

## The Simpatie project

Cule Cucic<sup>1</sup>, David Somekh<sup>2</sup>

<sup>1</sup>Dutch Institute for Healthcare Improvement, <sup>2</sup>European Society for Quality in Healthcare

Correspondence to: David Somekh, ESQH Isle of Wight office, Kingates Farm, Newport Road, Whitwell, Isle of Wight, PO38 2QP. UK

### Abstract

In this article a current European multi-national project in patient safety is described. This project began in Feb. 2005 and will run for two years. It is managed by a consortium of seven NGO's led by the CBO (Dutch Institute for Healthcare Improvement) and receives 60% of its funding from DG SANCO (the health and social policy division of the European Commission).

The policy framework within which the project evolved is also described. Despite the constraints of Art 152 of the Treaty, support from Commissioner Byrne encouraged a High Level Reflection process (HLRP) on patient mobility and healthcare developments in the EU, which started in June 2002 and involved European Health Ministers.

As a result a series of very positive recommendations were made at the end of 2003 which subsequently were accepted and have affected policy direction in a number of areas e.g. co-operation on e-health, better use of resources as well as quality issues such as patient safety and quality implications of cross-border patient flows.

The paper then reviews current issues in patient safety activity within Europe.

Finally the Simpatie project is described. It is comprised of four main elements. First, a mapping exercise to determine the present status of patient safety activity within at least 20 European countries. It utilises extensive existing networks within and between the members of the consortium and other relevant stakeholders within Europe.

Secondly, a "tool-box" exercise attempts to define common terminology and an expert consensus on measurement tools. This is complemented by the third element, a strategy component which aims to define the basic elements of different approaches to implementing patient safety within health systems.

Finally, the last element is dissemination, where involvement of both public and health user organisations will be an important component.

*Key words: patient safety, Europe, patient mobility, quality, Simpatie, mapping, expert consensus, strategy and dissemination*

### Historical and political background

This description of our project is prefaced with a relatively detailed description of the historical and political background from which it arose; we feel that this provides a context for the structure of the project and helps to predict how the results may be utilised.

The High Level Process on patient mobility and healthcare developments in the EU (HLRP) was convened by the Commission following the Health Council meeting on June 26, 2002, during the Spanish EU Presidency. Its stated mission was as follows: 'As health systems and health policies across the EU become more interconnected than ever in the past, it is intended to provide a forum for developing a shared European vision in this area, while respecting national responsibility for health systems'. The question is, how do we translate this pronouncement from 'Brussels-speak' to plain English?

National policies on healthcare in Europe, although dealing fundamentally with similar issues, inevitably take different directions because of their geography, history, economics and culture, and so represent a wide range of strategies. There is always a variety of stakeholders and there will be a mixed economy of quality philosophies within each strategy, from quality control (for example, the use of ISO in laboratories) to total quality management (such as the adaptation of EFQM to healthcare organisations). How can this diversity be reconciled, to develop the 'European vision' referred to above?

The problem here is Article 152 of the Amsterdam Treaty, which prohibits any Community activities in health regarding the delivery of service, organisation and finances. The principle of subsidiarity being predominant.

Article 152 does allow quality-related harmonising measures but only in very restricted



areas, such as 'setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives...'.

Although it was recognised that other policies - for instance, on the environment - as well as European Court judgements on the internal market (such as Kohl and Decker in 1998), and the increasing cross-border movement of citizens who might require healthcare away from their country of origin, makes the absence of co-ordinated action on healthcare somewhat anomalous, without doubt there are still very strong feelings in some quarters regarding the integrity of national healthcare systems. In that context, it could be reasonably argued that the health ministers who agreed to set in motion the HLRP were in fact being quite adventurous.

A number of Working Groups on different topics had been set up in support of the HLRP deliberations. By January 2003 the HLRP's Working Group 3 (WG3) on quality and access had formulated some key questions. 'How do we develop a shared understanding of what quality means?' 'How do we develop a common vocabulary of terminology', and 'How do we develop a mutual knowledge of health systems?' It was felt that mapping of the current Community activity and facilitation of the exchange of experience between those agencies engaged in different parts of the quality agenda was needed.

Regarding the barriers to change, a WG3 think-tank in Patras in May 2003, involving policymakers, academics, clinicians and patient representatives, asked whether the Treaty Revision could assist by recognising that healthcare had a European dimension, underpinned by shared values, but which could accommodate national diversities. Professor McKee and colleagues in a subsequent paper [1] noted that, despite pressures to do so, the new Constitution did not provide a specific Article on healthcare, 'as national powers in this area are guarded jealously by the member states'.

In early December 2003 the HLRP reported; making 19 recommendations across five areas. [2] These included European co-operation to enable better use of resources, e-health, 'reconciling national objectives with European obligations' (which proposes inter alia the setting up of a permanent mechanism at EU level to support European co-operation in the field of healthcare and to monitor the impact of the EU on healthcare systems) and 'improving knowledge on access and quality issues' (WG3).

Apart from four recommendations on cross-border patient flows, mostly to do with

information gathering, the WG3 section ends with the recommendation 'to invite the Commission to prepare an analysis of Community activities to see how these can better contribute to access and quality in healthcare, taking into account relevant activities in other international organisations'.

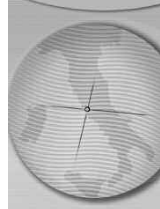
At first sight this seemed to be a depressingly colourless conclusion to the HLRP. Appearances can however be deceptive, and couple of months later, in late February 2004, the *Official Journal of the European Union* 2004 published the annual Call for Proposals and the Work Plan for 2004 in the Programme of Community Action in the Field of Public Health (2003-2008).

For the first time, specific quality issues were identified as priorities. Section 2.1.6 'co-operation between member states' says: 'In 2004, work will be supported taking account of the HLRP. The following actions will be priorities: [1]. Quality assurance in Europe: this work will take stock of activities and initiatives related to quality assurance and improvement and accreditation systems across Europe, and develop perspectives for networking and collaboration, in particular at EU level, also covering patient safety'.

Compared to the 2003 work programme this marked a dramatic step forward by naming specific quality areas such as accreditation and patient safety as priorities for co-operation. In effect for the first time DG SANCO (the Health and Consumer Protection Directorate-General of the European Commission) was explicitly offering to provide financial support for projects involving co-operation between representatives of different member states in relation to health quality.

For the last few years Patient Safety could be described as the 'new kid on the block' in the health quality environment. This is an interesting phenomenon in itself because equally one might argue that clinical risk management has been a part of health quality activity for as long as the latter has existed. Perhaps by analogy, if one studied the speeches of President George Bush, one might wonder whether there was such a thing as International Terrorism prior to the 11<sup>th</sup> of September 2001. Of course there was, but by labelling the issue in a particular way a different perspective has been created. Certainly in the last five years a great deal of attention has been paid to the subject of Patient Safety in all spheres of healthcare.

Nevertheless, a recent editorial in the BMJ, by experts from AHRQ (US Agency for Healthcare Research and Quality) [3], concludes that despite substantial investment in infrastructure, particularly information technology (IT), the



evidence for sustainable improvement in safety is lacking, the weakness being in the area of 'a culture of safety' which appears to refer to the degree of penetration, or lack of it, into health care systems of the principles referred to in the 'To err is human (the Institute of Medicine)' report [4] or 'An organisation with a memory' (Sir Liam Donaldson's report for the UK NHS) [5].

This edition of the Journal helps illustrate the current status of activity across European countries. Common sense dictates that the level of development of such activities will conform to some kind of normal distribution. A 'quick and dirty' review of a few countries confirms this. The UK and Denmark with national agencies dedicated to the area of interest are more or less at the leading edge. Then there are a substantial number of countries where there is a good level of activity, for example, Spain, Germany, Netherlands and Italy and finally there are countries where, because of the overall status of their health economy and/or their recent history, are just at the beginning of the journey, for example, Greece or Poland and other accession states.

To illustrate this general point, a recent report from the Polish Society for Quality Improvement in Health, concluded that the rate of clinical errors in Poland was unknown, but in a recent survey as many as 78.5% of healthcare professionals reported being involved in adverse events. Senior clinicians advised that some of the factors contributing to this were lack of adequate patient care at weekends and/or holidays, lack of effective doctor-patient communication and the existence of incidents of sudden, unexpected death after simple surgery. The factors contributing to the inadequacy of data were the lack of separate legislative measures for malpractice claims, underinsurance on the part of hospitals and no data on the number or nature of malpractice claims. Current activities to attempt to improve the situation are involvement in the Agenda for Leadership in Programs for Healthcare Accreditation programme (ALPHA), active participation by Poland in the recent Council of Europe and WHO initiatives and ongoing training activities by the Polish Quality Society.

By contrast, in Spain, the FAD (Avedis Donabedian Foundation) in Barcelona in 2002 set up CISP, their patient safety institute, which has the following working areas: training and education, identifying safe practice and developing safety alerts (since 2003), an online enquiry system and due to go live January 2005 and a confidential reporting system for adverse events in hospitals. Other institutions active in the

field are ISMP (the Spanish division of the Institute for the Study of Medical Practice) and the Advisory Board on the Prevention of Medication Error. However, it is noted that these initiatives are mainly driven by professional or academic bodies and that there are few that include the active participation of health authorities.

The UK is illustrative of a situation where there has been substantial investment by the major health service provider, the NHS. The CMO, following the publication of 'An organisation with a memory', has championed the implementation of a rational programme to address the patient safety agenda, the foremost component of which has been the NPSA, which completed its third full year of activity in March 2005. These developments are described in more detail elsewhere in this edition of the Journal as are the first group of initiatives described below.

Europe-wide initiatives fall into two categories. Firstly, arising from pan-European organisations with an interest in patient safety (particularly the OECD indicator project, the Council of Europe whose working party recommendation will be published shortly and the work arising from WHO-Europe) and secondly pan-European projects supported by the public health policy division of the EC, DGSANCO.

It is immediately obvious that there is a danger of duplication of effort here; however, in the field of European public health, trouble is being taken to ensure that this risk is minimized by having multi-agency oversight groups that facilitate communication between the active players. The Luxembourg conference, held in early April 2005, was an example of interested parties, policy makers, academics and NGOs attempting to get a snapshot of the current state of activity and following on from the Luxembourg presidency of the EU, the UK presidency in the latter part of 2005, has patient safety as one of its health policy priorities.

It appears logical then that the issues to be addressed by a project in this area arise out of the interest on the part of the policy makers to have accessible to all stakeholders, information on what is going on in different countries (mapping), on taxonomy, quality tools etc. The other drivers are patient mobility (the need to be able to make meaningful contracts for care across borders) and the recognition that despite differences in language, culture and health economy there may be actual benefits in attempting to share good practice across borders, notwithstanding the recognition of the difficulties inherent in this process even within countries.



### The SIMPATIE Project

The above describes the remit of the recently launched project (Safety Improvement for Patients In Europe), 60% part funded by DGSANCO, which involves a consortium designed to maximise utilisation of existing networks for information exchange, namely CBO (Dutch Institute for Healthcare Improvement), ESQH (European Society for Quality in Healthcare, itself a network of European NGO quality organisations), HOPE (European Hospital and Healthcare Federation), CPME (Standing Committee of European Doctors), HAS (Haute Autorite de Sante, the state quality organisation in France, formerly ANAES), a representative of the Council of Europe group already mentioned and, representing patients, LMCA (an umbrella organisation for disease specific patient groups, the Long term Medical Conditions Alliance).

As can be seen, the project harnesses a number of large multi-professional expert networks already established across Europe including a large network of patient organisations. As far as geographical scope is concerned, data collection for the mapping exercise aims to involve a minimum of 20 member and accession states.

The concept of a standardised database to capture complex health information by country is well established. A good example was the ExPeRT (External peer review techniques) project funded by the EU under the BIOMED 2 Public Health Research Programme in 1999. This demonstrated the viability of the method, although it was necessary to ensure that data collected was frequently monitored and cross-checked against additional data sources to ensure internal consistency and accuracy.

The principle underlying the data collection is to develop a systematic overview of activities in the field which would lead to the creation of an easily accessible knowledge repository related to legislation, regulation and actions in the field. There are obviously a number of problems to be solved if such a goal is to be achieved. The team delegated to this part of the work, assembled a group of experts to gain agreement as to how the interests of policy makers, managers, clinicians and the general public could all be met. They have proposed a matrix approach to data management which locates information on the dimensions of product (system design, control and improvement) and actors (national, specialist and local).

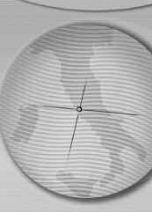
More details of the approach can be found by consulting the open access website for the project, address [www.simpatie.org](http://www.simpatie.org). Twenty-four

advisors from all across Europe who will act as country co-ordinators have already been identified and data is now starting to flow. The deadline for completion of this part of the project is Month 20, i.e. July 2006. Finally, the challenge of creating a database that can be continuously updated to maintain its relevance is to be tackled by using technology that CBO have developed in their 'living guideline' project. An additional output for this part of the project will be a database to allow benchmarking of good practice.

In parallel with the mapping exercise several working groups of experts will be developing a common vocabulary, outcome indicators and internal and external instruments for measuring improvement in patient safety. Although working separately, the groups will liaise on a regular basis and will also ensure consistency of their direction with ongoing work by OECD and WHO-Europe. In addition, the Council of Europe work reported on at the Luxembourg Presidency meeting in early 2005, referred to above, will be used as a framework, all of these links aim to avoid unnecessary duplication of effort. Ongoing liaison with WHO was formalised via a joint WHO and Simpatie seminar in Copenhagen in early September 2005. In fact, the working groups for this part of the project, the so-called 'tool-box' started their work mid-September and will report after eight months. A seminar will be held roughly half-way through that period to allow sharing of information and discussion between experts as to the implications of work so far accomplished.

The third part of the project utilises the outputs of the first two streams of work and involves a two to three day consensus conference similar to the Patras 2003 event described above. The idea is to agree strategy models for patient safety, keeping in mind particularly those countries who are less advanced in this area with the aim of helping to ensure that they do not have to 're-invent the wheel'.

The final part of the project is central to the philosophy of the project, namely the dissemination phase. The composition of the partner group partly reflects this in providing networks which represent many of the stakeholders, e.g. managers, doctors, quality personnel and patients. Nevertheless, there is a strong brief to report the findings in a form that is most amenable and accessible to each group. The question of translation from English to other languages is still under discussion with DGSANCO but certainly electronic dissemination is likely to be enhanced by the proposed use of the EU health portal.



### A comment on the methodology.

The contribution from the Commission was granted on the proviso that there were clearly defined activity indicators available through the duration of the project to ensure that progress was regularly monitored and deliverables were produced as per schedule. The other requirement was that there were output indicators to assess the quality of the deliverables where possible. To give just one example, following the determination of a set of outcome measures for patient safety activity, the results would be submitted to an external reference group of experts who would use standard methodology to independently evaluate their quality i.e. using simple measures of face validity, evidence-base, availability of data etc.

As stated at the beginning of the paper, the history of the project explains the choice of the measures chosen to be studied. In addition to developing a 'living database' to serve policy development and research in this area, as well as providing amenable information for citizens, the project aspires to demonstrate the value of information sharing on health quality activity between professionals in different countries within the EU. Equally, the networks for

information exchange developed in the course of the work provide a potential resource for further work in the field of both policy development and research.

*Further information can be obtained from the project website, [www.simpatie.org](http://www.simpatie.org), or mail: [simpatie@cbo.nl](mailto:simpatie@cbo.nl).*

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### References

- 1) Belcher P, McKee M, Rose T. Is Health in the European Convention? *Eurohealth* 2003;9(2):1-4.
- 2) High level process of reflection on patient mobility and healthcare developments in the EU: outcome of the reflection process 09.12.03. [http://www.europa.eu.int/comm/health/ph\\_overview/Documents/key01\\_mobility\\_en.pdf](http://www.europa.eu.int/comm/health/ph_overview/Documents/key01_mobility_en.pdf).
- 3) Stryer D, Clancy C. Patient safety. *BMJ* 2005;330:553-4.
- 4) Kohn LT, Corrigan JM, Donaldson MS Eds. *To err is human: building a safer health system*. Washington D.C.: National Academy Press, 2000.
- 5) Department of Health. *An organisation with a memory: Report of an expert group on learning from adverse events in the NHS chaired by the Chief Medical Officer*. Crownright. Department of Health. HMSO. 2000.