Chapter 14
Going Global: The World Health Organization

Where was the World Health Organization on patient safety? Patient safety was taking off in the USA and the UK, and there were stirrings in Canada, Australia, Denmark, Spain, and a few other European countries, but what about the rest of the world? What about developing countries? With fewer resources, their needs for attention to medical harm might well be even greater.

Enter Liam Donaldson. After establishing the National Patient Safety Agency in the UK, Liam turned his attention and considerable skills to the rest of the world, to the WHO.

He was well-positioned for the task. As Chief Medical Officer of the NHS, he represented the UK to the WHO and was on the executive body. He persuaded them to put patient safety on the agenda for the 2002 World Health Assembly. He made his proposal compelling by pledging annual support of $25 million from the UK.

By good fortune, the Presidency of the European Union around that time was on rotation to the UK. Liam also persuaded the UK government to make patient safety a priority for its Presidency. This meant that the European Commission established and funded a program of work that stretched forward into the future.

It worked. The World Health Assembly passed resolution WHA55.18, which urged countries to pay attention to patient safety and directed the Director-General of the WHO to carry out a series of actions to promote patient safety: development of global norms and

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standards, promotion of evidenced-based policies, and encouragement of research in patient safety [1]. The resolution made the drive for safer health care a worldwide endeavor.

In November 2003, at Liam's urging, the WHO collaborated with the UK to convene a meeting of senior policy makers and international experts from all WHO regions to discuss future international collaboration on patient safety. At the meeting Donaldson proposed the establishment of the World Alliance for Patient Safety.

The World Alliance for Patient Safety

A year later, the World Alliance for Patient Safety was formally inaugurated on October 27, 2004, by the Director-General of the WHO, Dr. Lee Jong-Wook, in Washington, DC, at an event hosted by the Pan American Health Organization. The event was remarkable in that it was the first time that heads of agencies, health policy makers, representatives of patients' groups from multiple nations, and the WHO came together to address the problem of unsafe health care. Donaldson and Carolyn Clancy, Director of the US Agency for Health Research and Quality, gave keynote addresses.

The World Alliance was Liam Donaldson's baby. He envisioned it, he funded it, and he led it for the first 5 years.

The Alliance goals were ambitious: to develop standards for patient safety and assist UN Member States in improving the safety of health care by "raising awareness and political commitment to improve safety and facilitate the development of patient safety policy and practice in all WHO Member States" [2]. The program focused on six areas of action:

1. Global patient safety challenge
2. Patient and consumer involvement
3. Developing a patient safety taxonomy
4. Research in patient safety
5. Solutions that improve safety
6. Reporting and learning to improve patient safety

Before the year was out, the Alliance moved ahead on two initiatives that I was privileged to be involved in: reporting and learning

and the global patient safety challenge. These initiatives illustrate the scope and power of the WHO to influence change.

Guidelines for Adverse Event Reporting and Learning Systems

In the USA, the most common reaction to the IOM report was to call for more reporting of errors and adverse events. The same was true internationally. By the time the Alliance was formed 4 years later, 38 countries had indicated to the WHO their interest in developing reporting systems. Indeed, there seemed to be a fixation on reporting as the solution to the patient safety problem. But no country had a system they were satisfied with.

Accordingly, it was reasonable that reporting was one of the six areas of action called for in the Alliance prospectus: "The Alliance will develop best-practice guidelines that can be used to facilitate the development of new reporting systems to improve patient safety and to improve existing reporting systems." The statement that followed of core principles to underlie the guideline development quoted almost verbatim from the paper on reporting systems that I wrote in 2002 for the New England Journal of Medicine [3] as part of our series of patient safety topics. (See Chap. 17.)

So I was not totally surprised when Pauline Phillip called from the WHO and asked me to write the reporting guideline. I was not eager to take on another project at that time and had some reservations about working with the WHO because of its reputation for being excessively bureaucratic, but I was very excited about what Liam was doing with the World Alliance and anxious to help it succeed.

It was also another opportunity to bring some balance and reality to the thinking about reporting. So many people thought reporting was the solution to medical errors: "Just make them report their mistakes and they will be more careful," the thinking went. Not only was it not true—there was no evidence that reporting made people more careful—it also was not the solution to the safety problem. The problem was bad systems, not careless people.

Beyond the conceptual fallacy, the logistics of establishing and managing a reporting system were formidable. The costs were

daunting for rich countries and far beyond consideration for developing or middle-income countries. We could provide a reality check.

I agreed to write the guideline on the condition that I share the project with a co-author, who would be paid. I had someone in mind: Susan Abookire, a former student of mine and physician who was currently working in safety at Brigham and Women's Hospital. Indeed, when I approached her, Susan was interested and willingly took on the huge task of digging out the historical information on what already was being done worldwide. We wrote the monograph and shepherded it through the labyrinth of WHO approval. We succeeded despite the resistance of an internal reviewer who considered herself much better qualified to write it and at one point suggested it all be redone!

The document was comprehensive. It described and compared the many types of systems in use worldwide. We spelled out in detail the key components of a reporting system and described the requirements for making it work. Controversial issues such as accountability, public disclosure, and confidentiality were addressed [4].

We reiterated the earlier admonition that the fundamental role of a reporting system is to enhance safety by learning from failures. Reporting must be safe—individuals who report must not be punished or suffer other consequences. Reporting is of little value unless it leads to a constructive response. At a minimum, this requires data analysis to identify hazards. But for significant impact, to justify the effort and expense, the system must include root cause analysis of incidents to uncover the contributing factors and lead to recommendations for systems changes.

We described alternatives to reporting for gaining useful information to improve patient safety, such as WalkRounds, focus groups, focused review on specific problems, failure modes and effects analysis, and analysis of malpractice claims data. Existing data sources, such as that generated by the voluntary National Nosocomial Infections Surveillance System and the US National Surgical Quality Improvement Program, can be used to identify hazards. We described the characteristics of successful systems and provided a checklist for developing a reporting system

The monograph was published the following year, as "draft" guidelines [4]. I never got an explanation of why they weren't given the full WHO endorsement, which suggests it was political. The realistic tone

of the document—you need experts, it is expensive, and it isn't worth doing if you are unable to respond to the reports with analysis and system changes—undoubtedly was not what many wanted to hear, both within the WHO and among Member States!

The requirements we laid out for establishing a reporting system were indeed formidable; it was unlikely that many governments would be willing to provide the funds to do it right. At this time in the USA, we had no national system, none of the state mandatory systems were effective, and all of them were underfunded.

A few years later, Pennsylvania implemented a comprehensive reporting and analysis system, wisely funded by a tax on hospitals. It has yielded valuable information and stimulated change. Other states have improved their systems with variable results. Britain, on the other hand, had already made a substantial investment in a national reporting system when they established the National Patient Safety Agency.

The majority of members of the WHO are low- and middle-income countries. If they took the Guidelines seriously, they would quickly recognize that there were better ways to deploy their limited resources. That, of course, was the lesson that was implied: there are more effective ways to improve patient safety for far less. Perhaps not exactly what the WHO had in mind when it conceived the project. Nonetheless, the "draft" guidelines are still the WHO publication on reporting 15 years later.

Patient and Consumer Involvement—Patients for Patient Safety (P4PS)

Liam Donaldson's passion for patient safety was rooted in his deep concern for the victims—the injured patients. He was moved by his personal experience as a physician, as well as the writings of Charles Vincent, one of the first to call attention to the psychological impact of unanticipated harm on the patient [5]. On the various occasions when I had the opportunity to hear Donaldson speak, I was impressed that he started every talk on patient safety with a story of a patient. That was the point, that was why we were here.

The Alliance's second major early initiative, **Patients for Patient Safety**, was his mechanism for involving patients in the solution. Launched in 2004, it was based on the recognition that the patient and family have unique information because they are the only ones present through the entire continuum of care, which may have involved care from multiple providers at different institutions. Those who have experienced harm have special insights concerning systems failures. It would seem obvious that they should play a central role in efforts to improve the quality and safety of health care around the world. Patients for Patient Safety (P4PS) would tap that resource.

Founding leaders included Margaret Murphy from Ireland, who also advised the UK National Institute for Healthcare Research, Stephanie Newall from Australia, and Sue Sheridan and Helen Haskell from the USA. All of them had lost children or a spouse as the result of medical errors, and all were, and still are, active and effective leaders in changing policy in their local and national environments. They were motivated to give meaning to their tragedies by sharing their experiences and advocating for change.

The WHO convened the first Patients for Patient Safety workshop in London in 2005. Participants developed the "London Declaration" that enunciated the common vision and commitment for positive engagement of patients in their care. It called for honesty, openness, and transparency, making reduction of health-care errors a basic human right, and for promoting programs for patient safety and patient empowerment by dialogue with all partners (Appendix 14.1).

At this meeting, P4PS created a global network of patients, consumers, caregivers, and consumer organizations to support patient involvement in patient safety programs, both within countries and in the global programs of the World Alliance for Patient Safety [6].

The Patients for Patient Safety network has continued to grow. By 2012 it had 250 members in 52 countries. They are champions for patient engagement and empowerment on hospital boards, medical school councils, governmental policy groups, and professional conferences around the world. The patient's voice is being heard.

Support of Patient Safety Research

At the outset the Alliance wanted to create a proper evidence base for patient safety, an entirely new field of health services research. David Bates of Harvard University was charged with setting out research priorities in the WHO's three bands of countries: high-, middle-, and low-income [7].

The Alliance's first major research initiative was an ambitious project to estimate the extent of medical harm in developing countries. The WHO recognized that to convince people in the developing world that medical errors were a serious problem, they would need to show them the extent of the problem in their own countries. Data from advanced western countries would not do it.

Many of us thought this would be an exercise in futility. The most serious limitation in the MPS—the factor that raised the most questions about its validity—was that much of the data came from poor medical records, those with few progress notes. In the USA, this was especially a problem in small rural hospitals. The records in hospitals in developing countries would surely be worse.

And the logistics! Imagine getting cooperation from such a diverse group. Well, the WHO was undaunted, and Ross Wilson of Australia agreed to take it on and attempt to recreate the MPS in these unpromising environments.

The objectives of the study were to assess the frequency and nature of adverse events in patients in developing or transitional economies and to determine whether the established method for review of records would work in resource poor health-care systems in which medical records might be less comprehensive.

Ten Ministries of Health initially volunteered, but two later withdrew in the face of objections from hospital leaders who feared damage to their reputations. The eight countries that participated were Egypt, Jordan, Kenya, Morocco, Tunisia, Sudan, South Africa, and Yemen. The WHO appropriated $30,000 for each country to conduct

the study, a retrospective review of randomly selected medical records from hospital admissions during 2005 in a convenience sample of 26 hospitals. These Middle Eastern and African countries had a combined population of nearly 265 million, about a third of whom lived below the poverty line. The average health expenditure was $133 per person.

The research team used the Medical Practice Study approach in which records are screened using 18 explicit criteria, followed by review of those records that screened positive by a senior physician who would determine if there were an adverse event and evaluate its preventability and resulting disability.

Of the 15,548 records reviewed, 8.2% showed at least 1 adverse event (range 2.5—18.4% by country), of which 83% were judged to be preventable and 30% were associated with death of the patient. About 34% of these adverse events were from therapeutic errors in relatively non-complex clinical situation [8].

Disturbing as these results were, they were undoubtedly underestimates because of poor record keeping in the hospitals. Nursing notes, pathology reports, and procedure notes were not available in some countries. Many hospitals started a new record each time a patient presented, so earlier clinical information was not available, limiting the rate of positives in the primary review.

Further, because the results came from a "convenience sample," i.e., hospitals that volunteered to participate, not ones that were randomly chosen, the data cannot be used to estimate national rates for the studied countries. In addition, research teams noted that some of the hospitals that volunteered were those that were generally regarded as providing some of the best care in that country. Thus, the overall national injury rates were undoubtedly higher.

Like their American predecessors years before in the Medical Practice Study, reviewers had difficulty recognizing systems problems such as lack of availability of information or equipment, bad protocols, poor hand hygiene, etc. Most events were attributed to inadequate training and supervision of clinical staff or to the failure to follow policies or protocols.

Nonetheless, some important conclusions could be drawn. The authors concluded that the problem of unnecessary harm "will not be solved only by providing more staff and equipment, even if that were

immediately possible. Basic clinical processes of diagnosis and treatment need broad attention, aided by the provision of clinical policies and protocols standardized on best practice and supervised in their implementation." [8]

Despite its limitations, the study accomplished its objective of arousing awareness of the extent of medical harm. It undoubtedly made them more receptive to doing something about it. For that, the Alliance had a plan: a global patient safety challenge.

The Global Patient Safety Challenge

Liam Donaldson's purpose in setting up the World Alliance was to advance patient safety globally, to get all countries involved. The Global Patient Safety Challenge was the action area to make that happen. The idea was to identify a significant universal safety problem and then catalyze worldwide commitment by policy makers, healthcare workers, and patients to implement a safe practice that would address that problem and significantly reduce harm.

It was, to say the least, ambitious! There were only two criteria for selecting the practice, but they were formidable: it had to be a practice that would have a measurable impact on safety, and it must be possible to implement the practice worldwide—in all environments, from rural clinics in developing countries to sophisticated modern academic medical centers in Western cities.

The first Global Patient Safety Challenge fits the bill. It focused on preventing health-care-associated infections. It was led by Didier Pettit, an epidemiologist from the University of Geneva. The campaign was launched at WHO Headquarters in Geneva Switzerland in October 2005 and titled "Clean Care is Safer Care." Ministers of health from all WHO Member States were called on "to make a formal statement pledging to tackle health care-associated infection within their country." [9] To "catalyse and sustain strong and visible leadership and stewardship by government, health authorities and professionals, and minimize complacency" [10].

They were asked to do that by improving hand hygiene (washing or disinfecting your hands before touching a patient). Pettit had brought

together over 200 leading specialists in infection prevention and patient safety. They decided that improving hand hygiene could be a powerful and feasible intervention. They developed the safe practice, *Guidelines on Hand Hygiene in Health Care* [11], and a plan for worldwide adoption.

Expert task forces addressed critical implementation topics, such as strategies to promote greater patient involvement and global implementation of the disinfectant. They developed indications for glove use and reuse and addressed the religious, cultural, and behavioral aspects of hand hygiene [12].

Then the specialists took the crucial step that would make hand disinfection possible in low-resource environments: they found an inexpensive way to make a disinfectant for dipping hands which could be readily produced anywhere.

In 2007 and 2008, the Challenge team pilot tested the new hand hygiene guidelines at 6 pilot sites involving 43 hospitals in Costa Rica, Italy, Mali, Pakistan, and Saudi Arabia [13]. Compliance increased overall from 51.0% before the intervention to 67.2% after.

Significant improvement of hand-hygiene compliance was seen in all sites, across all professional categories, and for all indications for hand hygiene. It was greater in low-income and middle-income countries, which had lower compliance rates before the study. Improvement was sustained: 2 years after the intervention, all sites reported

Didier Pettit. (All rights reserved)

continuing or further improvement, including in some cases national scale-up.

Subsequently, over 50 countries ran successful hand hygiene national campaigns, and almost 20,000 health facilities in 177 countries eventually joined the campaign. The need for supporting infection prevention and control improvement was clear. *Clean Care is Safer Care* generated so much momentum and so great a sense of solidarity across the world that it led the WHO to institute a new, formalized infection prevention and control global unit. That unit is still active 10 years after the launch, renewing engagement of thousands of health workers around hand hygiene every year on May 5.

The Alliance Challenge also motivated health organizations in the West. The nationwide movement to improve hand hygiene in American hospitals has been the most successful patient safety initiative. Compliance rates now approach 100% in many hospitals.

The first Global Patient Safety Challenge represented a proven change model that mobilized the world around infection prevention through: (a) awareness-raising about the burden of the problem to engage stakeholders, (b) an approach to engage nations through demonstrable commitment, and (c) the availability of evidence-based guidance and implementation tools to drive improvement.

The second Global Patient Safety Challenge also had a big impact. It tackled surgical safety and resulted in the development of the surgical checklist. That is a more complicated story and is told in the next chapter.

Later Years

Despite the considerable success of these programs, by 2008 the World Alliance was merged into the WHO's mainstream management structure. While this strengthened its authority in relation to Member States and their health systems, the free-thinking and freewheeling style of the World Alliance was lost. This slowed its pace and meant that ideas and actions were subjected to scrutiny within the WHO's governance structure that sometimes had a stultifying effect. In addition, not unlike within the NHS in Britain, there were periods of reorganization within the WHO that created uncertainty in patient safety leadership.

Fortunately, Donaldson remained in his external advisory role as WHO Patient Safety Envoy and helped to build a powerful second phase to the global patient safety program. This included starting a third WHO Global Patient Safety Challenge, currently underway, *Medication Without Harm*, to address the widespread systems problems in medication processes everywhere [14].

Medication Without Harm asks all WHO Member States and professional bodies to commit to reducing severe avoidable medication-related harm by 50% globally within 5 years by taking action to manage medication safety in three areas: high-risk situations, polypharmacy, and transitions of care [15]. Hopefully, it will have an effect similar to its highly successful predecessors.

In 2019, the World Health Assembly adopted a fresh resolution on patient safety: WHA 72.6, *Global Action on Patient Safety*. This secured the future of patient safety as a global health priority for the next 10 years, ensuring that it would not succumb to further organizational change or the whim of new leadership [16].

Conclusion

The World Alliance for Patient Safety had a huge impact on reducing medical harm worldwide. It represented the WHO at its best: a catalyst for change that also provides practical expertise and financial support for those in need. The Global Patient Safety Challenges have saved millions of lives, not just in developing countries but also in Western countries with sophisticated health-care systems. They have stimulated other efforts such as practices to reduce maternal mortality in childbirth.

The Alliance and WHO's continuing programs in patient safety have also "changed the conversation" worldwide. Victims of health-care harm and their families now have a voice and are being heard. Preventing harm by changing systems is not just a theory, it saves lives. Even in situations with very limited resources, it is possible to make changes that make a difference. The patient safety experience provides insight into what the United Nations can do when nations pull together. An important lesson in these troubled times.

Appendix 14.1: The London Declaration

We, Patients for Patient Safety, envision a different world in which health-care errors are not harming people. We are partners in the effort to prevent all avoidable harm in health care. Risk and uncertainty are constant companions. So we come together in dialogue, participating in care with providers. We unite our strength as advocates for care without harm in the developing as well as the developed world.

We are committed to spread the word from person to person, town to town, country to country. There is a right to safe health care, and we will not let the current culture of error and denial continue. We call for honesty, openness, and transparency. We will make the reduction of health-care errors a basic human right that preserves life around the world.

We, Patients for Patient Safety, will be the voice for all people, but especially those who are now unheard. Together as partners, we will collaborate in:

- Devising and promoting programs for patient safety and patient empowerment
- Developing and driving a constructive dialogue with all partners concerned with patient safety
- Establishing systems for reporting and dealing with health-care harm on a worldwide basis
- Defining best practices in dealing with health-care harm of all kinds and promoting those practices throughout the world

In honor of those who have died, those left disabled, our loved ones today, and the world's children yet to be born, we will strive for excellence, so that all those involved in health care are as safe as possible as soon as possible. This is our pledge of partnership.

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