



Knowledge Is the Enemy of Unsafe Care

1st Meeting on the Global Research Program for Patient Safety

WHO World Alliance for Patient Safety in Collaboration with AHRQ

November 1, 2005

Meeting Summary

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Welcome and Introduction

Carolyn Clancy, M.D.

Director

Agency for Healthcare Research and Quality

Health care systems throughout the United States and around the world know patient safety is an important issue they must address. Dr. Clancy recognized that meeting participants would be approaching this subject from different perspectives.

She welcomed debate, but also expressed hope that with the incredible amount of intellectual capital gathered for the meeting, the participants could arrive at a united vision for patient safety and develop concrete steps to further research in this area.

Patient Safety Research: The Global Challenge

Sir Liam Donaldson, M.D., FRCS, FRCP, FFPHM

Chair

World Alliance for Patient Safety

World Health Organization

Sir Liam said that the meeting, which brings together all of the major players in patient safety and research worldwide, would begin to further another strand of the World Health Organization (WHO) World Alliance for Patient Safety's program—the strand of research and development. The goal of the conference would be to develop a global strategy for patient safety research.

He provided a brief overview of the history of worldwide patient safety research. There was little expertise in patient safety research until the late 1980s and early 1990s. He named important studies in chronological order, using a map to show the geographic distribution of these research projects. Major research projects included the Harvard study, the Utah study, the Australia Quality in Health Care Study, Charles Vincent's work in Britain, and studies in Denmark, New Zealand, Canada, and France. Research is in progress in Brazil, Japan, and South Africa, but the results have not been reported. There is a longer list of countries that are conducting less prevalent studies in patient safety.

The goal of patient safety research is to reduce unsafe care that results in patient death, disability, or harm. The first two presentations of the day provided examples from the "sharp end," the direct interactions between health care practitioners and patients that resulted in medical error and patient harm.

Sir Liam told the story of two boys, Lee Duggins and Wayne Jowett, who died when a chemotherapy drug to treat leukemia, vincristine, was administered incorrectly. Thirty years ago, Lee Duggins was the first child to die in Britain from the maladministration of this cancer drug, which is intended to be administered intravenously. Vincristine was administered to Lee intrathecally when it was confused with another drug.

Lee's mother recently read in the newspaper about the new research in the field of patient safety, and on the 30th anniversary of Lee's death, she approached the World Alliance for Patient Safety and asked if her story could finally be told.

Sir Liam presented a video of Lee's mother describing her son and his experience with radiotherapy and chemotherapy treatments for leukemia. She said while her son was the first child to die from the maladministration of vincristine, she hoped Jowett would be the last. She hoped that a safety device could be developed to make it impossible to administer vincristine intrathecally.

Sir Liam noted that 30 years ago, Lee's death was relatively unnoticed. There was an investigation, and a report was issued, but little was learned. In 2001, Jowett, a boy older than Lee Duggins, died under identical circumstances. Wayne was near the end of his courses of treatment for leukemia at one of the United Kingdom's premier medical centers in Nottingham, when vincristine was confused with another drug and administered intrathecally.

Vincristine syringes are nearly the same size as syringes containing another chemotherapy drug that is administered intrathecally. Sir Liam said the two syringes have differently colored caps but are easily confused, although the vincristine syringe carries the warning "not for intrathecal use" in small print. In most of the incidents where vincristine has been mistakenly administered intrathecally, the syringe has been labeled with this warning.

Jowett had missed some treatments, and his grandmother brought him to the hospital, where the doctors fit him in out-of-sequence so he could receive his treatment. After the vincristine was administered intrathecally, an attempt was made to operate and flush the fluid from his spine, but it did not work.

The intrathecal administration of vincristine is a rare, preventable event, but it still happens today. There has been an extraordinary effort in Britain to encourage hospitals to implement standards that can prevent these mistakes. Although all hospitals said they had complied with the standards, an independent inspection team found that a third of the hospitals had not. The problem is not just raising awareness but also understanding the barriers to compliance.

Danger in Disguise

Susan Sheridan, M.I.M., M.B.A.

President

Consumers Advancing Patient Safety

Ms. Sheridan thanked Sir Liam and Dr. Clancy for inviting her to speak, because consumers and patients often remain faceless and nameless in patient safety research. She spoke about her son, Cal, who suffers from kernicterus, a type of brain damage caused by newborn jaundice. Kernicterus once was the second leading cause of cerebral palsy in the United States, but thanks to research into the causes and treatments of jaundice, kernicterus nearly disappeared from the developed world by 1970. Today, it is reemerging in the United States and elsewhere.

Ms. Sheridan described the sequence of events that led to her son's condition. Although it was noted when Cal was 16.5 hours old and when he was 23 hours old that he appeared jaundiced, the biliruben test was not administered. At 36 hours old, Cal was discharged from the hospital, and the parent education on jaundice consisted of a brochure explaining the causes of jaundice, but not the dangers.

When Cal was 4 days old, Ms. Sheridan noticed that he was weak and lethargic. She took him to the pediatrician, but no biliruben test was performed. The next day, she took Cal to the hospital, where his biliruben was tested for the first time—Cal's biliruben was 34.6, a brain-damaging level. At 6 days old, Cal starting arching backwards, a sign of brain damage, but the hospital discharged him as a well baby. At 18 months, however, Cal was diagnosed with textbook kernicterus.

Ms. Sheridan asked why the health care community did not communicate the dangers of jaundice to the public. If she had known about the risk of brain damage, she would have asked doctors to perform a biliruben test. She took several prenatal classes and read the top-selling parenting books, but none of them addressed the dangers of jaundice. The only information available to the public was a brochure from the American Academy of Pediatricians, which advises parents, "If your baby has jaundice, do not be alarmed."

Ms. Sheridan began writing letters to people involved in patient safety in the United States, and in 2000 she was invited to testify at AHRQ's first patient safety meeting. AHRQ began a 5-year, \$5 million program called Managing Jaundice in Infants and Children (Majic) to examine the problems of jaundice. The results have not been translated into increased patient safety.

Ms. Sheridan's testimony at AHRQ drew attention to her son's story, and her family was featured in *USA TODAY*. After the story appeared, she began receiving calls from parents around the United States who had had similar experiences. They formed an organization called Parents of Infants and Children with Kernicterus (PICK). The PICK Web site has received more than 20 responses from countries other than the United States, indicating that kernicterus is a global problem.

PICK partners with the health care system to prevent kernicterus. The organization has worked with the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO), convincing them to issue two sentinel alerts on kernicterus. These were the first consumer-driven sentinel alerts issued. Initially, JCAHO was reluctant to issue an alert because they only issued alerts based on the evidence in their databank. However, working with PICK, they realized it was an important issue to report to hospitals. Ms. Sheridan said that there was no "evidence" to create action because the number of cases of kernicterus in the United States had been underestimated. The Centers for Disease Control and Prevention (CDC) issued a *Morbidity and Mortality Weekly Report* on kernicterus and announced in 2002 that kernicterus was an emergent issue. CDC granted PICK \$500,000 to conduct more research on the database of children with kernicterus, which had grown to 90 in the United States, and to create a public education campaign. When CDC issued a newborn jaundice alert, PICK worked to make sure the word "alert" was in the title, and that the content of the alert used the term "brain damage" so parents and health care workers would know this was a serious condition.

PICK created a video to raise awareness about kernicterus and the failure to administer the \$1 test. PICK and its partners, including JCAHO, CDC, and the National Institutes of Health (NIH), believe that all babies should be screened before they are discharged. PICK conducted three focus groups in the United States, which found there was little public knowledge about kernicterus among expectant parents.

After 8 years of advocacy, children with kernicterus became recognized as evidence in a study of the reemergence of kernicterus published in a 2003 pediatrics journal. However, when a literature research study was conducted on kernicterus, the study featuring the children of PICK was not included because it missed the publication cutoff date. Ms. Sheridan said this is one of the challenges they have faced in getting their children recognized as evidence in patient safety research.

PICK is beginning a new public awareness campaign by distributing bracelets inscribed with the phrase “What’s My Baby’s Bili?” to encourage new parents to ask for the bilirubin test. They are embarking on the campaign without waiting for research to show whether or not it will be effective, because there is a great need for public education. Ms. Sheridan then read from an e-mail she received from a woman whose newborn son sustained brain damage from jaundice when the bilirubin test was not administered. Ms. Sheridan recently looked at the top-selling parenting books and found that the information on jaundice has not changed—most books say that jaundice is nothing to worry about. PICK sent a media packet to the authors of the popular book, *What to Expect When You’re Expecting*, but the information on kernicterus is included in the section on the first year of life, while research shows that the information needs to be part of prenatal education.

Ms. Sheridan invited and challenged the meeting participants to look at patient safety research from the perspective of the patient and consumer and to explore the role of the consumer in research.

Directions in Safety Research: Reviewing the Past, Guessing the Future

James Reason, Ph.D.

Professor Emeritus

University of Manchester

Dr. Reason presented a history of the development of safety research across hazardous industries. He discussed a list of examples of the major safety failures that characterized each decade, from the 1960s to the present.

During the 1960s, equipment failures were the focus of safety concerns. However, over time the focus shifted from “hardware” issues (mechanical failure, metal fatigue) to systems or “software” issues (the control of systems by engineered safety features). As the complexity of systems increases, systems become opaque to the people involved. Operators are increasingly remote from their processes.

He noted the Brown's Ferry incident in the mid-1970s was a major turning point in how the nuclear industry thought about safety—moving from a perspective focused on mechanical systems to a focus on individual human error. Two controllers using candles to find an electrical fault under the control room at a nuclear power plant in Browns Ferry, Alabama, started a fire that shut down most of the plant's safety systems and nearly led to a nuclear accident. The industry realized that human error can bypass all the engineered safety features.

Dr. Reason described the crash of an Air New Zealand DC 10 into Antarctica's Mt. Erebus, in which all passengers and crew were killed, as another turning point in the way various industries think about safety—a shift from a human error model to a systems model. While the initial investigation concluded that the crash was the result of pilot error, the senior judge of New Zealand carried out a 2-year inquiry, indicted Air New Zealand and the Civil Aviation Authority (CAA), and uncovered what he called “an organized tissue of lies” from the CAA.

Dr. Reason discussed other examples in which safety research looked at the problems with systems rather than erring individuals, such as the Chernobyl accident. He said in the field of safety for many industries, there is an ever-widening search for “upstream” factors, moving from the individual to the workplace, to the organization, to regulators, and to society at large.

Dr. Reason said safety research is going too far in looking at upstream, systems factors, and not examining individual errors at the “sharp end.” He noted that investigators attributed the Chernobyl accident to the general failure of the Soviet economy. However, while there may be some truth to this, it is not very helpful or causally accurate. Dr. Reason showed a model of the systems approach to error and discussed the major organizations that endorse this model. He acknowledged that this model has many benefits over the personal model of error, which ignores problems with the system and blames the individual.

He said there needs to be a balance between the personal model and the systems model of error to improve safety and strive for an error-resilient environment. He noted this balance was particularly important in the health care industry because of the unique features that distinguish it from other hazardous fields: diverse activities and equipment, hands-on work with more opportunity for error, uncertainty and incomplete knowledge, vulnerable patients, local event investigation, and one-to-one or few-to-one delivery of services. These features make consideration of errors at the “sharp end” even more important than in industries such as nuclear power or air travel.

Dr. Reason discussed a graphic representation of the development of safety models across industries—a grid with a vertical axis representing the person model from “human as hazard” to “human as hero” and a horizontal axis representing the systems model from “systemic factors concealed” to “systemic factors revealed.” He proposed that safety research evolves circularly, moving clockwise around these axes, as follows:

- Moving through the upper right quadrant (A), from “human as hazard” to “systemic factors revealed,” one recognizes that blaming the individual has no remedial value and that understanding systemic problems is more successful in identifying potential errors.

- Moving through the lower right quadrant (B), from “systemic factors revealed” to “human as hero,” one sees that excellence has to do with individuals who can recognize and recover from errors.
- Moving through the lower left quadrant (C), from “human as hero” to “systemic factors concealed,” individuals are empowered to find local fixes and “work-arounds,” but these hide systemic problems from management; individuals at the “sharp end” do too little with too much and forget to fear error.
- Moving through the upper left quadrant (D), from “systemic factors concealed” to “human as hazard,” management strives to remove fallible people from the system, increase administrative controls, and diminish the autonomy of those at the “sharp end.”

Dr. Reason said that, as industries move through this cycle, the circle becomes smaller, variability decreases, and error resistance increases.

How Will Research Effectively Contribute to Eliminate Patient Harm? Where Are the Gaps in Patient Safety Research?

Carolyn Clancy, M.D.

Agency for Healthcare Research and Quality

Dr. Clancy said this is the substance of the meeting—to find the continuing gaps in patient safety research. After the publication of the Institute of Medicine report *To Err Is Human*, AHRQ began to invest in patient safety. Since then, they have struggled to balance the development of new knowledge—particularly about health care beyond the hospital setting—with trying to gain momentum on the many dimensions of patient safety.

In the fall of 2000, AHRQ convened its first meeting on patient safety in Washington, DC, with the goal of allowing those at the “sharp end” to help set priorities. The meeting had a large attendance, with each attendee allotted a short time to testify. AHRQ identified key areas for patient safety research based on that input:

1. Using reporting systems to uncover errors and harms
2. Understanding the health care environment (i.e., the organization of health care workers, staffing ratios, etc.)
3. Training health care workers to use strategies to detect, reduce, and prevent errors
4. Translating knowledge into practice
5. Using information technology (IT) to solve problems

AHRQ has work in progress and demonstrations to test strategies of reporting errors. Dr. Clancy noted that the new *Patient Safety and Quality Improvement Act*, which the President signed into law last July, will encourage organizations to work together to identify problems in patient safety and test strategies to solve those problems. The new law removes a barrier to cooperation by protecting such efforts from legal liability.

She outlined major frontiers in patient safety research in the United States. The top two priorities for measurement are developing measures for ambulatory care and developing measures generally. Because of the new legislation, a detailed inventory of reporting systems in use throughout the country is under way, and the results of this work will be available to the WHO group. Several years after the publication of *To Err Is Human*, concern about patient safety has increased, but patient safety has not increased measurably.

Donald Berwick, M.D., and the Institute for Healthcare Improvement is focusing on a discrete campaign to deploy rapid response teams for deteriorating patients; prevent adverse drug events, especially at the time of hospital discharge; prevent central line blood stream infections; and prevent ventilator-associated pneumonia.

A second major area of research is the “Clean Care Is Safe Care” worldwide campaign. Approximately 2,500 hospitals are part of the campaign already, although it is not clear what that level of participation really means. Improvement is apparent in some targeted areas; however, a major goal is to align enthusiasm for taking action in the wake of an error with research to determine whether the actions taken are effective. Otherwise, there is a potential to waste resources on implementing ineffective strategies.

IT can be a powerful tool for putting evidence into practice. For example, portable IT tools for checking medications at the bedside can reduce errors. IT tools can be used in a variety of settings. William Tierney, M.D., Indiana University School of Medicine, one of the researchers whom AHRQ has funded for a number of years, has been working with Kenya and other countries to use widely available database systems to track diseases such as HIV.

AHRQ also has developed training programs to reduce medical errors. They have worked with the Veterans Administration (VA) to develop the Patient Safety Improvement Corps, because of the VA’s success with improving patient safety in their own facilities. Dr. Clancy said there is a critical need for research to determine which aspects of training programs are effective and how often training needs to be reinforced.

Methodology Gaps

Ross Wilson, M.B., B.S., FRACP, FJFICM

Director

Centre for Healthcare Improvement

Dr. Wilson said it is difficult to talk about methodology if you do not know what kind of problem you want to solve. While some experts have become pessimistic about the possibility of reducing medical errors, he assured the participants that safety improvement is possible. He used the example of the decrease in traffic fatalities to show that significant safety improvement can be achieved, but it takes efforts at a number of levels.

To begin to develop a methodology, researchers must first ask themselves some questions: what do they already know; what do they not know; what do they need to know; what do they need to know first; what resources are available; and how do they keep learning.

Because health care is a complex system, where patient care is affected by clinicians, clinician teams, organizations, and even the larger governmental, political, and financial environment, research is necessary at all these levels and requires a broad array of methodologies. Randomized clinical trials and quantitative research alone is insufficient.

AHRQ's Patient Safety Summit in 2000 identified seven areas of research. Out of this meeting came the sense that a strategic approach to this research was required, setting priorities based on patients' needs, not researchers' interests or government funding. It is also important to consider which areas the research led to a change in practice or reduction of harm.

Dr. Wilson said researchers have new measurements, but many of those measurements are not very good. He discussed studies of harm frequency that have been conducted in health care systems around the world. The results of the studies vary depending on the methodology used, but the studies show that the rate of patient harm is high. Prevention should be an area of focus, but it is a difficult area of research, methodologically.

Before determining the methodology that should be applied to patient safety research, researchers must determine what areas need more work. Researchers currently have a significant amount of information about acute hospital care and about the health care systems in some developed countries. Researchers also know that rates of harm increase with patient age and length of stay in the hospital. However, researchers have little information about the majority of health care delivery, including community and primary care, private health care, mental health care, health care in developing and transitional countries, and care of indigenous populations.

Based on what researchers know, the relationship between patient age and harm is one of the first challenges that can be addressed. A second focus of research should be how knowledge is implemented in health care settings. Dr. Wilson noted that while the science of western medicine is incredibly advanced, the implementation of that scientific knowledge often lags behind.

He added that it is important to acknowledge what researchers do not know to set priorities for further research. As an example, he cited a paper from National Health Services reporting that "slips, trips, and falls" were the most frequent adverse events in the U.K. health system, based on data gathered from a national reporting system. However, it is not clear if that is the most significant problem researchers should work on.

Another study based on medical records showed that nearly half of adverse events were associated with operations, including problems with infection and bleeding. The information varies greatly depending on the data reporting system. A variety of data sources are available—medical records, performance indicators, insurance claims, reporting systems, etc.—but no one source is sufficient. Measurement is important so researchers can determine the size and nature of problems to better prioritize limited resources.

Dr. Wilson asked what the scope of patient safety research should be. Most of the research has measured how management plans are implemented; more research is needed in patient assessment and the development of management plans. A recent study in the United States showed that only 54.9 percent of patients actually received the recommended care,

demonstrating that a failure to adhere to recommended processes of care poses a major threat to patients.

Dr. Wilson said more research is necessary on the impact information technology in patient safety. As an example, he cited a paper from the *Journal of the American Medical Association* that concluded that computerized clinical decision support systems (CCDSS) improve practitioner performance. However, patient outcomes have either not been studied or, where they have been studied, the patient outcomes have been found inconsistent with improvement in practitioner performance. The CCDSS implementation has led to 22 unanticipated new problems. He urged caution and continued research into new solutions before they are widely implemented.

He said there needs to be more effort to learn from episodes of harm. Improved detection and monitoring systems and error analysis are needed to develop solutions that follow the causes and can be implemented locally, with current resources, and in the future. Research needs to find ways to share solutions.

He argued that it would be important to combine quantitative research with qualitative techniques, working with anthropologists, ethnographers, and others. “This is no longer the realm of the randomized control trial—this is priority-driven, strategically guided research.” Qualitative techniques are needed to examine the culture of health care organizations—cultures that frequently encourage clinicians to hide mistakes, rather than learn from them.

Dr. Wilson closed by emphasizing that research needs to focus on local safety issues, discovering what causes the most harm, implementing existing knowledge, incorporating qualitative methods, developing sharing mechanisms, and fostering a strategic approach to international patient safety research. Researchers must make measures easy to implement, and remember that all improvement is local, although the research agenda is global.

Patient Safety: Constrainers to Research in Developing Countries

Thandinkosi E. Madiba, M.B.Ch.B., M.Med., FCS

Professor, General Surgery

University of KwaZulu-Natal

Dr. Madiba described the obstacles to research in developing countries. Because of the burden of disease in the medical facilities in many developing countries, clinicians lack the time and resources to conduct research. The frequent hospital follow up visits research requires also are a drain on hospital resources, leading researchers to take their laboratory work outside the hospital. Thus, hospitals do not build their own capacity to support research.

When patients become part of a research program, they often have the misconception that it will be a form of treatment. Patients become frustrated when their conditions do not improve and when researchers do not report back with results. Follow-up visits are also a burden for patients in developing countries. For example, many research subjects miss work and lose their employment as a result.

Because of a lack of time to conduct research and publish papers and because health care organizations do not make research a priority in developing countries, there are few researchers in developing countries. Those researchers lack experience, knowledge of research methodology, grant-writing skills, and funding.

Experienced researchers are often lured to developed countries. For researchers working in developing countries, there is a large gap of experience between the senior and junior researchers. Senior researchers lack the time to mentor junior researchers at the local level. As a consequence, research activities are colonized at the local level.

Patient safety is an area that is particularly under-researched in developing countries because resources are channeled to other research projects. Another barrier to research is that protocols written in funder countries do not take local cultural issues into account. The research community has not worked to build the capacity of developing countries to conduct research at the local level, and this lack of capacity perpetuates dependency, the colonization of research, and the exploitation of poor communities.

Dr. Madiba noted that there is insufficient understanding of research ethics and the ethics of patient care in many developing countries. To further scientific discovery, researchers sometimes understate the risks involved. The research process needs to be monitored closely, especially the process of obtaining informed consent.

Another obstacle to research in developing countries is expense. The development of new health technologies is increasingly expensive, but research and the development of health care solutions that primarily affect the poor are not commercially attractive. The governments of many developing countries do not finance institutions and scientists, which perpetuates the “90/10 divide”—90 percent of the disease burden is not addressed and 90 percent of the budget is used to address 10 percent of the disease burden. There also is a disconnect between policymakers and researchers—researchers do not address the health problems that policymakers and the community perceive as top priorities, and policymakers do not make use of research findings in their decisionmaking.

Dr. Madiba concluded that addressing these capacity gaps is a challenge for both developed and developing countries. It requires developing the methodology and grant-writing skills of local researchers and ending the colonization of research. Research must be responsive to institutions and governments to encourage investment in human resources, financial resources, and facilities for research. Foreign and domestic funding are both necessary to support research in developing countries, and senior researchers must mentor junior researchers to build future research capacity. Finally, both developed and developing countries must improve education and awareness of research ethics.

Building Capacity and Capability to Conduct Research Integrating Global Research Agenda and Local Utilization: Challenges from the Mexico Summit on Health Research

Ulysses de Barros Panisset, M.D., Ph.D., M.A.

Scientist

Research Policy and Cooperation

World Health Organization

Dr. Panisset said people do not get sick globally, they get sick locally—this is where they are treated and confront their personal experience with disease and health. The role of WHO is to determine how to call attention globally and help implementation locally. The stories of individuals who suffered harm because of medical error are reminders of the WHO’s purpose and the importance of reducing preventable medical errors. Implementing research evidence is an important part of that purpose.

Dr. Panisset noted that it is part of the WHO’s 1946 constitution that “the extension to all peoples of the benefits of medical, psychological, and related knowledge is essential to the fullest attainment of health.” This still remains crucial to the WHO’s mission. He cited current WHO Director-General Dr. J. W. Lee, who said in 2003, “Now is the time to make it happen where it matters, by turning scientific knowledge into effective action for people’s health.”

The *World Report on Knowledge for Better Health*, published before the Mexico Ministerial Summit on Health Research, reported that knowledge is needed to strengthen health systems, which will be necessary to meet Millennium Development Goals to guarantee equity and quality.

The Summit, held in Mexico City on November 16–20, 2004, was organized around the theme that stronger emphasis should be placed on turning knowledge into action to improve health. The 58th World Health Assembly, held in Geneva on May 16–25, 2005, issued a resolution urging member states “to establish or strengthen mechanisms to transfer knowledge in support of evidence-based public health and health care delivery systems and evidence-based health-related policies” and directing the WHO director-general “to assist in the development of more effective mechanisms to bridge the divide between ways in which knowledge is generated and ways in which it is used, including the transformation of health-research findings into policy and practice.”

Dr. Panisset addressed the challenges in bridging the gap between knowledge and action (i.e., the “know-do gap”). One challenge is that knowledge—whether or not it is global knowledge—is always put into practice locally. To apply state-of-the-art scientific knowledge to a local context, it is vital that researchers work with policymakers, who have experience with and knowledge of complex local policy problems and health systems. The interests and methods of policymakers contrast sharply with those of researchers in many areas, but researchers must find ways to bridge these gaps, especially by translating and transforming evidence so it is relevant to users. Users and stakeholders must become involved in framing research.

WHO has developed three instruments to bridge the “know-do gap.” The first is an international clinical trial registry platform to investigate the impact of research on patient safety. A second is the Evidence Informed Policy Network (EVIPNET), which brings together policy

decisionmakers, researchers, nongovernmental organizations, patient groups, and the public. The first EVIPNET has been established in the Western Pacific Region in Asia and includes Cambodia; Laos; Vietnam; the three Chinese provinces of Beijing, Shendong, and Sechuan; Malaysia, and the Philippines. In Malaysia, EVIPNET focuses on issues of patient safety; it will serve as a pilot program to be applied to other countries. Two similar networks are being formed in Africa. WHO also develops guidelines as instruments for turning knowledge into action safely, with high quality. WHO reviews the guidelines to ensure they do no harm. In developing guidelines, the WHO takes a population perspective, ensures scientific integrity, and ensures the guidelines are sensitive to local contexts. However, a challenge for the WHO is to ensure that recommendations are implemented and improve outcomes.

International Networks and Health Research

Willem Ouwehand, M.D., Ph.D.

Reader in Platelet Biology and Genetics

Cambridge University

Dr. Ouwehand shared experience with two networks with which he has been involved, Serious Hazards of Transfusion (SHOT) and Bloodomics.

SHOT, a national network in the United Kingdom that is embedded in a global framework through the International Society of Blood Transfusion, began in the mid-1990s. A boy was given the wrong blood type during a routine procedure, leading to cerebral palsy. SHOT began to better catalog how often errors related to blood transfusion occurred in the United Kingdom. Once SHOT created a registry of adverse transfusion events, they saw that most events (98.2 percent) were immunological and only 1.8 percent were infectious. Dr. Ouwehand showed a figure that illustrated the number of transfusion complications resulting from four causes—wrong blood, immunological factors, bacterial factors, and viral factors.

This study led Sir Liam Donaldson, Chief Medical Officer of the United Kingdom, to issue an instruction to the National Health Services hospitals to ensure better blood transfusion practices. The Department of Health also distributed toolkits to help implement the changes.

Dr. Ouwehand leads Bloodomics, a network of 14 research groups in Europe, working together to determine which genetic markers are associated with an increased risk of atherothrombosis. The group brings together physicians, protein engineers, geneticists, statisticians, and health care economists.

To create an effective research network across several cultures and localities, the group agreed on several founding principles, including equality (each member has one vote); a strong legal and ethical framework; coordination and accountability; and tasks, milestones, and deliverables. Like the genome project in Europe, Bloodomics also has an open data culture, giving members of the network direct access to data and outcomes. They also established clear guidelines for publications and policies for intellectual property rights, which allow knowledge to benefit patients as soon as possible.

A not-for-profit company, the European Cardiovascular Genetics Foundation (ECGF), is at the heart of the Bloodomics network. ECGF—established for patients, by scientists—funds research in universities, institutes, and small- and medium-sized enterprises, and the resulting intellectual property returns to the foundation. ECGF then puts the information into practice through a commercial company. Advisory boards for scientific research, intellectual property and publication, and ethics and auditing oversee ECGF.

Dr. Ouwehand showed video clips of researchers discussing the Bloodomics project. He concluded that the following characteristics are needed to build successful global research networks: a shared vision, interdisciplinarity, a legal framework, strong coordination, clear task allocation, an open data culture, positive and negative outcomes sharing, accountability, and delivery of results.

Facilitated Discussion of the Presentations

Sir Liam Donaldson, Moderator

Rhona Flin, Ph.D., Professor, School of Psychology, University of Aberdeen, King’s College, United Kingdom, who has worked on industry safety projects, increasingly in health care, noted that the focus of the research discussed so far is on practitioners at the “sharp end.” She said research should also focus on the individuals running health care systems, such as managers and supervisors, to consider how safety is prioritized by organizational management.

Dr. Reason responded that to engineer a safe culture, that culture must be CEO-proof. He said CEOs are “birds of passage,” who change positions frequently and do not have much impact. Efforts to improve safety should be directed at middle and front-line managers, because they are in the best position to assess changing situations and adapt.

Dr. Flin responded that while she agreed that CEO’s are “birds of passage,” CEOs and upper managers have a significant impact on the culture of an organization. To improve safety, it is necessary to look at all levels—upper as well as front-end management.

William Ben Runciman, Ph.D., Professor, Department of Anesthesia and Intensive Care, Royal Adelaide Hospital, Australia, said it is important to develop tools rather than guidelines. Tools can be disseminated easily and used consistently in a variety of health care settings, whereas guidelines are more difficult to implement consistently.

Dr. Wilson agreed that it is important to get beyond guidelines and focus on creating protocols that are decision-based, written by health care providers, and locally endorsed. On the subject of management, he thought that the role of organizational leadership in patient safety is worth exploring. Without leadership, he did not believe that local efforts to improve patient safety would be sustainable.

Beth Lilja, M.D., Director, Danish Society for Patient Safety, Denmark, discussed the Danish Health Services’ use of pictorial tools to disseminate and reinforce health guidelines. She noted that the guidelines are still posted, but guidelines are not enough.

Didier Pittet, M.D., M.S., Geneva University Hospitals, Switzerland, agreed that tools are useful at the bedside to change behavior, but there is a problem of having too many tools—and the tools are not always based on evidence. Evidence-based guidelines are needed first so those guidelines may translate into tools. There are many guidelines that health care workers are not aware of or not following; better tools are needed to transform behavior.

Richard Lilford, M.D., Ph.D., Professor of Clinical Epidemiology, Head, Division of Primary Care, Occupational and Public Health, University of Birmingham, United Kingdom, shared three findings from his research, funded by the National Health Services Research and Development program on safe practice in maternity care. His research showed no correlation between a person's propensity to follow one guideline and propensity to follow another. If culture determined whether or not guidelines were followed, why would there be no correlation? His research found no difference between teaching and nonteaching hospitals. When individuals were asked about their motivations for taking actions, no one mentioned CEOs or managers as sources of motivation. Their motivation was either personal reasons or professional leadership. He concluded that professionals, rather than CEOs or managers, created change.

Sir Liam said CEOs have roles beyond ensuring compliance with safety alerts and guidelines—they have a wider strategic responsibility to ensure that their organizations are designed as safely as possible.

Ms. Sheridan encouraged researchers to develop toolkits that also provide patients with actions they can take to improve safety. While she supported evidence-based research, she asked if it was possible to broaden the definition of evidence. When her son suffered his injury, researchers concluded there was not enough “evidence” to take action. She asked if there was a way to speed up the process of recognizing victims of medical error as evidence, so action can be taken to prevent further harm.

James Conway, M.Sc., Senior Consultant, Dana-Farber Cancer Institute, and Senior Fellow, Institute for Healthcare Improvement, United States, mentioned that 10 years ago, a *Boston Globe* reporter, Betsy Layman, tried to tell the hospital that something was wrong with her care, but she was ignored. She died as a result of a chemotherapy error. Patients and family members now populate all decision-making bodies of the institution, so health care workers can learn from their experiences. Years of research have shown that there needs to be active communication between clinicians, patients, and families, but that knowledge has not been translated into practice.

Sir Liam said consumer groups are regarded as pressure groups for change, and policymakers prioritize their response according to the severity of the health care problem. Patient safety is different in that consumer or patient groups are not asking for more resources; they are asking for an opportunity, free of cost, to solve a problem.

Ms. Sheridan agreed that consumers have a lot to contribute in the area of patient safety. Most patient safety advocates see medical errors as systems errors and want to partner with the health care system to make sure those errors do not happen again.

Dr. Panisset also thought researchers need to look at different methods of revealing and analyzing evidence and information technology can help, although it is not a panacea. He agreed that it is important to go beyond guidelines to create manuals and toolkits to change behavior, but researchers are the worst people to develop toolkits because they focus on results and forget about implementation. Consumer input can be very helpful in translating evidence-based guidelines into practice.

Sir Liam remarked said that most research into the implementation of clinical guidelines has focused on “best practice” or “more appropriate practice,” with little research on implementing guidelines for “safe practice.” It would be interesting to see if the results would be different in that field.

David Bates, M.D., Chief of the Division of General Medicine, Brigham and Women’s Hospital, United States, disagreed with Dr. Wilson’s criticism of clinical decision support systems because they have not affected outcomes. Dr. Bates said the trials that have been conducted have not had sufficient power to detect a difference if one is present. AHRQ supports this research, but the size of grants is not sufficient to detect a difference in outcomes for key measures. Safety is unique because of the rarity of some outcomes. There could never be a randomized trial large enough for kernicterus to show a benefit. However, an approach that ensured that everyone was tested, or everyone with a sufficiently high biliruben was tested, would be a positive outcome.

Orlando Urroz Torres, Ph.D., Pediatric Surgeon and TQM, Director, National Program in Patient Safety, Costa Rica, commented that the global research agenda has given his organization the opportunity to improve patient safety through a National Quality program in Costa Rica. They have linked guidelines, protocols, and tools, with a clear objective of improving patient safety. They have joined with Japan in the Evidence Participator Quality Improvement initiative, which looks at deficiencies in patient safety as opportunities to learn and to improve.

Lucian Leape, M.D., Harvard School of Public Health, United States, noted that a major obstacle to implementing safe or best practices is resistance to change from physicians. Health care organizations are different from other industries, in that other industries do not involve key actors who are independent contractors, as physicians are in the U.S. health care system. While physicians may not literally be independent contractors in other countries, they are still trained to be intellectually autonomous in most cultures. Dr. Leape described a major effort in Massachusetts to implement guidelines for reconciling medications—ensuring that a patient received the same medications in the hospital they were taking before they entered. The effort only had a 20 percent success rate—80 percent of hospitals did not succeed in implementing this practice, primarily due to lack of support from CEOs and physicians. He concluded that it is vital for physicians to make safety a priority, particularly in the United States.

Towards Setting a Global Health Research Agenda What Have We Learned About Patient Safety Research?

Carolyn Clancy, M.D.

Agency for Healthcare Research and Quality

Based on her experience with AHRQ, Dr. Clancy said setting priorities in health care research requires an ongoing discussion with health care providers, health care organizations leaders, policymakers, and consumers and patients. Within this framework, research is a means to an end, rather than an end in itself. In each country, researchers must consider the constituencies who need to support their work.

AHRQ has established a four-part framework for setting research priorities:

1. Identify threats to patient safety
2. Design and test effective safety practices
3. Disseminate and implement effective practices
4. Maintain vigilance

It is important that all constituents agree to the priorities, and AHRQ continually consults with the constituents involved to find out if the priorities need to be revised.

Dr. Clancy noted that collecting data is not the same thing as system improvement, and a bottom-up approach can have only a limited impact. It is also important to invest in leadership, and WHO can serve as a leader and as a trusted source of evidence-based tools and information on patient safety. Synthesizing knowledge and making it applicable to practice will be a vital part of the WHO's and the AHRQ's efforts to improve patient safety.

Facilitated Discussion: Research Methodologies

Sir Liam Donaldson, Moderator

As Sir Liam opened the discussion, he asked the participants to think about the following five objectives:

1. Understanding the underlying concepts as a foundation for exploring new knowledge
2. Acquiring new knowledge and evidence
3. Drawing in knowledge and evidence from other safety fields
4. Finding where current knowledge can be implemented
5. Researching how the application of knowledge can be successful or unsuccessful

Sir Liam asked what more needs to be done on the methodological front.

G. Ross Baker, Ph.D., M.A., Professor, Department of Health Policy, Management, and Evaluation, University of Toronto, Canada, responded that the first issue to address is providing tools and methods to assess patient safety locally—whether safety is a problem, and if it is, what type of problem. A second issue is evidence: what is evidence, and how do you separate evidence about the outcomes of a practice with evidence about the problems in implementing

that practice? He also discussed the merit trial of emergency medical teams in 17 Australian hospitals, which suggested that medical emergency teams are not effective in providing resources to people on the floor for patients who are at risk of cardiac arrest. This is a case, said Dr. Baker, in which we need to separate the evidence of the effectiveness of the intervention from evidence about the way the intervention was implemented.

Dr. Leape said the recent and as yet unpublished labor and delivery adverse outcomes study makes a significant advance in measurement and should be part of the WHO's research agenda. The study developed a scale that assigned a weight to the different adverse outcomes of labor and delivery. At the end of the year, they added up the scores, divided by the number of deliveries, and arrived at an adverse outcomes index. Weighted measurements helped demonstrate that team training in patient safety made a difference, reducing the adverse outcomes index substantially. Such measures can be used to show that safety has been improved in a particular domain. Dr. Leape suggested that indexes might be developed for emergency care, intensive care, operating rooms, etc. These measures can help clinicians understand the severity of a safety problem and show that patient safety measures make a difference.

Sir Liam asked how much new research is needed to understand why intervention methodologies do and do not work, and how much research is needed to identify and validate intervention techniques that have been demonstrated to work, but are not widely recognized. He asked if both types of research are needed.

Dr. Lilford said there is "no one-size-fits-all" methodology in patient safety. The subject is so large and so nuanced it needs the commissioning of a thoughtful report, which could be the basis of a discussion to follow today's meeting. Participants need to reach an agreement about what counts as evidence.

Dr. Runciman supports an evaluation of a spectrum of research methodologies. Errors occur in myriad ways in patient safety, and there is a tendency to lump events together so they can be counted, when they may in fact be disparate events. Global measures and indexes do not reveal why problems occurred—or how the problems can be avoided. Instead of lumping events together, Dr. Runciman recommended using qualitative methodology to address low-frequency events. He acknowledged that medical science is ill equipped for qualitative methods and would need input from qualitative researchers.

Dr. Antonio Carlos de Azevedo, Pan American Health Organization, Brazil, asked whether it is possible to discuss methodologies for gathering evidence to improve patient safety outside a framework of quality management. If they do operate within a quality management framework, then they should not only look at the physician/patient relationship but also the team/patient relationship. He suggested that it would be important to look at the relationship between user/patient satisfaction and user/patient safety.

Mr. Conway said that they should develop a methodology to measure the effectiveness of campaigns that are already under way. There are 2,800 organizations in the 100,000 Lives campaign—but it is easier for the organizations to commit than to take action. Most collaboratives and campaigns do not achieve their vision. What are the characteristics of the

organizations that are most successful in implementing these campaigns, and do those organizations achieve their goals?

David Studdert, LL.B., Sc.D., M.P.H., Associate Professor of Law and Public Health, Department of Health Policy and Management, Harvard School of Public Health, United States, asked whether research should be focused on measurable outcomes or on looking at the errors and mishaps in the process. In the United States, researchers still do not know how to measure avoidable adverse events. He agreed with Dr. Leape that it would be useful to develop a single basic metric to measure patient safety in a field. Such a measurement may not have a clear link to specific errors, but it does measure outcomes. Health care workers can then try different interventions and examine the outcomes before and after the intervention to see if safety has improved. Researchers may not always know why a specific intervention made a difference, but they can know that outcomes have improved.

Sir Liam asked Dr. Studdert if there would be enough events in an individual institution for an evaluative study, or if the study would need to include events from a range of institutions. Dr. Studdert responded that for many events, a simple index would work at a single institution. He said the benefit of a simple index is that every physician could be a part of the patient safety effort and see results at an institutional level.

Sir Liam then asked if such indices should draw a distinction between the natural complications of health care and unsafe care. Dr. Studdert answered that such a distinction would not be necessary, because only the difference before and after the intervention would be important.

Peter Angood, M.D., Vice President and Chief Patient Safety Officer, International Center for Patient Safety, JCAHO, noted that the meeting had focused on systems and systems reengineering, but the participants had not addressed issues of human behavior and cultural adaptation to change. He suggested that in this area, patient safety researchers should learn from non-health care industries or academia. Other industries have spent 30 years implementing changes to successfully improve safety. The field of patient safety cannot wait another generation or two for improvement.

Jerod Loeb, Ph.D., Executive Vice President of Research, Division of Research, JCAHO, supported Dr. Leape's suggestion of developing simple indices, but first they would need to be based on a common lexicon that does not exist yet. He also said he was not convinced that increasing the evidence base will make care safer. He mentioned a paper published in *Health Affairs* a year ago, in which researchers studied four eras in quality improvement. Over the course of these four eras, publication of research, meta-analyses of research, development of quality indicators, and systems reengineering—making it easy to do the right thing and impossible to do the wrong thing—have been introduced sequentially as means of putting quality improvement research into practice. He asserted that it was a fallacy that simply augmenting the evidence would improve safety practices.

Dr. Lilford thought a whole day could be devoted to discussing methodology alone, and it is unsatisfactory to try to resolve the issue of methodology in such a short time. He disagreed with Dr. Studdert and said because of a low signal-to-noise ratio in measuring outcomes, models show

there is little chance of finding a difference in outcomes, unless the intervention has a chance to achieve those outcomes in spite of all the noise.

Dr. Clancy suggested that to make the best use of the time remaining, they find a way (perhaps via the Internet) to continue the debate about methodology after the meeting. To shift the discussion, she noted that to build momentum for the alliance, it would be important to show success. She suggested looking to other industries to see how they achieved early successes, such as standardization and making the right thing to do the easy thing to do.

Dr. Reason acknowledged that the idea of a single basic metric is appealing and a similar measurement strategy was used in the oil and gas and coal mining industries. The problem is that safety is not a simple business. One of the dangers of the basic metric is that it does not measure the big bangs—the major disasters that really affect the bottom line. Experiencing early success in driving down basic safety indices is very motivating, but the situation and the nature of the risks change.

Sir Ara Darzi, KBE, M.D., FRCS, FRCSI, FACS, FRCPSG, F.Med.Sci., Professor of Surgery and Head, Division of Surgery, Oncology, Reproductive Biology, and Anesthetics, Department of Biosurgery and Surgical Technology, United Kingdom, said that researchers need to engage the stakeholders in safety technology, such as the medical devices industry and pharmaceutical industry. We need to use safety technologies to make it easier to do things right than it has been in the past.

Sir Liam asked Sir Ara to talk about simulation techniques. He said that they must not forget about the development side of research and development. If evidence shows that simulation improves safety, they should encourage the development of technology, so every high-risk procedure can be simulated.

Sir Ara agreed. He described two roles of simulation: to show the user the advantages of a change in practice and to practice advanced procedures. It is important to engage the end users (nurses, surgeons, etc.) in training simulations, so they understand the benefits of using simulations.

Dr. Flin discussed lessons learned in the petroleum industry after the Piper Alpha accident, in which a platform was lost and 167 men were killed. The industry realized they needed better diagnostic tools to find safety problems before accidents happened. They also shifted their attention to the nontechnical behaviors of the workforce. Similarly, in patient safety, research must also examine non-clinical behaviors—failure of teamwork, weak leadership, poor decisionmaking, poor risk assessment, etc.—that contribute to medical errors.

Dr. Wilson said, given that research capacity and resources are limited, researchers should decide on a topic and let that determine their measurement methods. Without understanding the sources of harm at a population-level, researchers risk working on the wrong problems.

Sally Davies, M.B., Director of Research and Development, Department of Health, United Kingdom, noted that in the United Kingdom, there are good hospitals (with good research bids,

stars awarded by the health care commission, and happy patients) and bad hospitals (with bad research bids, stars removed by health care commission, and unhappy patients). Dr. Davies hypothesized that good hospitals have fewer medical errors than bad hospitals. If this were the case in other industries—that safety was better in successful organizations than in failing organizations—instead of investigating a variety of problems, you would examine the organizational problems. Dr. Davies asked what should be done with a failing organization.

Dr. Lilford said there is a tendency to seek generic problems, but the problems are not always generic. He described a study that showed there was no correlation between death rates and safety attitudes in intensive care units in the United Kingdom.

Naruo Uehara, M.D., D.Ph., Professor, Division of International Health, Graduate School of Medicine, Japan, noted that two initiatives in Japan are changing the health care system to improve safety and safety training for health care practitioners. Japan's health care system has learned from studying safety in other disciplines and industries—especially the error reduction process many other industries undertook about 20 years ago. The health care system has worked with industrial quality management experts, safety engineers, and psychologists. There are plans to involve professionals from other disciplines—sociology, political science, journalism, etc.—in health care safety and quality efforts in the near future, through the formation of a Japanese academic society of quality and safety.

Dr. Madiba spoke about the need for capacity building. For the Alliance to be successful, there has to be buy-in from physicians in all the countries. Capacity building will need to come from outside and from within health care institutions in developing countries. The Alliance must formulate strategies of capacity building and reach out on research on patient safety, as it has done for patient safety, to institutions in developing countries that may not even know about patient safety research.

Dr. Pittet said he organized a meeting about infection control in Europe 2 years ago, at which politicians, infection control practitioners, and public health doctors discussed similar issues in patient safety research. The attendees agreed that interventions were the top priority. Dr. Pittet also commented on the idea of creating a simple index to measure safety. The risk of an adverse event is made of both endogenous and exogenous factors. The endogenous factor is that sicker patients have a higher risk of complications. Little can be done to change the endogenous factor, but researchers can work on the exogenous factors by changing systems and behaviors. If a measurement tool or index does not take both endogenous and exogenous factors into account, it will not work.

Dr. Torres noted that safety is a large dimension of quality, but health services should not be forgotten. Research needs to be conducted on both health systems policies and health services policies. It also is important for researchers to consider how research can influence policymakers—to do so, research needs to remain flexible and change with changing priorities.

Dr. Reason said the field of patient safety can learn from safety systems in other hazardous domains. In many other fields, however, safety systems can eliminate negative events, so researchers eventually can take a more proactive approach to safety—anticipating future

problems rather than just solving existing problems. In health care, new problems always arise. This makes it difficult for researchers to divert resources from solving current problems and devote resources to anticipating future problems.

Dr. Flin suggested there needs to be greater focus on training the generation of health care workers in school now, who will be entering the health care field soon. Schools need to teach the basics of patient safety earlier. She also echoed earlier comments about the value of inviting professionals from a variety of disciplines to contribute to patient safety research.

Sir Liam summarized the methodology discussion and identified eight key issues. Five key issues the group had discussed were as follows:

1. Metrics and outcomes
2. Methodologies used to evaluate interventions and solutions and the role of traditional clinical methodologies, such as randomized control trials
3. Methodologies drawn from other disciplines or industries
4. Methodologies for achieving change—traditional methodologies (guidelines, toolkits, etc.) and new methodologies (simulations)
5. The need for methodologies that are of a more proactive nature—looking at hazards in a system, rather than waiting for things go wrong

Sir Liam added three key issues that were not discussed, but should be noted:

6. Consumer involvement in developing methodologies
7. The need for economic analysis of patient safety, to influence policymakers
8. The need to develop methodologies for the investigation of adverse events

Sir Liam asked for additions to this list.

- Martin Hatlie, J.D., President, Partnership for Patient Safety, United States, added the issue of resources. He noted that “lack of resources” is often used as an excuse for lack of progress. He proposed that if the public recognized patient safety as an emergency, they would help patient safety researchers find additional resources.
- Luis Cuervo, M.D., Unit Chief for Research Promotion and Development, Pan American Health Organization, called attention to the reverse incentives that work against patient safety. He said that more information was needed about the barriers to identifying and treating patient safety problems.
- Michael Cohen, R.Ph., M.S., Sc.D., President, Institute for Safe Medication Practices, United States, remarked that the design and procurement of equipment was an aspect of patient safety they had not addressed. The device and pharmaceutical industries need to take part in the discussions about patient safety.
- Dr. Ouwehand suggested that the enormous power of information technology to prevent errors should be considered.
- Dr. Wilson said more work is needed to build on the economic arguments for improving patient safety.

- Dr. Lilford indicated it is important to recognize the different problems low-income countries face.
- Dr. Panisset suggested that more research should be conducted on human resources in the health care field, especially team dynamics and team training.

Facilitated Discussion: Infrastructure and Networks

Sir Liam Donaldson, Moderator

Sir Liam proposed two strands of discussion:

1. Infrastructure: What is the state of the infrastructure—researchers, resources, facilities, and research departments—in the field of patient safety?
2. Networks: How can people come together to create an international movement that is more than the sum of its parts?

Infrastructure

Dr. Lilford agreed with Dr. Madiba that they need to develop capacity for patient safety research in developing countries.

Sir Ara noted that universities, institutes, and governments offer few incentives for research in patient safety. The United Kingdom possesses some capacity for research, but not enough to fund both research and development in patient safety.

Sir Liam asked if anyone knew of professorial appointments in patient safety around the world.

Dr. Clancy responded that in the United States a few institutions have created patient safety centers. The intersection of patient safety and technology is the area most likely to attract resources for research. For example, in the United States, there is strong interest in simulation. Dr. Clancy noted that AHRQ is the world's leading funder in patient safety research—and their annual budget is not even equal to the annual interest of the NIH budget. She asked to what extent patient safety research could be built into other clinical research programs.

Dr. Davies noted that the World Alliance for Patient Safety meeting did not draw the elite funders to the meeting—funders who can supply the resources that lead to tenure, promotion, and all the other drivers of high-quality researchers. Patient safety is a limited field of aficionados. In addition to the “aficionados,” the field needs to draw in experts from other fields, but there is not enough funding to do so. She said the patient safety field in the developed world has a capacity issue at every level, mirroring the capacity issues in the developing world. To make progress, the Alliance will need to make economic arguments, as well as arguments for equity and quality, to advocate for greater resources.

Dr. Runciman said there is a great deal of interest in patient safety research, although there is little funding. The Australian National Health and Medical Research Council recently made money available for grants for health services research; 77 applications were submitted, although only 3 could be funded.

Dr. Leape added that although funding is scarce, funding for patient safety research has increased in the last few years. The U.S. government appropriated \$50 million for patient safety research 5 years ago. As a result, the field now has a cadre of young investigators who form the nucleus of the development of the patient safety discipline. Patient safety is recognized as a legitimate intellectual pursuit, so scholars and researchers can be published and receive promotions on the basis of their work. Dr. Leape also noted private foundations are beginning to contribute funding for patient safety research.

Dr. Bates said the extraordinary number of research proposals in the field demonstrates that there is a great deal of interest, although there is little funding.

Khalid Alaiban, Ph.D., C.H.Q., P.D., Deputy Minister for Planning and Development, Ministry of Health, Saudi Arabia, commented that an obstacle to research in Saudi Arabia is a lack of information about reporting systems and the health system. Funding for research is not a great concern because even when research is conducted, there is no way to apply the findings. He said his country has excellent researchers, but because the health care system is government-based there is little support for research. The World Bank is working with Saudi Arabia to privatize the health system in the next 3 years.

Dr. Wilson said that it took 2 years of preparation to fund the merit study on first responder teams in Australia. The National Health and Medical Research Council was unable to fully fund the study. The Australian Council for Safety and Quality, not an organization that traditionally funds research, contributed to the study as a secondary funder to keep the project alive. Because patient safety and patient safety researchers do not have sufficient standing, going through traditional competitive means of funding will be a struggle.

Dr. Pittet related a similar experience in seeking funding for infection prevention research from the Swiss equivalent of NIH. Because the issue of preventing infection was a patient safety issue, the institute said that the hospital should pay for half of the research costs. This has never happened in any other field of research.

Mr. Conway noted that in his organization, the Dana-Farber Cancer Institute, the CEO did not believe health care quality had academic legitimacy. Mr. Conway said the large academic centers are going to have to develop that legitimacy. He added that in the United States, family foundations have shown interest in driving the improvement of patient safety. Insurers have also been funding small research grants because it is in their best interest to improve practice and reduce risk.

Kevin McCarthy, Head of Sector, Public Health Research, and Directorate-General for Research, Health Research Directorate, European Commission, Belgium, agreed with Dr. Davies' remarks. Proposals for delivering health care to European citizens are on the table before the 25-member states in the European parliament. He said that for the first time, patient safety and the traditional research in the medical area are categorized as "health research." Previously, patient safety research was called "biomedical," "life sciences," or "biotech for health" research. It is also the first time that health research has been a top priority.

Mr. Hatlie commented that the participants had not discussed *Patients for Patients Safety*, a part of the WHO Alliance that Ms. Sheridan chairs. He suggested that rather than focus exclusively on what patient safety research can do for patients, they should also consider how patients and consumers can assist with research. For example, consumers and patients can help attract funding. *Patients for Patient Safety* has already performed a worldwide search for stories that put a human face on medical error; these could be used to assist with some of the fundraising challenges.

Dr. Angood suggested looking beyond traditional sources of funding, such as government-supported research agencies, and exploring industry-based funding. Arguments for the return-on-investment in patient safety could encourage industry support. He asked how health services research focused on safety could seek funding from sources that support social science research.

Mr. Conway suggested the patient safety movement should develop a greater understanding of how to lead change in complex organizations. A culture for safety is defined by words such as “healing,” “trust,” “forgiveness,” and “respect.” These core values must permeate every facet of an organization—not just its patient safety efforts.

Dr. Abu Bakar Suleiman, President, Chancellery, International Medical University, Malaysia, said patient safety issues may be overwhelming for many developing countries. Malaysia is fortunate because national initiatives for health care quality assurance began 20 years ago. He asked what the priorities for developing countries should be, given that a lot needs to be accomplished with limited resources of funding and expertise. He noted that when he chaired the committee to allocate funds for health care research, it was very difficult to get approval for health services research, including patient safety projects, because greater emphasis was placed on biomedical research. He suggested more patient safety research in developing countries should focus on health care settings outside the hospital. Patient safety research and initiatives should involve allied health professionals, focusing on shared care and teamwork.

Networks

Dr. Cuervo commented that some Latin American countries have allocated money for research, but there are not enough research proposals. He discussed several initiatives that would support a more comprehensive approach to patient safety. One is to create a “database of ignorance” to begin framing the questions that need to be addressed. Funding agencies, consumers, researchers, and publishers should be involved in this process, so the research will have a greater opportunity to have an impact on public policy. He also suggested working with journals and publishers. The *British Medical Journal* and the Cochrane Collaboration began an initiative to improve access to information on harms, so people would have full information about both the benefits and harms of medical practices. The Alliance should invite other initiatives that have been successful, like the Cochran Collaboration, to be involved in global patient safety efforts.

Sir Liam said the ideal would be to have people working in different institutions who feel they are part of a global research movement. He asked Dr. Ouwehand to expand on his experience with building such networks.

Dr. Ouwehand responded that the Bloodomics network was based on the model of the genome project—a model of international cooperation based on the principle of open data sources. This model was partially a reaction to prevent the commercial sector from taking total control of the genome sequence. He said global networks require trust and open data flows from the earliest moment and a strong management structure.

Dr. Baker said in Canada, researchers must work together over long distances. For 10 years, the National Centers for Excellence have successfully assembled groups of researchers in all areas of science and medicine. One office at one university links researchers who share interests across the country.

Dr. Runciman argued for the creation of task-specific networks, instead of generic networks. He said it was important to seek volunteers for such networks, so experts interested in specific fields will bring come forward. With limited funding for planning and organizing, the parts of the project can proceed with local funding and local expertise if the components are coordinated. Endorsement from the WHO would give task-specific networks the currency to attract funding and resources.

Mr. McCarthy said Bloodomics is a product of European funding, bringing together the best of Europe in one project. Not all networks are as successful. Success depends on strong leadership and the ability of the coordinator and staff of the project to bring different stakeholders together. He added that the structure has also been extended to developing countries, with a criterion of equal partnerships between Europe and developing regions.

Dr. Panisset said in Latin America, virtual health libraries (VHLs) have been developed, which provide a platform that networks can work from. There are country-specific VHLs and thematic VHLs that enable researchers to share lessons in health, health legislation, and health research. VHLs are inexpensive and provide information and spaces for interaction and discussion. This format can promote networks.

Dr. Ouwehand agreed with earlier comments that networks need to focus on a specific topic in order to be successful.

Sir Liam summarized the topics discussed, related to networks:

1. Patient safety research should be a field in its own right.
2. The academic legitimacy of this sort of research (health services research) needs to be examined and bolstered.
3. The research infrastructure needs of developing countries should be considered.
4. Research collaborations can be created and encouraged to take on broad themes of patient safety.
5. It is important to think about the governance and management arrangements of a network before developing a network.
6. Funding, fund raising, and how to spend funds are vital issues. Funding professorial appointments and academic centers dealing with patient safety sow seeds for the long

term. Recognizable individuals leading such centers can speak publicly about the issues in patient safety. Funding fellowships and training programs can bring young researchers into the field. Families of patients who have suffered medical errors can be a source of funding. Litigation settlements might include donations for safety research, centers, or professorial appointments.

Facilitated Discussion: Reports on Other World Alliance for Patient Safety Initiatives

Sir Liam asked for reports on the other WHO World Alliance for Patient Safety initiatives. The Alliance recently launched the global patient safety challenge: to choose one topic every 2 years that would be relevant to the whole world in the field of patient safety. They chose the problem of health care infection. The program on clean care and safe care led by Dr. Pittet was launched in Geneva.

Dr. Pittet reported that they have promoted hand hygiene to address the problem of infection in hospitals. One hundred fifty international experts have contributed to writing new guidelines. They also are developing tools to help health care organizations improve hand hygiene. Part of the implementation strategy is to have pilot testing of the guidelines in the six WHO districts.

Dr. Torres asked Dr. Pittet how they measure the impact or result with the patient or the organization. Dr. Pittet responded that because hundreds of millions of patients worldwide get infections, the cost of surveillance for all infections before and after implementing the new guidelines is too high. They are using pilot studies and quality indicators in the field of infection management and hand hygiene to measure outcomes.

Ms. Sheridan reported on the Patients for Patient Safety group, mentioned earlier. She said the group is built on the premise that patients can contribute in a powerful, positive way to patient safety research. In a month, they will meet with 24 patient safety champions, who have experienced medical error and have chosen to partner with their countries, physicians, and institutions to create safer health care systems. These patient safety champions were chosen from 150 applications from around the world. They were selected for their positive outlook and dedication to using errors as opportunities for change.

Martin Fletcher, Performance Manager, WHO World Alliance for Patient Safety, Australia, reported on the first meeting on taxonomy and nomenclature for patient safety, which was held in Vancouver a week earlier. A small group of experts in patient safety, information management, and classification systems gathered to discuss developing an internationally agreed-upon approach. This is the area of the Alliance's work that has received the most unsolicited stakeholder interest, and they are making an effort to include stakeholders in the process. Different taxonomies are currently being used, and the challenge is to take these diverse approaches to consolidate and build on them to classify information that is useful for patient safety. The group agreed on a program of work for the next 18 months. One goal is to nest this work within the WHO family of classification; the long-term sustainability of the taxonomy system will depend on its relationship to the broader world of classification.

Mr. Conway asked if the key players indicated that when the new taxonomy is issued, it will lead to a consensus approach that will be embraced. Mr. Fletcher answered that they have not begun outreach yet. The end users for the taxonomy will include three groups: (1) researchers who want to compare data across countries; (2) countries that are establishing reporting systems; and (3) countries that have established reporting systems, to which the new taxonomy can be adapted.

Dr. Clancy asked if a report was available from the recent meeting. Mr. Fletcher answered that a report is still being written.

Dr. Studdert applauded the work of the Alliance in this area. The prospect of a benchmark and a basis for comparison in this area is exciting and a great initiative.

Dr. Leape reported on the development of guidelines for reporting and learning systems. One of the first things countries do when they become concerned with patient safety is develop a reporting system. He added there is a need for guidance in this area. Dr. Leape's group is surveying reporting systems worldwide to provide a compendium of the existing reporting systems and list important comparative characteristics, as a reference for countries developing new reporting systems. Dr. Leape listed four core principles of effective reporting systems:

1. They should be learning systems, not just accountability systems.
2. They must be safe, so there is no risk to the reporter for reporting.
3. They must provide a constructive response to the reporter.
4. They must incorporate expert analysis, to provide a constructive response.

Dr. Angood reported on JCAHO's work as a collaborating center to lead the Alliance's work on implementing solutions. JCAHO formed the Center for Patient Safety recently to bring together all of its work on patient safety. Dr. Angood said working with the WHO is a wonderful opportunity. They have developed a reasonably aggressive agenda for the development of solutions, and they will be collaborating with many different organizations and individuals and will be convening a variety of advisory groups. Their focus has been on health care organizations, but they also will focus on increasing the participation of patients and their families in their own care. They also will work on helping practitioners better understand issues related to patient safety in their practice environments. Dr. Angood added that JCAHO is examining two examples of solutions—the U.K. National Patient Safety Agency's nasogastric tube protocol and JCAHO's protocol for wrong site surgery—to examine how these solutions can be applied in a wide variety of environments. They will be examining a variety of solutions in the future.

Dr. Wilson reported on planning for prevalence studies of medical errors in developing countries. He said they were trying to achieve a measurement of 10 or 12 countries over the next 18 to 20 months. Two countries were nominated from each WHO region, and representatives from each country met in Amsterdam a year ago. A workshop in Cairo is scheduled for December of this year.

Facilitated Discussion: Final Thoughts

Sir Liam Donaldson, Moderator

Sir Liam introduced two final topics of discussion:

1. The management/team issues raised earlier in the day
2. Any additional issues that have not been addressed

Juan Fernandez, Pan American Health Organization, United States, discussed an initiative in WHO Europe to develop a tool to evaluate institutional cultures. He asked if the tool will be available for the rest of the regions of the WHO.

Sir Liam said that Diane Parker developed a diagnostic tool to assess the error-resistance and safety of organizations, which is a safety-oriented organization. On behalf of the Alliance, she has been doing a series of in-depth qualitative interviews with patient safety leaders in different countries as a basis for developing and evolving this tool. It should be available in the next few months for discussion.

Dr. Lilford said more research is needed to determine whether those tools correlate with safety for the patient. Martin Marshall and colleagues have conducted a systematic review of the correlation between safety, as measured by some type of error rate, and these tools. They found no confirmation that these tools do correlate with safety. However, the evidence is not strong enough to say these tools do not correlate with safety.

Dr. Angood commented that a critical area is the oversight boards and corporate board members. In the United States, it is sometimes difficult to learn the identities of board members. Educational materials about patient safety should be developed for board members. The knowledge then would trickle down all the way through organizations.

Dr. Leape said they have had success involving doctors in team training. Liability insurance providers may give discounts to doctors who receive team training, which could serve as a strong incentive.

Dr. Runciman disagreed with Dr. Lilford and argued that standard operating procedures have intrinsic merit, particularly when teams are operating in situations with time constraint. Additional studies are not necessary to show that tools to standardize operations are valuable.

Dr. Azevedo suggested investing in creating medical courses, in addition to changing the attitudes of practicing professionals. In Brazil, one of 74 medical schools in the country is working on a model of evidence-based medical education.

Mr. Conway said his organization had helped develop a self-assessment tool for leaders to evaluate their role in patient safety. The question they most frequently receive is, "What does effective leadership engagement with patient safety look like?" He predicted that helping people answer this question will drive change. Within the 100,000 Lives Campaign, they have the most success when boards of trustees and senior leadership are actively engaged in driving interventions and change.

Sir Liam offered two reflections: (1) in the airline industry, teams are able to work together efficiently, when the individuals have never worked together before; (2) in the United States, tragedies galvanized every member of the staff to participate in change. In all cases, the tragedy had not just galvanized change a management level, but every member of staff; however, organizations in the United Kingdom did not respond to error in the same way. More research could be conducted on these issues of organizational culture.

Ms. Sheridan suggested WHO undertake research to understand how consumer participation can affect patient safety. There is no evidence to show that consumer involvement will keep us safer. She asked if there is a way that the WHO and AHRQ can inform the public so the public can participate?

Dr. Bates said better information is needed to prioritize among potential interventions.

Dr. Clancy suggested that more work could be done on the psychology of measurement. Fundamentally, how do workers respond to measurement—as a useful tool or just something to be endured?

Prof. Uehara said the Alliance can do many things to support local change through global efforts. Global standards are needed for safety in the device and pharmaceutical industries, where companies are reluctant to change. For example, there is no global color code for packaging; companies use their own, which leads to problems in the workplace. A clearinghouse of patient safety data would help collect information that could be used to convince policymakers and organizations to make safety a priority. Safety issues and materials should not be private property—they should be a public good. WHO can develop safety materials that can be shared.

Sir Liam suggested WHO take a more provocative stand in pressuring companies and industries to change.

Mr. Hatlie said more research is needed on the topic of adult education—research into the impact of training or the lack of it.

Dr. Angood suggested post marketing surveillance on the success of research within the public and within the patient/family populations.

Dr. Torres said communication is important, particularly communication about beneficial projects to the media.

Dr. Wilson noted a need for a communication mechanism to continue these conversations and communication among researchers, especially about solutions that work and those that do not.

Dr. Baker said international collaboration is needed to identify areas in which research is currently under way and find issues that are not being addressed. The Alliance also could identify worldwide opportunities for scholarships and programs in patient safety.