Global Priorities for Research in Patient Safety
(first edition)

The Research Priority Setting Working Group
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Patient Safety
A World Alliance for Safer Health Care

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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 data[1] 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.

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[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)

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[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.

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[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	**All areas related to patient safety, both outside and inside hospitals** **Use global priorities as indicative**
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	• 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	• modified Rand Delphi approach; • identification of areas of agreement and disagreement; • discussion of discrepancies; • re-ranking until consensus is reached.
Process	• 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	Research questions: 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? What are the minimum system needs for effective reporting of medication errors in both inpatient and outpatient settings? What strategies are effective for detecting and preventing medication errors in both inpatient and outpatient settings?
Adverse events associated with medical devices	Research questions: What are the frequencies of reporting and lack of reporting of adverse events associated with medical devices? What are the principal causes of and the potential solutions for reducing these events or mitigating the harm they cause? What is the impact of adverse events associated with medical devices on patient safety? Do medical device surveillance systems improve the use, maintenance and development of medical devices?
Care of the frail and elderly	Research questions: What is the epidemiology of adverse events among the elderly? How does the epidemiology in this group differ from that in other groups? What are the factors in non-adherence among the elderly?