



A brief synopsis on patient safety

ABSTRACT

This document provides a simplified and non-exhaustive synopsis of the major international patient safety initiatives – past and present – undertaken in the WHO European Region. While patient safety is a complex issue spanning numerous public health and health-care domains, this document adopts a generic understanding of the subject in respect to avoidable harm. As such, most of the patient safety interventions chosen for this document have a general and cross-cutting character and do not include the many complementary and dedicated actions developed at various levels of the health system and beyond. Moreover, as patient safety is constantly developing better ways to respond to health, economic, social and environmental challenges, the document is to be seen as a 'snapshot' of the current state of affairs in the WHO European Region, and as a work in progress.

Keywords

PATIENT CARE - standards
PATIENT RIGHTS
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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 medical practice.

Patient safety – an issue of increasing concern

Definition

The definition of patient safety has evolved from untoward events related to health care in hospitals¹ and work around anaesthesia error monitoring² to a broader content and context, requiring complex interventions. The 1999 report of the United States Institute of Medicine, *To err is human*³, brought patient safety to public and political attention.

It is generally agreed that patient safety can be defined as *freedom for a patient from unnecessary harm or potential harm associated with health care*⁴. Medical errors can occur at various stages during the provision of health care, such as during prevention, diagnostics, treatment and follow up⁵. Errors can include communication failures, equipment failures and other system failures. Rather comprehensive taxonomies have been developed due to the difficulty in setting boundaries at the conceptual level. The intricate relationships within the complex environment of health care practices have been further illustrated by the eight direct definitions and seven complementary descriptions using safety as an entry point, identified through the World Health Organization (WHO) International Classification for Patient Safety⁶.

Subsequently, patient safety could be viewed in a practical way as the mechanisms, tools, underlying resources and required actions to reduce and ultimately avoid unintentional harm to patients. These can cover any aspect of care, including organizational factors, health-care personnel, the systems and environments that can contribute to a safety breach (i.e. prevalence of health-care acquired infections, diagnostic and medication errors, addressing more specific risks associated with certain treatments, medicines or devices, etc.).

While patient safety is a complex issue spanning numerous public health and health-care domains, this document adopts a generic understanding of the subject in respect to avoidable harm. As such, most of the patient safety interventions chosen have a general and cross-cutting character and do not include the many complementary and dedicated actions developed at various levels of the health system and beyond. Moreover, as patient safety is constantly developing better ways to respond to health, economic, social and environmental challenges, the document is to be seen as a 'snapshot' of the current state of affairs in the WHO European Region, and as a work in progress.

¹ Schimmel EM. The hazards of hospitalization. *Annals of Internal Medicine*, 1964, 60:100–110.

² Gaba DM. Anaesthesiology as a model for patient safety in health care, *British Medical Journal*, 2000, 320(7237):785, doi:10.1136/bmj.320.7237.785 (<http://www.bmj.com/cgi/content/full/320/7237/785>).

³ Kohn LT, Corrigan JM, Donaldson MS, eds. *To err is human – building a safer health system*. Institute of Medicine, Washington, DC, National Academies Press, 2000.

⁴ Council of the European Union. *European Council Recommendation on patient safety, including the prevention and control of healthcare associated infections*, Brussels 2009 (http://ec.europa.eu/health/ph_systems/docs/patient_rec2009_en.pdf).

⁵ Leape LL et al. Preventing medical injury. *Quality Review Bulletin*, 1993, 19(5):144–149.

⁶ The conceptual framework for the international classification for patient safety, Version 1.1, Technical annex 2, Glossary of patient safety concepts and references, World Health Organization, 2009.

Background

Patient safety is a serious concern all over the world, as a consequence of increased awareness of the issue. While health care has become more effective it has also become more complex, with greater use of new technologies, medicines and treatments. Health services are treating older and sicker patients who often present with significant co-morbidities requiring increasingly difficult decision-making in health care prioritization. Economic constraints are leading to often overloaded and besieged health-care environments⁷. Reduced revenues and increasing expenditures in times of financial crisis⁸ are likely to increase pressure on the health systems to further contain costs, and thus affect service quality and patient safety.

Evidence has shown that health systems must be strengthened to face current and future challenges in maintaining and increasing the health status of populations and their quality of life⁹. Weak legal and regulatory oversight of health service delivery, inappropriate infrastructure, including outdated or overused technologies, insufficiently distributed, trained or simply exhausted health-care personnel, uninformed patients/consumers, are all factors which usually converge in various proportions towards the occurrence of safety failures. Unexpected/ unwanted events might take place in all settings where health care is delivered (primary, secondary and tertiary care, community care, social and private care, acute and chronic, including palliative care).

European data, mostly available for the European Union Member States, consistently show that medical errors and health-care related adverse events occur in between 8% and 12% of hospitalizations¹⁰. For example, the United Kingdom Department of Health, in its 2000 report, *An organisation with a memory*¹¹, estimated that there were approximately 850,000 adverse events a year (10% of hospital admissions), while Spain in its National Study of Adverse Events (ENEAS report 2005)¹², France and Denmark have presented incidence studies with similar results. A report by the Hospitals for Europe's Working Party on Quality Care in Hospitals (HOPE)¹³ has also estimated that every tenth patient in hospitals in Europe suffers from preventable harm.

Healthcare-associated infections (HAI), which are pathognomic of unsafe care, affect an estimated one in twenty hospital patients on average every year (estimated at 4.1 million patients). The four most common infection types are: urinary tract infections (27%), lower respiratory tract infections (24%), surgical site infections (17%) and bloodstream infections (10.5%). In addition, these infections are often difficult to treat due to antimicrobial resistance

⁷ Conklin A et al. *Improving Patient Safety in the EU. Assessing the expected effects of three policy areas for future action*. RAND Technical Report prepared for the European Commission, 2008 (http://www.rand.org/pubs/technical_reports/TR596/).

⁸ EUROSTAT [online database] 2009 figures (<http://epp.eurostat.ec.europa.eu/portal/page/portal/eurostat/home/>)

⁹ Klazinga N, Overtveit J. *Guidance on developing quality and safety strategies with a health system approach*, WHO Regional Office for Europe, 2008.

¹⁰ Conklin, A. Room for improvement; Strong patient safety systems could limit health, social and economic harms from medical error. RAND Europe, 2009 (http://www.rand.org/pubs/research_briefs/2009/RAND_RB9472.pdf).

¹¹ United Kingdom Department of Health. *An organization with a memory*. Report of the United Kingdom Department of Health, 2000

(http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4065083).

¹² Ministry of Health and Social Policy. *National study on hospitalization-related adverse effects*. ENEAS, 2005, Madrid, 2006 (http://www.msc.es/organizacion/sns/planCalidadSNS/docs/ENEAS_ENG.pdf).

¹³ Standing Committee of the Hospitals of the European Union. *The quality of hospital care in the European Union*. HOPE, 1996 (http://www.hope.be/05eventsandpublications/docpublications/43_quality/43_quality_1996.pdf).

(AMR) of the causative microorganisms. Multi-resistant *Staphylococcus Aureus* (MRSA) is isolated in approximately 5% of all HAI¹⁴. The United Kingdom National Audit Office estimated the cost of HAI at £1 billion per year¹⁵.

Looking from a consumers' point of view, the 2006 *Eurobarometer*¹⁶ survey on medical error revealed that 23% of Europeans state they were directly affected by medical error, 18% experienced a serious medical error in a hospital and 11% were prescribed the wrong medication. Almost all respondents (98%) felt that having national political support for patient safety is of high importance. The latest 2010 *Eurobarometer*¹⁷ survey on patient safety and quality of care showed increased public awareness about the issue (50% of respondents fear that they might be harmed by health care), but limited knowledge relating to the actual patient/consumer role in reducing the potential failure process (too few know about the responsible patient safety organizations/structures in their countries).

Medical-error-prevention evidence shows that around 50% of such harm can be prevented through comprehensive systematic approaches to patient safety¹⁸. The Spanish APEAS study on primary care goes beyond these figures, identifying up to 70.2% of all medical errors as avoidable¹⁹. The model prepared by RAND research in their report²⁰ for the European Commission estimated that strategies aiming to reduce the rate of adverse events in the European Union (EU) would lead to the prevention of more than 750,000 harm-inflicting medical errors per year, leading in turn to the reduction of more than 3.2 million days of hospitalization, 260,000 fewer incidents of permanent disability, and 95,000 fewer deaths annually.

The costs of patient safety, in both human and financial terms, require a comprehensive response to increase the performance, quality and efficiency of health care and to prevent adverse events, making them visible and mitigating their effects when these occur. The topic is becoming increasingly prominent on political agendas, at national and international levels²¹.

Addressed already by previous EU presidencies, patient safety is one of the main health-related priorities for the current Spanish Presidency, which runs from 1 January 2010 to the end of June 2010. The EU presidency trio of Spain, Belgium and Hungary has a focus on patient safety issues in their joint 18-month programme.

¹⁴ European Centre for Disease Prevention and Control, [web site]

([http://www.ecdc.europa.eu/en/healthtopics/Pages/Healthcare-associated_Infections_\(HCAI\).aspx](http://www.ecdc.europa.eu/en/healthtopics/Pages/Healthcare-associated_Infections_(HCAI).aspx))

¹⁵ European Commission Health and Consumer Protection Directorate-General. *Public consultation on strategies for improving patient safety by prevention and control of healthcare-associated infections*, (http://ec.europa.eu/health/ph_threats/com/cons01_txt_en.pdf)

¹⁶ European Commission. Medical Errors. *Special Eurobarometer*, January 2006, 241 (http://ec.europa.eu/health/ph_information/documents/eb_64_en.pdf).

¹⁷ European Commission. Patient safety and quality of care. *Special Eurobarometer*, April 2010, 327 (http://ec.europa.eu/public_opinion/archives/ebs/ebs_327_sum_en.pdf).

¹⁸ Adler L et al. Global Trigger Tool: Implementation Basics. *Journal of Patient Safety*, 2008, 4:245–249 (http://journals.lww.com/journalpatientsafety/Abstract/2008/12000/Global_Trigger_Tool__Implementation_Basics.7.aspx)

¹⁹ *Ministero de Salud y Consumo*, APEAS Study: *Patient Safety in Primary Healthcare Summary* (in Spanish), 2005 (http://www.msc.es/organizacion/sns/planCalidadSNS/ec03_doc.htm, accessed 24 April 2010).

²⁰ Vilamoska A, Conklin, A. Improving patient safety: Addressing Patient Harm Arising from Medical Error, *Policy Insight*, 2009, 3(2), RAND Corporation (http://www.rand.org/pubs/corporate_pubs/CP521-2009-04/).

²¹ *The Tallinn Charter: Health Systems for Health and Wealth, Draft 13 June 2008*. Copenhagen, WHO Regional Office for Europe, 2008 (http://www.euro.who.int/document/hsm/6_hsc08_edoc06.pdf).

Patient safety in the EU context

EU scope of action and legal basis

Health systems in the EU Member States face further complexity in harmonizing quality of care in service delivery as a result of increasing mobility across borders, with patients and consumers empowered to seek better care and lower out-of-pocket expenditures, and providers looking for better job opportunities²². There is a need to ensure that citizens will receive quality care across the EU, and to address concomitantly the added public health concerns, such as containment of influenza outbreaks/pandemics, antimicrobial resistance, etc. These call for ‘standardized’ inputs (quality and safety norms and standards, guidelines, certification of professionals, etc.) and monitored outputs (reporting, evaluation etc.). The aging populations and the measured impact of health determinants demand higher valuation of health as a reason for increased awareness and sensitivity.

According to the subsidiarity principle in the field of health the governance, oversight and financing of health services and medical care are primarily the responsibility of Member States. Action for patient safety – a cornerstone of quality of care – became a priority on the health policy agenda, supported by the growing body of evidence on preventable health-care related harm, and its direct and indirect human and economic costs.

Under the Lisbon Treaty²³, the Union should strive towards “a high level of human health protection in [...] all Union policies and activities” (Article 168 on public health), by complementing national policies, promoting cooperation and complementarity between health services of Member States, protecting consumers safety and fostering availability and exchange of information and best practices (Article 169 on consumer protection and Article 170 on trans European networks).

Actions at the EU level work towards providing political weight and visibility to patient safety, economies of scale through wide collection of data and sharing of best practices, as well as striving for sustainability of action at a Community level. It is therefore essential that the main players collaborate and coordinate their work in this area to ensure progress towards strengthening quality of care.

The European Commission, expected to protect public health, has already taken a number of steps in this direction. As a key dimension of quality of care, patient safety is supported and shared via diverse EU level tools and activities²⁴, such as policies, programs, research projects, health indicators and statistics, as well as legislation when needed. Quality of medical goods, standards for the safety and performance of medical technology, and standard training of health professionals are areas of activity identified to improve quality and prevent adverse events for

²² Commission of the European Communities. *Summary of the impact assessment, accompanying document to the Communication and Recommendation on patient safety including the prevention and control of healthcare-associated infections*, SEC(2008) 3005, 15 February 2008.

²³ Consolidated version of the treaty on the functioning of the European Union. *Official Journal of the European Union*, C115/47, 9 May 2008

(<http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2008:115:0047:0199:EN:PDF>).

²⁴ Health EU: The Public Health Portal of the European Union [web site] Health-EU Portal (http://ec.europa.eu/health-eu/health_in_the_eu/index_en.htm).

patients. Legislative measures coupled with the setting-up of agencies and working groups (delivering scientifically sound opinions) are the backbone of the EU's activities in this field.²⁵

EU projects on patient safety are funded through different themes, such as the Health Programme under Health and Consumer Directorate-General (e.g. 2003–2008 and 2008–2013), information and communications technologies activities, and the EU Research Framework Programme (FP) under Research and Development Directorate-General (e.g. FP6 2002–2006 and FP7 2007–2013)²⁶. The Commission, through the FP7, supports research in health systems, in particular in quality of health care and patient safety, under the Health Theme and under the Information and Communication Technology Theme.

History and developments at EU level

Various safety challenges have been addressed at EU level through sectoral legislation. The Commission took steps addressing progressively specific sources of risk, such as the safety of medicines, blood components, medical devices and antimicrobial resistance. With knowledge and understanding of patient safety evolving, these began to be considered in a more comprehensive manner and addressed through transversal policies. Work at the EU level specifically dedicated to patient safety started in 2004.

2004

21 April - Regulation (EC) No 851/2004 of the European Parliament and of the Council establishing a European Centre for Disease Prevention and Control (ECDC)²⁷

4 May - Establishment of a High Level Group on Health Care

A High Level Group on Health Services and Medical Care²⁸ was established following a Communication²⁹ from the European Commission in order to enhance European cooperation for helping Member States to achieve their health objectives. Reporting annually to the Employment, Social Policy, Health and Consumer Affairs Council (EPSCO)³⁰, this High Level Group was originally divided into six working groups.

5 October - High Level Group on Health Services and Medical Care introduced the report "Patient safety: a worldwide issue"³¹

At the High Level Group meeting, the United Kingdom introduced an evidence based paper on patient safety. Other Member States (in particular Italy, Ireland, France and Austria) broadly

²⁵ Health EU: The Public Health Portal of the European Union [web site]. Quality Assurance (http://ec.europa.eu/health-eu/care_for_me/quality_assurance/index_en.htm).

²⁶ European Commission [web site] Seventh Framework Program. FP7 calls (<http://cordis.europa.eu/fp7/dc/index.cfm>).

²⁷ Regulation (EC) 851/2004 of the European Parliament and of the Council establishing ECDC, OJL142, 30 April 2004, 1 (http://ecdc.europa.eu/en/aboutus/Key%20Documents/0404_KD_Regulation_establishing_ECDC.pdf).

²⁸ Public Health [web site]. High Level Group on Health Services and Medical Care (http://ec.europa.eu/health/ph_overview/co_operation/mobility/high_level_hsmc_en.htm).

²⁹ Communication COM (2004) 301 of 20 April 2004 on the follow-up to the High Level Process of Reflection on patient mobility and healthcare developments in the European Union.

³⁰ EPSCO [web site] (<http://www.consilium.europa.eu/showPage.aspx?id=411&lang=en>).

³¹ European Commission. Health and Consumer Protection Directorate-General. *Patient safety: a worldwide issue*. Submitted by the United Kingdom, HLG/2004/13 REV1, EC, 5 October 2004 (http://ec.europa.eu/health/ph_overview/co_operation/mobility/docs/highlevel_2004_019_en.pdf).

welcomed the paper and supported the idea of having some focus on patient safety in the work of the High Level Group. It was suggested that pharmacovigilance might be better addressed separately, considering the already established nature of cooperation in this area.

2005

5 April - Luxembourg EU Presidency's declaration on patient safety³²

Emerging from a dedicated conference organized under the EU Presidency of Luxembourg, a declaration on patient safety was adopted, "Patient Safety – Making it Happen!", providing dedicated recommendations at EU level, national level and the level of health-care providers. It recognized that access to high-quality health care is a key human right to be valued by the EU, its Institutions and the citizens of Europe.

6 April - Commission Communication: Healthier, safer, more confident citizens: a health and consumer protection strategy and proposal for a decision establishing a programme of community action in the field of health and consumer protection 2007-2013³³

The joint programme, drawing on similarities between health and consumer policies, aims to enhance synergies and savings while developing core actions on health and consumer protection. One of its stated objectives is to improve effectiveness and efficiency in health systems where there is a need for developing and implementing actions to promote patient safety and high-quality care.

6 April - Creation of a working group on patient safety³⁴

Not originally foreseen in the composition of the High Level Group, the Patient Safety Working Group (PSWG) was created under the impulsion of the United Kingdom, which outlined the seriousness of the issue and the need to address patient safety as a whole and establish a forum for shared best practices³⁵. The working group aimed at developing the following key actions³⁶:

- to support the establishment of national patient safety programmes;
- to support the establishment of effective patient safety reporting and learning systems;
- to lead an initiative on 'design for patient safety';
- to commission research on the economic impact of patient safety; and
- to lead a global initiative to develop a framework for patient safety education.

The PSWG is now the main body contributing to the development of proposals and EU policies on patient safety. Besides the Member States and the Commission, WHO, the Council of Europe (CoE), the Organization for Economic Co-operation and Development (OECD) and European associations of patients, doctors, nurses, pharmacists, dentists and hospitals are also part of its active members. The creation of this working group was the first expression of the added value

³² European Commission DG Health and Consumer Protection. *Patient safety – Making it Happen!* Luxembourg declaration on patient safety, 5 April 2005, (http://ec.europa.eu/health/ph_overview/Documents/ev_20050405_rd01_en.pdf).

³³ Commission of the European Communities. *Commission Communication COM(2005) on Healthier, safer, more confident citizens: a health and consumer protection strategy, 2007–2013* (http://eur-lex.europa.eu/LexUriServ/site/en/com/2005/com2005_0115en01.pdf).

³⁴ Public Health [web site]. Minutes of PSWG (web archive) (http://ec.europa.eu/health/ph_systems/events_pswg_en.htm).

³⁵ European Commission. Health and Consumer Protection Directorate-General. *Patient safety: a worldwide issue*. High Level Group on Health Services and Medical Care, HLG/2004/13Rev.1, 5 October 2004 (http://ec.europa.eu/health/ph_overview/co_operation/mobility/docs/highlevel_2004_019_en.pdf).

³⁶ European Commission. Health and Consumer Protection Directorate-General. *Minutes of the High Level Group on 29 September 2005*, HLG/2005/12, (http://ec.europa.eu/health/ph_overview/co_operation/mobility/docs/highlevel_2005_015_en.pdf).

for facilitated cooperation on patient safety at the EU level, even if the responsibility for ensuring patient safety remains primarily with the Member States.

Public consultation on strategies for improving patient safety by prevention and control of healthcare-associated infections³⁷

The results of the open consultation were used at a later stage in defining the Commission communication on patient safety including prevention and control of HAI³⁸.

Establishment of the European Centre for Disease Prevention and Control ECDC³⁹

The European Centre for Disease Prevention and Control (ECDC) operates surveillance networks and assists the Commission in operating early warning systems for emergency situations. In addition, ECDC started coordinated work on HAI and AMR. It publishes an annual epidemiological report on communicable diseases in Europe, which provides some data on patient safety⁴⁰.

EU co-funded projects

Hospital in Europe Link for Infection Control through Surveillance (HELICS)⁴¹

HELICS had two phases: the first phase aimed to lay the practical foundations for a European Network on hospital acquired infections and the second phase aimed to create a robust and validated surveillance system and establish reference data sets. The HELICS 2 implementation report was presented in 2005, and the surveillance network continued to operate through the 'Improving Patient Safety in Europe' (IPSE)⁴² project, which was just starting.

2006

January - Special Eurobarometer on medical errors⁴³

Following the Luxembourg declaration, the DG SANCO launched a *Eurobarometer* survey on medical errors. This first analysis of medical errors based on citizens' perceptions found that approximately four out of five EU citizens (78%) consider medical errors as an important problem in their country, while almost all respondents (98%) felt that it is of high importance to have national political support for patient safety.

³⁷ European Commission. Health and Consumer Protection Directorate-General. *Public consultation on strategies for improving patient safety by prevention and control of healthcare-associated infections* (http://ec.europa.eu/health/ph_threats/com/cons01_txt_en.pdf).

³⁸ Public Health [web site]. Healthcare associated infections (http://ec.europa.eu/health/patient_safety/healthcare_associated_infections/index_en.htm).

³⁹ ECDC [web site] (<http://www.ecdc.europa.eu/>).

⁴⁰ ECDC [web site]. Annual epidemiological report on communicable diseases, 2009 (http://ecdc.europa.eu/en/publications/Publications/0910_SUR_Annual_Epidemiological_Report_on_Communicable_Diseases_in_Europe.pdf).

⁴¹ Hospital in Europe Link for Infection Control through Surveillance (HELICS) [web site] (<http://helics.univ-lyon1.fr/helicshome.htm>).

⁴² Improving Patient Safety in Europe [web site] (<http://ipse.univ-lyon1.fr>).

⁴³ European Commission. Medical Errors. *Special Eurobarometer*, January 2006, 241 (http://ec.europa.eu/public_opinion/archives/ebs/ebs_241_en.pdf).

22 June - Adoption of Council Conclusions on Common Values and Principles in European Union Health Systems⁴⁴

The Council, in its conclusions on common values and principles in European Union health systems acknowledged that “patients can expect each EU health system to secure a systematic approach to ensuring patient safety, including the monitoring of risk factors and adequate, training for health professionals, and protection against misleading advertising of health products and treatments”.

11 September - Discussion paper: Strategic approach to patient safety⁴⁵

The Patient Safety Working Group developed a paper defining strategic approaches to patient safety that proposed the establishment of a European Network on patient safety for information exchange and shared best practices and called for political commitment of all Member States to the issue.

2007

15 March - European Parliament resolution on Community action on the provision of cross-border health care⁴⁶

The resolution urges the Commission to develop common principles and basic guidelines for health care to guarantee patient safety and stresses the need to ensure patient safety in all circumstances, regardless of where and how health care is provided. It calls for effective information exchange between national authorities on the registration and disciplinary status of health-care professionals and considers it a necessity to create a mechanism for appeals on malpractice in cross-border health care.

23 May - European Parliament vote on the ‘Implications of the removal of health from the Services Directive’ (Vergnaud Report)⁴⁷

The report, adopted by the European Parliament, is an own-initiative analysis on “the consequences of the exclusion of health services from the scope of the Services Directive”, which does not go through the co-decision procedure and therefore is not legally binding. It emphasizes, among other things, the introduction of a European Charter of Patients’ Rights⁴⁸.

⁴⁴ Council Conclusions on Common values and principles in European Union Health Systems, *Official Journal of the European Union*, (2006/C 146/01), 22 June 2006

(<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2006:146:0001:0003:EN:PDF>).

⁴⁵ European Commission. *Discussion Paper “Strategic approach to patient safety”*

(http://ec.europa.eu/health/ph_systems/docs/ev_20060914_rd01_en.pdf).

⁴⁶ European Parliament resolution on Community action on the provision of cross-border healthcare, B6-0098/2007 (<http://www.europarl.europa.eu/sides/getDoc.do?type=MOTION&reference=B6-2007-0098&language=EN>).

⁴⁷ European Parliament legislative observatory, procedure file including Bernadette Vergnaud draft report, 6 March 2007 (<http://www.europarl.europa.eu/oeil/FindByProcnum.do?lang=2&procnum=INI/2006/2275>).

⁴⁸ Active Citizenship Network. *European Charter of Patient Rights*, 2002 (http://www.patientstalk.info/european_charter.pdf).

2 October - PSWG transmitted its Recommendation on patient safety to the High Level Group on Health Services and Medical Care⁴⁹

The PSWG delivered to the High Level Group a Recommendation on patient safety aiming to provide a possible European framework towards improving patient safety in all sectors of health care and to identify key areas where patient safety action is most effective and should be promoted at national and European levels. To this end, this Recommendation calls for action at:

a) the national level to:

- support development of national policies and programmes;
- empower citizens and patients;
- develop positive patient safety cultures, leadership and clinical governance at the health-care setting level;
- promote education and training of health professionals and all other staff;
- establish effective reporting and learning mechanisms; and
- develop and enhance redress mechanisms for patients affected by adverse events.

b) both the EU and the national level to:

- develop the knowledge and evidence base for patient safety;
- use that knowledge and evidence to implement change for safer care; and
- engage and involve stakeholders.

EU co-funded projects

May - Findings of the “Safety Improvement for Patients in Europe” (SIMPatIE) project⁵⁰

SIMPatIE (funded by DG SANCO) was led by the Dutch Institute for Healthcare Improvement. It aimed to develop EU-wide transparency on patient safety in health care and to use Europe-wide networks of organizations, professionals and other stakeholders to establish a common vocabulary, indicators, and instruments for improvement of safety in health care. It underlined the added value of EU cooperation on patient safety.

24-26 September - “Patient Safety Research - shaping the European agenda” conference⁵¹

The conference held in Porto, Portugal, was funded through FP6 Research, and led by a consortium with the United Kingdom Faculty of Public Health, University College London and the WHO World Alliance for Patient Safety. The conference achieved its aim of creating a dialogue between health researchers and policy-makers in Europe and an agenda for patient safety research. The conference declared a “call for action” for dedicated activities at local, national and European levels.

Setting up of “European information system on patient safety (EuInfoPas) project⁵²

EuInfoPas was submitted during an FP6 call by Denmark. The project proposal aimed at encouraging and supporting Member States in establishing effective patient safety reporting and learning systems, and paving the way for EU-wide sharing and analysis of information on patient safety problems drawn from national patient safety reporting systems.

⁴⁹ European Commission. Health and Consumer Protection Directorate-General. *PSWG Recommendation on patient safety to the High Level Group*, 2007 (http://ec.europa.eu/health/ph_systems/docs/ev_20080617_rd01_en.pdf).

⁵⁰ Safety Improvements for Patients in Europe (SIMPATIE) [web site] (<http://www.simpatie.org/Main>).

⁵¹ European Commission. *Patient Safety Research: shaping the European agenda conference report*, Porto, 2007 (http://ec.europa.eu/health/ph_systems/docs/ev_20071122_rd01_en.pdf).

⁵² National Board of Health, Denmark. *The European information system on patient safety (EuInfoPas)* (http://ec.europa.eu/health/ph_systems/docs/ev_20060607_co01_en.pdf).

2008

17 April - Open consultation on patient safety⁵³

This consultation gathered 184 replies, including competent authorities at national, regional or local levels. Working groups representing Member States and key stakeholder groups, including health professionals and patients, also contributed on the general patient safety aspects and on the topic of HAI.

Respondents ranked as important or very important the need for (continued) action on:

- budgetary commitment to patient safety;
- patient and public involvement;
- local health-care management engagement;
- education and training of health professionals;
- a common taxonomy and set of indicators;
- reporting and learning systems;
- standards and external assessment;
- more research; and
- more information on redress for patients.

The results were used in the development of the Commission's proposals on patient safety.

RAND report “Improving Patient Safety in the EU” prepared for the European Commission⁵⁴

The report was prepared for the Health and Consumer Protection Commission in support of their *Impact Assessment of the Patient Safety and Quality Legislative proposal for 2008*. It was compiled using a mixture of methods, including existing European and international studies and evaluations on patient safety and related initiatives, as well as primary qualitative data based on 32 key informant interviews with identified experts. The aim of this report was to allow patient safety experts, the Commission and other interested stakeholders to understand the extent to which it is possible to provide a clear and compelling account of the expected impacts of: a) establishing effective reporting and learning systems, b) redress mechanisms, and c) developing and using knowledge and evidence at the EU level.

2 July - European Commission proposal for a directive of the European Parliament and of the Council on the application of patients’ rights in cross-border health care⁵⁵

The proposal, which covers the application of patients’ rights in cross-border health care, addresses ensuring safe and high-quality health care as well as the expected lines of responsibility for quality and safety of care in cross-border settings⁵⁶. The (amended)⁵⁷ draft directive will be considered during 2010⁵⁸.

⁵³ Public Health [web site]European Commission Public Consultation on patient safety, 2008 (http://ec.europa.eu/health/ph_systems/patient_consult_en.htm)

⁵⁴ Conklin A, et al. *Improving Patient Safety in the EU. Assessing the expected effects of three policy areas for future action*, Rand Technical Report for the European Commission, 2008 (http://www.rand.org/pubs/technical_reports/2008/RAND_TR596.pdf).

⁵⁵ European Commission. *Opening the door to better healthcare across Europe*, July 2008 (http://ec.europa.eu/health/ph_overview/co_operation/healthcare/docs/brochure_en.pdf).

⁵⁶ Health EU: The Public Health Portal of the European Union [web site]. New Commission initiative on patients' rights in cross-border healthcare, 2009 (http://ec.europa.eu/health-eu/news/streaming/crossborder/crossborder_en.htm).

⁵⁷ European Parliament. P6_TA-PROV(2009)0286, Patients' rights in cross-border healthcare, European Parliament legislative resolution of 23 April 2009 on the proposal for a directive of the European Parliament and of the Council

2 July - Commission Recommendation C (2008) 3282 on cross-border interoperability of electronic health record systems⁵⁹

The Recommendation aims at improving the quality and safety of patient care, and reducing adverse events by making key clinical data (including data on medications) accessible when the patient is treated in another country through use of electronic health records.

12 September - Patient Safety Working Group is renamed Patient Safety and Quality of Care Working Group⁶⁰

With the growing emphasis on wider health-care quality issues brought to the attention of the Commission (e.g. Council conclusions on common values and principles in European Union health systems) and since it was agreed that patient safety is considered to be a core part of health-care quality, the High Level Group decided to widen the remit of the working group to include health-care quality issues and to re-name it to Patient Safety and Quality of Care Working Group (PSQCWG).

September - launch of “Europe for patients” ongoing campaign⁶¹

Available in all EU official languages, this campaign brings together different policy initiatives that share a common goal: better health care for all in Europe. It also provides a coherent message about the vision and priorities in EU health care for partners and stakeholders. It covers 11 initiatives: cross-border health care, rare diseases, health workforce, patient safety, organ donation and transplantation, cancer screening, flu vaccination, prudent use of antibiotics, mental health, childhood vaccination, Alzheimer’s disease and other dementias.

10 December - Commission GREEN PAPER on the European Workforce for Health⁶²

This document highlighted the influencing factors and possible areas for action to improve the status of the workforce for health and stressed the importance of health personnel training as a prerequisite for ensuring patient safety.

15 December - European Commission adopted a Communication⁶³ and a proposal for a Council Recommendation on patient safety, including the prevention and control of healthcare-associated infections

on the application of patients' rights in cross-border healthcare (COM(2008)0414 – C6-0257/2008 – 2008/0142(COD)) (Co-decision procedure: first reading)

(http://www.pickereurope.org/Filestore/Policy/other/Cross-border_Directive_-_EP_amendments.pdf).

⁵⁸ Picker Institute Europe: Making patients’ views count [web site] (<http://www.pickereurope.org/181>).

⁵⁹ European Commission. *Commission Recommendation on cross-border interoperability of electronic health record systems* (notified under document number C(2008) 3282), OJ L 190, 18 July 2008

(<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32008H0594:EN:NOT>).

⁶⁰ European Commission. Health and Consumer Protection Directorate-General. High Level Group on Health Services and Medical Care. *Report on the work of the High Level Group in 2008*, HLG/2008/5 FINAL, (http://ec.europa.eu/health/ph_overview/co_operation/healthcare/docs/highlevel_2008_005_en.pdf).

⁶¹ Health EU: The Public Health Portal of the European Union [web site]. Europe for patients.

(http://ec.europa.eu/health-eu/europe_for_patients/index_en.htm)

⁶² Commission of the European Communities. *Green paper on the European Workforce for Health*, COM(2008)725 final(http://ec.europa.eu/health/ph_systems/docs/workforce_gp_en.pdf).

⁶³ Commission of the European Communities. *Communication from the Commission to the European Parliament and the Council on patient safety, including the prevention and control of healthcare-associated infections* {COM(2008) 837 final} {SEC(2008) 3004} {SEC(2008) 3005}, Brussels 2008 (http://ec.europa.eu/health/ph_systems/docs/patient_com2008_en.pdf)

EU co-funded projects

28 February - Setting up of the European network for patient safety (EUNetPaS)⁶⁴

EuNetPaS was funded through the Health Programme and led by France. The project represents a platform for collaboration and networking between Member States, international organizations and other stakeholders in the field of patient safety. It builds on the work of SImPatIE, MARQuIS, the OECD's work on patient safety indicators, the work of WHO on patient safety and the CoE recommendations. EUNetPaS addresses the following key topic areas:

- promoting a culture of patient safety (culture measurement);
- structuring education and training in patient safety (guidelines);
- implementing reporting and learning systems (library of reporting systems for Member States that do not have such a system); and
- pilot implementation of medication safety (seven good practices for medication safety).

31 March - Final report of Methods of Assessing Response to Quality Improvement Strategies (MARQuIS) project⁶⁵

MARQuIS (funded through FP6) brought together six European research centres, the European Hospital and Healthcare Federation (HOPE) and the European Society for Quality in Healthcare led by the Avedis Donabedian Foundation in Spain. Not specifically dedicated to patient safety, the project included an analysis of the quality improvement strategy for patient safety systems. The results of the study suggested that patient safety strategies maximize impact of broader quality improvement strategies⁶⁶. It recommended the use of common quality improvement strategies and basic quality improvement requisites to be adopted and also recommended the promotion of external assessments of patient safety problems in hospitals⁶⁷.

Final deliverables “Improving Patient Safety in Europe” (IPSE) project⁶⁸

The IPSE project aimed to reduce the burden of HAI and the related threats of AMR by providing evidence-based guidance and educational tools, strengthening the status of infection control professionals, strengthening surveillance and developing indicators. The project deliverables will be further described in this report.

2009

23 April - European Parliament legislative resolution on the Council Recommendation on patient safety, including the prevention and control of healthcare-associated infections⁶⁹

9 June - EU Member States adopted the proposal for a Council Recommendation on patient safety, including the prevention and control of healthcare-associated infections⁷⁰

⁶⁴ European Union Network for Patient Safety (EUNetPaS) [web site] (<http://www.eunetpas.eu/>)

⁶⁵ Methods of Assessing Response to Quality Improvement Strategies (MARQuIS) [web site] (<http://www.marquis.be/Main>).

⁶⁶ Sunol R, Vallejo, P. *MARQuIS Deliverable 12, WP6 Final Report with Recommendations*, 2008 (<http://www.marquis.be/Main/wp1114091582/ff1119451343/MARQuISFinalReport.pdf/download>).

⁶⁷ Sunol R, *MARQuIS: Methods of Assessing Response to Quality Improvement Strategies in Europe*, 2007 (http://ec.europa.eu/health/ph_systems/docs/ev_20071122_co02_en.pdf).

⁶⁸ Improving Patient Safety in Europe [web site] (<http://ipse.univ-lyon1.fr>).

⁶⁹ European Parliament legislative resolution of 23 April 2009 on the proposal for a Council recommendation on patient safety {COM(2008)0837 – C6-0032/2009 – 2009/0003(CNS)} (<http://www.europarl.europa.eu/sides/getDoc.do?type=TA&language=EN&reference=P6-TA-2009-0287>).

⁷⁰ Council of the European Union. *Council Recommendation on patient safety, including the prevention and control of healthcare associated infections*, Brussels, 2009, Interinstitutional File 2009/0003 (CNS) (http://ec.europa.eu/health/ph_systems/docs/patient_rec2009_en.pdf)

2010

Eurobarometer survey on antimicrobial resistance⁷¹

This survey reveals worrying trends in public attitudes towards the use of antibiotics, indicating that citizens need more information on the correct use of antibiotics.

- 40% of respondents have taken antibiotics in the past year, and over a third took them for a viral infection like cold or flu;
- 53% of those surveyed consider that antibiotics kill viruses and this was a common belief in the 15–24 year-old age group;
- 62% of those who received correct information did not change their opinion on antibiotics.

Progress report on the implementation of the 2002 Council Recommendation on the prudent use of antibiotics⁷²

The strategies included in the Recommendation involve the development of surveillance systems, control measures, education training and awareness-raising campaigns. The present report shows that good progress has been made in several areas⁷³.

Eurobarometer survey on Patient safety and quality of care⁷⁴

This survey reveals increased awareness of the possibility of the occurrence of health-care related failure, and reports reduced confidence in the quality of care and limited knowledge of patient safety responsible bodies.

- Nearly 50% of respondents feared that they could be harmed by health care.
- 73% of respondents indicated television as a main source regarding adverse events in health care, with only 9% using official hospital statistics.
- One third of respondents did not know which organization was responsible for patient safety in their country.

The publication of the survey coincided with the European Patients' Rights Day, which is organized by the Active Citizenship Network⁷⁵ on 18 April each year, with events taking place around Europe to raise awareness of the importance of safeguarding the rights of patients.

EU co-funded projects

Deepening our understanding of quality improvement (DUQuE) project⁷⁶

The project, which builds on MARQuIS outcomes, aims to explore the impact of quality improvement approaches (organization culture, profession, patient) on health-care performance in EU hospitals based on a 'maturity classification model', test associations with clinical

⁷¹ European Commission. Antimicrobial resistance. *Special Eurobarometer*, April 2010, 338. (http://ec.europa.eu/health/antimicrobial_resistance/docs/ebs_338_en.pdf).

⁷² European Commission. *Second report on the basis of Member States' reports on the implementation of Council Recommendation (2002/77/EC) on the prudent use of antimicrobial agents in human medicine* (http://ec.europa.eu/health/antimicrobial_resistance/docs/amr_report2_en.pdf).

⁷³ European Commission. *Staff working paper of the services of the Commission on antimicrobial resistance, 2009{SANCO/6876/2009r6} {COM (2009) ZZZ}* (http://ec.europa.eu/food/food/biosafety/salmonella/antimicrobial_resistance.pdf).

⁷⁴ European Commission. Patient safety and quality of care. *Special Eurobarometer*, April 2010, 327. (http://ec.europa.eu/public_opinion/archives/ebs/ebs_327_en.pdf)

⁷⁵ Active Citizenship Network [web site]. European Patients' rights day, April 2010 (<http://www.activecitizenship.net/>).

⁷⁶ Groene O, Kutryba, B. *DUQuE Scientific Design. Deepening our understanding of quality improvement in Europe*, (http://www.esqh.net/www/about/presentations/files/folder_1255000789/European_Research_-_DUQuE_Project__proposed_.pdf).

effectiveness and patient safety and involvement. It aims to identify key factors influencing quality improvement activities in hospitals.

It is expected to produce: a) guidance for hospitals in their service advancement (effectiveness of quality and safety strategies and how to integrate these) and b) appraisal schemes (core quality and safety strategies that should be in place) for purchasers in contracting hospital services.

Learning from International Networks about Errors and Understanding Safety in Primary Care (LINNEAUS EURO-PC) project⁷⁷

The project aims to address patient safety issues in primary care, as well as the primary/secondary care interface. It builds on current knowledge and experience towards the development of a complex set of deliverables applied at primary care level, including taxonomy of adverse events and errors, a standardized reporting system that could be used on a Europe wide basis, performance measures (patient safety outcome indicators), a repository of evidence-based best practices for improving patient safety across multiple clinical settings, and involving patients in primary care safety.

Information, knowledge and experience of participant countries are expected to be shared and extended through the pan European network fostered by the project, ensuring the appropriate focus on primary health care and encouraging cooperation and collaboration for future interventions through large-scale trials.

Next steps
2011

February - Future joint action for patient safety?

There is a possible move from a EU patient safety network (EUNetPaS⁷⁸) towards a joint action in the field of patient safety, inspired from the project of Joint Action on Health Technology Assessment (EUNetHTA⁷⁹) started in 2010. The call for the joint action will be released in February 2011 (with co-funding from the Commission) and the joint action is expected to start in October 2011.

June - Member States report on the implementation of the Council Recommendation on patient safety, including the prevention and control of healthcare-associated infections

The Member States are expected to report to the Commission about the progress of implementing the Council Recommendation, by June 2011.

2012

June - Commission's report on the implementation of the Council Recommendation on patient safety, including the prevention and control of healthcare-associated infections

The Commission is invited by the EU Member States to produce an implementation report for the Council assessing the impact of the Council Recommendation by June 2012.

⁷⁷ LINNEAUS EURO-PC [web site] (<http://www.linneaus-pc.eu/>).

⁷⁸ European Union Network for Patient Safety (EUNetPaS) [web site] (<http://www.eunetpas.eu/>).

⁷⁹ European network for Health Technology Assessment (EUNetHTA) [web site] (<http://www.eunetha.net/>).

EU current policy and legislation on patient safety

Patient safety is identified in the health strategy white paper *Together for Health*⁸⁰ as one of the priorities for EU action. Subsequently, the Second Programme of the Community Action in the Field of Health (2008–2013)⁸¹ promotes measures improving patient safety through high quality and safe health care⁸².

In December 2008, drawing from the various Patient Safety and Quality of Care Working Group (PSQCWG) meetings, and from dedicated studies and open consultations that have been made on this theme, the Commission published its *Communication on Patient Safety including the prevention and control of healthcare-associated infections* outlining the future of EU actions.

Communication from the Commission on patient safety including the prevention and control of healthcare-associated infections

The Commission Communication intends to foster political commitments by Member States to make patient safety a priority in national public-health objectives, and recommends a comprehensive approach to improving patient safety. Member States are encouraged to put in place and consolidate strategies to prevent and control adverse events in all health-care settings. The primary focus is on addressing systemic and organizational failures responsible for most harm to patients. With this Communication, the Commission aims to put in place an integrated approach to strengthen patient safety in the long term.

Recommendation on patients' safety including the prevention and control of healthcare-associated infections

With this Recommendation, Member States are expected to implement a series of measures, either individually or collectively, supported by the Commission, to improve patient safety, starting with addressing systemic and organizational failures. This Council Recommendation is composed of two parts, one part covering general patient safety issues (seven recommendations) and another part covering the prevention and control of HAI.

On general patient safety issues, this Council Recommendation calls Member States to:

- **support the development of national patient safety policies and programmes:** defining patient safety as a priority in national health policies, the development of safe systems, processes and tools, regular updates of safety standards and best practices, and active involvement of health professional organizations in the process;
- **empower and inform citizens and patients:** involve patient organizations in policy making, inform patients about standards, safety measures and complaints procedures, and develop core competences in patient safety for patients;
- **establish/strengthen reporting and learning systems on adverse events:** provide information about adverse events, errors and near-misses, encourage health-care workers to report, provide opportunity for patients and families to report their experiences, and complement other safety reporting systems; and

⁸⁰ Commission of the European Communities. *White paper – Together for Health: A Strategic Approach for the EU 2008–2013* {COM(2007)630 Final} (http://ec.europa.eu/health/ph_overview/Documents/strategy_wp_en.pdf).

⁸¹ Public Health [web site]. European Commission. Health Programme 2008–2013: Together for health (http://ec.europa.eu/health/ph_programme/pgm2008_2013_en.htm).

⁸² Decision No 1350/2007/EC of the European Parliament and of the Council establishing a second programme of Community action in the field of health (2008–2013). *Official Journal of the European Union*, 301/November 2007 (<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:301:0003:0013:EN:PDF>).

- **promote education and training of health professionals in patient safety:** a multi-disciplinary patient safety education and training for health workers, including under- and postgraduate education and core competencies, development of knowledge and skills in patient safety.

Besides these actions recommended for Member States, the Council Recommendation also calls the EU to:

- **classify, codify and measure patient safety:** develop common definitions and terminology, a set of comparable indicators to identify safety problems, evaluate effectiveness of interventions, and facilitate mutual learning, as well as to gather and share comparable data and information on patient safety outcomes;
- **share knowledge, experience and best practice:** establish efficient and transparent patient safety programmes, structures and policies, ensure effectiveness and transferability of patient safety interventions and solutions, and major patient safety alerts; and
- **develop and promote research on patient safety.**

Other European Organizations playing important roles in patient safety (alphabetical, and non-exhaustive list)

1. European Association of Hospital Pharmacists (EAHP)
2. European Association for Medical Device Reprocessing (EAMDR)
3. European Association of Senior Hospital Physicians (AEMH)
4. European Diagnostic Manufacturers Association⁸³ (EDMA)
5. European Federation of Pharmaceutical Industries and Associations⁸⁴ (EFPIA)
6. European Federation of Nurses Association⁸⁵ (EFN)
7. European Health Telematics Association⁸⁶ (EHTEL)
8. European Health Management Association⁸⁷ (EHMA)
9. European Hospital and Healthcare Federation⁸⁸ (HOPE)
10. European Medical Technology Industry Association⁸⁹ (Eucomed)
11. European Medicines Agency⁹⁰ (EMA) (an EU decentralized agency with headquarters in London and main responsibility in the protection and promotion of public and animal health, through the evaluation and supervision of medicines for human and veterinary use)
12. European Monitoring Centre for Drugs and Drug Addiction⁹¹ (EMCDDA) (an EU decentralized agency established in 1993, and inaugurated in Lisbon in 1995, providing a European overview of drug problems and solid evidence base to support the drugs debate)
13. European Patients' Forum⁹² (EPF)
14. European Society for Quality in Healthcare⁹³ (ESQH)

⁸³ European Diagnostic Manufacturers Association [web site] (<http://www.edma-ivd.be/>).

⁸⁴ European Federation of Pharmaceutical Industries and Associations [web site] (<http://www.efpia.eu/>).

⁸⁵ European federation of Nurses Association [web site] (<http://www.efnweb.org/version1/EN/index.html>).

⁸⁶ European Health Telematics Association [web site] (<http://www.ehtel.org/>).

⁸⁷ European Health Management association [web site] (<http://www.ehma.org/?q=node/575>).

⁸⁸ European Hospital and Healthcare Federation [web site] (<http://www.hope.be/>).

⁸⁹ European Medical Technology Industry Association [web site] (<http://en.wikipedia.org/wiki/Eucomed>).

⁹⁰ European Medicines Agency [web site] (<http://www.ema.europa.eu/home.htm>).

⁹¹ European Monitoring Centre for drugs and drug addiction [web site] (<http://www.emcdda.europa.eu/>).

⁹² European Patients Forum [web site] (<http://www.eu-patient.eu/>).

⁹³ European Society for Quality of Care [web site] (<http://www.esqh.net/>).

15. Pharmaceutical Group of the European Union⁹⁴ (PGEU) (the European association representing community pharmacists)
16. Picker Institute Europe⁹⁵ (works at a European level to shape Europe-wide legal and regulatory frameworks relevant to health services, health and medicines information, and patients' rights and experiences of health care)
17. Standing Committee of European Doctors⁹⁶ (CPME)

Legal provisions:

- Recommendation from the Council June 2009 on patient safety, including prevention and control of healthcare-associated infections (2009)
(http://ec.europa.eu/health/ph_systems/docs/patient_rec2009_en.pdf)
- Communication from 15 December 2008 on patient safety, including the prevention and control of healthcare-associated infections
(http://ec.europa.eu/health/ph_systems/docs/patient_com2008_en.pdf)
- Recommendation from 15 December 2008 on patient safety, including the prevention and control of healthcare-associated infections
(http://ec.europa.eu/health/ph_systems/docs/patient_rec2008_en.pdf)

Supporting documents:

- Summary of the impact assessment accompanying the Council Recommendation
(http://ec.europa.eu/health/ph_systems/docs/patient_ia_exs_en.pdf)
- Impact assessment accompanying the Council Recommendation
(http://ec.europa.eu/health/ph_systems/docs/patient_ia_en.pdf)
- Open Consultation on Patient Safety from 25 March to 20 May 2008(http://ec.europa.eu/health/ph_systems/docs/patient_consult_frep_en.pdf)
- Opinion of the European Economic and Social Committee on Council Recommendation
(<http://eescopinions.eesc.europa.eu/eescopiniondocument.aspx?language=EN&docnr=0632&year=2009>)
- ENVI Committee's Report on Council Recommendation
(<http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+COMPARL+PE-419.906+01+DOC+PDF+V0//EN&language=EN>)

⁹⁴ Pharmaceutical group of the European Union [web site] (<http://www.pgeu.eu/Home/tabid/134/Default.aspx>).

⁹⁵ Picker Institute Europe [web site] (<http://www.pickereurope.org/117>).

⁹⁶ Standing Committee of European Doctors [web site] (<http://www.cpme.be/index.php>).

CoE, OECD and WHO on patient safety

Complementary and supportive actions are being developed by the major European actors on the health scene, with increased emphasis on a broad conceptual approach to patient safety (system thinking). The CoE, the OECD and WHO were chosen for the purpose of this briefing, for their international perspective and European (countries) membership. These international organizations, coordinating their efforts within respective mandates and expertise, work on implementing effective quality and patient safety improvements.

CoE and patient safety

Health protection and promotion are part of the work deployed within the CoE towards ethical European health policies, by:

- merging human rights, social cohesion and health agendas;
- harmonizing Member States' health policies in terms of safety and quality;
- developing preventive medicine and health education; and
- promoting patients' rights, access to health care, citizen participation and protection of vulnerable groups.

These four objectives support, through different mechanisms, action on patient safety, making particular reference to the harmonization of quality standards in Member States' health policies, health education and promotion of patients' rights.

In line with the above, work started with specific actions, addressing, e.g. quality and safety standards for substances of human origin⁹⁷, quality of care⁹⁸, data management⁹⁹, patient participation¹⁰⁰ and medication safety¹⁰¹.

Besides sectoral intervention, the CoE started to develop horizontal policy statements (such as the Convention on Human Rights and Biomedicine) inspired by its overall aim to achieve common rules in the health field and foster access to safe health care as a basic right in all Member States¹⁰².

Patient safety was specifically addressed in 2003, with the establishment of the ad hoc Committee of Experts on Management of Safety and Quality in Health Care (SP-SQS) to generally examine this issue, and the ad hoc Expert Group on Safe Medication Practices (P-SP-PH/SAFE) within the Committee of Experts on Pharmaceutical questions (P-SP-PH).

⁹⁷ Council of Europe. *European Agreement on the Exchange of Therapeutic Substances of Human Origin*, European Treaty Series, No. 26, 1958.

⁹⁸ *Recommendation No R (97)17 of the Committee of Ministers to Member States on the development and implementation of quality improvement systems (QIS) in health care*. Council of Europe, Committee of Ministers, 1997.

⁹⁹ *Recommendation No. R (97) 5 on the protection of medical data*. Council of Europe, Committee of Ministers, 1997.

¹⁰⁰ *Recommendation No. R (2000) 5 on the development of structures for citizen and patient participation in the decision-making process affecting health care*. Council of Europe, Committee of Ministers, 2000.

¹⁰¹ *Resolution ResAP (2001)2 concerning the pharmacist's role in the framework of health security*. Council of Europe, Committee of Ministers, 2001.

¹⁰² *Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine*. Council of Europe, 1997 (<http://conventions.coe.int/Treaty/EN/Treaties/html/164.htm>).

Work of the expert committees is supported by conferences and cooperation activities examining key challenges in the health field and facilitating dialogue and information exchange. Within this framework, the “Patient Safety as European Challenge” Conference was held in Warsaw in 2005. On this occasion, the draft Recommendation of the CoE Committee of Ministers to Member States on management of safety and quality in health care was presented and considered as a useful tool and vehicle for introducing changes to improve patient safety. The Warsaw statement endorsed the Luxembourg declaration on patient safety¹⁰³. According to its conclusion, the important areas to address are:

- developing a culture of safety with a system approach
- establishing reporting systems for learning and action
- involving patients/citizens in the processes of improving safety.

It was stated that patient safety should be a priority on the international and national political agendas, sustained by the collaboration between the CoE, EU, WHO and other relevant organizations and networks to ensure the implementation of patient safety actions.

The Committee of Ministers of the CoE adopted the Recommendation Rec(2006)7 on management of patient safety and prevention of adverse events in health care¹⁰⁴ at the 965th meeting of the Ministers’ Deputies on 24 May 2006. The recommendations (abridged below) call the Member States to:

- ensure that patient safety is the cornerstone of all relevant health policies, and develop a coherent patient safety policy framework promoting safety culture at all levels of care;
- encourage the development of non-punitive reporting and learning systems aggregated at national level and review other existing complementary patient safety information;
- promote the development of educational programmes for health-care personnel, support research, and produce regular reports on dedicated actions taken;
- set up reliable patient safety indicators for various health-care settings, to identify safety problems, evaluate the effectiveness of interventions, facilitate international comparison; and
- cooperate internationally to build a platform for the mutual exchange of experience and knowledge of all aspects of health-care safety.

Appendix E of the Recommendation Rec(2006)7 includes a specific strategy promoting medication safety, based on the consideration that medication errors are a common preventable cause of adverse events related to health care (30.3–47% of all adverse drug events are preventable, with the most serious being caused by medication errors). The Expert Group on Safe Medication Practices made publicly available in March 2007 the first international report¹⁰⁵ on medication error in Europe, proposing a multi-disciplinary integrated approach to enhance safety of medication practices.

¹⁰³ The Secretary General of the Council of Europe. *Warsaw statement on patient safety*, 2005 (http://www.coe.int/t/dg3/health/Source/2005Warsawstatement_en.doc).

¹⁰⁴ *Recommendation Rec(2006)7 of the Committee of Ministers to Member States on management of patient safety and prevention of adverse events in health care*. Council of Europe, Committee of Ministers, 2006. (<https://wcd.coe.int/ViewDoc.jsp?id=1005439&BackColorInternet=9999CC&BackColorIntranet=FFBB55&BackColorLogged=FFAC75>).

¹⁰⁵ Council of Europe. Partial Agreement in the Social and Public Health Field. Expert Group on Safe Medication Practices. *Creation of a better medication safety culture in Europe: building up safe medication practices*, 2006, available 19 March 2007 (http://www.coe.int/t/e/social_cohesion/soc-sp/Medication%20safety%20culture%20report%20E.pdf).

OECD and patient safety

Through its Health Committee, the OECD aims to foster improvements in the performance of Member States for higher economic growth and improved welfare. Since the importance of patient safety and quality of health care has been recognized, work is focusing on defining common measurables and metrics.

In line with the above, the OECD Health Care Quality Indicators project (HCQI) was initiated in 2001, and built on the work of two pre-existing international collaborative projects organized by the Commonwealth Fund and the Nordic Council of Ministers¹⁰⁶. Other measurement initiatives launched by WHO¹⁰⁷, the WHO Regional Office for Europe¹⁰⁸ and the European Commission (Eurocare¹⁰⁹ and European Community Health Indicators¹¹⁰ project) were also considered. The HCQI expert group works towards defining a set of indicators that reflect a robust picture of health-care quality and can be reliably reported and compared across countries.

Patient safety was identified as one of the core directions of work and a set of comprehensive indicators across five priority domains (hospital-acquired infections; (post)operative complications; obstetrics; sentinel events; and adverse events) was recommended. The 2004 report of the expert group agreed upon 21 indicators (based on their importance and scientific soundness) out of 59 identified possibilities¹¹¹.

A new phase of work was started to improve data systems in five priority areas, including patient safety (along with cardiac care, primary care, mental health care and diabetes care). The round of data collection conducted in 2006 to support this work confirmed the paucity of available national statistics to meaningfully track patient safety.

Subsequently, the OECD ad hoc Expert Sub-Group on Patient Safety¹¹² was created and met in June 2006, in Dublin. It was agreed to develop a comprehensive technical manual supporting the measurement of 15 patient safety indicators to be collected in national hospital administrative databases for international harmonization of data comparability.

The technical manual was released in 2008¹¹³, providing definitions of the indicators, coding and calculation processes and a crosswalk from ICD 9 to ICD 10 coding¹¹⁴. Based on the decision of

¹⁰⁶ Mattke S, Epstein AM, Leatherman S. The OECD Health Care Quality Indicators Project: history and background. *International Journal for Quality in Health Care*, 2006 18(Supplement 1):1–4;doi:10.1093/intqhc/mzl019 (<http://intqhc.oxfordjournals.org/misc/terms.shtml>).

¹⁰⁷ *World Health Report 2000 – Health systems: Improving performance*. World Health Organization, 2000.

¹⁰⁸ Veillard J et al. A performance assessment framework for hospitals: the WHO regional office for Europe PATH project. *International Journal for Quality in Health Care*, 2002, 17:487–496.

¹⁰⁹ EUROCARE-3: Survival of cancer patients diagnosed 1990–94, results and commentary. *Annals of Oncology*, 14:v61–v118 (<http://www.eurocare.it/>).

¹¹⁰ Kramers PG. The ECHI project: health indicators for the European Community. *European Journal of Public Health*, 2003, 13:101–106 (<http://www.ncbi.nlm.nih.gov/pubmed/14533758>).

¹¹¹ Millar J et al. *Selecting indicators for patient safety at the health system level in the OECD countries*. OECD Health Technical Papers, DELSA/ELSA/WD/HTP(2004)18 (<http://www.oecd.org/dataoecd/53/26/33878001.pdf>).

¹¹² On-Line Guide to OECD Intergovernmental Activity [online database]. HCQI Sub-group of Patient Safety Experts, 2007 (http://webnet3.oecd.org/OECDgroups/Bodies.asp?body_id=7384&lng=E).

¹¹³ Drösler S. *Facilitating cross national comparison of indicators for patient safety at the health system level in the OECD countries*. OECD Health Technical Papers, DELSA/ELSA/WD/HTP(2008)1 (<http://www.oecd.org/dataoecd/24/48/40401929.pdf>).

the OECD's Patient Safety Expert Subgroup in October 2008, only 7 indicators of the 15 selected proved to be ready for data collection and analysis. The remainder appeared to rely on procedure codes that proved difficult to map across countries (e.g. postoperative respiratory failure), or they were found to have limited validity in studies that distinguished conditions present on admission from hospital-acquired complications.

The 2009 Patient Safety Indicators (PSI) Report¹¹⁵ reviewed the progress of research and development of the indicators (differences in reporting attributable to diagnostic coding were found to account for 28–52% variation in PSI rates), and included an updated and revised technical manual.

The patient safety indicators (PSI), as part of the larger set of quality indicators, represent measures selected for their importance (effect on health, policy relevance and susceptibility to influence the health-care system) and scientific soundness (face validity, content validity and reliability).

Work still in progress in this field was complemented by other HCQI projects, such as:

- the Responsiveness and Patient Experiences priority area project¹¹⁶: reviewing the role of patient experiences and perspectives on quality of health care in improving health-service performance in terms of responsiveness to patients' needs;
- the Health Promotion, Prevention and Primary Care project¹¹⁷: the resulting report provides a detailed discussion on the scientific soundness and policy relevance of 27 dedicated indicators, (6 related to health promotion, 13 to preventive care with a focus on prenatal care and immunizations and 8 to primary clinical care addressing activities related to risk reduction), putting strong emphasis on the public health aspects of primary care¹¹⁸.

Current work in 2010 includes further analysis with a group of countries with the aim of validating the methodological approach for the calculation of these indicators. HCQI activities and the use of the HCQI indicators have been promoted among the countries of the European Union through successful cooperation with the EC's Patient Safety and Quality of Care Working Group and the related EUNetPaS project¹¹⁹.

The long-term objective of the HCQI project is to develop a set of internationally comparable indicators that can then be used to raise questions for further exploration of the underlying reasons of differences that exist across and within countries.

¹¹⁴ WHO *International Classification of Disease ICD 10*. Geneva, World Health Organization, 1994 (<http://www.who.int/whosis/icd10/>).

¹¹⁵ Drösler S. *Health care quality indicators project, patient safety indicators report 2009*. OECD Health Working Papers, DELSA/HEA/WD/HWP(2009)5/ANN (<http://www.oecd.org/dataoecd/56/30/44193189.pdf>)

¹¹⁶ Garrat AM, Solheim E, Danielsen K. *National and cross national survey of patient experiences: a structured review*. Norwegian Knowledge Centre for the Health Services, 2008, 7 (<http://www.oecd.org/dataoecd/43/58/39493930.pdf>).

¹¹⁷ Marshall M et al. *Selecting indicators for the quality of health promotion, prevention and primary care at the health system level in OECD countries*, OECD Health Technical Papers, 2004, DELSA/ELSA/WD/HTP(2004)6, (<http://www.oecd.org/dataoecd/27/52/33865865.pdf>).

¹¹⁸ Marshall M et al. OECD Health Care Quality Indicator Project. The expert panel on primary care prevention and health promotion. *International Journal for Quality in Health Care*, 2006, 18(Supplement 1):21–25, doi:10.1093/intqhc/mzl021

¹¹⁹ Directorate for Employment, Labour and Social Affairs [website]. HCQI Related Work (http://www.oecd.org/document/5/0,3343,en_2649_33929_37159877_1_1_1_1,00.html)

WHO patient safety programme

For WHO, patient safety is a fundamental principle of health care. It is, however, a known fact that every point in the process of care-giving implies a certain degree of risk. Adverse events may result from problems in practice, products, procedures or systems. Patient safety improvements demand a complex system-wide effort, involving a broad range of actions in performance improvement and environmental safety and risk management, including infection control, safe use of medicines, equipment safety, safe clinical practice and safe environment of care.

WHO has deployed extensive work dedicated to global and regional health priorities, guiding, advising and supporting its Member States in improving quality and safety of care. Targeted interventions took a comprehensive stance in addressing patient safety in 2002, with its first dedicated Resolution. The actions summarized below relate mainly to the patient safety programme activities, and do not include actions developed under health systems programmes (e.g. pharmaceuticals, blood safety, health financing etc) neither by specific disease prevention and control programmes (e.g. immunization, HIV/AIDS, tuberculosis, mental health etc).

Basis of WHO comprehensive action on patient safety: Resolution WHA55.18

On 18 May 2002, the Resolution WHA55.18: *Quality of care: patient safety* was adopted by the 55th World Health Assembly.

Drawing from a background report¹²⁰ of the WHO Secretariat, the World Health Assembly Resolution WHA55.18¹²¹ urged Member States to pay the closest possible attention to patient safety and establish science-based systems for its improvement, and requested the Director-General to endorse a series of actions promoting patient safety. The resolution ensured that the drive for safer health care is becoming a worldwide endeavour that could bring significant benefits to patients in all countries around the globe, irrespective of their level of resources or degree of development.

In response to this backbone Resolution, WHO launched in October 2004 a patient safety programme – a world alliance for safer care.

WHO patient safety programme

This dedicated programme was launched to raise awareness and political commitment to improving the safety of care and to facilitate the development of patient safety policies and practices in all countries. It provides a vehicle for international collaboration and action between Member States, WHO's Secretariat, technical experts, consumers, professionals and industry groups.

Its initial six global directions of work developed exponentially in time, trying to respond to the complexities of patient safety challenges and to the resulting needs for comprehensive and coordinated actions¹²². While directions of work are set globally, and led by dedicated international expert groups, these are subject to regional adaptation to facilitate the establishment

¹²⁰ Report by the secretariat, WHA 55.13. Quality of care: patient safety. In: *Fifty-fifth World Health Assembly, Provisional Agenda Item 13.9*. Geneva, World Health Organization, 2002 (document A55/13). (http://apps.who.int/gb/archive/pdf_files/WHA55/ea5513.pdf).

¹²¹ Resolution WHA 55.18/2002. Quality of care: patient safety. In: *Fifty-fifth World Health Assembly, Agenda Item 13.1.May 2002*. Geneva, World Health Organization, 2002 (document WHA55.18) (http://apps.who.int/gb/archive/pdf_files/WHA55/ewha5518.pdf).

¹²² WHO patient safety – programme areas [web site] (<http://www.who.int/patientsafety/about/programmes/en/>).

and strengthening of patient safety programmes within Member States. A network of regional focal points is leading this work in collaboration with the WHO patient safety programme (WHO Patient Safety), by identifying country priorities, areas for regional collaboration, knowledge-sharing, and ways in which regional action can support global work.

The activities deployed by WHO Patient Safety can be summarized¹²³ as follows:

1. Assessing and understanding the problems of unsafe care

• Reporting and Learning for Patient Safety

Generating best practice guidelines for reporting and learning aims to help countries develop or improve reporting and learning systems in order to strengthen the safety of patient care. In this respect, guidelines on adverse event reporting and learning systems were drafted in 2005¹²⁴. While providing directions for the above, the draft guidelines also suggest other sources of patient safety information considered important for a complete picture of sources of risk and patient harm¹²⁵.

• The International Classification for Patient Safety

*Patient safety taxonomy*¹²⁶ represents a core priority towards ensuring consistency in concepts, principles, and norms existing in patient safety work. The numerous existing patient safety classification systems and the lack of universal agreement and method for standardizing patient safety principles hampered efforts to compare and learn from data within and across countries.

The International Patient Safety Classification (IPSC) project started in 2005. Work drew on already developed taxonomies (i.e. Joint Commission's Patient Safety Event Taxonomy-US; National Patient Safety Agency National Reporting and Learning System-UK, Australian Patient Safety Foundation's Advanced Incident Management System, Eindhoven University of Technology and Leiden University Medical Centre's Eindhoven/PRISMA-Medical Classification Model-Netherlands), and linked to the WHO Family of International Classifications, specifically the International Statistical Classification of Diseases and Related Health Problems (ICD)¹²⁷ and the WHO Drug Dictionary¹²⁸.

The Final Technical Report for the Conceptual Framework for the IPSC was issued in February 2009¹²⁹. It is composed of ten high-level stable classes and contains distinct and unambiguous

¹²³ World Alliance for Patient Safety. *Forward Programme 2008–2009, First Edition*. Geneva, World Health Organization, 2008 (WHO/IER/PSP/2008.04) (http://www.who.int/entity/patientsafety/information_centre/reports/Alliance_Forward_Programme_2008.pdf).

¹²⁴ World Alliance for Patient Safety. *WHO draft guidelines for adverse event reporting and learning systems*. Geneva, World Health Organization, 2005 (WHO/EIP/SPO/QPS/05.3) (http://www.who.int/patientsafety/events/05/Reporting_Guidelines.pdf).

¹²⁵ WHO Patient safety. From information to action [web site] (http://www.who.int/patientsafety/reporting_and_learning/en/, accessed 10 April 2010).

¹²⁶ WHO Patient Safety. Taxonomy. International Classification for Patient Safety (ICPS) [web site] (<http://www.who.int/patientsafety/taxonomy/en/>)

¹²⁷ WHO Classifications. International Classification of disease (ICD) [web site] (<http://www.who.int/whosis/icd10/>).

¹²⁸ Uppsala Monitoring Centre. WHO Drug Dictionary Enhanced [web site] (<http://www.umc-products.com/DynPage.aspx?id=73588&mn1=1107&mn2=1139>).

¹²⁹ *The Conceptual Framework for the International Classification for Patient Safety (v.1.1) - Final Technical Report and Technical Annexes*. World Health Organization, 2009 (http://www.who.int/patientsafety/implementation/taxonomy/icps_download/en/index.html).

concepts described by a term (label). Forty-eight key concepts have been defined and assigned preferred terms to facilitate understanding and transfer of information relevant to patient safety. These concepts represent the start of a continual process of progressively improving a common international language relevant to patient safety. The framework is intended to be adaptable across the spectrum of health care (comparability across cultures, languages, disciplines, organizations, boundaries and time)¹³⁰. Collaborative work continues towards the development of the full ICPS.

• **Research for patient safety**

Research for patient safety aims to establish a set of global research priorities, an internationally agreed agenda drawn up with researchers, research funders, research users and consumers, and to strengthen the foundations for dedicated research. To date, there are important knowledge gaps about the burden of unsafe care, particularly in developing and transitional countries, and about the essential interventions and solutions that are necessary to improve patient safety globally. One of the limitations of current patient safety data is that they are primarily drawn from developed countries.

→ Defining the global priorities for patient safety

The 2009 report, *Global Priorities for Patient Safety Research: Better knowledge for safer care*¹³¹, identifies 50 patient safety priority topics ranked according to developing, transitional and developed nations, with existing differences and similarities. Effectiveness and cost efficiency were most important for developing countries, while communication and safety culture were predominant for developed nations. Transitional countries tended to incorporate a mix of both sets of priorities. WHO Patient Safety refined these further to a shortlist of six issues that are of greatest relevance to all countries, and produced a comprehensive report on current knowledge and gaps in patient safety research.

→ Strengthening patient safety research

Addressing the lack of research capacity in patient safety is one of the goals of the programme, placing emphasis on developing institutional competency and mainstreaming research programmes within existing health systems. The work is focused around three key areas: funding research activities, training leaders in patient safety research and developing a global network for research on patient safety.

- Patient safety small research grants¹³² (launched in June 2008) aim to build local capacity by focusing on applied research in line with the global priorities identified. The grants programme was developed to stimulate research on patient safety primarily in developing countries, and to promote patient safety culture through dissemination of research findings to the global community.
- The Patient Safety Research Curriculum Guide was developed in 2009, to help learners achieve the competencies required for patient safety research worldwide. The curriculum contents are based on the competencies that were identified and agreed upon by a group

¹³⁰ *The Conceptual Framework for the International Classification for Patient Safety, an overview*. World Health Organization, (http://ec.europa.eu/health/ph_systems/docs/ev_20080313_co04_en.pdf).

¹³¹ *Global priorities for patient safety research: Better knowledge for safer Care*. Geneva World Health Organization, 2009 (http://whqlibdoc.who.int/publications/2009/9789241598620_eng.pdf).

¹³² WHO Patient safety. WHO Patient Safety Small Research Grants [web site] (<http://www.who.int/patientsafety/research/grants/en/index.html>).

of experts as part of the WHO patient safety research education programme. It includes teaching and learning strategies, together with evaluation techniques.

- A Global Patient Safety Research Network is being developed to promote greater communication and collaboration among researchers and research users. It currently broadcasts training activities on patient safety research, facilitates exchange between young researchers worldwide and supports collaborative projects.

2. Developing norms and establishing standards to reduce harm

• Solutions for patient safety

*Solutions to reduce the risk of health care and improve its safety*¹³³ translate knowledge into practical interventions that prevent patient safety problems recurring and reduce risk to patients. A wide range of solutions already exists in a number of countries.

→ WHO Collaborating Centre on Patient Safety Solutions¹³⁴

In 2005, the Joint Commission on Accreditation of Healthcare Organizations and Joint Commission International (USA) were jointly designated as a WHO Collaborating Centre (WHOCC) on Patient Safety Solutions (PSS). The WHOCC defined PSS as “any system design or intervention that has demonstrated the ability to prevent or mitigate patient harm stemming from the processes of health care”.

The PSS, presented in the form of an *Aide-mémoire*, intend to promote an environment and support systems that minimize the risk of harm overcoming the complexity and lack of standardization in modern health care.

Nine initial solutions were developed and made available for use in April 2007:

- Look-Alike, Sound-Alike Medications
- Patient Identification
- Communication During Patient Handovers
- Performance of Correct Procedure at Correct Body Site
- Control of Concentrated Electrolyte Solutions
- Assuring Medication Accuracy at Transitions in Care
- Avoiding Catheter and Tubing Misconnections
- Single Use of Injection Devices
- Improved Hand Hygiene to Prevent HAI

In 2008–2009, a new solution was developed focusing on the prevention of bloodstream infections associated with central lines. This solution has a detailed format with recommendations to a wide range of target audiences, including policy- and decision-makers, health-care workers and patients. This solution is due to be released in 2010.

¹³³ WHO Patient safety. Patient Safety Solutions [web site]
(<http://www.who.int/patientsafety/implementation/solutions/patientsafety/en/>).

¹³⁴ The Joint Commission. WHO Collaborating Centre for Patient Safety Solutions [web site]
(<http://www.ccforsafety.org/>).

• **High 5s Initiative**¹³⁵

The goal of this initiative is to achieve significant, sustained and measurable reduction of high-risk patient safety problems, by facilitating the implementation and evaluation of the standardized patient safety solutions, and sharing knowledge and experience gained through a joint learning network. The initiative was launched in 2006 and is now a multi-country, multi-agency collaboration supporting patient safety objectives. It is supported by WHO, the Agency for Healthcare Research and Quality and the Commonwealth Fund in the USA, and the WHOCC for Patient Safety. The participating countries are: Australia, Canada, France, Germany, the Netherlands, Singapore, the United Kingdom, and the United States of America.

The major components of the High 5s initiative include:

- development and implementation of problem-specific Standardized Operating Protocols (SOPs);
- creation of a comprehensive Impact Evaluation Strategy;
- collection of data, reporting and analysis; and
- the establishment of an electronic collaborative learning community.

The High 5s initiative is designed to assess the feasibility and success of implementing standardized approaches to specific patient safety problems across multiple countries and cultures, and enable further SOPs improvement.

Between 2007 and 2009, five SOPs were developed to address:

1. concentrated injectable medicines;
2. medication accuracy at transitions in care;
3. correct procedure at the correct body site;
4. communication failures during patient handovers;
5. HAI.

Testing and implementation of the first three SOPs started in 2010 in the participating countries. The remaining two SOPs have been deferred to a later time. Each SOP summarizes the problem, the strength of evidence that supports the solution, potential barriers to adoption, potential unintended consequences created by the solution, patient and family roles in the solution, and references and resources. The evaluation strategy seeks to identify the factors underlying the adverse events of concern, match these factors against those that the SOPs are trying to prevent, and track changes in the safety cultures of the participating hospitals.

• **Technology for Patient Safety**

WHO Patient Safety and its stakeholders have undertaken a scoping exercise to identify and clarify the role, objectives, and future possible directions (concerning research, education and implementation) regarding technology for patient safety¹³⁶ both in the developed and developing world.

Focusing on the opportunities to harness new technologies to improve the safety of care, four work streams were identified: information technology for patient safety; making technology safer; introducing new technology safely; and training and simulation technology. In line with

¹³⁵ *Action on patient safety: High 5s*. Geneva, World Health Organization (http://www.who.int/patientsafety/solutions/high5s/High5_overview.pdf)

¹³⁶ WHO Patient safety. Technology [web site] (<http://www.who.int/patientsafety/implementation/technology/en/index.html>, accessed 10 April 2010).

the above, an international dedicated conference took place in London, May 2010, on the appropriateness of the choice of technology, with a focus on patient safety¹³⁷.

3. Improving knowledge access, use and evaluating impact

• Global Patient Safety Challenges (GPSC)

The GPSC aims to address a significant area of risk to patient safety that is relevant to all countries, and through shared expertise and identified best practices create a safer environment of care.

Every few years a GPSC is formulated to galvanize global commitment and action on a core patient safety issue that addresses a significant area of risk for all WHO Member States. The momentum of each GPSC is being kept through awareness campaigns, country experiences and quantification of gain. To date, the following GPSC have been identified:

- the first GPSC “Clean Care is Safer Care”¹³⁸ (2005–2006) addressing prevention of HAI, with an emphasis on hand hygiene;
- the second GPSC “Safe Surgery Saves Lives”¹³⁹ (2007–2008) addressing the safety of surgical care through the Surgical Safety Checklist and associated Global Pulse Oximetry Project.

The **first GPSC “Clean Care is Safer Care”** was launched in October 2005. The challenge addresses clean products (i.e. blood safety), clean practices (i.e. safe clinical procedures), clean equipment (i.e. injection safety) and clean environment (i.e. safe water and sanitation). Safe hand hygiene practices at all levels of health care stay at the core of the challenge, as a first step in ensuring high standards of infection control and significantly contributing to a measurable reduction in the burden of disease attributable to HAI. Dedicated guidelines and tools have been developed to support its implementation.

→ WHO Guidelines on Hand Hygiene in Health Care¹⁴⁰ (revised edition released 2009) provide health-care workers, hospital administrators and health authorities with a review of evidence and specific recommendations for improving safety practices in health-care settings.

→ WHO Multimodal Hand Hygiene Improvement Strategy¹⁴¹ aimed at translating the guidelines into practice. A testing phase (seven countries in the six WHO regions) was undertaken to generate information on feasibility, validity, reliability and cost-effectiveness of the interventions; and to adapt and refine proposed implementation strategies¹⁴².

¹³⁷ WHO Patient safety .International conference on technology and patient safety [web site].World Health Organization, 2010 (<http://www.who.int/patientsafety/events/10/130510/en/index.html>, accessed 10 April 2010).

¹³⁸ WHO Clean Care is Safer Care [web site]. World Health Organization, 2010 (<http://www.who.int/gpsc/en/index.html>).

¹³⁹ WHO Patient safety. Safe Surgery Saves Lives [web site]. World Health Organization, 2010 (<http://www.who.int/patientsafety/safesurgery/en/index.html>).

¹⁴⁰ *WHO Guidelines on Hand Hygiene in Health Care*. World Health Organization, 2009 (http://whqlibdoc.who.int/publications/2009/9789241597906_eng.pdf).

¹⁴¹ *SAVE LIVES: Clean Your Hands. Guide to Implementation. A Guide to the Implementation of the WHO Multimodal Hand Hygiene Improvement Strategy*. World Health Organization, 2009 (WHO/IER/PSP/2009.02) (http://whqlibdoc.who.int/hq/2009/WHO_IER_PSP_2009.02_eng.pdf)

¹⁴² *Clean Care is Safer Care. Testing the WHO Guidelines on Hand Hygiene in Health Care in eight pilot sites worldwide*. World Health Organization, (http://www.who.int/gpsc/country_work/pilot_sites/introduction/en/index.html)

→ “SAVE LIVES: Clean Your Hands” initiative¹⁴³ was launched on 5 May 2009, as an annual global event to monitor progress in addressing the first GPSC and to exchange best practice in hand hygiene: cleaning hands at the right time and in the right way. Health-care facilities and countries were encouraged to register and endorse the multimodal hand hygiene implementation strategy, as well as running their own satellite events¹⁴⁴.

The second edition of this initiative was held on 5 May 2010¹⁴⁵ recording a major success: more than 11 500 health-care facilities in 130 countries around the globe registered online their commitment to improve hand hygiene, and the process is continuing. Additionally, many European nations and subnations are already running their own hand-hygiene campaigns¹⁴⁶: Belgium, Croatia, Denmark, England, France, Germany, Iceland, Ireland, Italy, Luxembourg, Northern Ireland, Norway, Portugal, Scotland, Spain, Sweden and Switzerland.

Further details about how the first Challenge is being addressed can be found in the following section of this document: Preventing health-care-associated infections.

The **second GPSC “Safe Surgery Saves Lives”**¹⁴⁷ was launched on 25 June 2008. The Challenge aims at improving the safety of surgical care and to this end, four areas in which dramatic improvements could be made were identified: clean surgery (antisepsis and control of contamination), safe anaesthesia (close patient monitoring), safe operators (technically competent operation and teamwork), and quality assurance (assessment, monitoring, feedback).

Information on the role and patterns of surgical safety in public health, a minimum set of ‘surgical vital statistics’ for national and international surveillance of surgical care, a WHO Surgical Safety Checklist listing minimum standards and monitoring implementation are all tools of the second GPSC.

→ WHO Guidelines for Safe Surgery¹⁴⁸ published in a second edition in 2009 include a review of the evidence in a wide range of settings and contexts and recommended practices to ensure the safety of surgical patients worldwide. The Guidelines were revised, drawing on the results of international pilot testing of the intervention using the WHO Surgical Safety Checklist.

→ WHO Surgical Safety Checklist¹⁴⁹ (the focus of the second GPSC campaign) aimed at improving compliance with safety standards and proved to decrease complications from surgery in the eight pilot hospitals from the six WHO regions, where it was evaluated¹⁵⁰. The checklist was established with a view to simplicity, wide applicability, and measurability. It identifies three phases of an operation, each corresponding to a specific period in the normal flow of work

¹⁴³ WHO Clean Care is Safer Care. About SAVE LIVES: Clean Your Hands [web site]. World Health Organization, 2010 (<http://www.who.int/gpsc/5may/background/en/index.html>).

¹⁴⁴ WHO Clean Care is Safer Care. Registration update - countries and territories [web site]. World Health Organization, 2010 (http://www.who.int/gpsc/5may/registration_update/en/index.html).

¹⁴⁵ WHO Clean Care is Safer Care. 5 May 2010: an incredible achievement [web site]. World Health Organization, 2010 (<http://www.who.int/gpsc/5may/en/index.html>).

¹⁴⁶ WHO Clean Care is Safer Care. Nations and subnations running hand hygiene campaigns [web site]. World Health Organization, 2010 (http://www.who.int/gpsc/national_campaigns/country_list/en/index.html).

¹⁴⁷ WHO Patient safety. Safe surgery saves lives: the second global patient safety challenge [web site]. World Health Organization, 2009 (<http://www.who.int/patientsafety/safesurgery/en/index.html>).

¹⁴⁸ *WHO Guidelines for Safe Surgery 2009*. World Health Organization, 2009 (http://whqlibdoc.who.int/publications/2009/9789241598552_eng.pdf).

¹⁴⁹ *Surgical Safety Checklist*. World Health Organization, 2009 (http://whqlibdoc.who.int/publications/2009/9789241598590_eng_Checklist.pdf).

¹⁵⁰ Haynes AB et al. For the Safe Surgery Saves Lives Study Group: A Surgical Safety Checklist to reduce morbidity and mortality in a global population. *The New England Journal of Medicine*, vol 360 (5):491–499, 29 January, 2009 (<http://content.nejm.org/cgi/content/full/NEJMs0810119>).

(before starting anaesthesia, before starting the operation, and before the patient leaves the operating room), and a standardized approach to safety management.

The success of the Surgical Safety intervention demonstrated by the significant reduction in surgery related morbidity and mortality has triggered a huge response. Over 3700 health-care facilities have registered as participating hospitals, implementing the checklist in their operating rooms and over 21 countries are starting nationwide implementation campaigns.

→ WHO Global Pulse Oximetry project¹⁵¹ aims to improve the quality of anaesthesia care globally by developing a) affordable pulse oximetry devices for operating rooms in the developing world (pulse oximetry technology is one component that is not currently available in every operating room); and b) a training programme to improve provider response to hypoxemia.

The World Federation of Societies of Anaesthesiologists plays a key role in encouraging anaesthetists around the world to adopt the WHO Surgical Safety Checklist and identifying low resource settings not currently using pulse oximeters. It has now increased participation in this project by taking on the responsibility for pulse oximeters' procurement.

• **Tackling antimicrobial resistance**¹⁵²

A comprehensive situation analysis on the growing threat to patient safety from antimicrobial resistance (AMR) was initiated in 2008 by WHO Patient Safety. Building on existing evidence and the WHO 2001 global strategy for containment of AMR¹⁵³, expert work started along five action areas (rational drug use, animal husbandry, research and development, surveillance, and infection control), towards developing a comprehensive work plan. The strategy to better contain anti-infective drug resistance necessitates several interventions, including: more prudent use of antibiotics in human and animal medicine, as well as in animal husbandry/agriculture; incentives to support research and development both for new anti-infective drugs and for vaccines; and additional measures to prevent the spread of drug-resistant organisms, including stronger surveillance, and tailored to the quantity and patterns of anti-infective drug use.

Currently, WHO Patient Safety is working towards finding solutions that could support the international activities to address AMR in the best possible way.

• **Eliminating central-line-associated bloodstream infections**¹⁵⁴

Central venous catheters – often used in intensive care unit (ICU) patients – can result in serious bloodstream infections and even death if not appropriately managed. The Keystone ICU¹⁵⁵ project in the state of Michigan, in the United States, reduced their central-line-associated bloodstream infection rates to 0%, drawing from the novel approach piloted by Johns Hopkins

¹⁵¹ WHO Patient Safety. Global Pulse Oximetry Project [web site] World Health Organization, 2010 (http://www.who.int/patientsafety/safesurgery/pulse_oximetry/en/ accessed 10 April 2010).

¹⁵² WHO Patient Safety. Tackling antimicrobial resistance [web site] World Health Organization, 2010 (<http://www.who.int/patientsafety/amr/en/>, accessed 10 April 2010).

¹⁵³ WHO *Global Strategy for Containment of Antimicrobial Resistance*. Geneva, World Health Organization, 2001 (WHO/CDS/CSR/DRS/2001.2) (http://www.who.int/drugresistance/WHO_Global_Strategy_English.pdf).

¹⁵⁴ WHO Patient safety. Preventing blood stream infections from central line venous catheters [web site] World Health Organization, 2010 (<http://www.who.int/patientsafety/implementation/bsi/en/>, accessed 10 April 2010).

¹⁵⁵ Pronovost P et al. An intervention to decrease catheter-related bloodstream infections in the ICU. *New England Journal of Medicine*, 2006, 355:2725–32.

University. This includes the development of a five-item checklist preventing the most common causes of the infection, as well as a comprehensive change management strategy involving input and leadership from ICU staff and management.

Drawing from this experience, WHO Patient Safety aims to produce a set of recommendations which, when applied, could lead to a reduction in central-line-associated bloodstream infections. As a preliminary step, work was initiated with some Member States to learn whether the experience of Michigan can be replicated on a large scale basis in different environments. In this respect, both the Ministry of Health and Social Policy of Spain¹⁵⁶ and the National Patient Safety Agency of England and Wales are collaborating with WHO Patient Safety in adapting and scaling up the project.

4. Promoting innovation and sustaining commitment

• Patients for Patient Safety (PfPS)¹⁵⁷

PfPS is building a patient-led, global network of patients and patient organizations to champion patient safety at country and regional levels. It aims to develop patient/consumer involvement in the design and development of safer health-care systems by enhancing open communication between patients and their health-care providers, within a team approach.

In line with the above, a *global network of patient safety champions* from different countries around the world has been established and is slowly growing. These champions are individuals with direct experience in health-care system failures and are committed to raise awareness on patient safety issues and to work in partnership with health-care professionals and policy-makers to shape effective improvement actions.

The outcomes of the first PfPS workshop held in London in November 2005, which brought together patients and patient safety advocates from all over the world, led to the *London Declaration on Patients for Patient Safety*¹⁵⁸ on 17 January 2006. The declaration advocates for care without harm and calls for the reduction of health-care errors as a basic human right. It also emphasizes the importance of collaborative steps in developing/strengthening patient empowerment, constructive dialogues, reporting, learning and redress and promoting best practices for health-care improvement.

The London Declaration was followed by regional and national actions, with among others, a European PfPS workshop¹⁵⁹ held in Dublin in 2006. The growing emphasis on health literacy facilitates empowerment and a wider involvement of patients in health-related policy initiatives. The virtual PfPS community and the global newsletters enhance dialogue, experience exchange and information sharing. Patient safety champions continue to work in promoting patient involvement and effective partnership in the process of care.

¹⁵⁶ WHO Patient safety. Bacteriemia-zero [web site]. World Health Organization, 2009 (http://www.who.int/patientsafety/implementation/bsi/bacteriemia_zero/en/index.html).

¹⁵⁷ WHO Patient safety. Patients for patient safety [web site]. World Health Organization, 2010 (http://www.who.int/patientsafety/patients_for_patient/en, accessed 10 April 2010).

¹⁵⁸ *London Declaration Patients for Patient Safety*. London, WHO World Alliance for Patient Safety, 17 January 2006 (http://www.who.int/patientsafety/information_centre/Final_London_Declaration_Feb06.pdf).

¹⁵⁹ *Report of the European Regional Patient for Patient Safety Workshop*, Dublin, Ireland, 3–5 September 2007, EUR/07/5074812. Copenhagen, WHO Regional Office for Europe, 2007.

- **The Patient Safety Award programme**¹⁶⁰

The purpose of the project is to acknowledge in a formal way excellent patient safety practice in the health-care sector across Member States. It will also serve as a means to raising awareness and driving patient safety improvements worldwide. Recognition will be made for excellence in patient safety, and can be given to individuals or groups of individuals who have shown sustained achievement in the field.

5. Strengthening capacity for patient safety worldwide

- **Education for Safer Care**

Published in January 2009, the first edition of the Patient Safety Curriculum Guide¹⁶¹ aimed to encourage and facilitate the teaching of patient safety topics to medical students. The guide is being piloted in ten medical schools throughout the world with each school implementing at least 3 of the 11 topics included as modules. In addition, an international evaluation study of the Curriculum Guide is in progress in ten countries across all six WHO regions, which will run until June 2010.

Work is continuing to widen the scope of the WHO Patient Safety Curriculum Guide and include multi-professional perspectives. A revised edition is being developed to include curricula for pre-service training of all health workers. The International Confederation of Midwives, International Council of Nurses, the International Pharmaceutical Federation, FDI World Dental and the World Medical Alliance are participating in this update.

- **The Knowledge Management programme**¹⁶²

This programme aims to provide a platform for accessing up-to-date patient safety information, as well as bringing together the wisdom and experience of people who are engaged in improving the safety of health care on many different fronts, from researchers and policy-makers to patients and hospital planners.

→ WHO Patient Safety Newsletter¹⁶³

September 2009 saw the publication of the first edition of the WHO Patient Safety newsletter, an informative resource on the development of various patient safety issues. Two newsletters mapping the progress of dedicated interventions have already been made available.

¹⁶⁰ WHO Patient safety. WHO Patient Safety - programme areas [web site]. World Health Organization, 2010 (<http://www.who.int/patientsafety/about/programmes/en/>).

¹⁶¹ WHO Patient Safety Curriculum Guide for Medical Schools. Geneva, World Health Organization, 2009 (http://whqlibdoc.who.int/publications/2009/9789241598316_eng.pdf).

¹⁶² World Alliance for Patient Safety. *Forward Programme 2008–2009, First Edition*. Geneva, World Health Organization, 2008 (WHO/IER/PSP/2008.04) (http://www.who.int/entity/patientsafety/information_centre/reports/Alliance_Forward_Programme_2008.pdf).

¹⁶³ WHO Patient safety. Quarterly newsletter [web site]. World Health Organization, 2010 (http://www.who.int/patientsafety/news_events/newsletter/en/index.html, accessed 10 April 2010).

- **Key actors working with WHO Patient Safety**¹⁶⁴ (the list is in alphabetical order and is non-exhaustive)

→ International Organizations:

- International Alliance of Patients' Organizations
- International Council of Nurses
- International Federation of Infection Control
- International Federation for Medical and Biological Engineering
- International Federation of Red Cross and Red Crescent Societies
- International Hospital Federation
- International Pharmaceutical Federation
- International Society for Quality in Health Care Inc. (ISQua)
- The Commonwealth Fund
- World Health Professional Alliance
- World Medical Association

→ National Organizations:

- Agency for Healthcare Research and Quality (AHRQ)
- Australian Commission on Safety and Quality in Health Care
- Spanish Agencia de Calidad del Sistema Nacional de Salud
- Canadian Patient Safety Institute
- Consumers Advancing Patient Safety
- Dutch Institute for Healthcare Improvement
- German Coalition for Patient Safety
- French Haute Autorité de Santé
- Ireland's Health Information and Quality Authority
- The Joint Commission
- UK National Patient Safety Agency
- National Patient Safety Foundation

¹⁶⁴ WHO Patient safety. International organizations working with WHO Patient Safety [web site]. World Health Organization, 2010 (http://www.who.int/patientsafety/about/international_organizations/en/index.html, accessed 10 April 2010).

Preventing health-care-associated infections

Definition

Health-care-associated infections (HAI)¹⁶⁵ are defined as infection(s) occurring in a patient during the process of care in a hospital or other health-care facility, which was not present or incubating at the time of admission. This includes infections acquired in the hospital but appearing after discharge, and also occupational infections among staff of the facility.

Background information

In developed countries, HAI concerns 5–15% of hospitalized patients and can affect 9–37% of those admitted to ICUs¹⁶⁶. Prevalence rates of infection acquired in ICUs vary from 9 to 37% when assessed in Europe and the USA, with crude mortality rates ranging from 12% to 80%. Many studies have documented that defective hand cleansing has been associated with endemic HAIs and also with several HAI outbreaks.

HAI burden in Europe¹⁶⁷:

- prevalence: 3.5–14.8% (average: 7.1%)
- 4 131 000 affected patients per year
- 4 544 100 episodes of HAI every year
- 16 million extra days of hospital stay per year
- 37 000 attributable deaths per year (and contribution to an additional 110 000)
- annual economic impact: about € 7 billion (including direct costs only)

HAI are often difficult to treat due to the multiple resistance to antibiotics of the causative microorganisms¹⁶⁸. Furthermore, with people's increasing mobility within and between health-care systems (and the freedom in the EU to seek medical treatment outside the country of residence) resistant microorganisms can spread rapidly between countries.

During outbreaks, health-care settings may often become amplifiers of disease, with impact on the hospital and community health. HAI was the primary accelerator of severe acute respiratory syndrome (SARS) infections, accounting for 55% to 72% of probable cases. The emergence of life-threatening infections, such as SARS and the risk of a new influenza pandemic, highlight the urgent need for efficient and basic infection control practices, like improving hand hygiene adherence.

¹⁶⁵ *SAVE LIVES: Clean Your Hands. Guide to Implementation. A Guide to the Implementation of the WHO Multimodal Hand Hygiene Improvement Strategy.* World Health Organization, 2009 (WHO/IER/PSP/2009.02) (http://whqlibdoc.who.int/hq/2009/WHO_IER_PSP_2009.02_eng.pdf).

¹⁶⁶ *WHO Guidelines on Hand Hygiene in Health Care: A Summary.* World Health Organization, 2009, (WHO/IER/PSP/2009.07).

¹⁶⁷ *The global burden of health care-associated infections.* Inaugural infection control webinar series. World Health Organization, 2010 (http://www.who.int/entity/gpsc/5may/media/infection_control_webinar_19012010.pdf).

¹⁶⁸ Public health. Healthcare associated infections [web site]. European Commission (http://ec.europa.eu/health/patient_safety/healthcare_associated_infections/index_en.htm).

Evidence shows that at least 35–50% of HAI can be reduced with preventive measures that are associated with only five patient care practices¹⁶⁹: hand hygiene and standard precautions; use and care of urinary catheters; use and care of vascular access lines; therapy and support of pulmonary functions; and surveillance of surgical procedures.

Surveillance, prevention, and control of HAI is a recognized priority, and coordinated actions, linked with addressing AMR, have been given increasing attention at global, regional, national and local levels.

Prevention of HAI is at the core of the first WHO Global Patient Safety Challenge (GPSC).

WHO patient safety addressing HAI

First WHO GPSC¹⁷⁰

Following its formal launch on 13 October 2005, the period 2005–2009 was globally significant for patient safety and infection control as rapid progress was made by key partners, WHO regions and country leaders to meet the first GPSC.

The main identified objectives were:

1. to raise global awareness about the importance of HAI;
2. to galvanize political commitment by Member States; and
3. to provide technical support and promote best practices at the point of care.

Hand hygiene promotion became a key focus in many health-care settings and in many countries and its successful improvement has galvanised further actions in other infection control and patient safety fields. It raised awareness about and political commitment for the importance of hand hygiene to address HAI in countries representing more than 78% of the world's population.¹⁷¹

Evidence-based, field-tested for feasibility and effectiveness and developed through the consensus of more than 100 international experts, the WHO Guidelines on Hand Hygiene in Health Care 2009¹⁷² is considered the cornerstone technical reference document on hand hygiene. At the core of its recommendations is the WHO "My 5 Moments for Hand Hygiene"¹⁷³ concept, published in 2007, essential for hand hygiene improvement at the point of care.

Starting in 2007, WHO catalysed sharing and learning among existing formal hand hygiene campaigns and initiatives brought together in the so-called CleanHandsNet.

¹⁶⁹Pittet D. *The modern approach to infection control*. Webinar presentation, 2010 (http://www.who.int/entity/gpsc/5may/media/infection_control_webinar_16022010.ppt).

¹⁷⁰ WHO Global Alert and Response (GAR). Infection prevention and control in health care [web site]. World Health Organization, 2010 (http://www.who.int/csr/bioriskreduction/infection_control/en/index.html, accessed 10 April 2010).

¹⁷¹ World Alliance for Patient Safety. *Forward Programme 2008–2009, First Edition*. Geneva, World Health Organization, 2008 (WHO/IER/PSP/2008.04) (http://www.who.int/entity/patientsafety/information_centre/reports/Alliance_Forward_Programme_2008.pdf).

¹⁷² WHO *Guidelines on Hand Hygiene in Health Care*, World Health Organization, 2009 (http://whqlibdoc.who.int/publications/2009/9789241597906_eng.pdf).

¹⁷³ WHO Patient safety. About SAVE LIVES: Clean Your Hands [web site]. World Health Organization, (<http://www.who.int/gpsc/5may/background/5moments/en/index.html>).

The key achievements corresponding to the three main objectives of the dedicated programme are summarized in the following table.

Table: Achievements of the first GPSC 2005–2009 (source: WHO, B. Allegranzi, 2010)

First GPSC objectives	Achievements
1. To raise global awareness about the importance of HAI	Support by key stakeholders: Association for Professionals in Infection Control and Epidemiology, Inc (APIC); Centers for Disease Control and Prevention (CDC); European Centre for Disease Prevention and Control (ECDC); European Society of Clinical Microbiology and Infectious Diseases (ESCMID); International Federation of Infection Control (IFIC); Infection Prevention and Control Africa Network (IPCAN); Society for Healthcare Epidemiology of America (SHEA); Patients for Patient Safety (PfPS).
	4 international workshops with more than 80 country representatives
	55 scientific publications and 23 abstracts in international conferences
	Invited lectures in more than 100 national and international conferences
	Launch of “Save Lives: Clean Your Hands”
	Systematic reviews on the burden of HAI
2. To galvanize political commitment	123 pledge signatures (30 in Europe)
	38 national/sub-national hand hygiene campaigns (16 in Europe), part of the WHO CleanHandsNet
	Survey of campaigning countries and report on the web
3. To provide technical support and promote best practices at the point of care	WHO Guidelines on Hand Hygiene in Health Care
	WHO Multimodal Hand Hygiene Improvement Strategy ¹⁷⁴
	Testing and finalization of 40 tools for the WHO Hand Hygiene Improvement Strategy (implementation toolkit)
	Translation of the tools into many languages including the other five official WHO languages

¹⁷⁴ *SAVE LIVES: Clean Your Hands. Guide to Implementation. A Guide to the Implementation of the WHO Multimodal Hand Hygiene Improvement Strategy.* World Health Organization, 2009 (WHO/IER/PSP/2009.02) (http://whqlibdoc.who.int/hq/2009/WHO_IER_PSP_2009.02_eng.pdf).

On 5 May 2009, the SAVE LIVES: Clean Your Hands initiative¹⁷⁵ was launched, with the finalized WHO Guidelines on Hand Hygiene in Health Care, their implementation toolkit¹⁷⁶ and newly designed web pages. This coincided with a global communications strategy leading to, by that date, 5000 registered health-care facilities (adhering to implementation) from around the globe. The goal of reaching 10 000 registered health-care facilities by the one-year anniversary (5 May 2010) of this initiative was successfully achieved, with more than 11 543 health-care facilities (4377 from Europe) in 130 countries (40 from Europe) stating their commitment with WHO to improve hand hygiene¹⁷⁷.

The first Challenge secretariat and key international experts have worked together to achieve the programme objectives and develop technical products through the following task forces: WHO CleanHandsNet (key projects for campaigning countries); SAVE LIVES: Clean Your Hands; education/training/tools; alcohol-based handrubs; global burden of HAI; new hand hygiene tools; infection control in developing countries; patient involvement; behavioural change; and infection control standards for accreditation.

Through the vision of “*Making infection control, with hand hygiene as the solid and essential basis, a priority in health care everywhere*”, the first Challenge works towards consolidating and building upon its achievements in close partnership with the WHOCC on Patient Safety (infection control and improving practices) established at the University of Geneva Hospital, in Switzerland. Further expected outcomes relate to:

- a) evaluating data available on the burden of HAI in specific countries/regions and globally, and the impact of interventions to reduce it;
- b) strengthening and developing infection control capacity and improvement at regional, subregional and country level to particularly affect knowledge, skills and behaviours through the provision of fit-for-purpose tools and materials;
- c) developing and coordinating educational, training and research programmes based on multimodal evidence-based strategies; and
- d) advising on infection-control measures and priorities, providing technical expertise to the development of wider associated guidelines, tools, education and information resources.

Eliminating central-line-associated bloodstream infections¹⁷⁸

Central-line-associated bloodstream infections (CLA BSI) occur routinely in ICUs and have proven to cause increased length of hospital stay, add a huge burden on treatment costs and are often also lethal. In the United States alone, it is estimated that 80 000 CLA BSI occur every year that may be associated with 28 000 deaths within ICUs. Given that the average cost of treating a patient with BSI is US\$ 45 000 (median BSI rates from 1.8 to 5.2 per 1000 catheter days), this adds up to about US\$ 2.3 billion annually¹⁷⁹. This situation is common and can be extrapolated to many other countries in the world.

¹⁷⁵ WHO Patient safety. Clean Care is Safer Care [web site] (<http://www.who.int/gpsc/en/index.html>).

¹⁷⁶ WHO Patient safety. Clean Care is Safer Care. Tools and resources [web site]. World Health Organization, (<http://www.who.int/gpsc/5may/tools/en/index.html>).

¹⁷⁷ WHO Patient safety. Clean Care is Safer Care. Sign up! Registration site for 5 May 2010 ‘Clean care’ event [web site]. World Health Organization, (<http://www.who.int/gpsc/5may/register/en/index.html>)

¹⁷⁸ World Alliance for Patient Safety. *Forward Programme 2008–2009, First Edition*. Geneva, World Health Organization, 2008 (WHO/IER/PSP/2008.04)

(http://www.who.int/entity/patientsafety/information_centre/reports/Alliance_Forward_Programme_2008.pdf).

¹⁷⁹ Kass N et al. Controversy and Quality Improvement: Lingerin Questions About Ethics, Oversight, and Patient Safety Research. *The Joint Commission Journal on Quality and Patient Safety*, 34(6):349–353, June 2008.

The intervention developed by the Johns Hopkins University team, included a range of evidence-based technical and adaptive tools that demonstrated a reduction to zero in the median CLA BSI rate in participating ICUs¹⁸⁰. The copyright of the intervention was donated to WHO to facilitate its use in other countries. Subsequently, two European countries have already started piloting the strategy: Spain and the United Kingdom.

The Ministry of Health and Social Policy of Spain in collaboration with *La Sociedad Española de Medicina Intensiva, Crítica y Unidades Coronarias* (SEMYCIUC), joined this initiative, launching the project “*Bacteriemia-zero*”, aimed to evaluate the effectiveness of the intervention in large scale implementation. *Bacteriemia-zero* aimed to scale-up the successful Michigan model on a nationwide basis in Spanish ICUs. The project started in late October 2008 with a training workshop involving national and regional ICU coordinators. To date, out of the 260 ICUs which were invited, 178 adult and surgical ICUs within teaching and non-teaching hospitals across the 17 Health Regions in Spain are participating in the study. The data collection process will finish in June 2010 when the outcomes as well as the experience from and barriers to implementation will be evaluated. The results and lessons learnt from the first 18 months of this project's implementation are being analyzed.

In the United Kingdom, in 2009, the National Patient Safety Agency (NPSA) of England and Wales started implementing the strategy for the reduction of CLA BSI in adult and paediatric patients receiving care in ICUs, under the project name of "Matching Michigan". The NPSA replicates the work in Michigan using a package of intervention tools and change management strategies adapted and implemented by the National Health Service (NHS). The work is focused on the 240 English adult ICUs within acute Hospital Trusts from 1 April 2009, for one year. To date, pilot work was undertaken in 15 adult and 4 paediatric ICUs within the Northeast Strategic Health Authority over five months and rolled out nationally October/November 2009. Data collection on a nationwide basis commenced on 1 December 2009 and to date, 130 ICUs are submitting data. This evaluation process is expected to provide valuable insights on its applicability and adaptability to various ICU settings.

Pandemic H1N1 Patient Care Checklist¹⁸¹

In 2009, in response to the pandemic threat of a new influenza A (H1N1) strain, the Pandemic H1N1 Patient Care Checklist was developed by WHO Patient Safety in collaboration with technical experts in health security and environment.

The checklist is intended for use by hospital staff treating a patient with a medically suspected or confirmed case of Pandemic (H1N1) 2009, and combines clinical management of the individual patient and infection control measures to limit transmission.

The checklist is an easy reference to ensure essential actions are performed and it is open to adaptations so that it will fit in a local context. Clinical teams in a number of settings have provided feedback on its clarity and usability, and its operability is subject to ongoing evaluation.

¹⁸⁰ Pronovost P et al. An intervention to decrease catheter-related bloodstream infections in the ICU, *New England Journal of Medicine*, 2006, 355:2725–32.

¹⁸¹ *Patient Care Checklist New Influenza A (H1N1)*. World Health Organization, June 2009 (http://www.who.int/entity/csr/resources/publications/swineflu/ah1n1_checklist.pdf).

Other WHO dedicated global programmes

Implementing the WHO interim guideline on infection prevention and control of epidemic and pandemic prone acute respiratory diseases (2007-2009)¹⁸²

The European region was the first to perform field evaluation of an interim WHO Infection Control (IC) guideline before its implementation. Sharing the lessons learnt with the process of infection prevention and control (IPC) of epidemic and pandemic prone acute respiratory diseases was essential in the implementation of a sustainable and feasible IPC programme at both hospital and national levels during the early stage of the influenza pandemic 2009.

Implementing WHO interim advice on IPC for confirmed or suspected cases of pandemic (H1N1) 2009 and of epidemic and pandemic prone acute respiratory diseases became feasible as IPC programmes became accountable, supported by reliable stakeholders in the health sector. Although many questions related to the application of infection control practices for confirmed or suspected cases of pandemic (H1N1) 2009 were raised, IPC programmes proved to be a key component to patient safety.

Implementing the core components for infection prevention and control programmes (2010–2011)¹⁸³

This ongoing initiative aims to assist Member States in promoting high-quality health care with a low risk of HAI for patients, health-care workers and all people associated with the health-care setting and its environment, and to accomplish these goals in a cost-effective manner.

Initiatives from the EC and the ECDC

Hospital in Europe Link for Infection Control through Surveillance “HELICS”¹⁸⁴

HELICS was established in the 1990s (DG SANCO funded framework). The general aim of the project was to establish a validated surveillance system and a European database on nosocomial infections (NI) to explore areas for improvement in health-care delivery. HELICS routine data collection continued¹⁸⁵ through the IPSE project (work package 4).

The project developed consensus protocols on surveillance of hospital-acquired infections by the creation and analysis of two databases: surgical site infections (SSI) and intensive care unit infections (ICUI), creating a basis for a common (surveillance) methodology.

It laid the foundations for a European network on hospital acquired infections by creating an SSI and ICUI database. The network maintained and strengthened the surveillance of SSI and ICUI at international level, and assisted countries in the European region in developing their own national surveillance networks. It provides a platform for communication and sharing information and best practices on infection control.

¹⁸² *Infection prevention and control of epidemic- and pandemic-prone acute respiratory disease in health care: WHO Interim Guidelines*. Geneva, World Health Organization, 2007 (http://www.who.int/csr/resources/publications/WHO_CDS_EPR_2007_6c.pdf).

¹⁸³ *Core components for infection prevention and control programmes*. Geneva, World Health Organization, June 2008 (http://whqlibdoc.who.int/hq/2009/WHO_HSE_EPR_2009.1_eng.pdf).

¹⁸⁴ HELICS Surgical Site Infections Statistical Report. European Commission /DG SANCO, March 2006 (http://whqlibdoc.who.int/hq/2009/WHO_HSE_EPR_2009.1_eng.pdf).

¹⁸⁵ Improving Patient Safety in Europe. IPSE Work Package 4 [web site] (<http://ipse.univ-lyon1.fr/Working%20packages/Working%20Package%204.htm>).

Improving Patient Safety in Europe (IPSE)¹⁸⁶

The IPSE project (DG SANCO funded) aimed to reduce the burden of HAI and their related threats of AMR by providing evidence-based guidance and educational tools, strengthening the status of infection control professionals and strengthening surveillance and developing indicators. It developed as an extended partnership between the European Commission, the WHO Regional Office for Europe, Claude Bernard University Lyon, leading European public health institutes, ECDC, the European Society of Clinical Microbiology and Infectious Diseases (ESCMID) and EU-supported networks, and was concluded in June 2008.

A brief overview of the project results is presented below¹⁸⁷:

- European training for infection control doctors and nurses in connection with ESCMID
 - Results: a core curriculum for training on HAI control, prevention and surveillance through the European Union.
- European standards and indicators for Public Health surveillance and technical guidelines for the control of HAI and AMR
 - Results: Guidelines on infection control in health care settings in Europe: recommended practices and indicators for monitoring and evaluating progress, including top 20 national indicators (national organization and extension of HAI and AMR control policy in hospitals).
- Event warning and rapid exchange on NI and AMR
 - Results: IT-secured tool for rapid exchange of standardized information on NI and AMR events that may diffuse widely and represent a threat to public health developed in collaboration with European AMR Surveillance System internet based information system (EARSS-ibis).
- Technical support for sustaining and extending HELICS surveillance of NI and control of HAI and AMR
 - Results: expanded HELICS surveillance to a few other countries and improved data completeness. The project maintained and further developed the HELICS surveillance network on SSI and ICUI.
- Improving surveillance and controlling antibiotic resistance in ICU
 - Results: the IT tool developed to gather basic information and AMR rates from ICU was very efficient, achieving quality of information technology for HELICS surveillance.
- Providing complementary tools for the study and control of AMR in ICUs, IPSE has addressed the neglected issue of NI in nursing homes
 - Results: a survey collecting information on long-term care (LTC) characteristics, infection control and infection surveillance in LTC showing that only a few European countries have surveillance of LTC characteristics in place, and those with a surveillance system have different standards and usually not enough resources to carry it out. In addition, LTC facilities are defined differently in the countries making comparison difficult.

The project revealed enormous differences within infection control programmes in the European Region and represented probably the most extensive international exercise performed to date in

¹⁸⁶ Improving Patient Safety in Europe (IPSE) [web site] (<http://ipse.univ-lyon1.fr/>, accessed 10 April 2010).

¹⁸⁷ Desenclos JC et al. *Review of IPSE Work Packages*. 6 August 2007 (<http://ipse.univ-lyon1.fr/Documents/IPSE%20WP%20Review.pdf>).

this field. Furthermore, a remarkable level of agreement on performance indicators was achieved and, as recognition of this work, the IPSE group was invited to contribute to the draft document on HAI prevention and control for the EU Council.

The WHO Regional Office for Europe (responsible in the IPSE project¹⁸⁸ with the review and development of policy recommendations, standards and indicators) continues to develop training materials on infection control measures that are critical for preparedness and control of communicable diseases transmission in health-care settings¹⁸⁹.

European Centre for Disease Prevention and Control (ECDC) activities on HAI¹⁹⁰

ECDC is addressing the threat of AMR and HAI, through implementing a specific programme with the following objectives:¹⁹¹

- to develop a reference point for data, information and scientific advice on AMR and HAI in the European Union;
- to provide information and guidance on important and emerging AMR and HAI issues;
- to promote implementation of the Council Recommendation of 15 November 2001 on the prudent use of antimicrobial agents in human medicine (2002/77/EC);
- to promote implementation of elements related to HAI that are part of the Council Recommendation of 9 June 2009 on patient safety, including the prevention and control of HAI (2009/C 151/01); and
- to contribute to building capacity for the prevention and control of AMR and HAI in Member States.

To achieve these objectives, the programme includes the following activities:

- collection and dissemination of epidemiological data on AMR and HAI, including transfer and integration of corresponding dedicated surveillance networks;
- guidance (systematic reviews) for the prevention and control of specific multidrug-resistant bacteria, e.g. MRSA, *Clostridium difficile* and HAI;
- an annually recurring campaign – European Antibiotic Awareness Day – to support national activities aimed at raising public awareness about AMR and responsible use of antimicrobials throughout the European Union;
- fostering effective exchange of experiences on AMR and HAI among Member States;
- reporting on:
 - the extent of over-the-counter use of antibiotics, i.e. without a prescription, in the European Union; and
 - the gap between multidrug-resistant bacteria in the European Union and development of novel antibacterial medicinal products; and

¹⁸⁸ Improving Patient Safety in Europe. IPSE Work Package 2 [web site] (<http://ipse.univ-lyon1.fr/Standards%20and%20Indicators.htm>, accessed 10 April 2010).

¹⁸⁹ Communicable diseases: Surveillance [web site]. Copenhagen, WHO Regional Office for Europe, March 2009 (http://www.euro.who.int/communicablediseases/20080909_3, accessed 10 April 2010).

¹⁹⁰ Healthcare-associated infections (HAI) [web site]. Stockholm, European Centre for Disease Prevention and Control (ECDC) ([http://ecdc.europa.eu/en/healthtopics/pages/healthcare-associated_infections_\(hcai\).aspx](http://ecdc.europa.eu/en/healthtopics/pages/healthcare-associated_infections_(hcai).aspx)).

¹⁹¹ Programme on antimicrobial resistance and healthcare-associated infections [web site]. Stockholm, European Centre for Disease Prevention and Control (ECDC), 2008 (http://ecdc.europa.eu/en/activities/diseaseprogrammes/Pages/Programme_on_antimicrobial_resistance_and_healthcare-associated_infections.aspx).

- development of:
 - an alert and response system for AMR and HAI events;
 - a European Union-wide prevalence survey on HAI; and
 - specific European training courses, e.g. on the control of multidrug-resistant bacteria in health-care settings.

***Eurosurveillance*¹⁹², the European scientific journal**

Eurosurveillance is an open-access European scientific journal devoted to the epidemiology, surveillance, prevention and control of communicable diseases. It was founded in 1995 and until March 2007 co-funded by the European Commission, the Institut de Veille Sanitaire in Paris, France and the Health Protection Agency in London, United Kingdom. As of March 2007, *Eurosurveillance* is being published by the ECDC in Stockholm, Sweden.

In January 2008, the journal became a weekly online publication, containing rapid communications, in-depth research articles, surveillance and outbreak reports and e-alerts on events that need to be urgently communicated to the readers for rapid public health action. All articles are indexed in the PubMed/MEDLINE and Scopus as well as several other databases. *Eurosurveillance* is now listed for an impact factor with Thomson Reuters¹⁹³.

In 2009, 156 peer-reviewed rapid communications, 112 peer-reviewed articles, as well as editorials, news items, letters and meeting reports were published.

In January 2010, *Eurosurveillance* was accredited by the Health on the Net (HON) Foundation¹⁹⁴ for its sound, reliable and trustworthy health information on the Internet.

Other EU co-funded projects addressing HAI and AMR (non-exhaustive list)

***Mastering hospital antimicrobial resistance and its spread into the community (MOSAR)*¹⁹⁵**

The project (start date 2007, funded FP6-LIFESCIHEALTH) is led by France and aims to gain breakthrough knowledge in the dynamics of transmission of antimicrobial-resistant bacteria (AMRB), which account for an increasing number of HAI that are subsequently spreading into the community. It includes interventional controlled studies in diverse hospital settings, mathematical modelling of resistance dynamics, health economics and health science research.

***Detecting and eliminating bacteria using information technologies (DEBUGIT)*¹⁹⁶**

The project (start date 2008, funded FP7-ICT) is led by Belgium. The project focuses on risk assessment and patient safety and aims to develop a Medical Knowledge Repository, drawing on information and temporal patterns of patient harm provided through a virtualized Clinical Data Repository (open framework, focused on infectious diseases). Knowledge gained is expected to be used as decision support and monitoring tool in the clinical environment to report and prevent patient safety issues.

¹⁹² Eurosurveillance [web site] (<http://www.eurosurveillance.org/Default.aspx>).

¹⁹³ Steffens L, Ekdahl K. Accepted for the impact factor – what is the impact of Eurosurveillance? *Eurosurveillance* 14 (38), 28 Sept 2009 (<http://www.eurosurveillance.org/ViewArticle.aspx?ArticleId=19339>).

¹⁹⁴ Health on the Net Foundation [web site] (<http://www.hon.ch>).

¹⁹⁵ MOSAR [web site] (<https://www.mosar-sic.org/mosar/en-GB/>).

¹⁹⁶ DEBUGIT [web site]. Seventh Framework Programme, European Commission (<http://www.debugit.eu/>).

Preventing community and nosocomial spread and infection with MRSA ST 398 – instruments for accelerated control and integrated risk management of antimicrobial resistance (PILGRIM)¹⁹⁷

The project (start date 2009, funded FP7-HEALTH) is led by the United Kingdom. It aims to provide deeper understanding of factors affecting pathogen-host interaction of resistant bacteria (MRSA ST398 - an animal-adapted, zoonotic, resistant pathogen that causes colonization and infection in humans in community and health-care settings) and subsequent novel and more effective measures for the accelerated identification and control of resistant bacteria, in order to prevent and eradicate community-acquired and nosocomial infections.

Prevention of Hospital Infections by Intervention and Training (PROHIBIT)¹⁹⁸

The project (start date 2010, funded FP7-HEALTH) is led by Switzerland, and aims to systematically review existing guidelines and practices (including surveillance and public reporting) to prevent HAI in European hospitals, and test the effectiveness of interventions of known efficacy. Particular attention will be given to catheter-related bloodstream infections, measuring compliance with key prevention practices, and uptake/impact of the WHO hand hygiene protocol and the ‘catheter bundle’ in ICUs. A set of recommendations and supportive guidance targeting various levels of intervention (policy-makers, managers and medical professionals) required to prevent HAI will be developed.

Translation Research On Combating Antimicrobial Resistance (TROCAR)¹⁹⁹

The project (start date 2008, funded FP7-HEALTH) is led by Spain. It aims to investigate the fundamentals of the epidemiology of new highly virulent multi-resistant strains and recommend comprehensive control measures to limit or prevent the spread of highly virulent multidrug-resistant clones. The three major outputs comprise: a) defining the major high-risk resistant clones based on an appropriate representative collection and new clinical strains; b) promoting collaborative European research to investigate the specific traits associated with virulence, transmission, persistence and resistance of epidemic clones, resistance determinants and their genetic environment; and c) developing bio-informatic tools to allow rapid identification of resistant strains with epidemic potential.

Burden of Disease and Resistance in European Nations (BURDEN)²⁰⁰

The project (end date 2010, funded DG SANCO) led by Germany, was established to understand the dimensions of the economic and societal consequences of AMR. It worked on identifying information needs, determining the excess morbidity, mortality and costs attributable to AMR in hospitals and ICUs in different European countries, including a forecast of AMR based on data available through EARSS and HELICS/IPSE. Mathematical modelling allowed estimation of the financial impact of AMR on care in European hospitals, while the human and societal dimensions of infections caused by resistant pathogens and the repercussions for the health-care systems were equally explored.

¹⁹⁷ European Commission, Research – Health, FP7 projects, PILGRIM[web site] (http://ec.europa.eu/research/health/infectious-diseases/antimicrobial-drug-resistance/projects/009_en.html).

¹⁹⁸ PROHIBIT [web site]. Seventh Framework Programme (<https://plone2.unige.ch/prohibit/>).

¹⁹⁹ TROCAR [web site]. Seventh Framework Programme (<http://www.trocarproject.eu/>).

²⁰⁰ BURDEN of Resistance and Disease in European Nations [web site]. Institute of Environmental Medicine and Hospital Epidemiology, University Medical Centre Freiburg (<http://www.eu-burden.info/burden/pages/objectives.php>).

Development and Dissemination of a School Antibiotic and Hygiene Education Pack and Website across Europe (EBUG PACK)²⁰¹

The project (end date 2009, funded DG SANCO) was led by the United Kingdom and drew on a successful evaluation of the Bug Investigator project. The Bug Investigator project is a United Kingdom educational campaign on the rationale of antibiotics use and reducing spread of infections through improved hygiene targeting school children. EBUG developed and disseminated across Europe a similar antibiotic and hygiene (hand and respiratory hygiene) teaching resource for children aged 9–16 years (one version for children aged 9–11 and another for the 13–16 age range). The teaching pack with worksheets linking in with each country's National Curriculum is accompanied by interactive web sites and estimated to reach at least 76% of the European population.

²⁰¹ Public Health. EBUG Pack - Development and Dissemination of a School Antibiotic and Hygiene Education Pack and website across Europe [web site] 2005 (http://ec.europa.eu/health/ph_projects/2005/action2/action2_2005_6_en.htm).

Work in progress

Moving from declarations and recommendations to action

Patient safety has acquired high-level recognition on political agendas in Europe. Legislative initiatives, guiding recommendations, declarations and targeted research were triggered to direct, identify and support the prioritization required in the translation of such a complex concept into actual practice.

The multiple entry points and implications in addressing patient safety have led, however, to delays of the implementation process. Completing the field application of dedicated policy initiatives that have been formulated requires investment in health system strengthening (Tallinn Charter 2008)²⁰² and integration of environmental and health concerns in all public policies and actions (Parma Declaration 2010)²⁰³.

While stewardship of the system is expected to provide visibility and political support, it also evaluates/enables the necessary funding mechanisms and resources for high-quality, patient-centred health services, a key to attaining and measuring health gain. Clear oversight procedures, defined and applied at institutional and professional levels, will support the implementation of integrated and standardized health-care delivery, monitoring and evaluation of inputs, outputs and patient satisfaction. The overall systemic perspective and intervention chain will produce economies of scale that will benefit health.

Patient safety (an integral component of the quality of care) is an overarching issue, which reflects the need for increased awareness and confidence in the system, as well as overcoming barriers generated by low investment in system redesign, limited use of information technology and inadequately resourced or competent staff. Reducing the occurrence of medical errors and health-care related adverse events are proven to result from the integration and coordination of services, and patient/consumer involvement.

A strong safety culture remains a mandatory background, and so are patient empowerment and the availability of general information related to health. Knowledge plays a catalytic role among both health-care professionals, patients and the public at large in strengthening patient safety.

Defining a core set of indicators and regular reporting

Implementation and long-term sustainability of interventions do usually rely on efficacy, but mostly on integration within the existing structures and enforcement mechanisms on the ground and the health systems approach. Country projects leading the way continue to show the feasibility and cost-effectiveness of various interventions and solutions, aimed at tackling the most relevant patient safety issues.

Several indicator packages were developed, and continue to be refined within national and internationally deployed initiatives, to seek the best ways to monitor health prevention and care performance, and public health gain. Compiled in various databases, these provide good opportunities for benchmarking and documenting progress achieved. An agreed set of evaluation

²⁰² *The Tallinn Charter: Health Systems for Health and Wealth, Draft 13 June 2008*. Copenhagen, WHO Regional Office for Europe, 2008 (http://www.euro.who.int/document/hsm/6_hsc08_edoc06.pdf).

²⁰³ *Parma Declaration on Environment and Health*. Copenhagen, WHO Regional Office for Europe, 2010 (http://www.euro.who.int/document/ceh/parma_eh_conf_edoc05-1rev2.pdf).

tools allowing international comparability of outcomes is expected to overcome existing overlaps and/or difficulties in collecting this information.

The need for good reporting systems is recognized as part of the learning and improvement process. General reporting mechanisms, following an agreed classification, appropriate for the increasingly specialized services and the expansion of the private secondary and tertiary health care, will require a wide consensus for their actual usability. The experience of the existing reporting systems can be a good way of learning how to overcome communication challenges and to support integrated reporting databases and responsive feedbacks to both patient and health-care provider. Active patient involvement, information and education on health will also build an accurate understanding of the potential and actual risks related to health-care delivery.

Accessible databases responding to the complexity of the system are expected to foster information exchange and shared experiences, and generate a critical mass of informed, concerned and skilled individuals/teams able to move the patient safety agenda forward.

Better interagency cooperation and coordination

The World Health Assembly recognized the importance of quality of care - patient safety (resolution WHA 55.18, 2002), and a WHO patient safety programme was initiated in 2004 to support coordination, accelerate international improvements and subsequently advance these goals. Since then, in pursuing its mandate, the fields of action of this dedicated programme have expanded, including global patient safety challenges and solutions, draft reporting guidelines, global research, education and knowledge management tools, and important advancement in ensuring that “the voice of patients is at the core of the patient safety movement worldwide”.

At the European level, in accordance with this, the WHO Regional Committee for Europe adopted resolution EUR/RC55/R8 on strengthening European health systems, and further work underlined the need for health in all policies, as a required comprehensive foundation.

The EC and the CoE have developed dedicated directives and recommendations and commissioned targeted research and innovative projects. Public statements, such as the Luxembourg Declaration and the Warsaw Statement on patient safety have further enhanced the political commitment to develop and support effective mechanisms for strengthening the quality of care. Several EU presidencies have chosen patient safety as a key issue for their political agenda, and this increasing recognition has prompted several international organizations and national stakeholders to take action.

Further, the special working group on patient safety under the High Level Group on Health Services and Medical Care of the European Commission, which included the participation of WHO, OECD, EU institutions and professional groups, has consistently contributed to sharing information and experiences in the field, including priority-setting processes and strategies for fostering patient safety at the EU level. An important part of the process is represented by the development of specific indicators to evaluate and monitor the quality of health services (e.g. WHO, OECD, EC indicators projects, etc.).

The importance of partnership and collaboration at all levels between the various partners and stakeholders is already recognized. Shared experience, information exchange and most of all joint coordination efforts, knowledge and resources are used to address patient safety.

Supported by national and regional aggregation and sharing of data, this partnership and collaboration at various levels provides a good background for action and a call for methodical engagement in the stepwise change towards strengthened patient safety – a road map for enhanced public health.

Annex:

Chronology of key international recommendations on patient safety and selected related initiatives (non-exhaustive listing)

Year	Key recommendations on patient safety and selected related interventions	Organization
1968	Resolution of the World Health Assembly WHA21.41 “Ethical and scientific criteria for drug promotion”	WHO
1969	Resolution of the World Health Assembly WHA22.51 “Training of Medical Personnel and the "Brain Drain".	WHO
1976	Resolution of the World Health Assembly WHA29.72 “Health manpower development”	WHO
1986	Resolution of the World Health Assembly WHA39.27 “Original drug strategy; rational use of drugs” (periodically revised)	WHO
1989	Recommendation R(89)13E of the Committee of Ministers to Member States on the organization of multidisciplinary care for cancer patients	CoE
1994	Resolution of the World Health Assembly WHA47.16 “WHO Ethical Criteria for Medicinal Drug Promotion”	WHO
	Resolution of the World Health Assembly WHA47.13 “Rational use of drugs; and the WHO Action Programme on Essential Drugs”	WHO
	Resolution of the World Health Assembly WHA47.12 “Role of the pharmacist”	WHO
1997	Recommendation R(97)17 of the Committee of Ministers to Member States on the development and implementation of quality improvement systems (QIS) in health care	CoE
2000	Recommendation R(2000)5 of the Committee of Ministers to Member States on the development of structures for citizen and patient participation in the decision-making process affecting health care	CoE
	Resolution EUR/RC50/R5: WHO Regional Office for Europe’s Country Strategy “Matching services to new needs”	WHO Regional Office for Europe

2001	Resolution of the World Health Assembly WHA54.11 “WHO medicines strategy”	WHO
	WHO Global Strategy for Containment of Antimicrobial Resistance	WHO
	Directive 2001/83/EC of the European parliament and of the Council on the community code relating to medicinal products for human use	EU
	Recommendation R(2001)13 on developing a methodology for drawing up guidelines on best medical practices	CoE
	OECD Health Care Quality Indicators project	OECD
	Communication from the Commission on a Community Strategy against antimicrobial resistance /COM/2001/0333 final Volume I and proposal for a Council Recommendation on the prudent use of antimicrobial agents in human medicine /COM/2001/0333 final Volume II	EU
2002	Resolution of the World Health Assembly WHA55.18 “Quality of care: patient safety”	WHO
	Resolution of the World Health Assembly WHA55.14 “Ensuring accessibility of essential medicines”	WHO
	European Charter of patient rights	
2003	Resolution of the Executive Board EB 113/37 Quality of care: patient safety, report of the secretariat	WHO
	EU Health Policy Forum - Recommendations on mobility of health professionals	EU
2004	Directive 2004/27/EC of the European parliament and the Council amending Directive 2001/83/EC on the Community code relating to medicinal products for human use.	EU
	Regulation (EC) No 851/2004 of the European Parliament and of the Council establishing a European Centre for disease prevention and control (ECDC) (OJ L 142, 30.4.2004, p. 1)	EU

	Establishment of a High Level Group on Health Services and Medical Care	EU
	High Level Group on Health Care introduced the document Patient safety: a worldwide issue (HLG/2004/13)	EU
	Report on Selecting Indicators for the Quality of Health Promotion, Prevention and Primary Care at the Health Systems Level in OECD Countries	OECD
	Report on Selecting Indicators for Patient Safety at the Health Systems Level in OECD Countries	OECD
	Establishment of a WHO Patient Safety Programme (World Alliance for Patient Safety)	WHO
2005	Launch of the First Global Patient Safety Challenge “Clean Care is Safer Care”	WHO
	Luxembourg EU presidency conference “Patient safety–making it happen” leading to Luxembourg Declaration on Patient Safety	EU
	Commission Communication: “Healthier, safer, more confident citizens: a health and consumer protection strategy” and Proposal for a Decision establishing a programme of Community action in the field of Health and Consumer Protection 2007–2013	EU
	Creation of a Working Group on Patient Safety under the High Level Group on Health Services and Medical care	EU
	Conference on “Patient Safety as European Challenge”, Warsaw, leading to the Warsaw Statement on Patient Safety	CoE
	Resolution of the World Health Assembly WHA58.27 “Improving the containment of antimicrobial resistance”	WHO
	Resolution of the World Health Assembly WHA58.16 “Strengthening active and healthy aging”	WHO
	Resolution of the World Health Assembly WHA58.17 “International migration of health personnel: a challenge for health systems in developing countries”	WHO
	EU Health Policy Forum: Recommendations on Health services and the internal market	EU

	United Kingdom EU presidency “Patient safety summit”, London, hosting first Patients for Patient Safety workshop, that led the way to the London Declaration of Patients for Patient Safety	EU
	Resolution EUR/RC55/R8 on Strengthening European health systems as a continuation of the WHO Regional Office for Europe’s country strategy “Matching services to new needs”	WHO Regional Office for Europe
	Public consultation on strategies for improving patient safety by prevention and control of HAI	EU
	Establishment of the European Centre for Disease Prevention and Control (ECDC), (after EC regulation 851/2004)	EU
2006	Special Eurobarometer on Medical errors	EU
	London Declaration of Patients for Patient Safety	WHO
	Resolution of the World Health Assembly WHA59.26 “International trade and health”	WHO
	Resolution of the World Health Assembly WHA59.23 “Rapid scaling up of health workforce production”	WHO
	Adoption of Council conclusions on Common Values and Principles in European Union Health Systems	EU
	Discussion Paper: Strategic Approach on Patient Safety	EU
	Recommendation REC(2006)7 of the Committee of Ministers to Member States on management of patient safety and prevention of adverse events in health care	CoE
	Recommendation R(2006)11 of the Committee of Ministers to Member States on trans-border mobility of health professionals and its implications for the functioning of health-care systems	CoE
	Communication from the Commission on Consultation regarding Community action on health services SEC (2006) 1195/4	EU
2007	European Parliament Resolution on Community action on the provision of cross-border health care	EU

	Vergnaud Report: proposal for a directive on the application of patients' rights in cross-border health care	EU
	Resolution of the World Health Assembly WHA60.16 “Progress in the rational use of medicines”	WHO
	Resolution of the World Health Assembly WHA60.27 “Strengthening of health information systems”	WHO
	Resolution of the World Health Assembly WHA60.29 “Health technologies”	WHO
	Resolution R AP(2007)2: on good practices for distributing medicines via mail order that protect patient safety and the quality of the delivered medicine	CoE
	Report of the Expert Group on Safe Medication Practices. “Creation of a better medication safety culture in Europe”	CoE
	Resolution EUR/RC57/R1 and its accompanying background document EUR/RC57/9 on health workforce policies in the European Region	WHO Regional Office for Europe
	“Patient Safety Research - shaping the European agenda” Portugal EU presidency conference, Porto	EU
	PSWG transmitted its Recommendation on Patient Safety to the High Level Group on Health Services and Medical Care	EU
2008	Open Consultation on Patient Safety	EU
	Issuing of the impact assessment accompanying the Council Recommendation on patient safety	EU
	Technical report “Improving Patient Safety in the EU” prepared for the EC by the RAND Corporation	EU
	Launch of the Second Global Patient Safety Challenge “Safe Surgery Saves Lives”	WHO
	Technical manual on facilitating cross-national comparisons of indicators for patient safety at the health system level in the OECD countries	OECD

	Resolution of the World Health Assembly WHA61.2 “Implementation of the International Health Regulations (2005)”	WHO
	Resolution of the World Health Assembly WHA61.14 “Prevention and control of non-communicable diseases: implementation of the global strategy”	WHO
	Resolution of the World Health Assembly WHA61.21 “Global strategy and plan of action on public health, innovation and intellectual property”	WHO
	Proposal for a Directive of the European Parliament and of the Council on the application of patients’ rights in cross-border health care - “Opening the door to better health care across Europe”	EU
	Commission Recommendation C(2008) 3282 on cross-border interoperability of electronic health record systems	EU
	The Tallinn Charter: Health systems for health and wealth	WHO Regional Office for Europe
	Patient Safety Working Group is renamed to Patient Safety and Quality of Care Working Group	EU
	Green paper on the European Workforce for Health	EU
	Resolution EUR/RC58/R4 “Stewardship/governance of health systems in the WHO European Region”	WHO Regional Office for Europe
	Resolution EUR/RC58/R8 “Behaviour change strategies and health: role of health systems”	WHO Regional Office for Europe
	Report on the open consultation on Patient Safety in the European Union	EU
	European Commission adopted a Communication and a proposal for a Council Recommendation on patient safety	EU
	National and cross-national surveys of patient experiences: a structured review	OECD
2009	International recruitment of health personnel: a draft global code of practice – report of the secretariat	WHO
	Czech EU presidency Ministerial Conference “The Microbial Threat to Patient Safety in Europe”	EU

	European Parliament legislative resolution on the Council Recommendation on patient safety	EU
	Progress report on implementing Resolution WHA60.16 “Rational use of medicines”	WHO
	Resolution of the World Health Assembly WHA62.12 “Primary health care, including health systems strengthening”	WHO
	EPF’s Patients’ Manifesto for the European Parliament and Commission	EU
	EU Member States adopted the proposal for a Council Recommendation on patient safety	EU
	Resolution EUR/RC59/R3 “Health in times of global economic financial crisis: implications for the WHO European Region”	WHO Regional Office for Europe
	Resolution EUR/RC59/R4 “Health Workforce Policies in the WHO European Region”	WHO Regional Office for Europe
	Technical Manual for Facilitating Cross-National Comparisons for Patient Safety Indicators (updated)	OECD
	Staff working paper of the services of the Commission on antimicrobial resistance SANCO/6876/2009r6	EU
	“Migration of health personnel in the WHO European region” Report	WHO Regional Office for Europe
2010	Resolution of the Executive Board 126/12 “Improvement of health through safe and environmentally sound waste management”	WHO
	Special Eurobarometer on Antimicrobial resistance	EU
	Special Eurobarometer on Patient safety and quality of care	EU
	Parma Declaration on Environment and Health	WHO Regional Office for Europe
	Joint European Pandemic Preparedness self assessment indicators	WHO Regional Office for Europe, ECDC and EC

