

1. Thank you for inviting me here to speak on this very important topic.
2. Patients and health professionals have great expectations on what can be achieved in health care. Furthermore, people across the EU, whether they seek care in other Member States or remain in their own countries, expect the care they receive to be of high quality and safe.
3. Against this, as the European healthcare system is becoming so complex, and interoperability is sought between previously isolated ICT systems, the ultimate safety and risk implications of changes anywhere in the system are already very difficult to foresee.
4. Studies from around the world consistently suggest that about 10% of hospital admissions involve some kind of harm to patients and that 50% of these patient safety incidents could have been avoided, if only lessons from previous incidents had been learned.
5. Very little is known about the direct and indirect costs associated with health care delivery inefficiencies and failures. In the US, total national costs of preventable adverse events (medical errors resulting in injury) are estimated to be between \$17 billion and \$29 billion, of which healthcare costs represent over one-half.

6. According to a Markle Foundation report, the U.S. healthcare system spends \$30 billion to as much as \$293 billion annually on unnecessary paperwork. In the UK, patient safety incidents cost the NHS an estimated £2 billion a year in extra bed days. Hospital acquired infections add a further £1 billion to these costs.
7. Despite growing interest in the safety of patients, there is still not enough awareness of the problem of adverse events and the best ways to minimize them.
8. Capacity for reporting, analysing and learning from experience is hampered by lack of methodological uniformity in identification and measurement, inadequate adverse event reporting schemes, concerns over data confidentiality, the fear of professional liability, and weak information systems.
9. Emerging new technologies, which potentially can bring remarkable benefits for patients, have also major cost implications.
10. Today, the new thinking on the safety of patients places the prime responsibility for adverse events on deficiencies in system design and organization, rather than on individual health professionals or products. A comprehensive approach is essential to prevent adverse events.

11. The Luxembourg and UK Presidencies gave a strong impetus for the European level action to improve patient safety.

The Luxembourg Declaration

12. The Luxembourg Presidency cosponsored, together with the European Commission, the first European Conference of Patient Safety organized by the Standing Committee of European Doctors in April in Luxembourg.
13. As a result of this the “Luxembourg Declaration” made a key number of recommendations to EU institutions, national authorities and healthcare providers key areas where progress should be made; from collecting data and information concerning adverse events in health care to ensuring that risk management procedures are in place.
14. In particular, health professionals should have working conditions where pharmaceuticals and medical devices can be used more safely and accurately.
15. It became clear at the conference that rather to continue with a “blame culture”, all key players; health professionals, hospital managers, patients, their families, national authorities and policy makers should consult, collaborate and do their part to face the challenge and in learning from near misses and adverse events.

UK Presidency

16. The UK Presidency built on this in seeking to agree priorities for actions, initiate concrete mechanisms and programmes of activity and promote greater alignment of patient safety initiatives across Europe.
17. A highly successful patient safety summit held last November in London highlighted current action on patient safety, bringing together hundreds of experts, patients, clinicians and politicians.
18. Discussions focused on a number of areas, including looking at the agenda from the perspective of patients themselves, i.e. how we empower patients to play an active role in their own safety. It also examined gaps in the knowledge base and priorities for research effort, where we can learn from high-risk industries such as aviation, oil and transport, and further looked at how we should address clinical priorities on such diverse issues as medical devices, changing organizational structures and tackling healthcare related infection.
19. There was a wide consensus that action on patient safety is imperative at all levels if people are to have a right to the same high level of care in all countries as they move freely across borders.

EU action

20. The Community is taking active steps to facilitate actions at EU level which will assist Member States in their efforts to tackle patient safety.

21. The safety of medicinal products has been improved over the years through European Directives and Regulations, with better structured national Adverse Events Reporting systems and an increasingly strong co-ordination of responses via the European Medicines Agency. Most recently in December last year political agreement was reached on the Commission proposal for the Regulation on Medicinal Products for Paediatric Use, ensuring that medicines will be routinely tested for use with children.

22. Biological substances such as blood, tissues and organs, which are of high therapeutic value, may also carry risks for the recipients. Here the Community contributes to reducing such risks by adopting legislation on quality and safety of these substances. Similar improvements should progressively be applied to medical devices.

23. Nevertheless, the organisation of Health services and the delivery of Health care cannot be regulated at European level under the Public Health Article of the EU Treaty of Nice (Article 152). Therefore most patient safety issues can only be addressed by non binding instruments such as European co-operation (Open method of co-ordination), joint projects, guidelines and recommendations.

24. In the area of Healthcare Acquired Infections, for example, health systems across Europe are facing similar issues. Healthcare-associated infections affect an estimated 1 in 10 patients and lead to considerable increase in illness, mortality and costs. Cooperation at European level has great potential to bring benefits, both to individual patients and to health systems overall. The Commission Directorate General for Health and Consumer Protection developed a basic text, in the form of a recommendation, on improving patient safety by prevention and control of healthcare-associated infections with the help of a group of international experts, discussed it with the Epidemiological surveillance group of the European Network for Communicable Diseases and presented it to the patient safety working group of the High Level Group on Health Services and Medical Care.

Since addressing this problem requests a truly multi-sectoral approach, DG SANCO organised a public consultation, which was open until the beginning of the year. DG SANCO C is now examining the comments, some of them accompanied by in depth expert opinion on the question,

which it received following the public consultation and will revise the text in the light of these comments in collaboration with experts from the Member States. Possibly the Commission can make a proposal for a Recommendation during the Finnish presidency and it would then be under the following German presidency to adopt it as a Council Recommendation.

25. Our Public Health Programme is presently funding a mapping exercise across 20 EU Member and Accession States called SIMPATIE (Safety Improvements for Patients in Europe). This will result in a systematic overview of activities related to patient safety in European countries, and from this the project team will develop a set of indicators and outcome measures for patient safety and also development of a toolkit for safety improvement.

26. Also within the Public Health Programme the Commission is cofinancing the European Network for Health Technology Assessment, which coordinates the efforts of 27 European countries including 24 Member States of the European Union in evaluating health technology in Europe. The Network aims to connect public national HTA agencies, research institutions and health ministries, and will enable an effective exchange of information among Member States on the clinical effectiveness and safety of new or established health technologies.

27. The network will also be in a good position to monitor emerging health technologies and identify those that will have greatest impact on health systems and patients, and to establish a support system to countries without institutionalised HTA activity.
28. There are a number of research areas proposed in the seventh Framework Programme from DG-Research. It is proposed for example that tools be developed to enable mining complex clinical data for research into patient safety, i.e. to discover instances where patient safety has been endangered and identify the causes.
29. These techniques might be applied to existing electronic health records and also to information not yet coded in a standard electronic format.
30. In addition, a programme of research is proposed to build health pathway models which encompass citizen / patient passage through clinical pathways, with predictive ability, focussing on the prior identification of all risks to a citizen's future health.

EU working group on patient safety

31. A report in 2003 following the high level reflection process on patient mobility in the European

Union represented a political milestone in recognising the potential value of European cooperation in helping Member States to achieve their health objectives. The primary mechanism for taking work in this area was to establish a High Level Group on health services and medical care. Safety issues are included within the remit of its work.

32. This EU working group on patient safety is chaired jointly by Sir Liam Donaldson from the UK and Dr Andrej Robida from Slovenia, and includes in addition to national authorities representatives of patients, doctors, nurses, pharmacists and hospital managers. The aim of the working group is to identify patient safety areas where European level collaboration and coordination of activities could bring added value. In practice, five priority areas have been identified for initial concrete work streams.

33. The first objective of the Group is to have a broad discussion on developing a European strategy on patient safety, and the Commission is preparing a draft strategic paper to provide a basis for structured discussions of patient safety in the working group. This exercise will also feed into the more general development of safe, efficient and high quality health services in the EU.

34. In parallel to this strategic thinking, the working group has an important task to consider and develop proposals for five priority areas which it set out in its work plan for the current year.

35. Firstly the Group is looking at reporting and learning systems of adverse events in health care by developing common approaches for reporting policies and strategies and by establishing a European-wide collation, analysis and sharing of information on patient safety problems. Several collaborating centres are participating in developing a project in this area.
36. Secondly the group has agreed to focus on developing national patient safety policies and programmes by establishing ways to share best practice and collaborate between countries. Several Ministries are currently developing a proposal on setting up a network between EU Member States, in close cooperation with the work on reporting and learning systems.
37. Thirdly, the group is looking at improving medication safety and safety of medical devices by identifying ways to develop and design safer devices and health care settings.
38. Fourthly, health professionals' organisations are developing ways to integrate patient safety more effectively in training and education programmes. The working group is also planning to make some recommendations on this.

39. And on research – the fifth area identified as an action for patient safety –DG Research will be financing a scientific conference on patient safety to set up European research agenda on patient safety, and I have already highlighted some of the areas they will be focussing on.
40. In addition, the wider stakeholder society (including industry associations) will address patient safety and they have just set up a patient safety working group under the EU Health Policy Forum last month to take this forward. These two working groups will complement each other in promoting patient safety in the EU.

Conclusion

41. It is pleasing to see that the issue of patient safety is playing an increasingly important role in all discussions on healthcare across the EU. Following the huge support from Member States generated by the Presidencies of Luxembourg and the UK, and events here today, we are now in a better position than ever before to set out a concrete programme of action and practical tools for the coming years in the area of patient safety and to support countries that are establishing their own patient safety programmes.

42. Systemic approaches to ensure patient safety will also help to drive up quality overall and maybe reduce some costs. In the

43. Patient organizations, health professionals and other key stakeholders should have a key role in implementing patient safety policies together with the national authorities.