Action against Medical Accidents (AvMA). The conference took place at the Jean Monnet Building in Luxembourg.

The 'Building a Strategy for Patient Safety in Europe' Consensus Conference is the 7<sup>th</sup> Working Package of the SIMPATIE project, which is funded by the Public Health Programme of the European Commission, DG Health and Consumer Protection. The objective of the conference was to present the preliminary results of the previous six working packages, to build consensus among the invited experts and to draw first conclusions as input for a strategy framework for patient safety in Europe. The SIMPATIE project's objective is to assist in improving the safety of patients throughout all European countries. Appendix 2 provides extended background information on the project.





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## Outline

At the conference, representatives of the European wide network presented and discussed the preliminary results of the different work packages (WP's). These WP's included a mapping exercise with the first overview of current patient safety activities in most Member States, a common European vocabulary and a set of indicators, internal and external instruments for the improvement of safety in healthcare organisations, as well as on a national and European level.

## Conclusions

### *Patient Safety Network*

The conference participants applauded the initiative of the High Level Group on Patient Safety to create 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*

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***

National platforms are to be introduced to reach harmonization on national level and to adapt proposed approaches to the different national, regional 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 to maintain 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***

With regard to reporting and risk management systems the discussions mainly focused on their scope and format. The relevance of insurance schemes to provide compensation, and the meaning of open-and-fair systems in practice were also topics that were debated. The importance of adequate competencies, state-of-the-art education, appropriate human resources and a real culture of safety were underlined 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 is needed to be able to produce the necessary economic evidence. However the tools must be practical and easy to implement within healthcare organisations.





### ***Clinical Governance and team approach***

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 potentially 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 that awareness and the necessity for action are generally recognized, the logical next step would be the development and implementation of the right tools and instruments 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.





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## Appendix 1: Brief Minutes

### Opening Plenary

Dr Frank Ulrich Montgomery (CPME) chaired the opening plenary which was opened by Boi Jongejan (CBO) with a general introduction to the SIMPATIE Project, explaining the background and the reasons for building a strategy for patient safety in Europe.

Beth Lilja Pedersen followed with an outline of the international perspectives on patient safety, by introducing recent activities performed by international organizations, especially in Europe. She highlighted the activities by the World Health Organisation and presented a model to determine the level of maturity with respect to a safety culture. With her presentation she updated everyone on the developments so far and prepared the ground for the presentation of the preliminary results of the different working packages of the SIMPATIE project.

David Somekh (ESQH) presented the preliminary results of the mapping exercise performed in 24 European countries, illustrating the patient safety regulations and activities performed on national level. He announced that this work was still in process, and the analysis of the data and preparation of a sustainable database were further being developed. He also stated that he is looking forward to receiving more data from a few missing countries.

Peter Walsh (AvMA) gave a patients' perspective to patient safety, highlighting the importance of fairness and justice when dealing with adverse events, as well as the necessity to include the patients in planning, solution work and monitoring of patient safety on institutional and national level.

### Discussion

A brief discussion followed on the availability of European and national data on patient safety and adverse events. Beth Lilja Pedersen stated that there would be data available for 3 EU countries, which showed similar results using comparable methodologies. The number of adverse events (including complications and medical errors) would be in the area of 10%. According to HAS a questionnaire and database could be available towards the end of the year including country and group data. Marianne Takki underlined that the European Commission did not have any concrete data yet, but that the SIMPATIE project should provide directions through the mapping exercise. Regarding the question on the EU activities in helping patients suffering adverse events, she reminded the audience that healthcare and patient safety are a national responsibility, but that the EC would be dedicated to find common elements to support the Member States, e.g. through the work within the High Level Group on Patient Safety.





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### **SIMPATIE Toolbox: Methodology, outcomes and discussion**

Piotr Mierzewski (CoE) introduced the 'Recommendation of the Council of Europe on Management of Patient Safety and Prevention of Adverse Events in Healthcare', developed by the patient safety working group, explaining the process and the background. He also highlighted the the four Ps (principles, policy, politics, practice): in which the principles are laid down by the Council of Europe, the policies developed by WHO, the politics laid down by the European Union and the Member States putting it all into practice.

Paul Bartels (ESQH) introduced the set of indicators/outcome measures and vocabulary developed for the SIMPATIE project and explained the methods of selection, characterization and evaluation of patient safety indicators used in the process. He reported that the vocabulary would already be available, as well as the selection/characterization framework for patient safety indicators, which would be tested with 4 known indicators. The full set of indicators will be selected for evaluation after the conference.

Charles Bruneau (HAS) explained the work performed on audit and external evaluation with regards to patient safety, by using the three times of auditing: making the objectives of auditing clear, introducing known methods and associated human resources, as well as by deciding on follow-up actions. He concluded by presenting the feasibility of different levels of harmonisation of external evaluation on European level.

Cule Cucic (CBO) presented a not inclusive set of instruments and internal audit mechanisms identified to improve patient safety in healthcare organizations. He advised instruments for measurement, analysis and intervention, but stressed that the instruments identified were not based on any preference or hierarchy, but that their use and combination should be adapted to the local needs.

### **Discussion**

A brief discussion followed in which the need for evidence based data on adverse events, and the effectiveness of patient safety interventions was addressed. The development of a, preferably web-based, toolkit for member states, healthcare organizations and healthcare professionals was promoted. Further research would be needed with regard to the analysis of patient safety instruments.

The representative of the Dutch Health Care Inspectorate indicated the need to further discuss the differences between certification and accreditation and the respective regulatory frameworks. He suggested using and discussing all alternatives presented.





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The audience also discussed the differences between the SIMPATIE vocabulary and the WHO taxonomy of events, which although similar in scope tackle different aspects in patient safety. Ed Kelley (OECD) briefly presented his experiences, based on his work for the OECD. Paul Bartels indicated that the 4 indicators presented were only examples used in the process, and echoed the difficulties in directly measuring indicators as they would not be stable over time and would often not be comparable in different settings. He also stressed that the indicators would be sensitive for biases by external evaluation or management interventions. For future use he suggested using a sophisticated database linked to a probability function to minimize bias and achieve comparable results.

## ***Parallel Workshops***

### **Workshop 1 - Patient safety on the National and European level**

Chair: Piotr Mierzewski (CoE)

The presented draft framework strategy document from the national and European perspective was topic of debate.

The following presentations were given:

- Barbara Kutryba (TPI): Patient Safety developments in Poland,
- Marianne Takki (EC, DG SANCO): Past, present and future activities of DG Health and Consumer Protection in the field of Patient Safety
- Peter Mansell (NPSA Patient Experience): The role of patients in ensuring patient safety

The participants discussed and reached consensus on the results of the previous working packages from a national and European perspective. The results of the mapping exercise (WP2), the Council of Europe Recommendations (WP3) and the report on external auditing (WP5) to develop recommendations for action on national and European level served as input for the debate.

David Somekh (ESQH) reported on behalf of the designated rapporteur Charles Bruneau (HAS) suggesting the following actions:





### **Proposed actions for EU Institutions:**

#### **Priorities:**

- Harmonisation at national level (Patient Safety Platform)
- Support Member States to adapt programs to local systems
- Make knowledge and experiences available (solutions database)
- Encourage Ministries of Health to report annually

#### **Instruments for EU level:**

- Establish a Patient Safety Network (HLG initiative of an EU platform involving all MS was applauded)
  - Include: all health care providers (not just hospitals), longterm and acute
  - Ensure patient voice at EU level
- Recognize the relevance of medical competence for PS
- Establish an inventory of indicators
- Introduce data sets on PS and objectives to build PS profiles
- Promote European twinning programmes and peer review

#### **Proposed actions on national level:**

- Establish a culture of change, by avoiding that professionals feel threatened by change
- Identify that no-fault compensation is a mixed blessing
- Ensure that indicators are owned by professional organisations to ensure state-of-the-art education
- Recognise the role and impact of the media
- Recognise the relevance of human resources in PS
- Recognise that the introduction of national PS platforms
- Convince the Member States of the value of investment in PS

#### **Questions for further study**

- How can EU recommendations work?
- Coordination mechanism? Use of drivers for change
- How to understand what open and fair system means in practice?
- How to identify the real costs of adverse events and financial benefits of PS interventions by following the 'cost and reality principle'?



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## Workshop 2 - Patient safety on the Provider level

Chair: Paul Bartels (ESQH)

The workshop discussed and supported the presented draft framework strategy document from the perspective of healthcare organizations.

The following presentations were given:

- Kaj Essinger (HOPE): Patient Safety - from the provider point of view
- Jesper Poulsen (CPME Expert): Patient Safety in a European perspective – seen from the healthcare professionals point of view
- Arnold Vulto (EAHP): The Hospital Pharmacist your stakeholder when it comes to medication safety

Input for the debate were the mapping exercise (WP2), the Council of Europe recommendations (WP3) and the definitions and indicators (WP4), as well as the instruments which can be used by health care providers to ensure patient safety (WP6 internal instruments). The participants agreed to the need of an increased exchange of best practices based on a basic vocabulary, common indicators and interventions, while taking the involvement of patients, as well as cultural, organisational and educational matters into account.

### Issues discussed:

- Organizational nature of differences in healthcare systems
- Implications of an increasing density of treatment
- The risk of purely focusing on cost-effectiveness might lead to a lack of competency
- Dissemination of information within and between healthcare organizations and healthcare professionals
- Qualitative aspects in healthcare organizations, accepting that medicines are high risk tools even after market approval
- Quantitative aspects with regard to human resources, more specifically the critical mass of healthcare professionals needed in direct contact to patients
- The added value of the EU support regarding reporting systems and the lessons being currently learned
- The importance of the involvement of all healthcare professionals, more specifically hospital pharmacists as 60% of adverse events involve medicines





**In addition to the issues raised in the draft strategy framework following actions were proposed on provider level:**

- Further define the collaboration between patients/carers and healthcare providers/healthcare professionals
- Develop instruments for clinical governance, esp. regarding the contribution of hospital managers to patient safety (toolbox)
  
- Identify the real costs of adverse events that are not reported (estimated at around 10% of hospital budget), by developing business cases for patient safety. These are to provide the economic evidence for patient safety interventions, and making it practical, by using indicators, instruments and external auditing
- Support national initiatives on patient safety and collaborate in the collection of national data. Provide the evidence needed to promote the implementation of concrete interventions
- Develop and promote high quality post-graduate training and continuous professional development in patient safety interventions
- Discuss the role of public private partnerships, especially with regard to medical devices industry and pharmaceutical industry
- The implementation and dissemination of solution banks and rapid alert systems for patient safety
- Implement concerted actions on European level incl. all stakeholders
- Increase the pace of the process by starting actions on all levels

**Open questions**

- What comes first: culture changes or actions?
- How to define the context in which a culture of safety develops?
- How to address the whole system instead of individual aspects?
- How to involve national decision makers and hospital managers?
- How to report adverse events to payers? (currently around 10%)
- Should patient safety interventions be introduced in a top down and/or bottom-up approach?

**Conclusion**

- General feeling of impatience, desire to do more



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## Closing Plenary

The closing plenary chaired by: Lisette Tiddens-Engwirda (CPME) started with a key-note speech on '**EU initiatives on Patient Safety**' by Dr. Andrzej Rys, Director at the Health and Consumer Protection DG of the European Commission, Public Health & Risk Assessment Directorate. In his speech he highlighted the past, current and future activities of the European Commission with regard to patient safety, covering initiatives from DG Health and Consumer Protection, the opportunities within the upcoming 7<sup>th</sup> Framework Programme by DG Research, as well as the activities performed by DG Information Society. He specified and explained the tasks and the 5 priority areas of the Patient Safety Working Group of the High Level Group on Health Services and Medical Care, set up in April 2005:

1. Education and training of health professionals,
2. Establishing effective reporting and learning mechanisms,
3. Develop knowledge and evidence,
4. Develop indicators of patient safety for different healthcare settings,
5. Support development of national policies and programmes.

In addition to the priority action areas, he also raised two cross cutting issues namely, empowering citizens and patients by providing them with information on patient safety and rights for safe health care services and patients, engaging stakeholders such as patients, health professionals, service providers in improving patient safety in health care settings.

He also announced that the Working Group will address a recommendation on patient safety for the High Level Group. The concrete proposal will be to recommend the establishment of a European network on patient safety to support Member States in promoting this area. All identified priority areas as well as new issues will be included. He also reminded that patient safety should be an integral part of undergraduate and postgraduate training of healthcare professionals and that respective proposals would be discussed the High Level Group meeting on 6 December.

Lisette Tiddens-Engwirda highlighted the EU involvement on patient safety. A brief discussion followed on the need and possibilities of funding for patient organizations, especially those dealing with adverse events. MEP Belohorska reminded the participants on the subsidiarity principle and the limitations regarding EU funding for national organizations.





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## Drawing conclusions

The rapporteurs of the two workshops, David Somekh on behalf of Charles Bruneau (Workshop 1 - Patient safety on the National and European level) and Benno van Beek (Workshop 2 - Patient safety on the Provider level) reported from the two workshops on day one and proposed conclusions.

In the discussion following the workshop presentations, Dr.Rys (European Commission) highlighted the importance of teamwork to ensure patient safety. The need for a multidisciplinary approach and the inclusion of patient safety education in national curricula of healthcare professionals were further aspects addressed by the audience. Mrs Tiddens Engwirda (CPME) explained the role of continuous professional development (CPD) as one step in the education of healthcare professionals, and thus a relevant action point in patient safety. A respective conference on CPD will be organized by the CPME under the auspices of the Finnish Presidency of the EU and the European Commission (14 December 2006). The possible involvement of the media as a stakeholder in patient safety advocacy was briefly discussed without reaching a consensus.

A roll-call on the **most important issues** followed highlighting following aspects:

- Collaborate with patients and patient organizations (Basia Kutryba, Poland; Elisabeth Rousseau, France)
- Increase the involvement of the insurance industry in patient safety (Agnes Jacquerye)
- Prevent adverse events by limiting access to and use of 'look-alike' and 'sound-alike' pharmaceuticals and medical devices (Marie-Claire Pickaert, EFPIA)
- Utilize professional organizations to educate healthcare professionals (Jason Bryan, UK)
- Ensure implementation of patient safety instruments on hospital level, e.g. using the presented toolbox WPs (Peter Waanders, the Netherlands)
- Use the effective collaboration on EU level (platform) to introduce similar projects and toolboxes on national level, ensuring that cultural differences on national level are addressed and taken into account (Brit Wendelboe, Denmark)
- Find a common definition for no-blame and open-and-fair systems (Alois Alkin, Austria)
- Keep the momentum and share knowledge and best-practices across the EU (NPSA)
- Apply the SIMPATIE experiences (way of working) to other settings (Ivana Silva, PGEU)





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- Create good conditions for healthcare professionals and deliver high quality healthcare services (Eugen Nagy, Slovak Republic)
- Develop local patient safety systems, taking special conditions and particularities into account and find ways to convince policy makers (Anne Broyart, France)
- Member States should get EU support to establish a legal framework for patient safety (Jean Bacou, HAS)
- Create a business case for patient safety proving the cost-effectiveness of patient safety interventions (UK Department of Health)
- All partners should recognize that besides involving the stakeholders, its needed to take notion of the 'mistake'holders and that the total costs of medical errors should be identified (Martin de Leeuw, NL)
- Establish national patient safety systems coordinated on an European level involving the European Union, the Council of Europe and the stakeholders (Jan Vesseur, NL)
- Involve all parties concerned and start acting into one direction, without mutual accusations (Raymond Lies, AEMH)
- Ensure that the voice of the patients is heard, that the patient rights are included in the EU constitution. Use the structural funds to support patient safety initiatives on Member State level (MEP Belohorska)
- Get the different working streams together and find common solutions by identifying the complexity of the business, showing healthcare professionals on how to ensure patient safety. Demonstrate the value of spending money to reduce the number of adverse event cases by a definition of the financial impact of patient safety interventions (Andrzej Rys, EC)
- Ensure that information gets through, especially regarding the wide variety of healthcare systems and problems within the EU (Benno van Beek, CBO)
- Be as practical as possible to ensure that the recommendations are implemented (Charles Bruneau, HAS)

Piotr Mierzewski concluded that cost-effectiveness and the search for a business/market approach would not always be the only way forward. He reminded the participants of the need for sustainability as topics which are hot on the agenda later on often get forgotten in the process. To ensure sustainability increased collaboration is needed on all levels, involving the EC, the Council of Europe and all stakeholders. Collaboration is essential as the EC is a powerful institution whose work and recommendations are often followed by all member states, not only of the EU but also of the Council of Europe. He reminded all on the need for an increased health democracy to ensure that the priorities of the citizens are well reflected in future policies. With regard to the upcoming dissemination of results, he





asked all participants to make the invisible visible and use Brussels as an inspiration and not an excuse.

The chairwoman Mrs Tiddens Engwirda reminded the participants to provide written input to the draft strategy framework until 1 October 2006 using the SIMPATIE website ([www.simpatie.org](http://www.simpatie.org)) and closed the meeting on behalf of the CPME and the SIMPATIE partner organisations.





## Appendix 2: Background SIMPATIE Project

### Overview

The overall objective of the SIMPATIE project is improving the safety of patients throughout all European countries. More specifically it uses a European wide network of organizations, experts, patients, professionals, and other stakeholders aiming to establish within its two years of duration a common European set of vocabulary, indicators, internal and external instruments for the improvement of safety in healthcare.

To reach the above stated goal the work of the Simpatie project has been divided into several work packages:

- one on mapping activities on patient safety in Europe
- one on vocabulary and indicators
- one on external evaluation of patient safety
- one on instruments for healthcare organisations to improve patient safety

The progress made so far in these work packages is portrayed in the annexes below.

In short the project results encompass the following:

To reach the overall Simpatie goal the mapping exercise provides a systematic overview of activities related to patient safety in the different European countries, which are categorised into regulations, policies and priorities and activities.

Another work package puts the first steps towards assessing the impact of patient safety efforts by formulating a common European vocabulary and by developing an evaluative framework for patient safety indicators.

Furthermore the work package on external evaluation of healthcare organisations discusses mandatory versus voluntary programs, European and national regulations, minimum versus desirable standards, transparency of results and success factors and barriers to external evaluation.

The last work package gives an overview of instruments to improve patient safety for healthcare organisations in the areas of registration of relevant data, analysis of risks and incidents and interventions aimed at the system or process level.

The Consensus Conference 'Building a strategy for patient safety in Europe' gathers and discusses these preliminary results of the project and draws first conclusions for the strategy framework, which will be developed based on the conference results.





## Content of the SIMPATIE project and strategy framework

The strategy framework is being based on findings of the SIMPATIE project. These can be delineated along four streams:

- present a mapping exercise that provides a systematic overview of activities related to patient safety in the different European countries, structured as legislation/ regulations, policies and priorities / activities
- sets the first steps towards assessing the impact of patient safety efforts by formulating a common European vocabulary and by developing an evaluative framework for patient safety indicators.
- discuss issues related to external evaluation of healthcare organisations: mandatory versus voluntary programs, European and national regulations, minimum versus desirable standards, transparency of results and success factors and barriers to external evaluation.
- give an overview of instruments to improve patient safety for healthcare organisations in the areas of registration of relevant data, analysis of risks and incidents and interventions aimed at the system or process level.

In addition, the framework is being based on the policy or position papers of key stakeholders at the European level, including: Recommendation of the Council of Europe, the work of the High Level Group on Health Services and Medical Care / working party on patient safety, The Luxembourg Declaration on Patient Safety (2005) and The European Hospital and Healthcare Federation resolution on patient safety.

Please find more information on the respective work packages in the annexes below.





## Work Package 2: The Mapping Exercise

In the last decade most European countries introduced a range of patient safety initiatives on local and national level. Therefore the SIMPATIE consortium introduced a mapping exercise to identify the existing patient safety endeavours, and better practices on European level, and make the findings available for all interested parties.

### 1. Regulatory background:

According to the data collected in the mapping exercise most member states introduced regulations and in some cases even legislation on patient safety. However, these initiatives are not consistent throughout the European Union.

The conference should further discuss the meaning of a 'no-blame' system, and to which extent national legislation could clarify this.

"There is a need for discussion and debate to reach better understanding of the real meaning of terms such as 'no-blame culture', 'no-blame systems', and 'open and fair' culture and systems. Ideally we should seek to reach common understanding around balancing the need to ensure accountability when things go wrong and open, honest reporting to patients, with the desire to develop a culture which is less focussed on blaming individuals and encourages reporting of and learning from incidents." (Peter Walsh, AvMA)

Issues highlighted by the mapping survey are: no fault compensation, legal disclosure and availability of data, liability arrangements and whistle blowing.

### 2. Policy content:

The conference should discuss the relevance and possibilities of a 'mix and match' approach to creating a national strategy e.g.

- sentinel event monitoring ( e.g. via national reporting systems)
- alerts (e.g. via national campaigns)
- subsidized national training schemes e.g. on RCA (root cause analysis)
- standardized software systems for incident collection and analysis
- clinical risk management systems (i.e. local incident reporting and training in risk management)
- patient partnership initiatives (cf. WHO Alliance 'speak up' campaign)

Currently existing national patient safety strategies to some extent seem not to reflect a clear consensus on priority within the elements of the strategy or overall level of resource allocation (partly



examined in section 3, below) but examples of good practice in e.g. guidelines and standards and national reporting systems provide an opportunity for benchmarking.

### 3. Policy priorities and actions

A comprehensive national patient safety strategy can be enabled to make informed choices regarding priorities when resources are a significant constraint. Granted the attempt to build a framework by consensus and using the results of previous European collaborations, how can the experience of some countries be made available to exchange information between member states in discussing and further developing their national strategy, taking into account the difference in history, culture and health systems between EU countries

The consensus conference provides an opportunity for discussion on the importance of building in evaluation of the impact of patient safety initiatives, something that current strategies show little evidence of, but which it is argued, is an important quality aspect, i.e. providing measures to demonstrate the efficacy and cost-effectiveness of components of a national strategy. Examples will be sought from the conference delegates of approaches that have been taken that go beyond academic research analyses.



### Work Package 3: Council of Europe's recommendations on safety and quality

- ensure that patient safety is the cornerstone of all relevant health policies, in particular policies to improve quality
- develop a coherent and comprehensive patient safety policy framework that
  - promotes a culture of safety
  - takes a proactive/preventive approach
  - puts patient safety as a leadership priority
  - emphasises learning from experience
- develop a Patient Safety Incident Reporting System for learning
  - non-punitive and fair in purpose
  - independent of other regulatory processes
  - encouraging reporting (*voluntary, anonymous and confidential*)
  - analysis of reports locally
  - national level when needed
  - involvement of patients/carers
- review existing data sources such as *patient complaints and compensation systems, clinical databases and monitoring systems*
- develop educational programs (*clinical decision making, safety, risk management*)
- develop reliable and valid indicators of patient safety for various health-care settings
- promote research on patient safety
- report regularly of actions taken
- *cooperate internationally, e.g. on: proactive design of safe health-care systems; nomenclature and taxonomy, methods of risk identification and management, standardised patient-safety indicators methods of involving patients and caregivers, content of training programmes standardisation methods*





- **Prerequisites of the Recommendation:**
- *Patient safety recognised as the foundation of good quality and the basic right of everybody*
- *A system-based approach*
- *Creating a culture of safety – no blame, open and fair; a culture where everyone has a constant and active awareness of the potential for things to go wrong, that is open and fair, where people are able to learn about what is going wrong and then put things right*
- *Reporting to learn from errors and act upon it*
- *Education is a key*
- *Patient empowerment - patient safety as a cornerstone for solidarity with patients*
- *Safety first! Savings second!*
- *Legal protection of whistle blowers*
- *Patient safety is not a luxury for the rich, but a must for all!*



## Work Package 4: Toolbox, Developing indicators / outcome measures and vocabulary

1. **Choices in creating vocabulary of Patient Safety:** A common understanding and definition of basic elements is a prerequisite for comparative assessment of interventions , priority setting and surveillance in patient safety. Development of such a set of definitions ('Vocabulary') requires balancing of several factors:

- Definitions in already existing vocabularies
- Correspondence with acknowledged taxonomies/terminologies of patient safety (WHO)
- Selection of topics according to importance ( Which perspective ? – expert – healthcare professional – patient )
- Selection of topics according to cross-cultural (European) differences in basic assumptions about patient safety
- Selection of topics which supports the proper selection of patient safety tools - indicators

2. **Aims of patient safety indicators:**

- Surveillance and monitoring the impact of improvement activities in patient safety:
- Diagnosis of 'unsafe' practices in healthcare
- Monitor (unintended) patient safety consequences of organizational changes
- Continuous support of external accountability/ patient choice

With the general limitations inherent in interpretation of indicator data.

3. **Criteria for selection of patient safety indicators:**

A three step procedure has been developed:

1. Identification : Patient Safety Indicators are measures that directly/indirectly monitor preventable adverse events
2. Characterization in terms of :
  - Documented use in a relevant clinical setting
  - Risk reduction/ Harm prevention (Structure + Process/ Outcome)
  - Application domain ( Institutional property / Theme related / Patient group specific)
  - Technical specifications
3. Final selection based on evaluation of:
  - Relevance related to aims and clinical setting
  - Validity
  - Feasibility (Technical - clinical )



## Work Package 5: Toolbox, External evaluation of healthcare organisations

External evaluation mechanisms are an integral part of strategies regarding patient safety in health care organisations. They have taken various forms. More recently, in response to greater expressed needs for accountability and to the recognised value of external recognition to promote improvement, hospital-wide mechanisms, such as accreditation, have gained greater acceptance.

Our draft document categorises and references the trends and evolutions in external evaluation regarding patient safety over the last 20 years. Focuses have shifted from compliance to minimum general safety standards to compliance to safe clinical practices, to measurement of performance and very lately to evaluation of patient safety culture and leadership. To various extents, these trends are common to most programs.

We have also discussed success factors and limits of external evaluation mechanisms.

Many issues remain open to discussion. We are proposing a number of issues that should be addressed at this conference :

### 1. Character

The pros and cons of mandatory national versus voluntary programs and of the role of government in the development and generalisation of external auditing programs.

### 2. Transparency

Recognising that external auditing mechanisms rely in part on external incentives based on the publication of the results, the modalities of publication remain an important issue. Related to this issue is that of the possible links between the evaluation result and the attribution of resources.

### 3. Cooperation

How to cooperate in Europe to promote external evaluation mechanisms that effectively contribute to improved patient safety? What could constitute an European consensus today or in the near future? From sharing common goals and a portfolio of common methods obeying common principles, to common standards, to common process of evaluation and common logics of decision.

### 4. Diversity

How to take into consideration the realities of the different member countries with their different backgrounds, traditions and economic situations? How to prioritise between these strategies?





## Work Package 6: Toolbox, Improving patient safety in healthcare organisations

The progress in science and technology, combined with advanced specialisation in health care are leading to increasingly complex care situations for increasingly frail patients. We should realise that health care is becoming less safe partly because of this enormous progress in hospital care. Making errors is a normal, but with regard to outcome often undesired deviation in human behaviour. The risk of errors increases in complex situations with hierarchical relationships. To be able to reduce the risk of errors and incidents in hospitals, many different actions could be undertaken. These will be discussed further.

Increasing attention to and action on safety problems is urgently needed. Unfortunately, up to now there is limited scientific evidence on the effectiveness of specific interventions. We are forced to use whatever evidence or experience is available, combined with the analysis and understanding of the problem and the local situation, when selecting actions that should be undertaken in a given organization. The project has developed an overview of these actions / instruments, that is being presented for discussion. However, even as we are discussing them new knowledge is being generated about the ones listed here and new innovative approaches are being initiated.

Therefore the key issue being presented here for discussion is:

What would be the ways and means of further cooperation in Europe in order to increase learning, knowledge and exchange related to different approaches to improve patient safety and facilitate their implementation in health care organizations.

For the purpose of discussion we have classified instruments, evaluated within the scope of the project, in three groups. Some of the instruments include aspects from more than one group.

### 1. Instruments for registration of information (data) relevant for safety

These include both specific registration of safety incidents as well as possible data sources for safety information derived from other, more general, registration systems. Important feature here is the possibility to develop or define indicators and benchmarks that can be used for comparison on different level (within organization, between organizations on regional, national and European level)



## 2. Tools for analysis of safety incidents and risks

The group includes two types of instruments:

- for retroactive analysis: Root Cause Analysis (Systematic Incident Reconstruction and Evaluation, Prisma) and Trigger tool status study.
- for proactive analysis: Health Failure Mode Effect Analysis and Bow tie model

## 3. Intervention approaches

Two levels of intervention can be roughly distinguished here, although experience indicates that best results of these interventions can be achieved when action is taken simultaneously on both levels.

- Interventions directed towards the system, namely organizational leadership, culture, communication, management and relations. This includes attention to safety culture, involvement of patients, a safety management system, crew resource management and multidisciplinary team training.
- Interventions directed to specific processes of professional health care delivery. Many of them are specifically developed to improve communication within one or more care processes and teams, including walk rounds, briefings, time out or SBAR. Others have been designed with a specific group of patients at safety risk in mind, like bundles or rapid response teams. Some combine both aspects and include system components, like a package of interventions developed to decrease hospital mortality (move your dot or campaign approach).





## Appendix 3: Summary Conference Conclusions

### Background

On 18 and 19 September 65 patient safety experts from 13 European countries met in Luxembourg to gather and discuss the preliminary results of the SIMPATIE project and to draw first conclusions for a strategy framework for patient safety in Europe.

The SIMPATIE project is funded by the European Commission with the objective to assist in improving the safety of patients throughout all European countries. At the conference, representatives of the European wide network of organizations, experts, patients, professionals, and other stakeholders involved in the project, presented the preliminary results of the different work packages (WP's). These WPs included a mapping exercise with the first overview of current patient safety activities in most Member States, a common European vocabulary and a set of indicators, internal and external instruments for the improvement of safety in healthcare organisations, as well as on a national and European level.

### Conclusions

#### *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.



## Appendix 4: Strategy Framework

### Introduction

Making errors is a frequent occurrence causing an undesired result and leading to unintended harm to patients. The risk of errors increases in complex situations with hierarchical relationships. To be able to reduce the risk of errors and incidents in hospitals, many different actions could be undertaken.

There is an urgent need for attention and action with regard to safety problems. Unfortunately, up to now there is limited scientific evidence on the effectiveness of specific interventions. However, the limited evidence or experience that is available at the moment is being used, combined with the analysis and understanding of the problem and the local situation.

The SIMPATIE project has developed an overview of actions and instruments, regarding patient safety. Subdivided into several Work Packages (WP's), expertise had been gained to generate preliminary result and conclusions.

The project's overview of actions and instruments is being presented here for discussion. However, even as we are discussing them new knowledge is being generated and innovative approaches are being initiated. One of the key issues being presented here for discussion is:

*What could be ways and means of further cooperation in Europe in order to increase learning, knowledge and exchange related to different approaches to improve patient safety and facilitate their implementation in health care organisations?*

The Consensus Conference 'Building a strategy for patient safety in Europe' has gathered and discussed preliminary results of the SIMPATIE project and has drawn first conclusions for the strategy framework, which will be developed based on the conference results.



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## Methods

The Consensus Conference has been organized by the Standing Committee of European Doctors (CPME) in close cooperation with the Dutch Institute for Healthcare Improvement (CBO), the Council of Europe (COE), the European Society for Quality in Healthcare (ESQH), Haute Autorité de Santé (HAS), the European Hospital and Healthcare Federation (HOPE), the Long Term Medical Conditions Alliance (LMCA) and Action against Medical Accidents (AvMA).

Delegates of a European wide network attended the conference in 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 were presented and discussed, intended to reach expert consensus on a strategy for patient safety in Europe.

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.





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## **Towards a strategic approach to patient safety**

The input given by the conference participants have resulted in a set of recommendations.

These recommendations concern actions on different levels and should not be conceived in a particular order of priority.

Basic assumption here is that whilst patient safety, as issue of health care policy, is primarily the responsibility of Member States, action at EU level should be supportive to help Member States achieve their patient safety objectives. In addition, for a number of issues and specific actions concerted action and coordination on patient safety at EU level is desired, as listed below:

### Actions that should be considered by the EU institutions:

- Define an integrated approach to patient safety at European level and establish a coordination mechanism for patient safety like a European network to share and promote knowledge and solutions between Member States and stakeholders. All action should be reinforced by a political commitment of the Member States, as well as the European Parliament. This network should also liaise closely with other relevant international endeavours, including the Council of Europe, the OECD and the WHO (EURO and HQ- with the World Alliance on Patient Safety and Action on Patient Safety)
- Within such a network, facilitate development of knowledge repositories enabling collection and public access to relevant information; this could include regulation/legislation, policies, priorities, actions and best practices
- Facilitate, support and coordinate programs and projects at national level:
  - that promote the involvement of all stakeholders, including patients, patient organizations, acute and long term health care providers, healthcare professionals, patient safety organizations and insurers,
  - that define indicators, reporting and supporting mechanisms as well as a body of knowledge and evidence on interventions that could improve safety; including research on safety but also evaluation of interventions.
  - that develop national policies and programs, including education and training of health professionals
  - that facilitate the exchange of information and lead to the development of a new legal framework on several aspects of





safety including e.g. complaints procedures, compensation systems and professional responsibility, by using a network

- Adopt a common vocabulary, as well as a set of patient safety indicators and instruments for internal and external evaluation to ensure the comparability of results on EU level and to produce the necessary public health and economic evidence for patient safety interventions.
- Make use of the already existing agreements, procedures and regulations at European level to enhance safety; explore possibilities to improve the regulations on medical technologies, materials of biological origin and European registration of medicines.
- Raise awareness of the patient safety impact on public health
- Ensure Patient Safety is an integral part of the health services initiatives.
- Make an inventory of existing reporting systems regarding medical errors and describe them in such a way that this will lead to a common definition and understanding in Europe.

#### Actions that should be considered at national level

- Ensure that patient safety is the cornerstone of all relevant health policies, in particular policies to improve quality
- Develop national platforms to ensure a coherent and comprehensive patient safety policy framework that
  - promotes a culture of safety
  - takes a proactive/preventive approach
  - focuses on system errors
  - puts patient safety as a leadership priority
  - emphasises learning from experience
  - leads to harmonization of activities
  - collects annual reports on national and regional level
- Introduce 'no blame' reporting systems regarding medical errors, leading to respective cultural changes without jeopardizing the rights of patients getting compensation. Therefore these systems should combine liability issues and the development of non fault compensation regulations.



- Introduce policies and procedures to ensure that patients or their families affected by medical errors are fully informed of them and offered appropriate explanations, apologies and support
- develop state-of-the-art educational and training programs that ensure core patient safety competencies, including clinical governance, safety and risk management, and include them in basic and postgraduate curricula, as well as in continuous professional development programmes for health professionals
- Guarantee the needed quantity and quality of human resources to ensure a high level of safety
- Educate and empower patients on Patient Safety
- Promote research on patient safety
- Introduce regulations ensuring the safe design and safe use of medical devices and pharmaceuticals, thus preventing look-alike and sound-alike drugs, as well as unsafe medical devices. These regulations should be consistent with EU actions on this matter.
- Develop evaluation tools to ensure safe clinical practice, e.g. through regular performance measurement on clinical and administrative level
- Review and improve the quality of existing data sources such as patient complaints and compensation systems, clinical databases and monitoring systems
- Identify the public health and economic impact of adverse events and patient safety interventions
- Introduce monitoring systems ensuring external evaluation of healthcare organisations to
  - identify common goals
  - develop a portfolio of common methods, obeying common principles
  - aim for common standards, ensuring one process of evaluation and common logics of decision
  - ensure transparency in external evaluation
- Develop reliable and valid indicators of patient safety for various health-care settings, in order to improve patient safety and clinical governance, based on outcomes and findings within the EU network
- Develop a Patient Safety Incident Reporting System for learning, with the following principles and goals:





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- non-punitive and fair in purpose
- independent of other regulatory processes
- encouraging reporting (voluntary, anonymous and confidential )
- analysis of reports locally
- national level when needed
- involvement of patients/carers
- Report regularly of actions taken, e.g. through annual reports by the Ministries of Health

Actions that should be considered by health care providers (both individual providers and institutions/organisations)

- Facilitate a multidisciplinary and collaborative approach between health professionals and health care providers, aimed at enhancing patient safety
- Initiate and promote co-operation between patients/carers and health care professionals in order that patients/carers are made aware of near misses, adverse events and risks
- Implement work place projects focusing on patient safety and establish an open culture to deal with errors and omissions more effectively, for example “medical quality circles”, peer review groups and training of supervisors/presenters in peer review
- Exchange of information between healthcare organisations on best practices, open to the wider public
- Consider collaborating on national guidelines on complaints procedures, (economic) compensation systems and professional responsibility
- Implement evidence-based educational programs that ensure core patient safety competencies, including clinical governance, safety and risk management, in basic and postgraduate curricula, as well as in continuous professional development programmes for health professionals
- Evaluate new initiatives in dealing with adverse events, e.g. patient arbitration schemes or no-fault liability insurance. If successful, incorporate them into training and continuing professional development





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- Assess the economic impact of adverse events and patient safety interventions within healthcare organisations
- Introduce tools to measure and improve clinical governance based on sound scientific evidence
- Introduce instruments for registration of information and data relevant for safety in healthcare organisations, in line with proposals at EU level, to
  - ensure a common understanding and definition of basic elements through a common European vocabulary and a joint set of indicators
  - safeguard ongoing surveillance and monitoring of the impact of patient safety activities
  - support external accountability and patient choice
- Introduce tools for analysis of safety incidents and risks
  - for retroactive analysis: as e.g. Root Cause Analysis (Systematic Incident Reconstruction and Evaluation, Prisma) and Trigger tools.
  - for proactive analysis: for instance Health Failure Mode Effect Analysis and Bow tie model
- Implement intervention approaches
  - directed towards the system: namely organizational leadership, culture, communication and management (taking into account issues such as safety culture, involvement of patients, a safety management system, crew resource management and multidisciplinary team training).
  - directed to specific processes of professional health care delivery (including walk rounds, briefings, time out, SBAR (Situation-Background-Assessment-Recommendation), bundles or rapid response teams)
  - directed to the system and health care delivery, as e.g. packages of interventions developed to decrease hospital mortality (such as ‘move your dot’ or ‘campaign approach’).
- Implement internal and external evaluation mechanisms that effectively contribute to improve patient safety and transparency to patients and stakeholders. These evaluation mechanisms should be integrated into healthcare organisations’ quality and security improvement strategies.

