EU health stakeholders and patient safety

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Abstract

The Standing Committee of European Doctors (CPME) has been actively promoting patient safety for a long time, well before the issue was given a firm place on the European and international agendas.
Among its efforts to help raise the profile of patient safety, CPME organised a conference on the 4th and 5th April 2005 together with a group of EU health stakeholders that covered the whole spectrum of healthcare delivery. The European Conference 'Patient Safety – Making it happen!' took place in Luxembourg under the auspices of the Luxembourg EU presidency and EU Commissioner Kyprianou and resulted in the "Luxembourg Declaration on Patient Safety".
This Declaration contains recommendations to the EU, national authorities and healthcare organizations.
It underlines the added value of the EU and recommends joining forces with the WHO Alliance for Patient Safety. A culture of transparency, trust and safety is being sought for through the suggested use of e-health, flows of health information, patient involvement and reporting systems.
CPME saw perseverance and commitment pay off as patient safety is now seen as a priority by all health stakeholders and EU institutional bodies (European Commission, presidencies and Council).
However all parties realise full well that the Luxembourg Declaration on Patient Safety is only the first step. All efforts are now focussed on follow up and implementation.

Key words: patient safety, Standing Committee of European Doctors, CPME and Luxembourg Declaration

Introduction

On the 4th and 5th of April 2005 the European Conference 'Patient Safety – Making it happen!' took place in Luxembourg. This conference was organized by the Standing Committee of European Doctors (CPME) together with a group of EU health stakeholders that covered the whole spectrum of health care delivery.

Due to the broad range of EU health stakeholders involved in the preparations of the conference the resulting Luxembourg Declaration was a well-balanced document that was supported by all participants of the conference.[1]

The Luxembourg Declaration on Patient Safety has helped to put the issue of patient safety firmly on the European agenda. This article aims to explain the development of the declaration and to highlight the different recommendations it makes to the EU institutions, national authorities and health care providers.

The Luxembourg Declaration: getting there

CPME has been active in promoting patient safety for a long time, well-before the issue was firmly place on the international agenda. CPME members adopted several policies on patient safety in the past decade, resulting in the adoption of an action plan on patient safety in September 2003. Thus CPME committed itself among other things to foster mutual learning across countries by exchanging information among national medical associations, to consult with other healthcare stakeholders at the European level, and to consult with the European Commission.

The report 'To err is human' published in 1999 marked the first step in obtaining international recognition for patient safety. It also is the basis for CPME activities in this area. In this study the American Institute of Medicines (IOM) states that between 44,000 and 98,000 people die from adverse events in American hospitals each year. After the release of these shocking findings similar research was carried out in Europe, with similar results being demonstrated. A study in the United Kingdom found adverse event rates to be 11.7% [2] while a study in Denmark demonstrated adverse events to be 9.0% [3]. These research findings resulted in the needed increase of attention for the issue of patient safety by health professionals and politicians.

At the global level the World Health Assembly adopted a resolution on patient safety in May 2002. As a result the World Health Organization established the World Alliance for Patient Safety on 27 October 2004. The World Medical Association adopted a resolution on patient safety in October 2004. In August 2005 the WHO launched a Collaborating Centre on Patient Safety.

At the European level the issue of patient safety was included for the first time in the Work plan 2004 of DG Health and Consumer Protection. Several legislations are in process now that relate to patient safety, e.g. the revision of the Medical Devices Directives. A Working Group on Patient Safety in the High Level Group has been formed. It met for the first time in April 2005. Furthermore the Commission is co-financing several research projects in the field of patient safety. These projects are SimPatIE (Safety Improvement for Patients in Europe), MARQuIS (Methods of Assessing Response to Quality Improvement Strategies) and EUPHORIC (European Public Health Outcome Research and Indicators Collection).

In mid 2002, CPME started to assemble a group of EU health stakeholders to organize a European Conference on Patient Safety. European 'health oriented' organizations with different angles showed interest in joining. At the end ten European organizations joined to co-organize the conference (See Box 1). This consortium got the support of the European Commission DG Health and Consumer Protection, the Luxembourg Presidency, and the incoming UK Presidency (at that time)of the Council of the European Union.

Intended outcome

To achieve the desired impact of agenda building in Europe the target audience for the conference were policy-makers throughout Europe. In order to obtain sustainable results with this conference, the EU health stakeholders decided to develop a recommendation paper on patient safety in Europe, entitled the Luxembourg Declaration on Patient Safety, which would be included for discussion at the conference. A lengthy process of discussions and debates on the content of the declaration among the EU health stakeholders, the Commission and the two Presidencies followed. The draft declaration was presented to the participants during the conference. With some minor adaptations this draft declaration turned into the final Luxembourg Declaration on Patient Safety, that contains recommendations to the EU, national authorities and healthcare organizations.

The added value of the EU

The first step needed is the establishment of a 'safety culture' throughout the entire health system to prevent adverse events from happening. 'Risk management' should be introduced as a routine instrument within the entire health sector.

A precondition for the establishment of a safety culture with the help of risk management is an open and trusting working environment. The culture should focus on learning from near misses and adverse events as opposed to concentration on "blaming and shaming" and subsequent punishment.

The problems of patient safety are similar across countries as are the solutions. Therefore the establishment of an EU Forum to discuss patient safety activities across could contribute greatly to increasing patient safety. Lessons learned can be exchanged and concrete actions can be created in a coordinated way. An extensive website to support this forum will facilitate its operations and usefulness to the member states.

As there is no established method to measure patient safety in healthcare settings at the moment, it is hard to identify evidence-based practice that improves patient safety, highlighting the need for future research.

A tool to stimulate and direct this research, would be the sharing of best practice amongst organizations and countries.

The Luxembourg Declaration therefore recommends the establishment of an EU solutions bank.

Box 1. The group of EU health stakeholders that organized the conference

- **The Standing Committee of European Doctors (CPME)**
  - the European Association of Senior Hospital Physicians (AEMH)
  - the European Federation of Pharmaceutical Industries and Associations (EFPIA)
  - the European Health Management Association (EHMA)
  - the European Health Telematics Association (EHTEL)
  - the European Patients' Forum (EPF)
  - the European Society for Quality in Healthcare (ESQH)
  - the European Medical Technology Industry Association (Eucomed)
  - the Standing Committee of the Hospitals of the EU (HOPE)
  - the Standing Committee of Nurses of the EU (PCN)
  - the Pharmaceutical Group of the EU (PGEU)

A basis for this EU solutions bank will be provided by the SImPatIE project. This is a European co-financed research project on patient safety (See Box 2). The website established for the EU forum mentioned above could maintain this EU solutions bank and take up other functions like the instant sharing of alerts (potential dangerous situations discovered in one setting), an issue proposed by the High Level Reflection Process.

Close cooperation with WHO

Sharing knowledge within the EU is important and easy to achieve, but useful lessons can also be learned from organisations/countries in the rest of the world. The declaration therefore recommends that the Commission works towards a worldwide common understanding on patient safety by joining forces with the WHO Alliance for Patient Safety. This Alliance aims to establish taxonomy on patient safety, to increase research, to identify and communicate solutions and to develop guidelines based on reporting and learning. It is therefore important that the EU works closely together with this global alliance.

From small to all

New insights or possible innovations in the field of patient safety can be best analyzed on effectiveness and efficiency on a small scale. Proven solutions in such pilot projects can benefit the whole European Union if the insights gained are properly disseminated. The declaration therefore recommends that the Commission creates possible support mechanisms for national or regional patient safety projects. The European-wide establishment of national patient safety centres, like the National Patient Safety Agency (NPSA) in the UK and the Society for Patient Safety in Denmark, may facilitate the dissemination of knowledge.

Patient safety is affected by operations across the whole of the healthcare delivery continuum, from the research and manufacturing of medicines to the final treatment of the patient. Real patient safety improvement can only be achieved if activities for improvement are undertaken at all the stages of healthcare delivery. EU activities that aim to improve patient safety have to include across the whole spectrum of healthcare delivery in order to be effective.

Therefore the declaration recommends that EU regulations with regard to medical goods and related services are designed with patient safety in mind. Furthermore it recommends that EU regulations should encourage the development of international standards for the safety and performance of medical technologies.

E-health

At the e-health Conference in Tromso many new developments in the area of e-health were discussed, among them Electronic Healthcare Record Systems (EHRS), the European Health Insurance Card (EHIC) and a Smartcard containing health data. Also the European regulatory framework should protect the privacy and confidentiality of patient records in the best interests of the patient, while at the same time ensuring that relevant patient information is readily available to health care professionals.

Box 2. Simpatie-project

The project officially started on 15 February 2005 and will last two years.
The partners involved in the project are:

- CBO: Dutch Institute for Quality Improvement (*project leader*)
- Council of Europe
- CPME: Standing Committee of European Doctors
- ESQH: European Society for Quality in Healthcare
- HAS: the French High Authority of Health
- HOPE: Standing Committee of the Hospitals of the European Union
- LMCA: the UK Long-term Medical Conditions Alliance

The goal of this project is to use a European-wide network of organizations, experts, professionals and other stakeholders to establish within two years a common European vocabulary, a set of indicators as well as internal and external instruments for the improvement of safety in health care. The project team is now performing an extensive mapping exercise of patient safety activities throughout Europe. The final part of the project aims to reach expert consensus on a strategy framework for patient safety that can be modified to fit individual health care systems and organizations but that contains agreed components. As such the project will deliver useful information for the EU solutions bank. For more and up-to-date information, please visit: www.simpatie.org.

Recommendations to national authorities

The Luxembourg Declaration also makes recommendations to national authorities.

It is well-recognized nowadays that healthcare delivery is characterized by a patient-doctor partnership. This partnership emphasizes a collaborative approach between the doctor and the patient. In order for the patient to fulfil his/her role in this partnership, it is important that he/she receives appropriate and accurate information on their health status and treatment and that the information given is understandable. Knowledgeable patients are well positioned to help safeguard their health. Therefore the declaration recommends national authorities to strive to achieve 'informed patients'. A first step towards this would be for national authorities to line up with the WHO Alliance Patients for Patient Safety campaign called 'SPEAK UP'. This acronym (see Box 3) stands for seven actions patients can take themselves to reduce the risk of encountering an adverse event.

Reporting

As stated before it is important for organizations and countries to learn from adverse events. A starting point to establish a learning culture is to know of **all** adverse events that take place whether they result in harm or not. Therefore individual healthcare workers should feel free to report all types of patient safety incidents. This can only be achieved if the reporting system that is used is truly confidential, in that it may not be used to blame professionals.

A reporting system is the basis for risk management. It is only when all incidents are reported, that risks can be accurately calculated. When the risks are clear, work practices can be adjusted eliminating or decreasing high risks. By introducing standard working routines for example, a lot of adverse events can be prevented. The declaration therefore recommends that national authorities work towards the introduction of guidelines and indicators in the field of patient safety.

Advances in new technologies can contribute to patient safety to a great extent when properly dealt with.

Electronic patient records contain the medical profile of the patient as well as decision-making support programs for health professionals. By using electronic patient records properly medication errors can be reduced and compliance increased. The declaration recommends that national authorities support the optimal use of this type of new technology.

Exchange of information

Differences in practices, culture and patient population also exist within countries. It is important for organizations to learn how others deal with specific patient safety incidents, so they can determine the best response in their own setting. It is for these reasons that the declaration recommends national authorities to establish national fora for the exchange of information.

Health professionals are the prime actor in health care delivery and are therefore often in the best position to identify adverse events and to propose solutions. However, they need to be trained on patient safety incidents in order to be able to recognize and deal with adverse events. The declaration therefore recommends to national authorities to ensure that patient safety is included not only in the standard training of health professionals, but also in all activities aimed at continuous professional development. In the same line of reasoning it is important that working conditions, recruitment and retention are linked to patient safety.

National regulations have to aim at the whole spectrum of healthcare delivery in order to be effective.

The Luxembourg Declaration recommends that national authorities ensure the safe use of new medical technologies and surgical techniques. In order to achieve this, national authorities should recognize and support the user training provided by medical devices, tools and appliance manufacturers.

Box 3. Speak Up campaign

Speak up if you have questions or concerns: it's your right to know
Pay attention to the care you are receiving
Educate yourself about your diagnosis, test and treatment
Ask a trusted family member or friend to be your advocate
Know what medications you take and why you take them
Use a health-care provider that rigorously evaluates itself against safety standards
Participate in all decisions about your care

In the field of patient information it is important that national authorities guarantee privacy protection and confidentiality of patient information, whilst at the same time ensuring that relevant patient information is readily available to health care professionals.

In short National Authorities should establish a culture of safety, aimed at learning from near misses and adverse events in stead of focusing on blaming and punishing the individual.

Recommendations to health care providers

Finally the Luxembourg Declaration makes recommendations aimed at health care providers themselves.

Looking at the costs and subsequent savings possible, health care providers should make patient safety a priority. It is not enough however to simply prioritize patient safety in a work plan or management strategy. To establish a real culture of safety the involvement of all layers of personnel is needed. Therefore the declaration recommends to health care providers to facilitate a collaborative care approach between health professionals and health care providers.

Health care providers can introduce new approaches by demonstrating their use through the implementation of work place projects thus initiating cultural changes.

The involved patient

It is not only important to acknowledge and recognize the occurrence of patient safety incidents within healthcare settings and amongst health professionals. The patient remains the main partner in any healthcare delivery. When fully informed, patients can be enormous valuable sources of information to prevent or deal with adverse events. Furthermore when patients know that safety has a high priority and that latent system failures are the cause of patient safety incidents, they are more likely to be understandable towards healthcare providers. The Luxembourg Declaration recommends that healthcare providers initiate co-operation between patients/relatives and health professionals.

Conclusions

CPME saw their perseverance and commitment pay off especially now that patient safety is firmly on the European agenda and is seen as a priority by all health stakeholders and EU institutional bodies (European Commission, presidencies and Council).

The Luxembourg Declaration on Patient Safety was only the first step. Further steps must now be taken across the EU to bring about appropriate patient safety policies and systems that really function in practice.

To achieve this, CPME will keep on working, making EU added value a reality.

The Luxembourg declaration is available for signature on the CPME website [1]. The more signatures collected, the more we emphasise that we want safer patient care for all European Member States.

Acknowledgements

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