Patient safety: a European Union priority

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This article is based on a lecture given at the Royal College of Physicians on 21 July 2008 by Lee McGill BSc(Hons), a seconded national expert to the Directorate General for Health and Consumers, European Commission, from the Department of Health. This article has been updated to reflect European Union policy developments in the second half of 2008.

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ABSTRACT – Every year in the 27 member states of the European Union, patients are harmed when receiving healthcare. Sometimes this is the fault of individual or multiple healthcare workers but more often than not organisational or system failures are to blame. The injuries and deaths from unsafe healthcare can never be completely eradicated. However, steps can be taken by policymakers and those responsible for the delivery of healthcare in all countries to reduce the human and economic burden of adverse events in all healthcare settings. Patient safety is an area of healthcare where economies of scales can be achieved through a European Community approach to tackling the problems. Share experiences, expertise, best practice and research findings can help member states to improve the safety of their health systems. This is why the European Commission put forward its patient safety proposal at the end of 2008.

KEY WORDS: Council recommendation, European Commission, European Union, patient safety

The patient safety problem in Europe

People access healthcare when they are sick to make them better. Yet some of those people are harmed by that healthcare. Patient safety, defined by the World Health Organization as 'freedom for a patient from unnecessary harm or potential harm associated with healthcare', is an issue of increasing concern to global healthcare systems. This is unsurprising as patient safety must surely be the foundation of any high-quality health system.

In 2008, RAND Europe estimated that, in the 27 European Union (EU) member states, between 8% and 12% of patients admitted to hospital suffer from adverse effects while receiving healthcare.[1] In the UK, a 2000 report by the Chief Medical Officer revealed that patient safety was a major problem.[2] Data showed that adverse events occurred in around 10% of hospital admissions, equivalent to around 850,000 adverse events a year, in the NHS in England. As well as the human cost through suffering and loss of life, the report also highlighted the potential economic costs of unsafe care. It is reported that the NHS pays out around £400 million a year to settle clinical negligence claims with a potential liability of around £2.4 billion for existing and expected claims. These are huge amounts, representing money that could be better spent elsewhere in the health system, for example on patient care.

Subsequent studies in Denmark, Spain and France support this estimate that around one in 10 patients will be harmed by hospital care. Unsafe care also takes place in non-hospital settings, such as in primary and community care, although there is currently less available data to support this.[3–5]

'First, do no harm' is one of the core principles of medicine but medicine is not an exact science. Some adverse events are, of course, linked to the intrinsic risks of necessary interventions or treatments. However, studies in some EU countries show that harm to patients is preventable, perhaps by as much as 50%. For example, according to the Spanish national study, of the 9.3% of hospital patients in Spain in 2005 who suffered adverse events, 42.8% of these events were deemed preventable. The French national survey of inpatient adverse events found that in the course of seven days' observation per unit, at least one adverse event was observed in 55% of surgical and 40% of medical units. Of those events, 35.4% were considered to have been preventable.

According to respondents to the European Commission's public consultation on patient safety in 2008, the most common adverse events include:

- healthcare-associated infections (HCAIs)
- medication-related errors
- surgical errors
- medical equipment failures
- errors in diagnosis
- failure to act on the results of tests.[6]

While the results of such a consultation will have their limitations in terms of their subjectivity, this list does sit well with the type of threats to patient safety commonly identified in the literature and by patient safety experts.

So why are so many patients harmed by European health systems each year? Does this indicate that those systems are full of incompetent, badly trained or negligent health professionals? Not at all. It must be acknowledged that a small proportion of the preventable adverse events are down to errors by one or multiple healthcare workers and, in such cases, member states should of course have appropriate disciplinary and remedial systems in place. However, it is a widely held view that the vast majority of harm

to patients arises from systemic or organisational factors in busy, complex healthcare settings.

Therefore, most approaches to tackling patient safety, including that of the European Commission, now focus on trying to encourage a blame-free patient safety culture in which healthcare workers and patients feel comfortable reporting when things go wrong, so that lessons can be learned and solutions and interventions developed to improve the safety of patients.

The current situation in EU member states

Most EU countries do not routinely collect data at the national level on the type, causes and extent of adverse events in their healthcare systems and so, in most countries, there is no clear overall picture of the safety of patients. However, we do know from work by the SImPatIE project and RAND Europe that the 27 EU member states have made varying efforts to counter the patient safety problem with different strategies, structures, policies and processes.[7]

Patient safety is perhaps still too immature in the EU for us to make definitive judgments about the causal links between patient safety measures in place and the number of preventable adverse events which occur. However, patient safety experts, including the World Health Organization's World Alliance for Patient Safety, suggest that a number of structures and policies should help to reduce harm to patients. For example, a strong patient safety system could include: a national reporting and learning system; the embedding of patient safety into the curricula of health professionals; a common classification or taxonomy for patient safety; the use of patient safety indicators; a strong research base; and the involvement of patients in patient safety policymaking and reporting.

RAND Europe, building on the work of the SImPatIE project and based on a literature review and interviews with patient safety experts in most EU member states, attempted to rate countries according to the structures, policies and systems each had in place to improve patient safety. Only four countries, including the UK, were given RAND's highest ranking of 'exemplary' but it is the opinion of the European Commission that all 27 member states can do more. Errors and adverse events can never be completely eradicated in health systems – healthcare is a risky undertaking – but it would seem a logical step for countries to share their best practice with other member states.

Current EU action on patient safety

In 2005, the Luxembourg and UK Presidencies of the Council of the EU chose patient safety as a key health theme. Following the strong message that patient safety was now high on the European health agenda, the European Commission established a patient safety working group of the High Level Group on Health Services and Medical Care. This is a forum for discussion and the sharing of expertise and best practice among member states, key pan-European stakeholders (representing patients and health professionals), and international organisations with a patient safety focus. The UK co-chairs the meetings of this working group, through the Department of Health (DH) or the National Patient Safety Agency (NPSA). The group put forward a recommendation on patient safety in 2007, for which all member states subsequently signalled support through the High Level Group.

Patient safety is not a new policy area for the European Commission. Specific aspects are already addressed at European Community (EC) level, for example in the areas of the safety of medicines, medical devices, human tissues and cells, human organs, blood and blood components. There is existing, or planned, EU legislation in all these areas. None of these policy initiatives, however, have sought to address all possible causes of adverse events and overarching patient safety cultures.

A number of EU co-funded projects have also targeted patient safety, through the Commission's various funding mechanisms. A big step forward for patient safety at the European level was taken in 2008, when, for the first time, an EU network for patient safety, EUNetPaS, launched its 30-month programme.[8] This project involves all 27 member states and is led by the French Haute Autorité de Santé. It is running a number of work packages including: the setting up of a pan-EU rapid response mechanism and solutions bank; effective reporting and learning systems; the establishment and maintenance of patient safety cultures at all levels of healthcare planning and delivery; a core European curricula for patient safety in the higher education of health professionals; and a pilot to test medication safety solutions. Both the DH and the NPSA are partners in this project.

While this project is most welcome and its outcomes eagerly anticipated, it represents more of an operational mechanism than a high-level political commitment, and like all EU co-funded projects, is time limited.

The proposal from the European Commission

The Commission strongly believes that the EU can play an important role by lending its support to countries in their efforts to improve patient safety. In particular, the EU can provide political weight and visibility to the topic, achieve economies of scale by Community-wide collection of data and sharing of best practice, and can strive for sustainability of action on patient safety at an EC level. This is why the European Commission chose to prioritise patient safety in 2008, culminating in its communication and proposal for a Council recommendation on patient safety, including a specific focus on the prevention and control of HCAIs. The proposal was adopted by the Commission in December 2008.

The Commission's proposal is intended to bring about a sustained political commitment from all EU countries to address the patient safety challenge. Member states will be expected to implement a series of recommendations, either individually or collectively, to take practical steps to reduce harm resulting from all types of adverse events in all healthcare settings. The proposal contains a specific set of recommendations aimed at trying to prevent and control one of the biggest causes of adverse events in EU healthcare, HCAIs.

In drafting the proposal, the Commission has been careful to fully respect the competence of member states in the area of healthcare. This initiative does not take away any of the powers of countries in this field. A Council recommendation as a legal instrument will allow countries sufficient freedom to organise healthcare nationally as they do at present, while addressing the major challenge of improving patient safety and reducing preventable harm, including from HCAIs. Furthermore, article 152 of the EU treaty allows for the EC to encourage cooperation between countries and lend support to their action.

The recommendations put forward by the Commission were drawn up following a long period of engagement with interested parties. As mentioned previously, a public consultation on general patient safety issues, concerns and experiences took place over an eight-week period between March and May 2008, which followed an earlier public consultation in 2005/6 on HCAI-related issues. The patient safety working group's recommendation from 2007 was taken as the starting point for the recent proposal. On the HCAI aspect, a separate group of experts from member states played a key role in helping to shape those recommendations.

Proposed actions for member states

The Commission has put forward a number of suggested actions for member states, in the following areas:

- establishing, or further developing, national patient safety policies and programmes
- encouraging countries to set up or strengthen comprehensive blame-free incident reporting and learning systems
- promoting the integration of patient safety into the education, training and continuing professional development of healthcare workers
- informing and empowering patients and citizens on patient safety issues
- sharing knowledge, experiences and best practice
- classifying, codifying and measuring patient safety
- developing and promoting research on patient safety.

In addition, for HCAI specifically, member states are recommended to:

- implement infection prevention and control measures
- enhance infection prevention and control at the level of healthcare institutions
- establish or strengthen surveillance systems
- support research.

Proposed actions for the European Commission

Work can also be taken forward at the EU level to assist member states in their efforts to improve patient safety. For example, the Commission intends to:

- develop an EU-wide classification of key patient safety terminology
- develop an EU-wide set of patient safety indicators
- strengthen surveillance on HCAI, together with the European Centre for Disease Prevention and Control
- develop guidance on the prevention and control of HCAI.

While it is true that the UK is regarded as one of the countries leading the patient safety debate in Europe, this does not mean that it cannot learn from the experiences of others. The pooling of expertise and best practice, as well as comparisons at the EU level anticipated by the proposal for a Council recommendation, can help to improve patient safety cultures and performance in all member states.

Relationship with other current EU health initiatives

Patient safety is also relevant to the European Commission's proposal for a Directive on the Application of Patients' Rights on Cross-Border Healthcare and the Green Paper on the EU Workforce for Health, both published in 2008. These initiatives will complement each other.[9,10]

The draft directive is currently being discussed in the Council of Ministers so it is not possible to comment on its final content. However, at the time of writing, the draft makes it clear that it is the responsibility of the member state on whose territory healthcare is provided to define clear standards for patient safety, which should be made available to patients. The draft, however, does not attempt to go into detail about how patient safety can be improved. The proposal for a Council recommendation on patient safety is not specifically aimed at cross-border patients but safety improvements in all member states will of course benefit all patients.

The Green Paper and the ongoing public consultation will identify the key challenges EU health systems face in relation to their health workforce, and central to those challenges is the need for countries to have sufficient numbers of appropriately educated and trained healthcare workers to minimise risk to patients from unsafe care.

When will the proposal come into effect?

The patient safety proposal was submitted for debate and scrutiny to the Council of Ministers (who must formally adopt it) and for opinions to the European Parliament, the Committee of the Regions and the European Economic and Social Committee, in December 2008. At the time of writing, no accurate prediction can be made as to when this process will come to an end but it is hoped that the recommendation may secure Council adoption during the Czech Presidency of the EU later in this first half of 2009.

Conclusion

Adoption of the recommendation in Council by member states will signal a political commitment to further action on patient safety. Implementation can then commence at local, regional and national levels in all EU countries, as well as at the EU level.

This should lead to real benefits for European citizens, who, after all, are all potential patients. The result will be safer healthcare and greater confidence in the safety of that care. The reduction in physical and psychological suffering to patients and their families, the positive effects on healthcare workers through a healthier patient safety culture, and the potentially huge reduction in the economic burden of unsafe care make EU action on patient safety a very important addition to the great efforts already being made by member states.

References

1 Conklin A, Vilamovska A-M, de Vries H, Hatziandreu E. *Improving patient safety in the EU. Assessing the expected effects of three policy areas for future action.* Cambridge: RAND, 2008.

2 Department of Health Expert Group. *An organisation with a memory: report of an expert group on learning from adverse events in the NHS chaired by the Chief Medical Officer.* London: DH, 2000.

3 The Danish Society for Patient Safety. *Patient safety in Denmark: past, current and future activities.* Copenhagen: DSPS, 2005. www.sum.dk/publikationer/patient_safety/patient_safety.pdf

4 Aranaz JM, Aibar C, Vitaller J, Ruiz P. *National study of adverse events related to healthcare in hospitals.* ENEAS, 2005.

5 Michel P, Quenon JL, Djihoud A, Tricaud-Vialle S, de Sarasqueta AM. French national survey of inpatient adverse events prospectively assessed with ward staff. *Qual Saf Healthcare* 2007;16:369–77.

6 *Report on the Open Consultation on Patient Safety in the European Union.* Brussels: European Commission, 2008. http://ec.europa.eu/health/ph_systems/docs/patient_consult_frep_en.pdf

7 van Beek B, Cucic C. *Safety IMprovement for PATients In Europe Project findings, lessons and future.* SIMPATIE, 2007.

8 www.eunetpas.eu

9 COM (2008) 414 final.

10 COM (2008) 725.