

Better Knowledge for Safer Care

Global Priorities for Research in Patient Safety (first edition)

The Research Priority Setting Working Group
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**World Health
Organization**

Patient Safety

A World Alliance for Safer Health Care

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Research priority setting working group

Chairperson

David Bates, External Research Lead, WHO Patient Safety, and Chief of Division of General Medicine, Brigham and Women's Hospital, Boston, Massachusetts, United States

Members

Benedetta Allegranzi, WHO Patient Safety, World Health Organization, Geneva, Switzerland
Peter Angood, Joint Commission on Accreditation of Health Care Organizations, Chicago, Illinois, United States
Zulfiqar Bhutta, Aga Khan University, Karachi, Pakistan
Peter Davis, University of Auckland, Auckland, New Zealand
Daniel Grandt, Hospital of Saarbrücken, Saarbrücken, Germany
Maimunah Hamid, Institute for Health Systems Research, Kuala Lumpur, Malaysia
Jorge Insua, Hospital Universitario Austral, Buenos Aires, Argentina
Ashish Jha, Harvard School of Public Health and Veterans Health Administration, Boston, Massachusetts, United States
Robinah Kaitiritimba, Uganda National Health Consumers Organization, Kampala, Uganda
Selma Khamassi, Injection Safety, World Health Organization, Geneva, Switzerland
Thandinkosi Madiba, University of Kwazulu-Natal, Durban, South Africa
Takeshi Morimoto, Kyoto University, Kyoto, Japan
Douglas Noble, WHO Patient Safety, London, England
Peter Norton, University of Calgary, Calgary, Canada
Tikki Elka Pang, Research Policy and Cooperation, World Health Organization, Geneva, Switzerland
Ryan Sidorchuk, Winnipeg Regional Health Authority, Winnipeg, Manitoba, Canada
Anuwat Supachutikul, Institute of Hospital Quality Improvement and Accreditation, Bangkok, Thailand
Eric Thomas, University of Texas, Houston, Texas, United States

Secretariat

Itziar Larizgoitia, WHO Patient Safety, World Health Organization, Geneva, Switzerland
Nittita Prasopa-Plaizier, WHO Patient Safety, World Health Organization, Geneva, Switzerland
Pat J Martin, WHO Patient Safety, World Health Organization, Geneva, Switzerland

Executive Summary

Patient safety is a global issue, affecting countries at all levels of development. Although estimates of the size of the problem are scarce particularly in developing and transitional countries, it is likely that millions of patients worldwide suffer disabling injuries or death every year due to unsafe medical care.

Patient harm can occur as a result of a constellation of factors and circumstances. Understanding the magnitude of the problem and the main contributing factors that lead to patient harm is essential to devise effective and efficient solutions for different contexts and environments and to build safer health systems. However, available data on the epidemiology as well as on consequences of unsafe care are very scarce, particularly in developing countries and countries with economies in transition. It is therefore important that high level decision makers support more research efforts particularly in those areas that yield the greatest benefit and that more effectively contribute to improving patient safety and patients' lives.

This document is therefore addressing policy makers, research commissioners and leading agencies involved in research for patient safety. It raises the importance of targeting research efforts to obtain the maximum benefit for the patients and the public and it highlights the broad areas that have been considered essential targets for research on patient safety.

The document summarizes the work of an international expert working group set up by WHO Patient Safety during 2006-2007 to address global research needs on patient safety. The group produced a list of global research priorities that indicate to research commissioners and policy-makers worldwide, the broad areas where there are substantial knowledge gaps and where it is expected that further knowledge would significantly contribute to improving patient safety and reducing harm.

The main emphasis in developing countries and countries with economies in transition was given to the promotion of applied and evaluative research aimed at the identification and implementation of cost-effective solutions. Research on some of the perceived principal patient safety problems in these settings, such as maternal and neonatal care, counterfeited and substandard drugs, health care associated infections and difficulties with ensuring the trained and knowledgeable workforce was also emphasized.

The recommendations for developed countries focused more specifically on advancing the knowledge about the underlying processes and organizational factors that lead to unsafe care, such as those related to communication and coordination, human factors and the patient safety culture.

This first exercise must be monitored to assess the acceptability, uptake and usefulness to research commissioners and other bodies, and ultimately their impact on saving lives. The priority list must also be revised periodically to ensure that it remains useful for improving patient safety. These are among the goals of WHO Patient Safety for the upcoming years.

1. Introduction: improving patient safety through better research

Available data¹ suggest that health care is responsible for about one adverse event occurring in about 10% of hospitalizations in middle to high-income countries, and causing thousands of deaths every year.²³ The situation is thought to be more acute in developing countries, although currently there is insufficient information to sustain that assumption. The evidence base on patient safety, its root causes and contributing factors, as well as on the most cost-effective solutions to common problems is very limited. In 2006, WHO Patient Safety set up an international expert working group to identify a global agenda for patient safety research. Its aim was to provide general guidance to research commissioners and funding institutions on the priority topic areas where new research will significantly contribute to improve patient safety. The group consisted of 21 specialists in patient safety, health-care and health services research, and included researchers, policy-makers, patient advocates and research commissioners from a wide range of countries and socioeconomic contexts. In mid-2007, the group delivered a list of priority areas after a rigorous literature review, assessment and consensus building. The expert group stressed the importance of priority setting to respond to pressing local needs for knowledge. Therefore, the group recommended that countries use the global priorities as a starting point but expand them and set their own priorities.

Priority setting Process

The working group identified fifty patient safety issues for priority setting based on a comprehensive literature review and expert opinion. The topics were ranked independently by each member of the working group and then pooled. Means and standard deviations were calculated for each ranking. Rankings were established separately for three levels of socioeconomic development: developed countries, countries with economies in transition and developing countries. A country's level of development was determined from the World Bank's classification of economies,⁴ in which 'low-income' economies are those of developing countries, 'middle income' economies refer to those of countries in transition and 'high-income' economies are those of developed countries. The working group produced 3 rankings over a period of 10 months (final meeting in February 2007), interjecting discussions to agree on discrepancies.

The final research priorities are listed in Appendix 2.

Formulation of research questions

For example: the expert working group formulated some relevant research questions addressing some of the most important research gaps within each priority area. Nevertheless, the group encouraged further specification of research priorities depending on local needs and priorities. The research questions indicated in this report serve as illustration of the broad scope and research potential of each topic area and may guide research questions at local level.

Research questions are listed in Appendix 1.

¹ *Patient safety*. Health-EU. http://ec.europa.eu/health-eu/care_for_me/patient_safety/index_en.htm (last accessed August 2007).

² Institute of Medicine. *To err is human: building a safer health system*, Washington DC, 1999.

³ National Patient Safety Agency. *Seven steps to patient safety—an overview guide for NHS staff*, London, 2004.

⁴ World Bank. *Country classification*. <http://www.worldbank.org/>. (last accessed 13 September 2007).

2. Global priorities for research on patient safety

The topics identified and ranked correspond to relatively broad issues in patient safety. This section presents the rankings of the top 20 topics that were reviewed by the expert working group.

2.1 Research priorities for developing countries

The group concluded that the highest priority for research in developing countries is to facilitate the design and testing of locally effective, affordable solutions to patient safety problems. Therefore, the group favoured supporting applied and evaluative research as the top priority. This implies assessing the effectiveness, cost-effectiveness and feasibility of existing solutions, mostly identified and designed in most developed contexts, to specific developing country settings. This message also applies to the analysis of any risk-reducing strategies. The key message is that research in developing countries should be linked to action for improvement and development.⁵

Other high priorities included some of the patient safety issues responsible for most of the burden of death and disability related to unsafe care in developing countries, such as counterfeit and substandard drugs, inadequate competency, training and skills, inadequate knowledge and knowledge transfer, substandard maternal and newborn care, health-care-associated infections, inadequate understanding of the extent and nature of unsafe care, unsafe injection practices and unsafe blood practices. (See appendix 3 Table 1)

2.2 Research priorities for countries with economies in transition

Some of the research priorities of countries with economies in transition are the same as those of developing and developed countries. As in developing countries, the highest priorities are the fostering of applied and evaluative research leading to the identification, design and adoption of solutions that are affordable, effective and pertinent to the local setting and that can ensure sustained change and improvement. The group emphasized the importance of ensuring adequate transfer of knowledge and a knowledgeable and competent workforce. Other priorities were comparable to those identified for developed countries, including latent and organizational factors such as lack of coordination and communication, a poor safety culture, latent organizational failures, and research on the nature of the problem and monitoring improvement. (See appendix 3 Table 2)

2.3 Research priorities for developed countries

The expert group considered that the top priority areas for research in developed countries are related primarily to understanding how the processes and organizational structure of health care are involved in unsafe care. Topics such as communication and coordination in health care, latent organizational failures, safety culture and the cost-effectiveness of risk-reducing strategies were therefore ranked high. Other topics focused on the design of better indicators and monitoring tools, the re-engineering of procedures to incorporate human factors, and the health information technology. Incorporating patients' opinions into setting the research agenda was among the top 10 priorities. (See appendix 3 Table 3)

⁵ Lansang MA. *Essential national health research and priority setting: lessons learned*, COHRED Document 97.3, Geneva, Council on Health Research for Development, 1997.

2.4 Research priorities common to countries at different levels of development

Some of the research areas were consistently rated as top priority across all countries. As such, the analysis of the Cost-effectiveness of risk-reducing strategies emerged as a high priority, ranking second in developing countries and countries with economies in transition and fourth in developed countries.

Five of the top 10 priorities were common to developing countries and countries with economies in transition: identification, design and testing of locally effective and affordable solutions, inadequate competence, training and skills, health care-associated infections, inadequate knowledge of the extent and nature of the problem of patient safety and lack of appropriate knowledge and transfer of knowledge.

Four areas are common to countries with economies in transition and developed countries. These are priorities related to process or organizational issues, which are considered the highest priority for developed countries. They are: lack of communication and coordination, poor safety culture and blame-oriented processes, latent organizational failures and inadequate safety indicators.

3. Setting priorities at local level

In order that research priority setting is effective, consideration must be given to the context in which the research will be conducted.⁶ The resources available, the organizational culture, the ethos and values of the society and population groups involved either as researchers or users and beneficiaries, the cost implications and the distribution of benefits, all must be taken into account.

The working group noted that, although the identified priorities can guide research investment globally, local investors and research commissioners should set priorities at local level. The group stressed that the global priorities could suggest topics for countries but should not substitute for country specific priorities.

4. Conclusion

The list of priorities given in this report is designed to guide investments in research for patient safety at the global level. It is also meant to encourage research commissioners and research institutions to invest in and focus on research considered to be relevant for safer care.

Data on the epidemiology and consequences of unsafe care in developing countries and countries with economies in transition are scarce, and the expert group had little information on which to base their ranking of the priorities for these countries. The group did, however, have the benefit of the experience of numerous WHO and international development programmes that have addressed the pressing needs of health services in these countries. Experience shows that while many solutions exist for certain patient safety hazards, many countries cannot apply them as they are costly or inappropriate to the local context and circumstances. This is why the group strongly emphasized the importance of applied and evaluative research leading to developing and or adapting locally effective, appropriate and affordable solutions.

This first exercise in guiding research investment is only a start, and must be monitored and evaluated. The list must also be revised periodically to ensure that it remains useful for improving patient safety in the longer term.

The group recommended that the ranking be reviewed regularly and that countries be given the opportunity of ranking the topics differently according to their own priorities.

⁶ Ghaffar A. Three pillars of priority setting for health research: process, tools and values. In: *Global Forum Update on Research for Health*, Vol 3, *Applied health economics and health policy*, Geneva, 2004.

Appendix 1. Proposed principles to facilitate priority setting for patient safety research at local level

Scope	<p>All areas related to patient safety, both outside and inside hospitals</p> <p>Use global priorities as indicative</p>
Type of research	Epidemiology, methods, evaluation of interventions, economic, implementation, dissemination
Audience	To be reviewed and updated preferably every 4 years
Constituencies involved	Funders of research, health ministers, commissioners and other policy-makers, policy advisory institutions, research institutions, researchers, providers, general public
Criteria for ranking	<ul style="list-style-type: none"> • frequency of safety issue; • severity of issue (extent of harm); • distribution of harm (children, mothers, the elderly, people with low socio-economic status, patients, geographical location such as developing or developed countries); • effect on efficiency of the system and associated costs; • existing solutions, feasibility of designing or adapting solutions and sustainability of solutions; • urgency or political support to address the problem.
Ranking method	<ul style="list-style-type: none"> • modified Rand Delphi approach; • identification of areas of agreement and disagreement; • discussion of discrepancies; • re-ranking until consensus is reached.
Process	<ul style="list-style-type: none"> • problem definition; • building constituencies; • agreement on method, timetable, tasks and output; • implementation: (i) goal description, (ii) situation analysis: burden of the problem, analysis of solutions and resources, (iii) comparative advantages of methods of priority setting, (iv) application of priority setting criteria and ranking, (v) validity checks: external reviews; • communications; • impact evaluation and review (medium term).

Appendix 2. Examples of preliminary research questions covering the top 20 priority areas for countries at each level of development

Topic (in alphabetic order)	Research question
Adverse events due to drugs and medication errors	<p>Research questions:</p> <p>What is the prevalence/incidence of, and the risk factors for, adverse events due to drugs and medication errors in different population groups and settings?</p> <p>What are the minimum system needs for effective reporting of medication errors in both inpatient and outpatient settings?</p> <p>What strategies are effective for detecting and preventing medication errors in both inpatient and outpatient settings?</p>
Adverse events associated with medical devices	<p>Research questions:</p> <p>What are the frequencies of reporting and lack of reporting of adverse events associated with medical devices?</p> <p>What are the principal causes of and the potential solutions for reducing these events or mitigating the harm they cause?</p> <p>What is the impact of adverse events associated with medical devices on patient safety?</p> <p>Do medical device surveillance systems improve the use, maintenance and development of medical devices?</p>
Care of the frail and elderly	<p>Research questions:</p> <p>What is the epidemiology of adverse events among the elderly?</p> <p>How does the epidemiology in this group differ from that in other groups?</p> <p>What are the factors in non-adherence among the elderly?</p> <p>How can families or the community be most effectively engaged in providing health care to the elderly?</p>
Cost-effectiveness of risk-reducing strategies	<p>Research questions:</p> <p>What are the most valid, reliable and standardized methods for assessing the costs and benefits of interventions for prevention of medical errors?</p> <p>How cost-effective are interventions used in developed countries when adapted for local use in developing countries?</p> <p>What are the direct and indirect costs of medical errors to patients and families?</p>

Counterfeit and substandard drugs	<p>Research questions:</p> <p>How effective are regulatory actions and interventions in addressing this issue?</p> <p>How much do counterfeit and substandard drugs contribute to the problems of patient safety?</p> <p>What are the factors that lead to the use of counterfeit and substandard drugs?</p>
Extent and nature of the problem of patient safety	<p>Research questions:</p> <p>What are the incidence and prevalence of patient safety problems in various health-care settings?</p> <p>What is the burden of unsafe care of the general population in terms of morbidity and mortality?</p> <p>What is the burden of unsafe care on special populations, such as the elderly, minorities and children?</p>
Health care-associated infections	<p>Research questions:</p> <p>What are the epidemiology of and risk factors for health care-associated infections in hospitals?</p> <p>What is the availability and cost of commercial hand-rub products and how does that affect hand hygiene promotion strategies?</p> <p>What strategies are effective in optimizing participation in infection control practices?</p> <p>Are there effective, practised plans in place for control of epidemic outbreaks of health care-associated infections?</p> <p>Does use of new practices (e.g. silver-coated catheters) reduce the incidence of health care-associated infections?</p>
Identification, design and testing of locally effective and affordable solutions	<p>Research questions:</p> <p>What are the costs and benefits of adapting already established guidelines as opposed to designing new solutions?</p> <p>What mechanisms are needed to ensure that specific solutions are valid, effective and responsive to changing needs and sustainable and measurable over time?</p> <p>What solutions for preventing common adverse events are effective in low-resource situations?</p>

<p>Inadequate competence, training and skills</p>	<p>Research questions:</p> <p>Are health-care professionals adequately trained in assessing and dealing with patients with reported adverse events or medical errors?</p> <p>Is patient safety a specific topic in the core curricula of physicians, nurses and health managers?</p> <p>What kinds of continuing medical education programmes are most effective for ensuring that physicians and nurses retain competency in patient safety?</p>
<p>Inadequate regulations</p>	<p>Research questions:</p> <p>Are interventions through the judiciary system effective in improving patient safety?</p> <p>Are the existing regulations relating to patient safety sufficient and effective? How can they be improved?</p> <p>Which regulations or standards are most effective in improving patient safety?</p> <p>Are accreditation and regulation cost-effective, including the costs of using the standards and demonstrating compliance?</p>
<p>Inadequate safety indicators</p>	<p>Research questions:</p> <p>Are patient safety indicators designed in developed countries available, transferable and responsive to other settings?</p> <p>What effective, and user-friendly indicators for patient safety can be used in hospital and community settings?</p> <p>What are the optimal infrastructure, resources and systems required to use safety indicators effectively?</p>
<p>Unsafe injection practices</p>	<p>Research questions:</p> <p>What are the epidemiology and burden of diseases transmitted through unsafe injections?</p> <p>To what extent is unsafe injection attributable to lack of safe equipment?</p> <p>What educational strategies are most effective in improving injection practices?</p>

<p>Involvement of patients in setting the research agenda</p>	<p>Research questions:</p> <p>How can patients optimally and meaningfully be engaged in awareness raising, promotion and research?</p> <p>What resources and support are needed to effectively engage patients and their family members in strategies for improving patient safety?</p> <p>How can patients be effectively empowered to take active roles in programme planning and evaluation?</p>
<p>Lack of adequate reporting on patient safety</p>	<p>Research questions:</p> <p>What educational efforts are most effective in improving clinician reporting of adverse events?</p> <p>Are there systems and incentives in place to involve patients in reporting?</p> <p>Does increased patient reporting affect the frequency of litigation or compensation claims?</p> <p>What impact does regulation have on incident reporting?</p>
<p>Lack of adequate test follow-up</p>	<p>Research questions:</p> <p>How frequently are abnormal test results inappropriately followed up?</p> <p>What is the impact of inadequate follow-up on patient safety?</p> <p>What role can information technology play in reducing adverse events due to inadequate test follow-up?</p>
<p>Lack of communication and coordination (including coordination across organizations, discontinuity, and hand-overs)</p>	<p>Research questions:</p> <p>What is the frequency of adverse events resulting from problems in communication or coordination?</p> <p>What are the underlying causes, extent and impact of problems in communication and coordination in the health-care setting? How are these problems being addressed?</p> <p>How effective are protocols and standardized terms or language in facilitating hand-over communications for various environments?</p> <p>Are simulation team-based strategies effective for improving communication and coordination of care?</p>

Lack of consideration of human factors in design and operation of procedures	<p>Research questions:</p> <p>How cost-effective would it be to redesign procedures in order to account for human factors?</p> <p>Which procedures could benefit most from being redesigned?</p> <p>How important is the impact of lack of consideration of human factors on safety?</p>
Lack of recognition of adverse events	<p>Research questions:</p> <p>How often do clinicians fail to recognize adverse events?</p> <p>What factors result in lack of recognition and management of adverse events?</p> <p>What kinds of educational strategies are most effective for improving clinician recognition of adverse events?</p>
Maternal and newborn care	<p>Research questions:</p> <p>What are the main safety issues in maternal and newborn care?</p> <p>What is the burden of unsafe maternal and newborn care?</p> <p>What are the most cost-effective strategies for improving the safety of maternal and newborn care?</p> <p>What resources and systems are needed to implement recommended maternal and newborn care interventions effectively?</p>
Misdiagnosis	<p>Research questions:</p> <p>What are the epidemiology and impact of misdiagnosis on health outcomes and system costs?</p> <p>To what extent is there under-diagnosis of important diseases and to what extent does this contribute to the burden of those diseases?</p> <p>What strategies are effective for improving clinicians' performance and reducing misdiagnosis?</p> <p>How can health information technology solutions be designed to reduce misdiagnosis?</p>

Patient adherence	<p>Research questions:</p> <p>What factors influence patient adherence?</p> <p>What role can non-physician providers, such as nurses and pharmacists, play in improving adherence?</p> <p>What measures could be used to measure patient adherence appropriately?</p> <p>Which are the most cost-effective strategies for enhancing patient adherence?</p>
Poor safety culture and blame-oriented processes	<p>Research questions:</p> <p>What is the relation between culture and patient safety outcomes in different settings?</p> <p>What are the essential dimensions of safety culture and their relative importance?</p> <p>What strategies are effective for transferring knowledge and concepts of safety culture from developed to developing countries and countries with economies in transition?</p> <p>What are the validity, reliability and effectiveness of existing tools for measuring safety culture?</p>
Shaping the agenda by burden of disease	<p>Research questions:</p> <p>Is the research agenda of WHO aligned with the impact of patient safety issues on the world's citizens?</p> <p>How does the burden of unsafe care compare with other causes of high disease burden?</p> <p>How can research priorities most effectively be tailored to match patient safety issues?</p>
Unsafe blood practices	<p>Research questions:</p> <p>How often are clinical transfusion practices audited?</p> <p>How are the results of audits of clinical transfusion practices reported, disseminated and used?</p> <p>What is the frequency of conditions or disease associated with blood transfusion?</p> <p>Can blood safety strategies that are effective in developed countries be used in developing countries or countries with economies in transition?</p>

Unsafe blood products

Research questions:

How can unnecessary transfusions be reduced?
How capable are resource-poor settings at screening the blood supply?

What is the rate of infections averted by implementing blood safety strategies?

What facilities and systems are needed to ensure the safety of blood products?

Appendix 3

Table 1. Ranked research priority areas - Developing countries

Rank	Research priorities - Developing countries
1	Identifications, design and testing of locally effective and affordable solutions
2	Cost-effectiveness of risk-reducing strategies
3	Counterfeit and substandard drugs
4	Inadequate competence, training and skills
5	Maternal and newborn care
6	Health care-associated infections
7	Extent and nature of the problem of patient safety (across the continuum)
8	Lack of appropriate knowledge and its transfer
9	Unsafe injection practices
10	Unsafe blood practices
11	Misdiagnosis
12	Unsafe blood products
13	Poor safety culture and blame-oriented processes
14	Shaping the agenda by burden of disease
15	Lack of communication and coordination (including communication across organizations, discontinuity and hand-overs)
16	Inadequate regulations
17	Latent organizational failures
18	Adverse drug events due to drugs and medication errors
19	Lack of adequate reporting on patient safety
20	Inadequate safety indicators

Table 2. Ranked research priority areas- Countries with economies in transition

Rank	Research priorities - Countries with economies in transition
1	Identification, design and testing of locally effective and affordable solutions
2	Cost-effectiveness of risk-reducing strategies
3	Lack of appropriate knowledge and its transfer
4	Inadequate competence, training and skills
5	Lack of communication and coordination (including coordination across organizations, discontinuity and hand-overs)
6	Poor safety culture and blame-oriented processes
7	Health care-associated infections
8	Extent and nature of the problem of patient safety (across the continuum)
9	Latent organizational failures
10	Inadequate safety indicators
11	Misdiagnosis
12	Adverse drug events due to drugs and medication errors
13	Inadequate regulations
14	Involvement of patients in setting the research agenda
15	Maternal and newborn care
16	Counterfeit and substandard drugs
17	Adverse events associated with medical devices
18	Unsafe blood practices
19	Health information technology and information systems (including computerized physician order entry)
20	Surgical errors

Table 3. Ranked research priority areas - Developed countries

Rank	Research priorities - Developed countries
1	Lack of communication and coordination (including coordination across organizations, discontinuity, and hand-overs)
2	Latent organizational failures
3	Poor safety culture and blame-oriented processes
4	Cost-effectiveness of risk-reducing strategies
5	Inadequate safety indicators
6	Lack of consideration of human factors in design and operation of procedures
7	Health information technology and information systems (including computerized physician order entry)
8	Involvement of patients in setting the research agenda
9	Lack of consideration to human factors in design and operation of devices
10	Adverse events due to drugs and medication errors
11	Care of the frail and elderly
12	Patient adherence
13	Misdiagnosis
14	Identification, design and testing of locally effective and affordable solutions
15	Health care-associated infections
16	Lack of adequate test follow-up
17	Inadequate competence, training and skills
18	Lack of appropriate knowledge and its transfer
19	Lack of recognition of adverse events
20	Adverse events associated with medical devices