World Alliance for Patient Safety

Research for Patient Safety

Better Knowledge for Safer Care
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The global burden of unsafe care

WHO estimates that tens of millions of patients worldwide suffer disabling injuries or death every year due to unsafe medical practices and care. Nearly one in ten patients is harmed while receiving health care in well-funded and technologically advanced hospital settings. However, much less is known about the burden of unsafe care in non-hospital settings, which provide the majority of health-care services globally.

Even more importantly, there is very little evidence about the burden of unsafe care in developing countries, where there is likely to be an even greater risk of harm to patients due to limitations in infrastructure, technologies and human resources. For example, 16 billion injections are administered worldwide each year, mostly for curative care. Of these, 40% are administered using syringes and needles that are reused without sterilization, and in some countries this proportion is as high as 70%. Each year, unsafe injections cause 1.3 million deaths, and about 26 million years of life lost, primarily due to the transmission of blood-borne viruses such as hepatitis B and C and HIV.

The economic burden of unsafe care is also compelling. Studies show that additional medical expenses due to unsafe care, resulting in prolonged hospitalization, lost income, disability and litigation, cost some countries between US$ 6 billion and US$ 29 billion a year. The annual economic burden of unsafe injections alone is estimated to be US$535 million in direct medical costs.

Patient safety is therefore a global public health problem which affects countries at all levels of development. The World Alliance for Patient Safety was established to mobilize global efforts to improve the safety of health care for patients in all WHO Member States. The Alliance gives special emphasis to advancing research as one of the essential building blocks for achieving safer care.

More knowledge – and better use of the knowledge available – is essential for understanding the extent and causes of patient harm, and for developing innovative solutions that can be adapted to different contexts. Research is therefore needed in many areas (Fig. 1) to make health care safer, and thus to reduce patient harm.

Research for patient safety is still in its infancy. Even in countries where some progress has been made, infrastructure and funding for research are relatively sparse in relation to the magnitude of the problem, or have been established on a short-term basis. This hampers the development of the multidisciplinary research teams that are required to build the evidence base to support safer care.

Fostering research to improve patient safety will require significant efforts to strengthen research capacity. The goal of the Research Programme of the World Alliance for Patient Safety is to encourage qualitative and quantitative research projects, as well as the collaborative use of research evidence, to make health care safer and to reduce patient harm on a global scale.
More research for safer care

Better Knowledge for Safer Care

Fig 1. Examples where research is needed to reduce patient harm

- **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% to 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.

- **Adverse drug events:** Research estimates show that between 7% and 10% of patients in acute care settings experience an adverse drug event of which some 28-56% are preventable. Hospital admissions due to adverse drug reactions may be more than 10% of total admissions in some countries. More research is 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.

- **Surgery and anaesthesia:** These services are among the most complex and costly procedures for health systems to deliver. Evidence in developed countries indicates that adverse events in the operating room account for at least 50% of all adverse events in surgical patients. In developing countries, surgical care is constrained by poor facilities, lack of trained staff, inadequate technologies and limited supplies of drugs and materials. Research is needed to explore the reasons for geographical differences in the incidence of surgical and anaesthesia errors.

- **Unsafe injection practices:** Data show that worldwide up to 40% of injections are given with syringes and needles reused without sterilization and 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 evaluating the impact of unsafe injection practices.

- **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 medical device events:** In the United States, more than 1 million patients are harmed each year by medical devices. In some developing countries up to half of the medical devices available are unusable or only partly usable. Research is needed to detect types, frequency and the clinical settings where such events occur.
Different types of research to improve safety

Research for patient safety aims to identify solutions that can make care safer and reduce harm to patients. This involves an ongoing cycle of research to: 1) measure the magnitude and type of different adverse events that lead to patient harm, 2) understand the underlying causes of patient harm, 3) identify solutions to make health care safer, and 4) evaluate the impact of solutions in real-life settings (Fig. 2).

FIG 2. THE PATIENT SAFETY RESEARCH CYCLE
A common feature of most patient safety research is that it aims to help health-care professionals and policy-makers understand the complex causes that lead to unsafe care, and to come up with practical responses to reduce patient harm. Thus, patient safety research provides evidence and tools for taking action to make patient care safer.

• Measuring harm
Measuring what goes wrong in health care involves counting how many patients are harmed or killed, and from which 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 causes
Once priority areas have been identified, the next step is to understand the underlying causes of adverse events 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.

• 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 that are implemented in real-life settings.

Thus, there is a need for many different 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 countries and those with economies in transition, where research is scarce, research capacity is limited and research infrastructures and resources are often insufficient.
The World Alliance for Patient Safety fosters research and facilitates the use of research findings to inform safer health care and reduce patient harm in all WHO Member States. An important factor explaining the underdevelopment of patient safety research is the lack of awareness, as well as political and economic support for this particular subject area, together with the scarcity of appropriate tools and of qualified professionals. Much of the research in the area of patient safety so far has focused on hospital settings in developed countries, whereas there is an urgent need to develop further research in non-hospital settings and in developing countries. One of the greatest challenges is to build the capacity to better address those research questions that will have the greatest impact on reducing patient harm.
Since the establishment of the Research Programme of the World Alliance for Patient Safety in 2005, the Programme has primarily focused on:

1. disseminating and promoting the local adaptation of a global research agenda for making care safer;
2. identifying key methods and measures for conducting research in this multidisciplinary field;
3. developing education and training opportunities to foster leaders in patient safety research who can build the evidence for safer care;
4. providing small grant seed funding to help support researchers in carrying out promising patient safety research projects;
5. creating a global platform to support knowledge translation by patient safety researchers and research users;
6. supporting research projects in developing countries and in countries with economies in transition, where there is currently little evidence on patient safety;
7. synthesizing and disseminating the evidence on the magnitude of unsafe care and what works to reduce patient harm.

Developing a global research agenda for patient safety

Although there are many important areas that merit further research, resources are scarce and capacity is limited. It is therefore imperative to identify those areas that are responsible for the greatest preventable burdens to health, and where corrective action will lead to the greatest benefit in terms of reduction of patient harm. To identify priority areas, the World Alliance for Patient Safety has worked collaboratively with a panel of international experts in setting a Global Research Agenda for Patient Safety. The recommendations of the expert committee stress the importance of focusing research on identifying locally effective and affordable solutions (Figs. 3 & 4). Although the identified priorities can guide research investments globally, local investors and research commissioners can further expand and develop the prioritization process at the local level.
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 thus far has been a retrospective chart review. However, the benefits of using record review is limited in those countries where records are incomplete. 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.

The World Alliance for Patient Safety aims to identify methods and measures to advance research on patient safety, particularly in developing countries and those with economies in transition. Close attention is given to data-poor environments through the development of rapid assessment methods to estimate patient harm, and to achieving a balance between robust scientific methods and addressing urgent needs.

Training leaders in applied research

An important explanation for the underdevelopment of patient safety research is the scarcity of qualified professionals trained to use appropriate methodologies and tools to conduct research in this area. To address this gap, the World Alliance for Patient Safety is working with experts in patient safety and research capacity strengthening to develop education and training opportunities that will increase competency in patient safety research worldwide, with special emphasis being placed on developing countries and countries with economies in transition. The aim is to assist in the development of leaders in patient safety research who can help build the evidence base as well as translate evidence into policies and practices that reduce patient harm at the frontlines where care is delivered.

Developing education and training opportunities in patient safety research will involve two main strands of work focusing on the content and on the delivery of training. Developing appropriate content for capacity building in patient safety research involves: 1) identifying the core competencies that patient safety researchers require to conduct quality research, 2) prioritizing specific target audiences (e.g., early to mid-career researchers working in clinical or health policy settings), and 3) determining the key content of training materials (e.g., patient safety concepts, research methodology, change management theory, patient engagement and ethical issues). To ensure that the educational materials reach their intended audiences, the Alliance’s expert working group will also develop a strategy for the delivery of education programmes and ongoing mentoring in conjunction with important academic institutions and training organizations worldwide.

FIG 4. PRIORITY RESEARCH AREAS FOR DEVELOPED COUNTRIES

- Communication and coordination
- Latent organizational failures
- Safety culture
- Cost-effectiveness of risk-reducing strategies
- Safety indicators
- Human factors considerations in the design and operation of procedures and devices
- Health information technology/information systems
- Patients’ role in health-care delivery
- Adverse drug events
- Care of the frail and elderly
- Patient adherence
- Misdiagnosis
- Identification, development and testing of locally effective solutions
- Health-care associated infections
Providing funding to stimulate research

Much of the existing evidence on patient harm emanates from developed countries. This makes it difficult to recommend effective solutions to developing countries and countries with economies in transition. Strategies are needed to encourage and assist local researchers in identifying practical solutions that are effective and appropriate for their local context. Small grants can provide the seed funding to stimulate research activities. The results of these studies may help raise awareness among policy-makers and funding bodies, which may lead to sustainable support to the research community.

The World Alliance for Patient Safety has set aside US$ 500 000 to fund between 20 and 30 small research projects commencing in 2009, with an emphasis on supporting early to mid-career researchers in developing countries and countries with economies in transition. The small grants will be targeted at research projects that aim to identify, develop and evaluate local solutions to priority areas for patient safety. The grants will be awarded on a competitive basis using a peer review process.

Creating a global research network

It would be highly desirable to increase the pool of researchers working to improve patient safety, and to increase the translation of research evidence into safer care. This need is especially great in developing countries and those with economies in transition. The World Alliance for Patient Safety is developing the Global Patient Safety Research Network to promote greater communication and collaboration among researchers and research users. The special focus of the research network is to help novice researchers from developing countries and countries with economies in transition to establish careers in patient safety research, by identifying opportunities for mentorship, training and funding.

Building a strong research community which brings together researchers and research users from around the world requires a user-friendly and flexible platform for communication, collaboration and knowledge sharing. The development of the Global Patient Safety Research Network will therefore occur in phases, with the addition of different components to meet diverse needs. Creating a supportive environment for knowledge exchange will help ensure that researchers and research users feel part of a larger community all striving towards the same goal: to make health-care safer and thereby reduce patient harm.

Supporting research at country level

The Research Programme of the World Alliance for Patient Safety has initiated studies to measure the frequency and type of adverse events that lead to patient harm in over 30 hospitals in developing countries and those with economies in transition (Fig. 5). The research
projects help build awareness of patient safety problems and encourage concrete actions to reduce patient harm. This approach is also contributing to the reinforcement of local research capacities and is providing input for the global patient safety research agenda. Indeed, international experts are now collaborating with these countries and with WHO to gain insight into the causal mechanisms that lead to patient harm, particularly in resource-poor settings.

Specifically, the World Alliance for Patient Safety is supporting studies in the Eastern Mediterranean Region of WHO, involving Egypt, Jordan, Morocco, Tunisia, Sudan and Yemen, as well as Kenya and South Africa from the WHO African Region. The World Alliance for Patient Safety and the Spanish Ministry of Health have also developed a multi-national research project called IBEAS, in collaboration with the ministries of health of Argentina, Colombia, Costa Rica, Mexico and Peru.

**Synthesizing evidence and translating research into safer care**
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. A study to measure the global burden of unsafe care has been commissioned by the World Alliance to provide the evidence for governments to take action on this silent epidemic which until now has been understudied and has gone largely unnoticed.

**Engaging patients in shaping the research agenda**
Patients’ experiences and their health are at the heart of the World Alliance for Patient Safety. The goal of the Research Programme is to help make health care safer and to reduce patient harm worldwide.
The First International Conference on Patient Safety Research was held in Porto, Portugal, from September 24-26, 2007. Almost 400 patient safety researchers and policy-makers from over 60 countries attended the conference, which looked in depth at how research into patient safety incidents can provide a scientific basis for interventions, programmes and policies to improve health-care safety and quality.

The main conclusion from the conference was that more funding and increased collaboration for research into patient safety – whether in hospital or community settings – is urgently needed to improve the quality of health-care. There is also a great need for more training opportunities in patient safety research, improved systems of data collection and greater collaboration between developed and developing countries.

The Porto Message:
More patient safety research is needed

“Research in patient safety offers all WHO Member States a major innovative resource to assist their hospitals in avoiding harm from medical care and to ensure that health-care reduces patient suffering and does not contribute to it. Countries now have the opportunity to translate research findings into tangible actions that can actually save lives.”

Sir Liam Donaldson, Chief Medical Officer for England, and Chair of the WHO World Alliance for Patient Safety
Further information

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

For enquiries and to join the global patient safety research network please contact us at:
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