Research for Patient Safety:
Inauguration of the Governing Council

April 3, 2006
Knowledge is the enemy of unsafe care.

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Welcome and Introduction

Dr. Carolyn Clancy  
Chair of Council  
Director  
Agency for Healthcare Research and Quality

Dr. Clancy welcomed the participants and presented a video of Dr. John Eisenberg, former director of the Agency for Healthcare Research and Quality (AHRQ), speaking on the importance of research in preventing medical errors and promoting patient safety. He called for an international “war on medical errors” and noted that, in the field of patient safety, there is a tension between the desire to take immediate action and the need to gather evidence about problems and potential solutions before acting.

The Research Program: The Vision and Governance Structure

Sir Liam Donaldson  
Chair  
WHO World Alliance for Patient Safety  
Chief Medical Officer  
United Kingdom Department of Health

Sir Liam said that Dr. Eisenberg remains an inspiration, and the World Health Organization’s (WHO’s) World Alliance for Patient Safety continues his legacy. The Alliance, founded in October 2004 in Washington, DC, has six primary programs.

The first program is the global patient safety challenge, in which the Alliance selects a problem with a high burden of disease in every country that can galvanize the worldwide medical community and resonate with the public. The Alliance chose health care infection as the first global patient safety challenge. In 2005–2006, the Alliance launched the “Clean Care is Safer Care” project, under the leadership of Dr. Didier Pittet, an infections disease physician in Geneva, Switzerland. To date, the project has accomplished the following:

- Twenty countries have committed to fighting infection in their health systems, and 10 more have indicated they will make that commitment in the next year. By the end of 2006, more than 50 percent of the world’s population will be covered by medical systems that have pledged to fight infection.

- Sites have been selected in each WHO region for pilot programs that will demonstrate the progress that can be made in controlling infection.

- Experts from around the world have developed a set of guidelines for hand hygiene, one important aspect of infection control. These guidelines are currently under review.
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The Alliance’s second program is Patients for Patient Safety, which was formally launched in London, England, in November 2005. The meeting brought together 30 patient safety champions from 21 countries. By telling their stories of personal tragedy and calling attention to systemic problems, patient safety champions can help change the attitudes of policy makers, the media, and the public toward patient safety issues.

The Alliance’s third program focuses on creating a taxonomy for patient safety research. This program is vital for making comparisons across countries and developing global reporting systems. WHO taxonomy experts, who also work on the international classification of diseases, are leading this taxonomy program. The group expects to complete the taxonomy in 12 to 18 months.

The fourth program focuses in solutions development. The Alliance is creating a short list of solutions that can be tested and advocated to reduce risks in specific areas of health care. The evidence shows that, so far, very few solutions to patient safety problems have permanently reduced risk. For example, standards to prevent wrong-side surgery and intrathecal chemotherapy errors have failed to significantly reduce risk, often because new guidelines and protocols are not implemented.

The fifth program focuses on developing best practice guidelines for creating error reporting systems and learning from errors. However, risk reduction efforts should not be solely based on analyzing past mistakes. Proactive analyses should also be used to identify areas of potential risk.

The Alliance’s sixth program, research, is the topic of the current meeting. The goals of the research program are to set an international research agenda, establish a framework for potential funders, and commission research directly in some areas of patient safety research.

Sir Liam then described the next phase of the Alliance’s activities.


2. Establish, with the Commonwealth Fund, a program called “High Fives.” The program will identify five solutions that will be implemented over a 5-year period in five developed countries that are part of existing Commonwealth Fund studies. Five developing countries will be paired with the five developed countries.

3. Identify exemplar hospitals that have a high level of patient safety. While many hospitals have a high level of patient safety in some areas, few have holistic patient safety programs.

4. Establish a program focusing on acute care.

5. Explore technology for patient safety, including simulation technology and other education and training technologies.

Inauguration of the Governing Council of the Research Program

Dr. Carolyn Clancy
Chair of Council
Director
Agency for Healthcare Research and Quality

Dr. Clancy briefly described the Governing Council’s Terms of Reference (included in the meeting materials). This document describes the Governing Council’s objectives, guiding principles, reporting structure, membership, rules, and administration.
Dr. Somsak Chunharas, Secretary-General, National Health Foundation, Thailand, asked if the Alliance’s research program should respond to the Alliance’s current global patient safety challenge, or if the research program would have a broader scope. Dr. Clancy answered that the research program would be broader in scope. The global patient safety challenge should be chosen based on evidence derived from previous research.

Ms. Pauline Philip, Programme Lead, World Alliance for Patient Safety, WHO, Switzerland, called the participants’ attention to the full list of Governing Council members, as some members were unable to attend the meeting.

Report Back from the First Research Meeting on the Global Research Agenda

Dr. James Reason
Professor Emeritus
Department of Psychology
University of Manchester

Dr. Reason provided a brief overview of the Alliance’s November 2005 meeting, Knowledge Is the Enemy of Unsafe Care. The summary of that meeting was included in participants’ meeting materials.

He noted some of the major themes of the November 2005 meeting:

2. Dr. Reason discussed approaches to safety that target individuals as the source of error and approaches that target systems as the source of error. He argued that safety efforts cannot target systems alone. He emphasized the “human as hero” approach to improving safety.
3. While the field of patient safety can learn from safety improvements in other industries, it is important to consider the unique characteristics of the health care industry.
4. Some industries have developed simple indices of safety, but such simple metrics may not be able to assess all of the complexities of the health care system.
5. Patient safety is measured in terms of adverse outcomes. However, reactive outcome measures should be complemented with proactive process measures.
6. Patient safety research must go beyond quantitative measures, such as randomized controlled trials (RCTs), and incorporate qualitative measures.
7. There is a large gap between the research capacities of developed and developing countries.
8. Models of successful research networks were discussed. The success of research networks depends on good management.
9. It is important to recognize the limitations of “pure science” and question whether additional evidence is needed before patient safety problems are solved.

Discussion

Dr. Fiona Godlee, editor, British Medical Journal (BMJ), United Kingdom, commented that studies submitted to and published in journals tend to follow a rigid formula. The field needs to become
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more comfortable with studies that do not conform to the conventions of what is currently accepted as “pure science.” She suggested the focus of research should shift from discovering new knowledge toward knowledge implementation.

Dr. Reason said that the fight against medical error is a guerilla war. There can be no decisive victory, but the health care field must continue to strive for safety.

Dr. Atul Gawande, Assistant Professor, Department of Health Policy and Management, Harvard University, described safety improvements in the field of obstetrics. In 1960, in most of the western world the maternal death rate was 1/1,000, and the neonatal death rate was 1/50. Today, in the western world, the maternal death rate is 1/12,000, and the neonatal death rate is 1/1,000. The obstetrics field achieved these safety improvements at a time when it did not attract the best medical school graduates and when it had the worst evidence base of any medical specialty. Improvements in patient safety were not driven by evidence from RCTs. One factor was the implementation of the Apgar score, a tangible measure of infant health. Another factor was malpractice suits, which galvanized the field to create standards before other fields of medicine.

Dr. Gawande added that these improved patient safety practices are not applied in the developing world because of a lack of resources. Research is needed to determine how safety can be improved with limited resources.

Ms. Sheridan agreed that evidence-based medicine often defines evidence too narrowly, only recognizing studies published in peer-reviewed journals as valid evidence. Two years ago, a BMJ article criticized mothers of children with kernicterus for advocating policy changes that are based on anecdotal stories, rather than scientific evidence. Dr. Reason replied that numeric and anecdotal evidence both have power; he suggested that medicine should move beyond recognizing the validity of only one kind of evidence.

Sir Liam agreed, but argued that both types of evidence are necessary, and anecdotal evidence is sometimes faulty. For example, there was a time when the prevalent folk wisdom was that babies should be put to sleep on their stomachs. However, RCTs showed this practice was unsafe. As a result, in countries where babies were put to sleep on their backs, the incidence of crib death decreased.

Sir Liam added that it was important to consider the role of the individual practitioner in patient safety. Professionals in other industries undergo testing and recertification processes at regular intervals. However, physicians' skills are not objectively assessed during their careers. Four aspects of the individual practitioner's role in patient safety should be considered:

1. Can more be done to assess and improve technical skills?
2. Can more be done to assess and improve nontechnical skills (e.g., communication, teamwork, etc.)?
3. How much should medical and nursing students learn about the systemic aspects of safety?
4. How much should practitioners worry? What role does worry play in avoiding error?

Dr. Reason remarked that nontechnical skills involve both mental and social skills. The great neonatal surgeons are not the ones who do not make mistakes, but those who are able to compensate for mistakes because they have mentally prepared for and rehearsed the procedure. Health care practitioners can reduce error by striving to beat the odds of mistakes or failure.

Dr. Gawande said the best health care workers also anticipate and attempt to compensate for systemic failures, to ensure the success of their patients. Physicians need to take responsibility for both compensating for systemic failures and improving systems.
Sir Liam commented that some physicians feel that safety in the medical field is different from safety in other fields, such as the airline industry, because a pilot goes down with the plane and is therefore more likely to worry about safety. Dr. Godlee responded that, in a plane, the passengers are entirely passive. However, in medicine, patients can often contribute to ensuring their own safety by being informed and assertive.

**WHO Research Policy and the Patient Safety Research Agenda**

*Dr. Tikki Pang*

*Director*

*Department of Research Policy and Cooperation*

*World Health Organization*

Dr. Pang provided an overview of the current state of WHO research policy. At the WHO Ministerial Summit on Health Research, held in Mexico in November 2004, the four heads of the major research agencies in Canada, the United Kingdom, the European Commission, the United States, and Mexico joined health ministers from 52 other countries to discuss the direction of future health research. The summit arrived at three key goals:

1. Increase investment in health systems research.
2. Strengthen public confidence in science.
3. Translate knowledge into action to improve health.

These messages were embodied in the meeting report, which was introduced as a set of resolutions to the 58th WHO World Health Assembly in May 2005. The resolutions were approved. The 117th Session of the WHO Executive Board reinforced the resolutions in January 2006. The resolutions had four key components:

1. Establish a voluntary platform to link clinical trial registries.
2. Strengthen mechanisms to transform research and evidence into policy and practice.
3. Promote and strengthen health systems and health policy research.
4. Define WHO’s roles and responsibilities in health research.

In WHO’s General Programme of Work for the next 10 years (2006–2015), three core functions deal specifically with research (#’s 2–4):

2. Articulating ethical and evidence-based policy positions
3. Setting norms and standards, and promoting and monitoring their implementation
4. Shaping the research agenda and stimulating the generation, translation, and dissemination of valuable knowledge

This is the first time WHO’s General Programme of Work has addressed research so extensively.

At the last meeting of the Global Research Program for Patient Safety, several participants emphasized the importance of considering patient safety in a local context, especially in developing countries. Dr. Pang described four patient safety issues that are relevant to developing countries but are not currently being researched:
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1. Fake/counterfeit drugs are a problem throughout the developing world, and research is needed to inform drug policies. A study of this issue in Laos resulted in the adoption of national drug laws in that country.

2. Traditional and homeopathic medicines are largely unregulated and lack quality controls. This is a problem in developing countries and a growing problem in the West.

3. Violence and road traffic injuries are leading causes of death in many developing countries.

4. Patients are injured in clinical trials. WHO is establishing a clinical trial registry platform to strengthen public trust by promoting transparency and accountability. This platform will ensure that all trials are registered, ensure that all trials publicly report a minimum set of results, and support the use of trial registration information for patient recruitment and research planning.

Dr. Pang made three final suggestions for the participants to consider as they set the agenda for research in patient safety:


2. Consider local solutions and approaches to patient safety issues.

3. Integrate the research agenda within the broader frameworks of health systems and health services.


Dr. David Bates
External Program Lead
Director
Centers of Excellence in Patient Safety and Research
Chief
Division of General Medicine
Brigham and Women’s Hospital

Dr. Bates reviewed the 2004–2005 activities of the Global Research Program in Patient Safety. Copies of the presentation were distributed to the participants.

The program was initiated to provide data on the prevalence of adverse events from developing countries and to assess the relevance of actions on a global scale. In the last year, the program established a steering committee to guide prevalence studies. It also plan to study maternal care in Sub-Saharan Africa, and the prevalence of adverse events associated with HIV care. Finally, it conducted a training workshop on research methods in eastern Mediterranean countries.

The Alliance plans to commission a number of prevalence studies (two in each WHO region) in developing and transitional countries to measure the size and nature of patient harm, develop methodologies and tools that can be used in data-poor environments, provide input into the development of the global patient safety research agenda, and build local awareness of patient safety problems. The studies are based primarily on hospital medical record reviews, complemented by data from staff interviews. These studies must be adapted to their local contexts and build local research capacity.

Dr. Bates outlined the following needs for 2006:
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1. Build a strong governing structure, inclusive of the main constituencies of patient safety research.
2. Bring together world expertise in safety and patient safety research.
3. Strengthen links with international efforts.
4. Reinforce links with other areas of the Alliance.
5. Balance program capacity with country-level expectations.

The research program needs to develop resources, expertise, technical skills, and language and cultural sensitivity skills to increase knowledge about patient safety problems and how to implement solutions.

Dr. Bates concluded that the research agenda is off to a good start, but must follow through on the prevalence studies and develop a broader strategic plan.

Discussion

Ms. Sheridan asked how the research program can tap into the knowledge of patients. Dr. Bates agreed that patient knowledge is important; in a study of adverse drug events, he found eight times as many adverse drug events by contacting patients than he found by only examining their hospital charts. Dr. Clancy added that in the United States, a new bill on patient safety calls for the creation of a space, protected from discovery, for practitioners to identify errors and work to improve patient safety. The experts involved recognize that patients must also be included in this reporting system, as they can be an important source of information.

Dr. Somsak noted that the prevalence studies focused on documenting patient safety problems. He asked if any research had examined how those problems were solved. Dr. Bates responded that this would be part of the future agenda.

Dr. Pang said there is a great deal of tacit knowledge at the local level; research is needed to find effective methods for accessing that information.

Dr. Peter Pronovost, Professor, Departments of Anesthesiology and Critical Care, Surgery, and Health Policy and Management, The Johns Hopkins University School of Medicine, commented that there is a tension between advocates and detractors of evidence-based medicine. Rather than thinking of evidence as a dichotomy, he suggested thinking of evidence as a continuum. There are many types of evidence, and some are more prone to bias than others. Practitioners must consider the risks and rewards of acting based on different kinds of evidence. Dr. Luis Gabriel Cuervo Amore, Unit Chief, IKM/RC, WHO Regional Office of the Americas, agreed and added that personal values (influenced by public opinion and policy makers) affect how individuals weigh evidence.

Sir Liam agreed that patient input was necessary to fully understand patient safety issues at a local level.

Dr. Somsak noted that, in defining a research program, they are considering two issues: evidence that is not linked to action and the types of evidence being generated by research programs. The two issues could be addressed by applying knowledge management concepts, especially at the local level.
Dr. David Bates  
External Program Lead  
Director  
Centers of Excellence in Patient Safety and Research  
Chief  
Division of General Medicine  
Brigham and Women’s Hospital

Dr. Bates presented on the proposed research action plan for the Alliance. Copies of the presentation were distributed to meeting participants.

Patient safety was found to be a problem in every country that has been evaluated. The rate of adverse events in hospitals in developed countries is about 10 percent; less is known about the rates in developing countries. There is also a need for research on patient safety beyond the hospital setting and research about the efficiency of interventions, especially in settings with limited resources.

He described the role of the Governing Council of the research program and its management structure, and discussed the proposed action areas for research in 2006–2008:

1. Produce an agenda of research priorities for patient safety research worldwide.
2. Produce an inventory of methodologies used in patient safety research.
3. Build the infrastructure for research networks across cultures.
4. Foster research in developing countries.

A research budget of $1.2–1.5 million will be needed over the first 18 months. To be successful, the research program should connect with other areas of the Alliance, ensure geographical representation, and organize activities around existing events to conserve resources. A report on the state of safety worldwide would also be valuable.

Dr. Bates concluded by presenting a proposed timeline for the action plan and a set of criteria for its success:

1. A well-defined set of research priorities
2. A process for standardizing methods and measures
3. A substantial increase in research funding worldwide
4. A better definition of the problem of safety in the developing world
5. Undertaking/funding studies—including studies of patient safety solutions

**Discussion**

Dr. Gawande asked if “middle income” countries have different issues than developed and developing countries, and whether the role of the Alliance’s research program was to provide research guidance or to fund and conduct research directly. Dr. Bates agreed that “middle income” countries face different issues. The role of the Alliance’s research program is both to guide research—and make patient safety research a higher priority—and to fund studies directly.
Dr. Clancy said it was important to integrate patient safety research into other research in health care services.

Dr. Naruo Uehara, Professor, Division of International Health, Tohoku University Graduate School of Medicine, Japan, commented that in developing countries, in which the health care system is relatively new and resources are limited, simply measuring adverse events, without also developing the capacity for quality improvement, could foster a culture of blame. He suggested that a better approach would be to develop a successful model for solving safety problems in developing countries. He also suggested that research address the quality and safety of local health systems, rather than focusing on individual hospitals, especially in developing countries. He asked how the program would define the safety objectives for developing countries. Developing countries can learn lessons from the mistakes and problems developed countries’ health care systems have encountered and develop better health care systems.

Ms. Sheridan volunteered to help the Alliance’s research program collaborate with Patients for Patient Safety, which has developed a list of priorities of patients throughout the world. It is important to coordinate research priorities with the priorities of patients. She cautioned against devoting research to determining whether or not patient safety is a problem in developing countries and suggested research focus on discovering the categories of harm. A reporting mechanism, which may be less threatening to policy makers than requests to examine records for adverse events, could help gather this information from the patient population.

Dr. Somsak noted that the research agenda has emphasized trying to understand the patient safety problems in various countries, and then improving safety. He suggested that it may be more appropriate to find ways to improve patient safety while the research is conducted. Rather than beginning the research agenda by focusing on researchers and a global program, he proposed starting by creating research partnerships (with hospital administrators, patient groups, and policy makers) in individual countries. He added that the research program should focus on health care system development. If research is expected to lead to change, it must have a research systems approach, which involves the entire health care system, including various stakeholders. The Alliance’s research program must also take a knowledge management approach to gather tacit local knowledge and bridge the gap between evidence and action.

Dr. Cuervo Amore commented that developing countries are discussed as though they are very similar, but each developing country is distinct. For example, in Latin America and the Caribbean, some countries have little or no infrastructure or funding for research, but others do have health care and research resources. The Alliance should offer those countries opportunities to participate in patient safety research.

Sir Liam offered three observations: (1) at conferences and meetings around the world, the Alliance is succeeding in moving the hearts and minds of audiences, but does not provide audiences with a concrete plan of action to improve patient safety; (2) developing countries want to build in safety as they create their health care systems, but the Alliance does not have the evidence necessary to guide that process; and (3) most funders say they are interested in “strengthening health systems,” but they do not have a clear plan for allocating resources to accomplish this. The Alliance has the opportunity to provide guidance in this area.

Dr. Pronovost did not know who the consumer would be for research agenda priorities and asked if it would be more productive for the group to establish a process by which countries can determine their own research priorities. He also suggested that the group can serve as a network to allow researchers in different countries to share information about specific topics. He further suggested that the group focus on interventions. He also noted that patient safety has been a secondary concern in health care systems in developed countries; developing countries have the opportunity to build safety in from the beginning.
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Mr. Kevin McCarthy, Head of Sector, Public Health Research, Directorate for Health Research, European Commission, Belgium, said his organization funds research proposals in patient safety. The Alliance’s research program will play an important role in finding the gaps in current research and setting a research agenda. Setting the priorities for research in developing countries will require international cooperation and the establishment of regional dialogs in the developing world. His organization has singled out patient safety as a priority and will soon be evaluating bids to organize a patient safety conference in 2007, which may provide an opportunity for the Governing Council to meet.

Dr. Clancy asked whether the group should set a list of research priorities, create a process for countries to determine their own priorities, or do both. She also asked if there was an infrastructure at WHO through which the Governing Council could get local input. Ms. Philip agreed that it may be possible to learn about patient safety issues and research capacity at the local level by working through the WHO regional offices.

Sir Liam said the most effective WHO programs, such as the polio eradication program, have a “sharp end”—they affect people very directly. Such programs receive support from charitable and funding organizations and inspire deep local engagement because of the visibility of success. Ms. Philip added that WHO perceives patient safety as having a potentially “sharper end” than other broader quality initiatives.

Dr. Gawande agreed that the goal of “quality care” is more amorphous than the goal of “safe care,” which means “right care.” However, every country has a different system and set of issues. The WHO polio program was successful because it was a different program in every country; the details of implementation were determined at the local level, rather than the global level. He suggested that the Alliance’s research program would be more successful in establishing processes countries can implement to ensure “right care.”

Ms. Sheridan said Patients for Patient Safety will conduct six consumer workshops over the next 2 years to develop a structure for connecting with local health care systems in various WHO regions. The first workshop will bring together consumers who have experienced medical errors and health care researchers and leaders from Canada, Latin America, and the United States to establish two priorities for patient safety in each of those regions and develop regionally specific strategic and partnership plans. Similar meetings in the other WHO regions will follow.

Dr. Godlee agreed that setting research priorities at the country level is appropriate. She said WHO could most effectively assist in setting these priorities by facilitating the collection of patient stories at the country level, helping researchers develop research ideas into proposals that could be funded, and creating a Web-based networking structure through which countries can share success stories.

Dr. Somsak suggested the group begin by setting system development goals before setting priorities for research. He added that the Alliance can be a catalyst for greater concern for patient safety at the country level. Dr. Clancy said after the initial summit on patient safety, patient concerns provided a viable roadmap for the patient safety research agenda. She noted that little is known about patient safety beyond the hospital setting, even in the most developed countries. She felt the consensus of the discussion was that the group should focus on an action-oriented goal, rather than on research topics.

Dr. Bates said a few patient safety issues are global issues (e.g., hand washing, transfusions, medication safety, surgery safety, etc.), and different countries may weigh these priorities differently. He preferred to focus on specific areas of research, rather than developing processes for setting priorities.
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Sir Liam commented that in health care outside the hospital setting, errors of omission may be a greater problem than errors of commission. He felt the research should address this aspect of patient safety.

Dr. Bates noted that if the research group shifts its focus toward interventions, its work may overlap with the Alliance’s solutions group. Dr. Clancy responded that a recent evidence review of 73 safe practices in the United States resulted in a list of the top 11 interventions. This list has generated a great deal of interest. Dr. Bates added that the National Quality Forum’s adoption of those interventions into safe practices was very valuable, but the practices one would implement in the developing world would be very different. Dr. Janet Corrigan, President and Chief Executive Officer (CEO), National Quality Forum, asked if enough evidence was available to determine which of these top 11 interventions might be applicable in developing countries. Dr. Bates replied that it might make sense to create a short list of top practices for developing countries in a year, when more evidence is available.

Sir Liam noted that there is a tendency to avoid the issue of health care access because it is too large a problem. Addressing some problems of access and errors of omission can improve patient safety.

Dr. Gawande said a research agenda focused on interventions seems daunting because there are many thousands of interventions. He suggested focusing on researching which interventions save the most lives and prioritizing those interventions on a global scale.

Dr. Somsak commented that most approaches to solutions attempt to generalize, but the application of knowledge has to be contextualized. General safe practice guidelines may be scientifically justified, but it is important to consider how they can be applied in specific contexts. Dr. Clancy responded that a possible interface between interventions research and the solutions group would be identifying how interventions are applied in local contexts.

Dr. Pronovost noted that there is no shortage of world health problems the group could address. It is as important, if not more important, for the group to learn how to tackle these problems. Dr. Cuervo Amore responded that the group should offer a plan that identifies interventions that are not widely used but should be and identifies practices that should be stopped. Ms. Sheridan added that many solutions have been identified in the field of patient safety, but there are barriers to implementation. These barriers are often human factors. She suggested research should investigate why practitioners do not implement safety solutions.

Dr. Uehara remarked that two primary patient safety issues are errors in health care design and errors in health care application. Even with the best practice guidelines, there are still errors in practice. Research should focus on both increasing the efficacy of care by improving the design of health care systems and reducing the gap between the efficacy of care and the effectiveness of care as it is implemented. He noted that in developing countries, patients are harmed because of the gap between practitioners’ techniques and available technologies; practitioners are trained to use the latest technology and not trained to employ the outdated technologies that may be the only ones available. Research should focus on maximizing the effectiveness of care and reducing preventable deaths, with available resources.

Invited Speaker: A Practical Researcher’s View of Patient Safety Research

Dr. Peter Pronovost
Professor
Departments of Anesthesiology and Critical Care, Surgery, and Health Policy and Management
The Johns Hopkins University School of Medicine
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Dr. Pronovost began by discussing the polio epidemic. The vaccine was first developed and used in the United States in 1955. In 1988, when WHO committed to eradicating polio worldwide, there were 350,000 cases. Thanks to the remarkable success of this program, there were about 1,000 cases in 2004. This program highlights that (1) action was galvanized by the program’s measurable, empirical outcome; (2) the program provided a clear goal and plan for achieving it; and (3) the program fostered the creation of an infrastructure that could address other health care problems.

The patient safety effort involves both technical problems, for which there are solutions, and adaptive problems, which require changes in values, attitudes, and beliefs.

Dr. Pronovost used a grid to illustrate the status of patient safety. The horizontal axis represented the continuum of evidence for practices—from practices based on solid evidence to practices that are feasible but based on little evidence. The vertical axis represented the continuum from a centralized mandate to a focus on local wisdom. On these two continuums, patient safety currently leans toward practices that are feasible but have little scientific evidence and centralized mandates.

He said the field of patient safety needs to move toward the center, balancing evidence and feasibility, global efforts, and local knowledge.

His organization has worked to develop a framework to measure patient safety. In some areas, such as health care–acquired infections, outcomes can be scientifically measured as a rate. Process, structure, and culture/context measurements can gauge patient safety in other areas. These measures were used to create a safety scorecard.

He described how his organization packaged the scorecard within a patient safety program and implemented that program throughout the State of Michigan in a study funded by AHRQ. The goals of the program were to eliminate bloodstream infections and ventilator-acquired pneumonia, ensure that patients are informed of evidence-based practices for preventing these conditions 90 percent of the time, learn from one safety defect each month, improve culture of safety by 20 percent (as measured by focused outcomes), and learn how to enhance quality improvement efforts.

The culture improvement intervention is the Comprehensive Unit-based Safety Program (CUSP), which involves the following elements:

1. Evaluating the culture of safety
2. Educating the staff on the science of safety
3. Identifying defects (retrospectively and prospectively)
4. Assigning executives to adopt units
5. Learning from one defect per month (by developing a policy to address the defect, assessing staff knowledge of the policy, and auditing whether the policy is implemented) and introducing teamwork tools (e.g., daily goals, morning briefings, etc.)
6. Re-evaluating the culture

A goal of the program was to improve reliability by standardizing practices, creating independent checks for key processes, and learning from mistakes. For rate-based safety measures, the program implemented a reliability model, which combines evidence-based medicine with quality improvement by

- Identifying interventions associated with improved outcomes in specified populations,
- Selecting the strongest interventions and converting them to behaviors that can be implemented,
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- Developing measures to evaluate processes and outcomes, and
- Ensuring patients reliably receive evidence.

For example, the patient safety program in Michigan selected five “best practices” for preventing catheter-related bloodstream infections from the lengthy Centers for Disease Control and Prevention guidelines on the topic. To create change, the program targeted executive leaders, team leaders, and staff to engage them, educate them, provide information to allow them to execute the safety measures, and evaluate their performance.

Dr. Pronovost showed graphs that illustrated the changes in the teamwork and safety climate in Michigan intensive care units that were achieved in 1 year. He noted that cultural scores predict empirical outcomes in patient safety. For example, the strongest predictor of patient safety is a culture in which nurses feel they can speak up if they perceive a problem. At the beginning of the program, Michigan ranked in the 50th percentile for bloodstream infections. After 1 year, 100 Michigan intensive care units (ICUs) had eliminated bloodstream infections. After 18 months, 127 ICUs had eliminated these infections. He showed a video in which ICU staff from Michigan described how the program created cultures of safety in their organizations.

Dr. Pronovost proposed the following issues for discussion:

- What is WHO’s “polio campaign” for safety?
- How will the effects of the program be measured?
- How will patient safety research be disseminated?
- How can WHO build capacity to address other safety issues?

Discussion

Ms. Sheridan said, for some issues, patients can participate in the process of implementing safety measures, along with health care executives, team leaders, and staff.

Dr. Clancy asked if the study showing the correlation between nurse turnover and teamwork was cross-sectional. Dr. Pronovost responded that it was. He noted that a problem with gathering evidence was that only 30 of the ICUs involved in the study had a standard way to define nurse turnover. He added that to improve the science of improvement, the program collected responses to a team checkup tool and a senior leader checkup tool, and this feedback was provided to hospital CEOs so they could allocate resources to safety improvement and remove barriers. A participant added that this program continued even after AHRQ was no longer funding it.

Dr. Gawande remarked that the presentation can inform the group’s discussion of whether its purpose should be to identify and implement interventions or to create a process that can be applied at the local level to whatever issue a health care system chooses to address. Dr. Pronovost agreed that people are interested and engaged in safety problems, but they need tools to improve patient safety. He emphasized the need for better science and evidence and the need to disseminate information to countries and to individual practitioners.

Dr. Pang said the process Dr. Pronovost presented could be a useful tool. For a developing country, the adaptive elements of the process would need to be culturally specific. Dr. Pronovost agreed that the adaptive problems would have to be addressed locally.
How to Set up a Community of Interest of Researchers on Patient Safety

Dr. Pang suggested, based on the morning’s discussions, that it might be better not to focus on the researchers but rather to focus on creating a community of interested stakeholders (patients, policy makers, etc.).

Dr. Somsak asked how the program in Michigan was established and promoted. Dr. Pronovost explained that a safety coalition within the hospital association decided to address safety in the ICU and contacted him to create the program. AHRQ provided the funding initially, but the hospitals now fund the program.

Dr. Gawande noted that while the group’s focus is research, the research will not have any impact if it does not respond to the concerns of stakeholders. Dr. Pronovost’s model involves both technical and adaptive solutions. In that model, researchers play a role in identifying safety problems, devising technical solutions to those problems, and evaluating how the solutions were implemented.

Sir Liam said an important question is who should determine research needs. In patient safety, he suggested that both researchers and stakeholders should play a role.

Dr. Somsak thought research should not only identify interventions that work and do not work but also identify interventions that work and do not work in a systems context. He added that the group should consider systems development tools, as well as research methodology tools. He also proposed research on how knowledge about patient safety is generated and shared in a system context (e.g., how do patient groups, quality management mechanisms, or financial mechanisms influence the patient safety agenda).

Dr. Clancy commented that a goal should be to have active research projects in several countries. She asked how the group would build a community to share information and how that community would engage key stakeholders.

Dr. Pronovost noted that in the United States the capacity for patient safety research is woefully underdeveloped, and there is much less capacity in developing countries. He suggested that capacity building around the world should be a priority and that it would be feasible to raise funds to start programs for patient safety scholars in various countries.

Ms. Sheridan said the research should be more transparent to patients, perhaps through a publicly accessible database. Dr. Clancy replied that the United States has a clinical trials registry, but not all clinical trials are reliably listed there.

Dr. Bates asked if there are models of successful research communities that could be followed. Dr. Pang replied that the United Kingdom Department of Health is promoting a program to create a dialog between senior public policy makers, citizens, consumers, and researchers. The dialog format, which allows participants to speak freely without attribution, is being implemented in two WHO regions to build countries’ capacity to bridge the gap between researchers and policy makers.

Dr. Somsak suggested that quality improvement teams already in place in hospitals in different countries could serve as research partners. In Thailand, for example, there are quality management teams within hospitals that focus on systemwide improvement. Patient safety research could be incorporated into the quality management agenda. Medical schools in Thailand also have research promotion units that foster research within hospitals.

Dr. Clancy noted that the group agreed it should consider creating a program of WHO safety scholars, who would represent the leading edge of safety development. They would then be linked with existing WHO efforts and/or other existing in-country efforts. The work of these scholars would be available to the public. Dr. Gawande asked if WHO’s emerging and infectious diseases
knowledge is the enemy of unsafe care.

scholars program had been successful and if it could serve as a model for the patient safety scholars program. Ms. Philip replied that she did not know how successful the program was, but that she would look into it.

Dr. Pronovost said The Johns Hopkins School of Public Health created a similar scholars program with Taiwan’s Ministry of Health to have all of their health care leaders earn Master of Health Science degrees. The program provided training in the broader systems view of health care, and the scholars completed a practicum project in their hospitals as part of the program. This program transformed Taiwan’s health care system.

Sir Liam asked if it was important to consider safety within individual clinical specialties. Dr. Bates replied that he operates a program that teaches practitioners from a variety of clinical specialties to conduct clinical research. A similar program could be implemented in the field of patient safety. Dr. Pronovost said patient safety is not specialty-specific, but product-line specific. His patient safety initiatives have targeted a common group of providers (e.g., ICU physicians). It is important to build patient safety capacity within specialties, because there are not forums for cross-disciplinary research.

Dr. Pang mentioned that research capacity is already available in some developing countries. In Malaysia, for example, the top priority of health systems research is patient safety. WHO could partner with regional centers of excellence, which would give such institutions acknowledgement and help them to raise funds. Mr. McCarthy agreed that research priorities should consider both top-down and bottom-up perspectives. Dr. Cuervo Amore discussed the resources available in his WHO region, including collaborating centers, research officers, a database of Latin American and Caribbean researchers, a network of research councils, and strong links with health authorities in each country.

Dr. Somsak noted that part of the Alliance’s proposed research agenda for 2006–2007 would pair developing countries with developed countries and this pairing should not only involve researchers but also other groups working on patient safety to build capacity more broadly in systems perspectives and evidence-based decision-making. Ms. Philip commented that WHO is considering proposals to create a project focused on pairing hospitals in Africa with hospitals in other countries. She agreed with Dr. Pang’s suggestion to create collaborations with centers in various countries and added that the Alliance needs to collect, as quickly as possible, information about what patient safety research is currently being conducted.

Toward the Strategy of the Research Program: Setting Priorities

Dr. Bates asked for suggestions about funding opportunities. Sir Liam asked if there was a way a percentage of litigation settlements could fund patient safety research.

Dr. Cuervo Amore asked if funding would be available in connection with the possible avian flu pandemic. Little research has been conducted on the many interventions that will be needed if a pandemic occurs. Dr. Clancy agreed that this is a potential opportunity. Dr. Gawande commented that the Alliance’s hand hygiene guidelines would be published in time to intersect with the pandemic prevention effort, a major component of which would be preventing the in-hospital transmission of disease.

Dr. Clancy suggested that, with a clear statement of priorities, the patient safety research program might attract major donors. Dr. Pronovost suggested that international secondary insurers might be interested in funding research. Ms. Philip said the Alliance recently appointed a head of resource mobilization to investigate potential funding sources.
Knowledge is the enemy of unsafe care.

Dr. Pang commented on the current lack of knowledge about global patient safety research and that a database of information was purchased before the Mexico Summit. With funding to purchase the last few years of information and a search strategy, it could be a valuable source of information.

Dr. Bates asked if participants had any additional major priorities. Ms. Sheridan replied that patient safety champions from around the world had submitted research priorities, and she would send their list of priorities to Dr. Bates. She also proposed research on how patient safety materials communicate with patients. For instance, a study showed that parents wanted to know that jaundice could lead to brain damage, but the American Academy of Pediatrics resisted conveying this message, because members feel it is alarmist. Patients for Patient Safety advocates messages that motivate patient action. She asked if research had been conducted on what messages are appropriate from the perspective of patients, rather than providers.

Mr. McCarthy stated that he asked health care quality researchers in his organization about what patient safety research issues they felt were important. They mentioned the need for engagement with the public, improved patient communication skills, and a focus on organizational leadership in promoting patient safety cultures. They also felt that safety in ICUs and the overlap of primary and secondary care were topics that needed more research.

Dr. Somsak suggested that if the group’s goal is not to create priorities but provide a process that health care systems can implement to develop their own research priorities, the research program should avoid the word “priorities” and instead produce a “menu of opportunities”—a list of important and relevant research agendas in patient safety. The first step might be assessing, through WHO, what patient safety issues different countries are facing and what patient safety research they are already conducting.

Dr. Bates concluded that the agenda should include tools as well as topics. He noted that the group felt it was important to keep patients in mind and to incorporate interventions as soon as possible. He thanked the participants and invited them to send any additional suggestions to him by e-mail.

Wrap-Up and Summary

Dr. Carolyn Clancy  
Chair of Council  
Director  
Agency for Healthcare Research and Quality

Dr. Clancy summarized the following important points from the morning’s discussion that the group may want to return to:

1. The tension and/or synergy between the system and the individual
2. The distinction between a global and a local perspective: what is the unique value added by the WHO initiative?
3. The tension between doing something right now and doing something right
4. The need for a short list of high-impact interventions