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HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate C - Public Health and Risk Assessment
C5 - Health strategy

HIGH LEVEL GROUP ON HEALTH SERVICES AND MEDICAL CARE – PATIENT SAFETY WORKING GROUP (PSWG)

Document: Recommendation on Patient Safety	
Date: 2 October 2007	**Reference:**
To: Members of the High Level Group	**From:** Members of the Patient Safety Working Group
Action: For High Level Group Members to Endorse. (Subsequently endorsed by all EU 27 by end of 2007)	

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Subject: **RECOMMENDATION TO THE HIGH LEVEL GROUP ON HEALTH SERVICES AND MEDICAL CARE ON IMPROVING PATIENT SAFETY IN THE EUROPEAN UNION, FROM THE PATIENT SAFETY WORKING GROUP**

1. OBJECTIVES

1.1 The key objective of this recommendation to the High Level Group from the Patient Safety Working Group is to provide a possible European framework towards improving patient safety in all sectors of health care (e.g. in primary, secondary and community care, in long-term as well as acute care) in all Member States and to identify key areas where patient safety action is most effective and should be promoted at national and European levels.

1.2 Although patient safety is widely recognized as an important issue in health care across Member States and at an EU level, there is a need for further commitment towards setting up effective policies on patient safety and quality of health care services in general. In order to ensure European added value in the field of patient safety it is crucial that all Member States are involved in this work. Action at a European level should build on work undertaken by international bodies such as The World Health Organization (WHO), the Office for Economic Cooperation and Development (OECD) and the Council of Europe (CoE) and exploit, where appropriate, results of relevant research projects at the European level, two such examples being the Commission-funded SIMPATIE[1] (Safety Improvement for Patients in Europe) and MARQUIS[2] (Methods of Assessing Response to Quality Improvement Strategies) projects , and integrate their findings in further work.

1.3 Linked to this main objective, a set of potential solutions to address the problem of unsafe care should be identified and shared among Member States by ensuring effective collaboration in this field.

1.4. If the High Level Group endorses this recommendation, the working group suggests that an appropriately re-worded version of this recommendation is attached as an Annex to the High Level Group's Annual Report to the Health Council in 2007.

2. BACKGROUND

2.1 Europe's health systems are facing major challenges. While health care has become more effective it has also become more complex, with greater use of new technologies, medicines and treatments. Those health systems are treating older and sicker patients who often present with significant co-morbidities requiring more and more difficult decision-making in health care settings. Economic pressure on health systems is constant, leading to busy and pressurized health care environments.

2.2 In such circumstances, things can and do go wrong. Unintended harm to patients may result from a clinical procedure or as a result of a clinical intervention (or indeed lack of intervention). Errors in implementing the correct processes of care can also lead to injury. Sometimes the harm that people experience is serious and sometimes people die.

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[1] SIMPATIE: Safety Improvements for Patients in Europe, www.simpatie.org

[2] MARQUIS: Methods of Assessing Response to Quality Improvement Strategies, an EC Research Projct under the Scientific Support to Policies activity of the 6th Framework Programme (Project ref: SP21-CT-2004-513712)

2.3 No patient safety knowledge is more important than how to prevent harm to patients. Despite the increased risks of modern health care, there is an increasing body of knowledge about why adverse incidents and errors occur and about interventions and techniques which can be used to respond to those incidents, learning from their use to prevent harm to future patients.

2.4 Trying to ensure the safest possible patient care is as old as medicine itself. "First, do no harm" is one of the core principles of medicine. However, the transformational change now required to reduce risks to patients and improve safety can only move forward with strong and committed leadership at national and European levels.

2.5 Safety of health care services is valued highly by European citizens. According to the Eurobarometer survey published in January 2006, almost four in five European Union (EU) citizens (78%) consider medical errors as an important problem in their country.[3]

2.6 Since the late 1980s, several international studies show that about 10% of hospital admissions involve some kind of harm to patients. In the USA, the Institute of Medicine report *To err is human* (1999)[4] has shown that "medical errors" cause between 44,000 and 98,000 deaths annually in hospitals in the USA - more than car accidents, breast cancer or AIDS.

2.7 A number of studies have been carried out in the EU confirming that patient safety is a major concern in Europe. For example, the UK Department of Health, in its 2000 report, *An organisation with a memory*[5], estimated that adverse events occur in around 10% of hospital admissions or about 850,000 adverse events a year and more recently other countries such as Spain in its National Study of Adverse Events (ENEAS)[6] in 2005, France and Denmark have presented the results of adverse incident studies with similar results. A report by the Hospitals for Europe's Working Party on Quality Care in Hospitals (HOPE) has also estimated that every tenth patient in hospitals in Europe suffers from preventable harm[7].

2.8 It is estimated that a substantial proportion of the adverse events which take place annually in health care settings in the EU are preventable and effective interventions can be made to reduce the effect of error on morbidity and mortality.

2.9 It is difficult to obtain exact numbers. This not only reflects some of the methodological difficulties in counting adverse events, but also the fact that only a few Member States have national patient safety reporting systems and/or have undertaken detailed research on the prevalence of adverse events. What we do know from studies is that similar types of health care intervention-related adverse events happen in all health care systems, despite differences in how they are organized and financed.

2.10 Member States, as well as stakeholders, are becoming increasingly aware of the scale and scope of the patient safety problem in the European Union. For example, the Luxembourg and UK Presidencies had patient safety as a headline theme.

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3 http://ec.europa.eu/health/ph_information/documents/eb_64_en.pdf

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 Expert Group. *An organisation with a memory: report of an expert group on learning from adverse events in NHS*. Chairman: Chief Medical Officer London: The Stationery Office, 2000.

6 http://www.msc.es/en/organizacion/sns/planCalidadSNS/docs/eneas2005Baja.pdf

7 Standing Committee of the Hospitals of the EU. *The quality of health care/hospital activities: Report of the Working Party on quality of care in hospitals of the subcommittee on coordination*. September 2000.

2.11 Under the High Level Group on Health Services and Medical Care, a specific Working Group on Patient Safety has brought together 25 (now 27) Member States, the key stakeholders and the main international organizations working in this area[8].

2.12 International organizations such as the Council of Europe (CoE), the World Health Organization (WHO) and the Organization for Economic Cooperation and Development (OECD) in particular have done much work in developing patient safety expertise and tools on which EU Member States can build in their national programmes and policies.

2.13 All these key players have also shown strong commitment to set up programmes and policies to enhance patient safety in health care and as a group provide the strategic oversight and leadership of patient safety projects at an EU level. There is a need for and a willingness to put in place a true pan-European Union approach to tackling the challenge of preventing avoidable adverse events.

2.14 The Working Group has discussed and developed a clear framework for taking the patient safety agenda forward. The framework covers three main pillars or streams of action:

i) The Patient Safety Working Group;

ii) The recommendation for Patient Safety;

iii) A European Network for Patient Safety.

3. PRINCIPLES

3.1 Member States, of course, have the primary responsibility in this area. The role of the European Community is to provide support and assistance for their actions.

3.2 This is clearly set out in Article 152(2) of the Treaty on European Union[9] which states that "The Community shall encourage cooperation between the Member States in the areas referred to in this Article, and if necessary, lend support to their action. Member States shall, in liaison with the Commission, coordinate among themselves their policies and programmes……The Commission may, in close contact with Member States, take any initiative to promote such coordination."

3.3 Article 152(5) states that "Community action in the field of public health shall fully respect the responsibilities of the Member States for the organization and delivery of health services and medical care."

3.4 In line with this, Member States are called upon to make a commitment to firm action on patient safety at national, regional and local levels. The Commission would then support and help to coordinate and facilitate Member States' activities.

3.5 This recommendation sets out the roles for, and aims of, each of the three pillars which will take forward the proposals and views of the Patient Safety Working Group.

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[8] European Patients Forum (EPF), Standing Committee of European Doctors (CPME), European Federation of Nurses Associations (EFN), Pharmaceutical Group of the European Union (PGEU) and European Hospital and Healthcare Federation (HOPE), international organisations active in this field including the World Health Organisation (WHO), Council of Europe and the Organisation for Economic Co-operation and Development (OECD). Other relevant Commission services actively involved in the work include Directorates General for Research, Information Society, Enterprise and Industry and Education and Culture.

[9] *European Union Consolidated Versions on the Treaty of the European Union and of the Treaty Establishing the European Community*, Official Journal C 325 of 24.12.2002

4. KEY AREAS FOR ACTION FOR MEMBER STATES

Whilst recognizing that Member States are responsible for the funding, organisation and structure of their own health care services, the Patient Safety Working Group believe that further commitment from Member States, individually and collectively is required to improve patient safety and reduce harm at a national and European Union level. For each of the areas of patient safety listed below, a strategic approach needs to be developed at the appropriate level with appropriate arrangements to measure and monitor progress. The proposed European Network should promote the exchange of best practice in each of these areas.

At a national level

4.1 Support development of national policies and programmes

- Identify the competent authority/ies responsible for patient safety in each Member State, including those where political accountability and responsibility for policy-making, implementation and monitoring are spread across more than one competent authority.
- Embed patient safety in national health policy programmes and ensure that patient safety is at the core of the health care quality agenda at national, regional and local levels.
- Ensure political leadership and an acceptance of the challenge of addressing patient safety.
- Support the development of a preventive and proactive approach to the design of safer systems, processes, medicines and equipment.

4.2 Empower citizens and patients

- Involve patient representatives at all stages in designing policies and programmes on patient safety at all levels.
- Support patient organizations in their activities to develop and implement joint strategies on patient safety.
- Empower citizens and patients by providing them with information and education on patient safety and their rights to safe health care services.

4.3 Develop positive patient safety cultures, leadership and clinical governance at the health care setting level

- Identify ways to support health care providers across all sectors in applying quality systems and risk management principles and standards, in order to achieve intra- and inter-organisational continuity of care and safer and cleaner health care systems.
- Develop and embed a culture of safe care in health care management and leadership, including at board level, through patient safety awareness, education and training, and ensuring that patient safety is built into clinical governance systems and leadership models.
- Build responsibility and accountability for safer health care into the performance management and appraisal of responsible managers and board member(s).

- Develop policies and professional practices to involve patients along the safety pathway. (Links also to 4.7.)
- Promote a culture of, and develop models to ensure, effective multi-disciplinary practices in health care on safety. (Links also to 4.7.)

4.4 Promote education and training of health professionals and all other staff

- Encourage multi-disciplinary patient safety education and training of health professionals and all staff working in health care settings, embedding extensive patient safety education in their under-graduate, post-graduate and continuing professional development.
- Establish effective links and systematic collaboration with universities and other organisations involved in professional education in health care. Such collaboration shall ensure that safety and quality issues receive proper attention in higher education curricula, and ongoing education and training.
- Consider the development of core competencies in patient safety (i.e. the core knowledge, attitudes and skills required to achieve safer care) for dissemination to all involved in the delivery of health care, including health professionals, support staff and managers.

4.5 Establish effective reporting and learning mechanisms

- Establish effective reporting and learning systems on adverse events in health care in order to establish the extent of error and adverse events, monitor trends, develop effective interventions, observe changes following the introduction of those interventions and share learning on what interventions are effective (as well as those that are not). This needs to work alongside and complement other adverse incident reporting systems, such as the pharmacovigilance and medical device vigilance systems, already in operation in the areas of medication and medical device safety respectively. Periodic analysis of the effectiveness and appropriateness of these various systems should take place.
- Establish a transparent, open and honest patient safety culture in health care by clarifying legal issues around health professionals' liability and creating an environment where it is easy and safe to report and learn from mistakes through blame-free reporting. This type of reporting needs to be differentiated from Member States' disciplinary systems and procedures for health care professionals; for example, in cases of negligence. Patient safety reporting systems themselves should not be linked to punitive measures, including the withholding of remuneration from healthcare professionals

4.6 Develop and enhance redress mechanisms for patients affected by adverse events.

- Establish fair compensation and/or redress systems as appropriate for patients (or families of victims) affected by health care-related harm, including those from other Member States. Such systems should also be fair to health care professionals and provide value-for-money for health care funders.
- Inform patients and their families how those systems can be accessed by them.
- Monitor the effectiveness and efficiency of those systems.
- Align national systems for dealing with health care-related negligence with the broader patient safety and risk approach.

At a national and European level

4.7 Develop the knowledge and evidence base for patient safety

- Work towards common definitions and terminology at the European Union level, contributing to the development of, and taking into account, international standardisation activities on risk taxonomy, such as the *International Classification for Patient Safety* being developed by WHO and the CoE's work in this area.
- Map and review national patient safety policies and initiatives to provide a basis for mutual sharing of information and knowledge.
- Review and compare existing indicator systems according to their feasibility and relevance to safer health care.
- Develop and consider a minimum set of common core and valid indicators at a European level, building on the recommendations of work in this area undertaken by international organizations such as OECD.
- Develop and promote a research agenda on patient safety[10], in particular at the European level under the Health Theme of the 7th Framework Programme for Research[11] , including in the very important areas of effective interventions and assessments of the economic impact of unsafe services on health care systems and Member States' economies more generally.
- Review the results of relevant research projects at the European level and integrate their findings as a basis for refining the research agenda.

4.8 Use that knowledge and evidence to implement change for safer care

- Promote the use of research and other evidence-gathering to develop efficient interventions and communicate solutions across the EU.
- Pool data, information and expertise on patient safety and wider quality strategies to share good practice, through various mechanisms, including electronic forums, conferences and seminars, and the sharing of patient safety alerts.
- Use information and communication technology (ICT) to support information collection, processing and sharing, in order to support the integration of services and continuity of care.
- Encourage investment in design for patient safety, particularly in the pharmaceutical and medical devices sectors, including measures to address the problem of look-alike and sound-alike medicines.

4.9 Engage and involve stakeholders

- Engage stakeholders such as patients, health professionals, academia, health care managers and service providers in improving patient safety in health care settings.
- Involve relevant industry sectors in concrete actions with a key aim to design, develop and manufacture safer products for use in health care settings.

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[10] International conference on *Patient Safety Research: Shaping the European Agenda*, 24-26 September 2007 – www.patientsafetyresearch.org

[11] Decision No 1982/2006:EC of the European Parliament & of the Council of 18 December 2006 concerning the Seventh Framework Programme of the European Community for research and technological development and demonstration activities (2007-2013), OJ L412/1.

- Ensure effective collaboration with key European and international organisations, notably WHO, OECD and CoE, to ensure a common approach towards safe care.

5. IMPLEMENTATION AND MECHANISMS

5.1 The European Commission, in its role as a coordinator and facilitator, can help Member States to achieve these goals.

5.2 In order to ensure effective use of scarce resources and effective co-ordination of activities, it is important to establish at what level action in each of the areas described in paragraphs 4.1 to 4.9 above should be best focused.

5.3 The Patient Safety Working Group recommends that a single integrated umbrella Network should be set up to support Member States and co-operation in the field of patient safety at a EU level.

5.4 The Network would connect all Member States and provide a platform for the development of patient safety projects in the areas set out above, for exchanging good practice and experiences among Member States.

5.5 The report of the High Level Group to the Health Council at the end of 2006 has also highlighted the need for a political commitment at Member State level, in order to ensure consensus on this approach.

5.6 Further details about how a EU Patient Safety Network might work in practice can be found in the attached **Annex**.

6. CONCLUSION

6.1 This recommendation sets out a possible framework for the development and implementation of a strategy for patient safety at national and EU levels, and provides an overview of the key mechanisms that will be used to achieve EU and Member State goals across a range of patient safety issues. You are asked to note the proposed way forward in attempting to tackle the patient safety challenge at national and European levels.

6.2 By endorsing this recommendation, you are providing a statement of strong leadership and commitment to treating patient safety as a high priority for Member States to address at both national and EU levels.

6.3 The Patient Safety Working Group will continue to be to develop proposals and suggest national and European action under the framework for patient safety, at least in the short-term. It will provide directions for future work, including giving its steers on, and its endorsement to, proposals relating to the proposed EU Network.

6.4 Following the Consultation Regarding Community Action on Health Services[12] which ended on 31 January 2007, the Commission will consider appropriate ways to respond to the patient safety issues raised during that consultation process.

[12] http://www.ec.europa.eu/health/ph_overview/co_operation/mobility/community_framework_en.htm

ACTION FOR THE HIGH LEVEL GROUP

7.1 Commitment from Member States is vital to ensure consensus on the approach set out in this recommendation. The Patient Safety Working Group asks the High Level Group to consider and endorse this recommendation for patient safety.

7.2 Following endorsement by the High Level Group, the Patient Safety Working Group can develop appropriate and concrete proposals to achieve the patient safety objectives set out in the recommendation.

7.3 The High Level Group will receive regular updates from the Patient Safety Working Group on progress in the area of patient safety at the European level, under the overarching framework described.

Annex

A proposed EU Network for Patient Safety

1. A Patient Safety Network could be organised in a number of different ways but, to be effective it must involve and represent all Member States in its work, taking account of patient safety projects covering the key areas for action at national and European levels.

2. The Network would provide a platform for collaboration and networking between Member States, international organisations and stakeholders to identify and exchange good practices in order to support key national action such as the development of patient safety cultures, the strengthening of clinical governance and leadership, embedding patient safety in education and training and developing and sharing patient safety solutions and interventions.

3. It would make use of work which other organisations have carried out or are currently undertaking. For example, WHO, through its World Alliance for Patient Safety, has done much work on developing an international classification system (or taxonomy) for patient safety, and OECD is running a project to develop a set of patient safety indicators.

4. The Network should also have an outward-facing role. The lessons learnt by collaboration between EU Member States through the Network, in the area of patient safety solutions work, for example, could be shared with countries outside the EU, through close working with WHO's European Regional Office, which like WHO's World Alliance for Patient Safety and OECD, will be represented on the Network.

5. In support of the establishment of this kind of EU level collaboration, the Patient Safety Working Group and partners such as the Haute Autorité de Santé in France, developed a proposal for an EU Network for Patient Safety through a project bid for funding from the Public Health Programme, in May 2007. That project bid, together with others received, is under consideration by the Commission.