Introduction
Despite enormous strides in our knowledge about quality health services, and the continuously growing interest in the safety of patients among policy makers and clinical leaders, much remains to be done to avoid unintentionally harm occurring in health care. In May 2004, the Fifty-seventh World Health Assembly supported the creation of the World Alliance for Patient Safety which aims to coordinate, spread and accelerate improvements in patient safety worldwide. The Forward Programme 2005 of the World Alliance for Patient safety sets out an important and comprehensive programme of international work in areas such as reporting and learning, patient involvement and safety solutions. The experience of other high risk industries, suggests that patient safety problems are primarily a function of deficiencies in system design, organization and operation. Understanding and improving the design of processes, structures and culture of health care delivery is therefore central to making care safer. A number of core challenges emerge across many European countries including the need to continue to build strong political will and commitment to address patient safety problems, stronger engagement and leadership from health care professionals, and promoting positive cultural changes with health care.

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Patient safety - a global issue
The creation of the Alliance underlines the fact that improving the safety of patient care is becoming a global issue. Since WHO launched the Alliance a year ago, there has been an unprecedented level of interest and involvement from countries both large and small.

In seeking to improve the safety of patient care, three core challenges emerge for any country or for that matter healthcare organization [2]:

- firstly, how to prevent unintended harm to patients occurring in the first place;
- secondly, how to make such harm quickly visible when it does occur;
thirdly, how to mitigate the effects of unintended harm on both patients and health care staff.

There are of course differences of context particularly for developing countries and those in economic transition. However, no country - rich or poor - can safely claim to have solved the problem of patient safety.

Size of the problem

The problem of adverse events in health care is not new. Studies as early as the 1950s and 1960s reported on adverse events. Despite the fact that the findings were alarming, the subject remained largely neglected until the early 1990s. A body of evidence started to emerge in the early 1990s with the publication of the results of the Harvard Medical Practice Study in 1991. Subsequent research in Australia, England and the United States of America (USA) and in particular the 1999 publication *To err is human: building a safer health system* by the Institute of Medicine provided further data and brought the subject to the top of the policy agenda and public debate worldwide.

Today more countries, including many European countries are reviewing the problem. Large scale studies of adverse events have been published in New Zealand, Canada and Denmark. Extrapolating from the available data, the Institute of Medicine (IOM) report estimated that “medical errors” cause between 44 000 and 98 000 deaths annually in hospitals in the USA — more than car accidents, breast cancer or AIDS. The UK Department of Health, in its 2000 report, *An organisation with a memory*, estimated that adverse events occur in around 10% of hospital admissions or about 850 000 adverse events a year. The Hospitals for Europe’s Working Party on Quality Care in Hospitals estimated, in 2000, that every tenth patient in hospitals in Europe suffers from preventable harm and adverse effects related to his or her care.

Most of the current evidence on adverse events comes from hospitals, because the risks associated with hospital care are high. However, adverse events also occur in other health-care settings. Data and experience also highlight the particular risks associated with transfer of patients between one part of the health system and another, for example, discharge of patients from hospitals to primary care services.

Why do errors occur?

Caring for patients involves a complex interplay of people, technology, devices and medicines. Daily, there are many individual decisions and judgements by health-care workers. Things can and do go wrong.

The experience in both health care and other high risk industries demonstrates that errors and mistakes are often provoked by weak systems. Deficiencies in system design can impact at multiple levels including individual clinicians, health care teams, organizations and whole health care systems. Most adverse events are not the result of negligence or lack of training, but rather occur because of latent causes within systems. For example, a recent analysis of a series of 30 public inquiries into major failures in health care in the National Health Service of the United Kingdom identified common recurring themes which included isolation, inadequate leadership and management, ineffective systems and processes, poor communication and disempowerment.

Thinking “systems” therefore offers the greatest promise of definitive risk-reduction solutions. It places an emphasis on understanding and improving the design of processes and structures of health care delivery as being central to making care safer. For example, improving the safety of medicines use may require clearer and more distinctive packaging of certain medicines. It also suggests an important role for cultural change, in particular recognition of the risks of health care and an openness to change. A recent WHO European gathering on patient safety suggested seven deadly sins of clinical and management cultures within health care organizations. These include arrogance, denial, blame, shooting the messenger, averting the gaze, failure to think systems and passive learning.

Priorities of the World Alliance

The Forward Programme 2005 of the World Alliance for Patient safety sets out an important and comprehensive programme of international work.

Six major action areas are being pursued:

- **Global Patient Safety Challenge** focusing over 2005-2006 on the challenge of healthcare associated infection entitled ‘clean care is safer care’. A new topic that covers a significant aspect of risk to patients receiving health care and which is relevant to every WHO Member State will be identified for action over a two-year cycle.

- **Patients for Patient Safety** is working to develop an international network of patients and patient organizations active in raising awareness of patient safety and the importance of patient involvement. The Alliance is also keen
to ensure active patient involvement in all of its own work.

• **Research for Patient Safety** is working to develop an agreed international research agenda for patient safety. The Alliance is also commissioning research in specific areas in which there are knowledge gaps. This includes measuring the nature of patient harm in selected developing and transitional countries to develop better measurement methodologies and tools.

• **Solutions for Patient Safety** is working to increase international collaboration on promoting existing patient safety interventions and better coordination of international efforts to develop future solutions. A major vehicle for this work is the designation of the Joint Commission for Accreditation of Health Care Organizations as a WHO Collaborating Centre on Patient Safety (Solutions).

• **Taxonomy for Patient Safety** is working to develop an internationally acceptable framework for defining and classifying adverse events and near misses. This will enable international, comparative analysis of reported data on patient safety problems. See below for more detail.

• **Reporting and Learning** aims to develop guidelines and tools which help countries establish and improve patient safety reporting systems. See below for more detail.

The World Alliance also works closely with each of the six regional offices of WHO to contribute to the development of patient safety strategies at a regional level.

**Learning from experience**

Learning from adverse events is a major goal for improving the safety of health care. Initiatives are occurring in many Member States to collect and report data about patient safety problems. The Alliance has two major initiatives underway to support countries in these areas.

**Patient Safety reporting**

The fundamental role of patient safety reporting systems is to enhance patient safety by learning from failures of the health care system. Most problems are not just a series of random, unconnected one-off events. Rather, health care errors are provoked by weak systems and often have common root causes which can be generalised and corrected. Although each event is unique, there are likely to be similarities and patterns in sources of risk which may otherwise go unnoticed if incidents are not reported and analysed.

As a result, reporting systems are emerging as a major tool to help identify patient safety problems and provide data for organisational and system learning. To support country initiatives, the Alliance has recently launched draft WHO guidelines on adverse event reporting and learning systems in order to help countries develop or improve reporting and learning systems in order to improve the safety of patient care [15].

The 4 core principles underlying the guideline are:

• The fundamental role of patient safety reporting systems is to enhance patient safety by learning from failures of the health care system.

• Reporting must be safe. Individuals who report incidents must not be punished or suffer other ill effects from reporting.

• Reporting is only of value if it leads to a constructive response. At a minimum, this entails feedback of findings from data analysis. Ideally, it also includes recommendations for changes in processes and systems of health care.

• Meaningful analysis, learning, and dissemination of lessons learned requires expertise and other human and financial resources. The agency that receives reports must be capable of disseminating information and making recommendations for changes and informing the development of solutions.

**Patient Safety Taxonomy**

The lack of an internationally agreed and standardized nomenclature and taxonomy of near-misses and adverse events hinders efforts to share patient safety learning worldwide. The World Alliance for Patient Safety wants to ensure that information about harm to patients receiving healthcare is analysed, understood and relevant in countries and across the world, to make health care safer. A key aim is to build international consensus on a high level taxonomy that will help to support data analysis and aggregation within and across countries. It is not intended to replace existing taxonomies but rather to provide a framework in which diverse approaches can be aligned. Designed to be inter-operable with existing reporting systems, the taxonomy will allow for disparate patient safety data to be aggregated and analyzed. This will enable the global healthcare community to review, evaluate and learn from near miss and adverse event data at the international level, as well as enable countries to benchmark and monitor individual progress toward improving the safety of health care against international norms.
Future challenges

Despite growing interest in the safety of patients among policy makers and clinical leaders, much remains to be done. The same errors and system failures are often repeated. Action to reduce known risks is often too slow. Although there are examples of successful safety policy and programme initiatives, few have been expanded to the level of an entire health care system, let alone spread between countries worldwide.

The World Alliance for Patient Safety is an important vehicle for change and collaboration within Europe. A number of core challenges emerge across many European countries in the establishment and design of their own patient safety programmes including [1]:

• The need to continue to build strong political will and commitment to address patient safety problems. This includes being able to focus the policy and public debate towards a positive vision and constructive solutions for change rather than blaming healthcare professionals and organizations.

• Strong engagement and leadership from healthcare professionals. This includes bringing together professional groups from a range of backgrounds to work together on shared goals for patient safety.

• Promoting positive cultural changes with healthcare. Several key elements are suggested including the importance of a strong and explicit ethical base for the practice of healthcare, the need to encourage greater openness especially when things have gone wrong and using the identification of problems as a source of learning for change.

References

1) WHO Regional Office for Europe. Eight Futures Forum on Governance of Patient Safety WHO 2005.