World Health Organization

Patient Safety

A World Alliance for Safer Health Care

WHO Patient Safety Research

Better Knowledge for Safer Care

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Foreword

Every year, tens of millions of patients worldwide suffer disabling injuries or death due to unsafe medical care.[1] Nearly one in ten patients is harmed while receiving health care in well-funded and technologically advanced hospital settings. We know much less, however, about the burden of unsafe care in non-hospital settings, where the majority of health care is delivered globally. Even more importantly, we have very little evidence about the burden of unsafe care in developing countries where there may be greater risk of patient harm due to the limitations of infrastructure, technology and resources.

The economic burden of unsafe care is also compelling. Studies show that additional medical expenses due to unsafe care resulting in prolonged hospitalization, loss of income, disability and litigation cost some countries many billions of dollars a year. [2,3] Unsafe injections alone are estimated to cost the world US$ 535 million in direct medical costs.[4]

When the World Alliance for Patient Safety was established in 2004, one of the identified priority areas was research, since it is seen as an essential building block for achieving safer health care. To succeed with this goal, we need greater knowledge about what is required and better use of available knowledge. Research for patient safety is still in its infancy and although global priorities have now been determined and competencies for researchers identified, more work needs to be done. How research is translated into country health policies and individual health practices will be the key to future improvements in patient safety globally.

Fostering specific research to improve patient safety requires significant energy to strengthen research capacity. WHO Patient Safety's goal is to encourage qualitative and quantitative research initiatives as well as the collaborative use of research evidence to reduce patient harm worldwide and make health care safer.

Sir Liam Donaldson
Chair, WHO Patient Safety

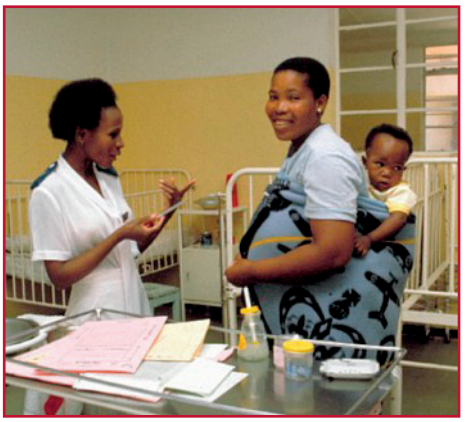
[1] The Research Priority Setting Working Group of WHO Patient Safety: Summary of the evidence on patient safety: Implications for research. Geneva: WHO 2008
[2] UK Department of Health: An Organization with a Memory. HMSO 2000.
[3] Institute of Medicine: To Err is Human. Kohn LT, Corrigan JM, Donaldson MS; Eds 1999
[4] The cost of unsafe infections: Miller MA; Pisani E; Bulletin of the WHO 1999 77 (10)

Types of research

There is a need for many types of research to improve patient safety. There is also a need to better understand how research findings can be translated into practice, especially in developing and transitional countries where research is relatively scarce and research capacity is limited. The following types of research are identified as those that can best help health-care professionals and policy-makers understand the complex causes that lead to unsafe care.

Measuring harm

Measuring what goes wrong in health care involves counting how many patients are harmed or killed and from what type of adverse events (e.g. medication error, hospital-acquired infection, etc.). This is essential for raising awareness and setting research priorities. However, it is only the first step.



Understanding the causes

Once the main types of adverse events have been identified, the next step is to understand the underlying causes that lead to patient harm. Because of the complex nature of health care, there is no single reason why things go wrong. Research is therefore needed to identify major modifiable factors in the causal pathway.

Developing solutions

To improve patient safety, solutions are needed that tackle the underlying causes of unsafe care. Research is needed to determine which solutions are effective in making care safer and reducing patient harm, compared to the standard of care.

Learning from implementation

Scaling up solutions is a complex endeavour. Varying health-care settings, differing organizational cultures, resourcing and infrastructure, as well as the specificities of the social, economic and political environment where health care operates, may condition the effectiveness of solutions, and may call for different strategies to effectively translate solutions to suit different environments. Learning from the conditions that enable, strengthen, or on the contrary limit the effectiveness of solutions and of implementation strategies is essential to improving patient safety.

Evaluating impact

Even when solutions have been shown to work effectively in controlled research settings, it is important to assess and evaluate the impact, acceptability and affordability of solutions once implemented in real life settings.

Translating improvements into policy and practice

Research findings are important pieces of information that if appropriately communicated to their potential users and translated into user-friendly tools for action can eventually turn into real benefits for patients. Successful translation of research findings into policy and practice requires a multidisciplinary set of skills and multifaceted strategies.

Global priorities for research

In May 2009, a list of 50 global priority areas for patient safety research was compiled by WHO Patient Safety. The list, put together by a group of research experts from around the world, gives prominence and focus to areas that are critical to improving the safety of patient care. Although priorities differ throughout the world, there is considerable overlap in priorities between developing countries and countries in transition.

Ranking the issues demonstrated that research on applied and evaluative research leading to the development or local adaptation of effective, appropriate and affordable solutions are the dominant directions to improve patient safety in real settings, particularly in developing and transitional countries.

From the list of 50 priorities, WHO Patient Safety has refined these further to a shortlist of six issues that are of greatest relevance to developing countries, countries with economies in transition and developed countries.

Table 1. Six ranked research priorities

	Developing countries	Countries in transition	Developed countries
	Strong emphasis on applied and evaluative research leading to the development of local cost-effective solutions		
1.	Counterfeit & substandard drugs	Inadequate competencies & skills	Lack of communication & coordination (including coordination across organizations, discontinuity & handovers)
2.	Inadequate competencies & skills	Lack of appropriate knowledge & transfer	Latent organizational failures
3.	Maternal & newborn care	Lack of communication & coordination (including coordination across organizations, discontinuity & handovers)	Poor safety culture & blame-oriented processes
4.	Health care-associated infections	Health care-associated infections	Inadequate safety indicators
5.	Unsafe injection practices	Maternal and newborn care	Adverse drug events due to drugs & medication errors
6.	Unsafe blood practices	Adverse events due to drugs & medication errors	Care of the frail & elderly

Examples where research is needed to reduce patient harm

- Maternal and newborn care: This is a priority area for WHO since more than two million babies and mothers die worldwide each year from childbirth complications. The majority of these deaths occur in developing countries and many could be avoided. Research is needed to understand what the main avoidable causes underlying this problem are and to identify effective, affordable and acceptable solutions to improve health care and prevent harm during labour and the post-labour period. Research to identify and overcome the barriers to implementation of recommended practices is essential.

- Health care-associated infections: Infection caused during health care is estimated to affect some 1.4 million people at any given time. In developed countries, the toll is 5-10% of patients admitted to hospitals, while in some developing countries, as many as a quarter of all patients may be affected by a health care-associated infection. With the sharp rise in antimicrobial resistance worldwide, it is crucial that research also focuses on reducing resistance to drugs and the spread of multidrug resistant pathogens. Research into the epidemiology of risk factors for health care-associated infections in hospitals and into the feasibility and effectiveness of infection control practices is necessary.

- Coordination and communication: Communication, transfer of knowledge and handovers between providers remain central to optimizing patient safety. An analysis in 2005 identified communication problems as the single biggest cause of nearly 70% of sentinel events in the hospital setting. Research is essential to advance the development and implementation of effective communication strategies that are critical to eliminating errors that occur as a result of human factors.

- Unsafe injection practices: Up to 40% of injections are given worldwide with syringes and needles reused without sterilization. In some countries this proportion is as high as 70%. Unsafe injection practices cause an estimated 1.3 million deaths each year worldwide, a loss of 26 million years of life and an annual burden of US$ 535 million in direct medical costs. Future research should focus on understanding the epidemiology and burden of disease transmitted through unsafe injection practices and developing strategies to improve practices that are acceptable and affordable.

- Unsafe blood products: An estimated 5-15% of HIV infections in developing countries are caused by unsafe blood transfusions. A WHO study showed that 60 countries were not able to screen all donated blood for blood-borne infections, including HIV. Research is urgently needed on the broader aspects of blood safety, including the effectiveness of blood safety strategies and behavioural risk factors among blood donors, particularly in developing countries.

- Adverse drug events: Research estimates show that about 10% of patients in acute care settings experience an adverse drug event of which a large fraction are preventable. Hospital admissions due to adverse drug reactions may represent more than 10% of total admissions in some countries. It is critical to identify effective strategies for detecting and preventing medication errors in both inpatient and outpatient settings. More research is also needed in this area, focusing on developing countries, where it is suspected that rates of adverse drug events are even higher than in developed countries.

- Inadequate knowledge, skills and competencies: One of the major structural challenges for health systems is the inadequate numbers and skills distribution of qualified health providers and the incomplete knowledge about safe practices. Developing and transitional countries have estimated the deficit of doctors, nurses and midwives to ensure the safety of their health-care systems to be in the millions. Even the best trained and well educated staff can be affected negatively by stress and fatigue, increasing the frequency of adverse patient outcomes. Research is needed to identify the most cost-effective mechanisms to ensure that health-care professionals retain the competency required to provide safe care.

Unveiling the extent and nature of patient harm

Unsafe medical care could represent a major source of morbidity and mortality throughout the world, but estimates of the size of the problem, particularly in developing and transitional countries, are imprecise.

Two major research studies have been completed which identify critical areas where proactive organizational and management change needs to be undertaken.

The aim of both studies was to describe the nature and extent of harm to hospitalized patients in selected developing and transitional countries in the Eastern Mediterranean, African and American regions of the World Health Organization.

Measuring the extent of harm caused by health care is the first step towards improving patient safety. Twenty-six hospitals from eight countries in the Middle East and Africa and 58 hospitals from five countries in the American region showed commitment and responsibility by participating in these studies. In total, the hospital experiences of about 30 000 patients were reviewed and analyzed.

The studies found that, similar to previous studies conducted in more developed settings, a substantial number of patients (from 10-20%) may suffer an adverse event while in hospital. Extrapolation of the study results to the annual workload of the hospitals involved, means that each year several thousand patients suffer an adverse event as a result of their health care, from which a significant number die and others suffer permanent disability. The vast majority of these outcomes are considered to be preventable within the existing resources and organizational culture.

The studies also found that the major issues reside in the areas of prescribing and delivering the correct therapy, making an accurate and timely diagnosis and the management of perioperative care. Energies should be directed towards improving the availability and implementation of protocols or standards for common conditions, ongoing education and supervision of clinical staff, as well as better communication and reporting between clinicians.

The two studies highlighted the importance of strong national leadership and coordination of improvement efforts and effective governance of clinical outcomes.

In summary, the studies revealed a substantial and urgent problem with patient harm and waste caused by current health-care practices in developing and transitional countries. Known approaches to improving basic clinical processes can and should form the basis of effective improvement strategies.

Map 1. Participants in the two collaborative studies

The Eastern Mediterranean and Africa study is the result of a collaboration between the ministries of health of Egypt, Jordan, Kenya, Morocco, Sudan, Tunisia, Yemen, the Council of Accreditation of Health Care Organizations (COHSASA) in South Africa and the WHO Regional Offices for the African and the Eastern Mediterranean Regions. The study covering the American Region is the result of a collaboration between the ministries of health of Argentina, Costa Rica, Colombia, Mexico, Peru, the Ministry of Health and Social Protection of Spain and the Pan-American Health Organization.

Strengthening capacity for patient safety research

An important explanation for the underdevelopment of patient safety research is the scarcity of research infrastructures, including the qualified professionals and research teams able to conduct research in this area. Strengthening capacity for research is a multifaceted endeavour that requires concurrent reinforcement of the organizational environment and its infrastructure, as well as the skills and abilities of the committed professionals that perform research projects. Developing educational and training opportunities to increase competencies in patient safety research, as well as facilitating the environment conducive to successful research activities are essential to fostering research activities worldwide.

Patient Safety Research Curriculum and Competencies

In 2009, WHO developed a patient safety research curriculum guide to help learners achieve the competencies required for patient safety research worldwide. It includes a tool designed to take into account the needs of researchers in all countries, cultures and contexts. It is also a comprehensive resource to help build capacity in patient safety research. The curriculum includes teaching and learning strategies, together with evaluation techniques.

The curriculum contents are based on the competencies that were identified and agreed upon by a group of experts as part of WHO's patient safety research education programme.

Patient Safety Research Competencies

1. The fundamental concepts of the science of patient safety in their specific social, cultural and economic context.

1.1 Basic definitions and foundational concepts, including human factors and organizational theory
1.2 The burden of unsafe care
1.3 The importance of a culture of safety
1.4 The importance of effective communication and collaboration in care delivery teams
1.5 The use of evidence-based strategies for improving the quality and safety of care
1.6 The identification and management of hazards and risks
1.7 The importance of creating environments for safe care
1.8 The importance of educating and empowering patients to be partners for safer care

2. How to design and conduct patient safety research

2.1 Search, appraise and synthesize the existing research evidence
2.2 Involve patients and carers in the research process starting with defining research objectives
2.3 Identify research questions that address important knowledge gaps
2.4 Select an appropriate qualitative or quantitative study design to answer the research questions
2.5 Conduct research using a systematic approach, valid methodologies and information technology
2.6 Employ valid and reliable data measurement and data analysis techniques
2.7 Foster interdisciplinary research teams and supportive environments for research
2.8 Write a grant proposal
2.9 Obtain research funding
2.10 Manage research projects
2.11 Write up research findings and disseminate key messages
2.12 Evaluate the impact of interventions as well as feasibility and resource requirements
2.13 Identify and evaluate indicators of patient safety for use in monitoring and surveillance
2.14 Ensure professionalism and ethical conduct in research

3. Be part of the process of translating research evidence to improve the safe care of patients

3.1 Appraise and adapt research evidence to specific social, cultural and economic contexts
3.2 Use research evidence to advocate for patient safety
3.3 Define goals and priorities for making health care safer
3.4 Translate research evidence into policies and practices that reduce harm
3.5 Partner with key stakeholders in overcoming barriers to change
3.6 Promote standards and legal frameworks to improve safety
3.7 Institutionalize changes to build supportive systems for safer care
3.8 Apply financial information for knowledge translation
3.9 Promote leadership, teaching and safety skills

Fostering research capacity: Patient Safety Research Small Grants

In 2008, WHO Patient Safety initiated a grants programme to provide seed funds for 20-30 small research projects per year, which would contribute to building local capacity for research worldwide. Specifically, the grants programme was developed to stimulate research on patient safety, primarily in developing countries and those with economies in transition, and to promote the culture of patient safety, by promoting the dissemination of research findings to the global community.

Eligibility criteria include:

- Well designed research projects which can be completed within a 12-18 month period;
- Research in all methodological and clinical disciplines that address patient safety;
- Studies may be conducted in any health-care setting, including hospitals, primary care, ambulatory care, community care and home care;
- Principal investigators must be affiliated with a recognized institution located in the country in which the project will be conducted;
- Collaboration between institutions as well as multidisciplinary research teams are strongly encouraged.

Seed funding for small grants focuses on applied research where there is an attempt to identify local solutions or evaluate the effectiveness of existing solutions. Grants are awarded annually on a competitive basis, following an external peer review process.

Map 2. Countries where research projects have been selected for funding, 2008-09

Research projects have been selected for funding in the following countries: Brazil, Chile, China, Ghana, Iran, Mali, Mexico, Myanmar, New Zealand, Nigeria, Pakistan, Peru, The Philippines, South Africa, Tanzania, Thailand, Tunisia, Viet Nam.

Developing locally adapted research tools

Research methods and data collection instruments for measuring patient harm have primarily been developed to identify near misses and adverse events within hospitals. The gold standard so far has been a retrospective chart review. However, the benefits of using record review are limited in those countries where records are incomplete. In general, existing data sources are limited in many settings adding significant challenges to research practice. Innovative approaches are therefore needed that are tailored to different contexts and settings, such as outpatient clinics and private medical offices.

Patient and staff interviews and direct observation of health-care encounters are potentially useful research methods that are currently underexploited. The absence of tools to cater to the different needs of many settings and contexts has resulted in limited evidence on the type, extent and causes of patient harm, which has in turn delayed the development and implementation of corrective solutions.

WHO Patient Safety, in collaboration with external experts, has developed a 'Guide of Methods to Assess Patient Harm and to Prioritize Actions in Developing and Transitional Countries'. This guide is aimed at national and local stakeholders in charge of patient safety initiatives, as well as researchers operating in environments with less reliable data systems. Close attention is given to achieving a balance between robust scientific methods and addressing urgent needs.

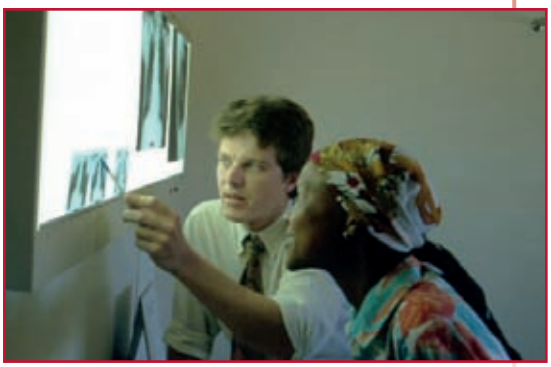
Creating a global research network

Building a global research community is highly desirable and is needed to bring people together who have a commitment to knowledge sharing and capacity building. Currently, e-based communities of practice are being established which will facilitate communication, collaboration and the development of partnerships.

Researchers throughout the world need to be able to share their knowledge and experiences. WHO Patient Safety is committed to creating a supportive environment for knowledge exchange which will contribute towards achieving the goal of making health care safer and thereby reducing patient harm.

Translating research and learning from implementation

Patient safety research is research for action. If the research evidence is not used to improve outcomes for patients, then it is of little use. It is therefore very important to better understand how to synthesize and communicate research findings in an effective way, so as to influence changes in health-care practices and health policies that will make care safer. It is also important that the new discoveries and solutions in patient safety are implemented within an evaluative framework that enables the learning of success factors and facilitates the effective spread of solutions worldwide.



Involving patients

Patients in all care settings are at the heart of global research. They have a leading role to play in contributing to research through their personal experiences. It is these documented experiences that help to identify issues and priority areas where further research can provide solutions to ensure patient harm is not repeated.

Patients can contribute to local research initiatives and provide background information on specific issues. They can also assist in locally driven solutions based on solid evidence and well defined research. Locally and regionally, patients can participate at all levels of the patient safety research agenda and help translate studies into practical outcomes that will help save lives.

'The burden of unsafe care remains unacceptably high. Through well planned research, this burden can be reduced. It will require studies of the causes of harm as well as interventions to prevent them and how to implement them widely which will in turn demand executive recognition and government commitment. As an emerging field of enquiry, patient safety research has the capacity to result in real improvements in all care settings particularly in developing countries and those in transition. By involving all clinical disciplines and engaging patients, we have the potential to make an enormous difference.'

Dr David Bates, Director, Centers of Excellence in Patient Safety and Research, Harvard.

WHO Patient Safety Research Advisory Council

WHO Patient Safety Research receives guidance from the WHO Patient Safety Research Advisory Council which includes the following membership:

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Dr Enrique Terol, Health Attaché to the Spanish Permanent Mission to the EU, Belgium.

WHO Patient Safety Chair : **Sir Donaldson**. ex officio.

WHO Patient Safety External Research Lead: **Dr David Bates,** Director, Centers of Excellence in Patient Safety and Research; Chief of Division of General Medicine at the Brigham and Women's Hospital; Harvard University, USA. ex officio.

WHO Patient Safety Research & Knowledge Management: **Dr Itziar Larizgoitia,** General Manager. ex officio.

Further information

For more information please visit: www.who.int/patientsafety/research/en

For all enquiries please contact us at: psresearch@who.int

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A World Alliance for Safer Health Care

World Health Organization
20 Avenue Appia
CH - 1211 Geneva 27
Switzerland

Tel. +41 (0) 22 791 50 60
Tel. +41 (0) 22 791 13 88
Email
patientsafety@who.int