2nd Global Ministerial Summit on Patient Safety — A Global Movement on Patient Safety

29–30 March 2017, Bonn, Germany
Foreword by the German Federal Ministry of Health

Our shared goal is to provide citizens with the best possible healthcare. Patient wellbeing is the decisive standard for our health policy decisions. The best possible care always means that this care also has to be safe: that patients who turn to medical practices, hospitals and other healthcare institutions for help are provided with sound and non-damaging medical care and treatment by health professionals. They are entitled to that. That is why Germany like other countries places special emphasis on patient safety.

In order to put a greater international focus on this, jointly approach global risks to safe treatment, and learn from each other, the ministers of health for the UK and Germany took the initiative in 2016 and issued invitations to a meeting for ministers of health on the topic of patient safety. After London in 2016, the 2nd Global Ministerial Summit on Patient Safety was held in Bonn, Germany on 29-30 March 2017. The World Health Organization as co-sponsor made a special contribution to the discussions with its international expertise, its network of international experts and its commitment to the concerns of low- and middle-income countries (LMIC).

Out of the numerous approaches to improving patient safety, two results of the summit deserve special emphasis: all participants supported the proposal for a resolution of the World Health Assembly (WHA) to call for a “Global Action on Patient Safety” and declare September 17 as the World Day on Patient Safety. Also, in view of the extensive and growing challenges in improving patient safety, continuing the Global Ministerial Summits was agreed. Tokyo 2018 will become another example of successful international cooperation!

Even though national healthcare structures still differ considerably, our shared goal is to focus on patient safety. A definitive safety culture must be a formative characteristic of healthcare. This is a leadership task we are embracing.

The recommendations for politics from science and practice compiled in this final report constitute our mission and obligation.
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Patient Safety
Global Ministerial Summit 2017

2nd Global Ministerial Summit on Patient Safety
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Executive Summary

Political commitment and leadership for patient safety flourished as Ministers of Health and high level delegates from more than 40 countries (across different geographical regions and levels of economic development), representatives from the World Health Organization (WHO), European Union (EU), World Bank (WB) and the Organization for Economic Co-operation and Development (OECD), and international and national experts convened at the second Global Ministerial Summit on Patient Safety. Approximately 350 attendees participated in the Summit which was held in Bonn, Germany on 29-30 March 2017, and was hosted by the German Federal Ministry of Health, with co-sponsorship from WHO.

The former capital of Germany where the contracts for the reunification of Germany were signed in 1990, provided an ideal backdrop for uniting global health leaders in the drive behind the progressive global patient safety movement. This event followed the first Global Ministerial Summit on Patient Safety held in London in 2016, hosted by the UK government. Therewith, the UK and German governments jointly laid the foundation for a ‘Global Movement on Patient Safety’. Each year a different country will host the Ministerial Summit, with Japan being the host of the 3rd Ministerial Summit in 2018.

The first day of the Summit was organised as an ‘Expert Summit’ with six parallel workshops addressing key technical areas in patient safety, and then elaborating the outcome of these workshops, as three key political messages for the ministerial briefing. The topics of the workshops were:
- Economy and efficiency of patient safety;
- Global patient safety: perspectives from low- and middle-income countries (hosted by WHO);
- Patient safety and m-Health/big data/hand-held services;
- Prevention and control of infectious diseases and Sepsis;
- Increased safety of diagnostics and treatment – checklists and other tools;
- Medication safety.

The second day of the Summit was organised as the ‘Ministerial Summit’, which was opened by Hermann Gröhe, Minister of Health, Germany and Jeremy Hunt, Secretary of State for Health, UK, followed by Margaret Chan, Director-General, WHO, and keynote-speaker Victor Dzau, President US National Academy of Medicine. Ministers of Health and representatives of WB and OECD then expressed their thoughts and commitment to patient safety.

In addition, the Summit provided a great opportunity and an ideal springboard to launch the WHO Global Patient Safety Challenge on Medication Safety in the presence of Ministers of Health, policy-makers and experts, through implementing solutions for strengthening systems to reduce medication errors and medication-related harm. The overall goal of this Challenge is to reduce severe, avoidable medication-related harm by 50 percent in the next five years, worldwide. This launch event provided an overview of the Challenge and outlined intended actions at country, regional and global levels. The Challenge seeks to improve safety through actions aimed at addressing each of four areas – patients, medicines, healthcare professionals and systems and practices of medication.
WHO Director-General Margaret Chan was overwhelmed with support for a ‘World Patient Safety Day’ to be celebrated annually on 17 September. In the words of keynote-speaker Victor Dzau, President of the US National Academy of Medicine, “this journey of a thousand miles begins with a first step – an official WHO World Patient Safety Day”. It was the shared understanding of all delegations that efforts to bring more attention to the cause of patient safety must be combined in this initiative. Acting on this, the German Federal Minister of Health, in agreement with the UK Secretary of State for Health, stepped up and announced: “Together with our colleagues from the United Kingdom, we will draft a resolution for the 2018 World Health Assembly and will be counting on your support.”

Apart from the obvious clinical imperative, the financial imperative of patient safety was stressed greatly, seeking prioritisation, unwavering support and commitment from all delegates for global patient safety. WHO Director-General signalled to Victor Dzau during the discussion that the Patient Safety argument should be presented to the Finance Ministers at one of the next major financial meetings hosted by the World Bank. This gained great traction, following the OECD representative statement that “every $1 invested, you could see between $9-$20 in return in low- and middle-income countries”. Additionally, in the era of the Sustainable-Development Goals, the World Bank representative declared “this is one of the greatest challenges for Universal Health Coverage – if health services are unsafe, your people will have no trust in it, and they will not use the service”.

The Ministers of Health and high level delegates from more than 40 countries who attended the Summit, all displayed great compassion and commitment to this cause, sharing stories of tragic patient harm in their countries as they pledged to drive forward this agenda at the political level. The Italian Minister of Health shared tragic stories of neonatal deaths due to poor patient care in her country claiming “I felt deep grief for those families” as she pledged to continue the fight against patient harm. This global patient safety movement represents the best of both top-down, political commitment from leaders and bottom-up grassroots support from patient testimonies. The Omani Health Minister stated “we have the tools, we have the knowledge, and now we have the political commitment. What we need now is action, and that is why we are here”.
The moral imperative of patient safety was emphasized throughout the Summit, urging Ministers to give their utmost attention to patient safety in order to improve the quality of life for all of their citizens through strengthening their healthcare systems and processes. The UK Secretary of State for Health stated “Every patient matters, be it brother, sister, mother or child. But the truth is, we have a high level of harm, and not every patient matters. Which is why the leadership displayed by each of the Ministers here matters, to display that commitment politically, yet it is where most ministers fear to go by speaking these uncomfortable truths”.

In his concluding remarks, the host of the 2nd Global Ministerial Summit, German Federal Minster of Health, Hermann Gröhe perfectly captured the spirit of the two-day Summit: “The need for developing a patient safety culture is indisputable. And so is the importance of leadership. Adding up those two simple truths should make each of us stand up and act.”

Weblinks to 2nd Global Ministerial Summit on Patient Safety:

- https://www.bundesgesundheitsministerium.de/topics/health/patient-safety-summit-2017/?L=1 (English)
- https://www.bundesgesundheitsministerium.de/index.php?id=2832 (German)
Political Messages from
Participating States
Pamela Rendi-Wagner, Federal Minister of Health and Women’s Affairs, Austria

All partners of the Austrian Healthcare System are committed to the highest standards of quality of care. Patient safety is one of the most important aspects of our efforts to improve quality and we know that the establishment of patient safety on all levels of the healthcare system requires competent leadership. The Ministerial Summit on Patient Safety is one of several very beneficial international initiatives, and the expertise and the models of good practice presented there are a valuable source of inspiration.

Many countries have similar aims, e.g. to strengthen the health competence of the population by providing reliable information and by facilitating good communication. We think it is of utmost importance to create a healthcare system where patients, relatives and the health workforce are actively taking part in improving patient safety and where the individual is at the centre of care.

Among our current initiatives in Austria are the implementation of a nationwide electronic health record and of a surveillance system, where healthcare associated infections and antimicrobial resistance can be monitored. We also try to empower patients to take care of their own health and to find helpful, correct and easily understandable information for health concerns. For this purpose we provide the platform kliniksuche.at, where people can get information when preparing for a stay in an Austrian hospital. At the moment, the platform offers information for the fifteen most important clinical interventions and covers about 60 percent of operations in hospitals. In Austria, patient safety is being assessed and measured and reports are published on a regular basis.

Although our measures for patient safety already cover all relevant areas of healthcare, we are aware that there is still room for improvement. We are convinced that international cooperation is a key factor and we are confident that by learning from the experiences of other countries, our patients as well as the healthcare providers will benefit.

The world-wide celebration of a Patient Safety Day is an important opportunity for showing leadership and a strong commitment for patient safety and person-centred care. Austria is proud to have been a founding member of this initiative and we will of course continue to be an enthusiastic partner in the international activities for this day.

Miroslav Ludvík, Minister of Health, The Czech Republic

The Czech Republic considers patient safety as one of the most important issues. Therefore, the Ministry of Health is committed to continuously improve patient safety in accordance with Council Recommendation on patient safety, including the prevention and control of healthcare-associated infections (2009/C 151/01) and WHO patient safety recommendations.

Therefore, we welcome all initiatives agreed upon at the Second Global Ministerial Summit on Patient Safety 2017 in Bonn. We are very interested in further cooperation in order to keep on building more awareness and solutions for patient safety together, and share the best practice in the field of patient safety.
Dr. Verónica Espinosa, Minister of Public Health, Ecuador

Healthcare is the main product of a Health System, in which quality is an essential attribute. A high level of quality, among other attributes that healthcare must have, is not achieved by chance. It must be actively managed, paying attention to proper planning, conduction, execution, supervision, evaluation and constant, continuous improvement. The Ministry of Public Health of Ecuador, as the National Sanitary Authority, and as an institution that implements the policies of the National Government, promotes a process of profound institutional changes, which allows it to comply with the constitutional commitment to guarantee health with quality and warmth to the whole Population of the country.

That is why the Ministry exercises leadership, with the development of policies, norms, protocols or quality standards, which are mandatory for the entire National Health System, considering that there is a high degree of financing to ensure compliance with quality assurance processes, such as qualification, certification and accreditation that favour the sustainability of quality.

With the creation of the Agency for Quality Assurance of Health Services and Prepaid Medicine (ACESS), the institutionalisation for the permanent improvement of the quality of health services will be promoted. Also, it will focus on Patient Safety as a primary basis in the management model.

Despite the difficulties raised in clinical care and the change in organizational culture focused on the quality of care, implementing the User Patient Safety Manual has become a real milestone for health establishments in Ecuador.

Reducing maternal-neonatal mortality and childhood chronic malnutrition, in addition to reducing infections associated with healthcare, are considered as National Strategies focused on guaranteeing quality in the delivery of services.

That is why, anchored in the agreements relating to the Consolidation of the Second Global Ministerial Summit on Patient Safety 2017, we strongly support the initiative presented by the governments of Germany and Great Britain, in order to establish on September 17th of every year, the “International Day of Patient Safety”. This date will certainly bring to remembrance the urgent need to work on Health Services Management Models with a focus on patient safety and health professionals.

It is worth noting that this Minister considers this initiative as a tool that will help join forces among all countries that have a similar view of providing quality healthcare, with fair practice, that benefits the population. Also, it is an opportunity to show the effort being made each year to ensure a safe care, with the active participation of the patient.
France commends the inclusion of Patient Safety in the global health agenda and supports holding an annual Health ministers’ summit on this extremely important topic.

France launched its National Patient Safety Program in 2013, in line with both the WHO policy and initiatives and the EU Council Recommendation (2009/C 151/01) of June 9, 2009. This program was implemented after France had gradually built up strong policies to promote patient safety and quality of care. The National Authority for health (HAS) had implemented and regularly strengthened the healthcare facilities accreditation procedure and taken numerous other initiatives to promote evidence-based healthcare. The ministerial policy for the control of healthcare associated infections, including antimicrobial resistance, had been eventually extended from hospitals to all care sectors (hospital, ambulatory and elderly care). Awareness of the issues of safety was growing among healthcare professionals and patients as well.

The French National Patient Safety Program runs from 2013 to 2017. It is working on a systemic conception of safety. The Program aims at reducing avoidable adverse events and securing each individual’s care by developing safety procedures and promoting a safety culture anchored in the whole system. It then improves patient’s involvement in the safety and quality of their own care. Specifically, the Program promotes a better recognition by healthcare professionals of the patients and users’ needs, expectations and experience-related knowledge. In 2016, the role of patients’ representatives in healthcare settings was also reinforced.

Michèle Perrin, Patient safety Project manager, Ministère des solidarités et de la santé, France

Reporting and learning habits are a major topic of the program. They are strongly fostered, and a nationwide online unified system for reporting serious adverse events has also been established this year. This scheme is based on a new regional organization to ensure better knowledge about adverse events and provide the necessary coordination to manage and prevent them. Along with this new regional organization, an annual nationwide feedback on the reported adverse events will be provided by the National Authority for health. To achieve these goals, a strong emphasis on education and on-going training is embedded in the Program, including major investments in simulation which led to enhance multi-professional training. Patient safety has also been notably incorporated in medical education, in 2013 and 2016.

The National Patient Safety Program is linked to the specific current policies and programs for healthcare associated infections, antibiotic resistance, medication safety, and surveillance networks. France has been organizing an annual Patient Safety Week since 2011, fostering an increased awareness of all stakeholders on patient safety issues in healthcare. Therefore, France welcomes and supports UK and Germany’s initiative to propose to the WHO the institution of a Global Patient Safety Day.

France is willing to share knowledge with other countries about how to ensure better patient safety and to seek ways of implementing it, with cost efficiency, for the benefit of patients, healthcare workers and for the benefit of the healthcare system as a whole.
I would like to congratulate the success of the 2nd Global Ministerial Summit on Patient Safety where we proposed to establish the World Patient Safety Day and to convene the consecutive summits. Patient safety cannot be achieved without the continuous effort of institutions and individuals. By establishing a special day for patient safety, people’s attention toward patient safety will increase and encourage them to further promote it. In addition, holding the summit is an excellent opportunity to raise political awareness and enhance momentum. We should carry on these two approaches; gathering people’s efforts and increasing political attention to improve and promote patient safety. Japan will give maximum support to realize the proposal.

I am honoured to succeed this important initiative, led by the Honourable German Minister Mr. Gröhe and the Honourable UK Secretary Mr. Hunt, together with the WHO, and would like to offer my deepest respect and appreciation for their great achievements. Based on the discussion held in previous summits, I will present the themes for the 3rd Summit formally later on.

In the 3rd Summit, I promise that there will be an active exchange of views on several agenda and hope that we will achieve a fruitful outcome. I look forward to meeting all of you at the 3rd Global Ministerial Summit on Patient Safety in the world famous cherry blossom season in 2018.
The Republic of Kenya applauds the convening of the 2nd Global Patient Safety Summit by the Federal Government of Germany and the World Health Organization to raise the collective political, financial and technical commitment to patient safety.

Kenya acknowledges that patient safety is a critical element towards achieving the highest level of care afforded to its citizens. To effectively address patient safety, Kenya conducted its first comprehensive Kenya Patient Safety Impact Evaluation (KEPSIE) study in 2013, with the support of the World Bank. The study measured patient safety indicators in 493 health facilities across five risk areas ranging from leadership and accountability; competent workforce; safety of environment for staff and patients; clinical care of patients; and improvement of quality and safety.

Kenya has recently enacted the Health Act 2017, which has provisions for the establishment of Heath regulatory structures which cut across fundamental system-based initiatives such as professional education and training, development of safety standards, norms on leadership and governance, human resources for health, and infrastructure. In addition, Kenya has also reviewed the Kenya Quality Model for Health to include standards for Health Service delivery, and this has been institutionalized within the healthcare facilities to support sustainability of patient safety initiatives.

Dr. Cleopa Mailu, EGH, Cabinet Secretary, Ministry of Health, Kenya

Kenya has made significant steps towards the reduction of healthcare associated infections and containment of antimicrobial resistance. To this end, the Ministry has recently revised the National Policy and Guidelines for Infection Prevention and Control and developed a training course on Basic Infection Prevention and Control. We have also designated model sites for Infection Prevention and Control and initiated hand hygiene audits and AMR surveillance in these select health facilities. Kenya has also developed a National Policy and Action Plan on containment of AMR complete with a National AMR Surveillance strategy from a One Health approach.

Kenya would like to reaffirm her commitment to Patient Safety and assure the global community of our support in ensuring a holistic system-based approach to strengthening patient safety initiatives. We welcome efforts to convene regular Ministerial Patient Safety Summits as well as the proposal to establish a World Patient Safety Day. We remain dedicated to provide leadership and accountability in the development & implementation of policies that encourage and enable a safe environment for patients.
Anda Čakša, Minister for Health, Latvia

Latvia fully supports activities of the Federal Ministry of Health of the Federal Republic of Germany in promoting and maintaining the patient safety topic on the high-level international agenda. We kindly welcome the efforts to bring together various stakeholders and initiate important discussions based on evidences and best practices, which emphasize the significance of patient safety for national healthcare systems.

Ministry of Health strongly supports the initiative to establish September 17th as a Global Patient Safety Day. We would be pleased to participate in this cross-border initiative and contribute to joint activities to mark this day. At the same time, we believe that it is crucial to continue working within the framework of the Global Ministerial Summit that enables countries to exchange valuable experience in patient safety and agree on further steps, as well as to provide opportunities to strengthen cooperation.

We believe that ensuring safe healthcare is crucial for our society. Adverse events and injuries resulting from unsafe care are significant challenges to our healthcare system. Therefore, patient safety has become one of the highest priorities of the national healthcare system. In this field Latvia has attained some important achievements. We have updated regulations and mandatory requirements for healthcare institutions to improve patient identification, facilitate effective communication between patient and healthcare professionals, provide timely notifications (especially in critical cases) and lower risks for surgery, anaesthesiology procedures, as well as for high risk patient groups. There will be blame-free reporting and learning systems on adverse events.

A key aspect to improving patient safety is educating different level healthcare professionals on patient safety, quality and risk management, and measures to reduce or prevent errors and harm, including best practices and promoting active involvement, as well as the awareness of patient safety among all stakeholders. Considering the importance of education, knowledge and understanding, a training program on patient safety for employees of the Ministry of Health and its subordinate institutions has been started, as well as the extended training course for healthcare professionals.

Moving towards clear and common understanding of patient safety issues, the Ministry of Health is establishing cooperation with medical educational institutions to include the patient safety topic in the pre- and post-degree study programmes for all healthcare specialties.

Even though Latvia still has progress to make in improving patient safety, we are eager not only to obtain the best up-to-date experience and knowledge, but also to contribute with our ideas and active participation.
Patient safety is a key theme in taking healthcare systems to the next level. Patients deserve safe, high quality and patient centred care. The damage caused to patients, healthcare institutions and the entire healthcare system by adverse events is significant. It worsens treatment results, causes negative short and long term consequences, increases the duration of hospitalization, increases treatment costs, and decreases public confidence in the healthcare system.

Every second EU citizen thinks that the services provided by a healthcare institution can be unsafe. Unfortunately, there is no magic bullet to deal with all these challenges. Therefore, it is vital to share best practices and to look at the different aspects of patient safety.

First, policy makers need to see the connection between patient safety and economy in order to give high priority to patient safety on the policy making agenda. Simply speaking, it costs too much for the healthcare system to tolerate unsafe treatment and medication. There is still a lot of room for growth in setting the safety standards, enhancing the prevention and control of infectious diseases, and increasing the safety of patient’s treatment and medication therapy. It is vital not only to create a registration system of adverse incidents but to also build a patient safety culture where the reporting of incidents is not associated with punishment, but a learning process and a way to avoid such cases in the future.

Aurelijus Veryga, Minister of Health, Lithuania

The involvement of patients in the processes of healthcare becomes a key part in enhancing the quality and safety of the healthcare services. The latest technologies offer the innovative ways to strengthen patient safety and quality. For instance, by using the Central E-Health System to collect patient information, the user has examinations, diagnoses, prescriptions and other important information in one place. With such comprehensive information on the patient’s condition, the doctor will be available to treat the patient and provide healthcare services more quickly and with higher quality.

Healthcare systems are still slow to adapt latest mobile technologies and mobile apps to improve healthcare quality and safety at national levels.

We fully support Great Britain’s and Germany’s governments initiative to announce the 17th of September as Global Patient Safety Day and to add this question into the agenda of the World Health Organization Executive Board meeting for January 2018, urging the World Health Assembly to adopt a resolution on this question in May 2018.

We are in favour of organising regular high level ministerial meetings.
Malaysia is honoured to be part of the 2nd Global Ministerial Summit on Patient Safety in Bonn, Germany, which was held from 29-30 March 2017. Malaysia was represented by His Excellency Dato’ Zulkifli Adnan, The Ambassador of Malaysia to the Federal Republic of Germany and Dato’ Dr. Azman Abu Bakar, Director of Medical Development of the Ministry of Health Malaysia. Apart from the official delegates, the Head of the Patient Safety Unit, Ministry of Health Malaysia, Dr. Nor’Aishah Abu Bakar, was also invited by the World Health Organization to share Malaysia’s experience in the Middle-Low Income Countries Workshop. She presented a paper entitled “Strengthening Implementation of Patient Safety Policies on Incident Reporting and Learning System – Malaysia’s Experience”. Malaysia also shared our low cost, high impact project entitled “Mandatory Patient Safety Course for House Officers in Malaysia – Doing More with Less” in the compilation report of this meeting called “Best Practices in Patient Safety”.

Malaysia feels that the involvement of high level country leaders is essential to elevate the safety aspect of the healthcare system. This requires the commitment, support and collaboration of leaders at all levels of the healthcare system – from the level of healthcare facilities all the way through state, country and global levels. A specific platform to discuss Patient Safety issues amongst the Ministers/High Level Delegates will be beneficial to produce “one voice” which will lead to impactful change in all countries. Malaysia therefore supports the initiative of having an annual Ministerial Meeting on Patient Safety and will demonstrate our commitment to this Meeting.

Malaysia would also like to express our support for the recommendation of having an official “World Patient Safety Day” annually on the 17th of September. Hence, it is essential to draft a resolution to be discussed at the coming 2018 World Health Assembly. This will institutionalise Patient Safety Day globally and highlight Patient Safety as one of the important health agendas worldwide.

Last but not least, we would like to thank the Federal Republic of Germany and the World Health Organization for giving Malaysia the opportunity to be part of this very important meeting. Hopefully it is envisaged that this vital collaboration will result in the enhancement of patient safety at all levels of the healthcare system and make patient safety an integral feature of healthcare systems worldwide.
Sultanate of Oman, through its five-year annual strategic plan since the year 1976, has made patients safety as one of the focal elements in developing its healthcare system. The ninth five year-strategic plan (2016-2020) of the Ministry of Health includes many dimensions that serve the purpose of developing patient safety systems. This is to be done by several strategies including the collaboration with international healthcare systems and organisations. The second ministerial meeting on patient safety that was held in March 2017 in Bonn is one of the major collaborative platforms that would help Oman’s momentum toward developing patient safety systems by learning and sharing experiences with the German healthcare system as well as other countries and the World Health Organization. Hence Oman through the Ministry of Health, will spare no effort to support actions toward developing the healthcare systems, thus ensuring safe delivery of care to its community members.

Dr. Ahmed Al-Mandhari, Director-General of Quality Assurance Center, Ministry of Health, Oman
Tanja Mate, Director-General, Health Care Directorate, Ministry of Health of the Republic of Slovenia, Slovenia

Slovenia has a well-developed health system with good population health outcomes. Access to healthcare is also generally sound. The Slovene healthcare system remains relatively centralized. One of the most important tasks of the Ministry of Health of the Republic of Slovenia includes ensuring the quality and safety of healthcare. Patient safety is a priority within the Slovenian health system agenda and solid foundations for the patient safety need to be laid. The modernization of the system for monitoring and implementing measures for sentinel and other adverse events represents an important part of these efforts and the continuation of improving quality and accessibility of healthcare services. It is envisaged in the Resolution on the National Healthcare Plan 2016–2025. Greater investment in prevention programmes is justified. Government should provide integrated guidelines; these should be converted into instructions at the local level. Reporting of sentinel and adverse events cannot represent isolated, but rather an organic part of an overall well-functioning healthcare system. Healthcare-associated infections are one of the most common adverse events in care delivery and are often caused by antibiotic resistant pathogens; both healthcare-associated infections, endemic burden and the occurrence of nosocomial epidemics are a major public health problem and antimicrobial resistance is one of the biggest threats to the global health today. In Slovenia, we have started to prepare the National Strategy for the rational use of antimicrobial drugs and the management of antimicrobial resistance in human and veterinary medicine with an action plan. A review of existing study programs for healthcare professions has been carried out, upon which a proposal on the content of the provision of patient safety for inclusion in the curricula of educational programmes at all levels of education and in the framework of lifelong learning will be prepared.

Slovenia participates in many international working groups whose goals are aimed at improving the efficiency of the healthcare system. In providing the best healthcare possible, we strive for an integrated approach. Ministry of Health of Republic Slovenia follows the global messages and challenges of the Ministerial Meeting: efforts for patient safety need to be more visible with teamwork as a key to patient safety, since this is our shared responsibility. We support the regular organization of Global Ministerial meetings and an initiative for September 17th being declared the World Patient Safety Day.

The safety of healthcare is a result that should be pursued at all levels and integrated in different ways.
We believe that improving patient safety should be among the highest priorities of healthcare providers globally, whether it be government or private sector, in order to reduce healthcare errors as much as it is possible by bringing necessary organizational change across the board with an unequivocal commitment espousing transparency and accountability. To achieve the desired end result, it is also important to create awareness among patient rights to medical care. In this regard, we are pleased to note the initiative by the Governments of Great Britain and Germany to identify 17th of September as the World Patient Safety Day and wish to endorse this move as a very positive step in ensuring patient safety globally.

Dr. Rajitha Senaratne, Minister of Health, Nutrition and Indigenous Medicine, Sri Lanka
We all know that demographic changes are creating major challenges for our healthcare systems. Among other things, chronic diseases and the number of polymorbid patients are on the rise. Thus, the relevance of patient safety increases, for example in the area of medication safety. To be more specific, we know that about half of medical incidents in hospitals are preventable. It is all the more astonishing how little importance patient safety is currently given in the health systems of the 21st century.

In addition to improved evidence and data, one issue is central: strengthening patient safety must receive the necessary attention at all levels of health policy and the health system. For example, in the education and training of health professionals or in the daily work in the hospital.

Pascal Strupler, Director-General, Federal Office of Public Health, Switzerland

However, it is not enough for individually motivated doctors and some patient safety advocates to work for patient safety. Rather, the importance and strengthening of patient safety throughout the system and up to the top management level of hospitals must be anchored in the “DNA” of those responsible.

The current developments confirm all the more that clear measures and programs must be formulated. Systematic monitoring and improved transparency are indispensable. In Switzerland, there is the Patient Safety Foundation, which is equally supported by the state and the stakeholders. We will have to increasingly measure and compare to set some benchmarks. These results must also be published.

Another key aspect is ensuring sustainable financing. Investing in patient safety results in a return on investment for which many business leaders would be grateful. This return on investment is not limited to financial aspects. Rather, it also arises in human and health terms.

Last but not least, Switzerland affirms its support for a repeated and broad awareness of politics as well as of the population. We are fully committed to setting up an annual “World Patient Safety Day”.

Pascal Strupler, Director-General, Federal Office of Public Health, Switzerland
Turning healthcare systems into learning organisations

Jeremy Hunt

Secretary of State for Health and Social Care, United Kingdom

Jeremy Hunt is Secretary of State for Health and Social Care since 2018. Beforehand he served as Secretary of State for Health since 2012. He was elected Conservative MP for South West Surrey in May 2005. Before his election as a Member of Parliament, he ran his own educational publishing business, Hotcourses. He also set up a charity to help AIDS orphans in Africa in which he continues to play an active role. Jeremy Hunt was educated at Oxford University.

Every country has inspirational patient safety advocates. People who have tragedy in their lives but rather than seeking closure, put energy into stopping harm happening to others. They must repeatedly re-live their experience in order to do so, and their experiences and their commitment are the inspiration for my focus on patient safety.

You cannot solve a problem unless you know it exists, so the first step towards improving patient safety has to be establishing transparency. In England, we set up the Care Quality Commission to give every hospital a simple rating. Inspecting all the country’s hospitals took three years, and this comprehensive round of inspections has now completed. The Commission’s Chief Inspector for Hospitals said that 13 hospitals were outstanding. 31 got the worst rating, so we put them into a special measures support programme. Since then, 19 have come out of the support programme, having made big improvements.

Intelligent transparency – being open to collecting, sharing and learning from patient safety information – leads to action, and that means we need to understand the scale of the patient safety challenges, both nationally and internationally.

We cannot afford not to solve these problems. In England, the “Getting it Right First Time” programme has shown huge variation in infection rates, even within a single city. Every infection takes substantial resources to resolve that could be better used elsewhere in the system. OECD research has shown that up to ten percent of health spending is correcting hospital harm – a message that is as important for finance ministers as it is for health ministers.

At the heart of this problem isn’t failure or lack of good clinical practice. It is a failure to share it. Our focus needs to be on supporting our staff to make the most of their learning and the greatest difference to patients. Sharing and learning from others at events like this Summit in Bonn – and as this global movement develops – will help maximise global benefits from local ingenuity and innovation.
There is an economic imperative, a clinical imperative, but fundamentally there is a moral imperative. When we founded the NHS in 1948 it was one of the first comprehensive health systems. When we focus on patient safety, what we are saying is that every patient matters, as much as if they were our own family.

So now is the time to take these steps and turn our healthcare systems into learning organisations – to give our patients the safe, high quality care they deserve.
Opening Remarks of the Summit: Global Exchange – Our Opportunity to Improve Patient Safety

Karin Knufmann-Happe

Ministerialdirektorin (Director-General), Head of Directorate-General 3 for “Health Protection, Disease Control and Biomedicine” at the German Federal Ministry of Health

Karin Knufmann-Happe heads the Directorate-General for “Health Protection, Disease Control and Biomedicine” at the German Federal Ministry of Health after having been appointed Director-General in 2005. Her responsibilities include legislation and programmes on patients’ rights and patient safety, communicable and non-communicable diseases, organ transplantation, reproductive medicine and biomedicine, health professions and public health. Since 2012, she has chaired the Global Health Security Initiative. Ms Knufmann-Happe is a fully trained lawyer.

Patients all over the world rely on the fact that their healthcare is safe. The resulting challenges are different in every healthcare system and require measures to strengthen patient safety, which are adapted to the respective circumstances.

Nevertheless, we can learn from each other, and together we can ensure that medical care not only remains safe, but also becomes safer. The wealth of international experience in dealing with the new challenges of patient safety is a valuable resource that we want to use.

We are breaking new ground with the Global Ministerial Summits on Patient Safety. We make it possible for high-ranking decision-makers in the field of health policy to meet directly with the leading experts in science and healthcare. This direct information exchange is important to us. This is how expert knowledge inspires political action. We took great effort in finding the right meeting place as symbol for the idea of bridging the gap between healthcare decision-makers and practitioners. The summit takes place in the former building of the German Bundestag in Bonn. The German Parliament convened in this room from 1992 to 1999. During these years, politicians built many strong bridges, which connected the two states and helped them to grow together. Many fruitful dialogues started here. In this spirit, everyone will have a good time cooperating across disciplines and nationalities towards a common goal – the continuous improvement of patient safety.

I like to share one more thought about the venue with you: The plenary hall was not designed as closed space for politicians. The airiness of glass and steel, light wood and aluminium symbolises transparency as well as modesty. The Parliament should be accessible and approachable to citizens. Similarly, patient safety can improve only if all involved parties work together. This includes the people who are responsible for health care and above all, the patients. Transparency is the foremost prerequisite for improvements in patient safety. Living a culture of patient safety requires responsible and visible leadership. Let us lead by example!
Patient Safety
Doctor‘s point of view

Dr. Guenther Jonitz

Berlin Chamber of Physicians, President
Born 1958, surgeon (1994), President of Berlin Chamber of Physicians (since 1999), Founding Member of the German Network Evidence-based Medicine (2000), Founding Member and former chair of the German Coalition Patient Safety.

Patient safety is positively driven by progress in medicine and patient care and negatively by lack of resources. Patient safety is as old as medicine itself: “primum nil nocere” is a fundamental ethical principle in health care, and patient safety management puts it on a systematic ground. Patient safety is not a threat but a chance to act where it really hurts. Combined action both on an individual and on a system level is necessary and possible. Tools and knowledge about what and how to do is publicly available (e.g. WHO, projects like PaSQ, High5’s, national and regional institutions and projects). Doing it right provides a win-win-win situation – for patients, health care professionals and the system. Patient safety is a problem and bad topic – but with good news! You can do something! Wise leadership is necessary.
The modern patient safety movement dates back nearly 20 years. Landmark reports, such as the Institute of Medicine’s (now the National Academy of Medicine) “To Err is Human: Building a Safer Health System” dramatically drew attention to the issue of patient safety in health care. The subsequent report, “Crossing the Quality Chasm: A New Health System for the 21st Century”, called for fundamental change and provided a roadmap to close the health care quality gap in America.

These two reports argued that the majority of errors are caused by faulty systems, processes, and conditions that lead people to make mistakes or fail to prevent them. As a result, a systems approach encompassing culture, communication, and transparency are fundamental prerequisites for patient safety. Furthermore, investing in patient safety also requires knowledge about the strength and flaws of our national systems, our hospitals, our practices.

The patient safety movement has continued to advance and evolve since its inception. As health systems increasingly struggle to confront rising health care costs, the economic case for patient safety grows in importance. The economic burden of medical error is considerable and initial studies have shown that initiatives to prevent medical error can save money.

The US National Academy of Medicine has continued to advance the quality and safety agenda, expanding upon aspects of the quality framework outlined in “To Err is Human” and “Crossing the Quality Chasm” or applying facets of the framework to specific populations or system characteristics. Notably, in 2015, the US National Academies published a follow up report on diagnostic errors and more recently launched a study to examine quality and safety in low- and middle-income countries.

Victor J Dzau, MD

National Academy of Medicine (USA), President

Victor J Dzau, MD, is President of the National Academy of Medicine. He is an internationally acclaimed leader and scientist whose work has improved health care in the US and globally.
Patient Safety first –
and not economic interests

Dr. med. Ruth Hecker
Vice-chairman of Action Alliance Patient Safety (Aktionsbündnis Patientensicherheit) & Head of Quality and Clinical Risk Management, University Hospital of Essen, Germany

Dr. Ruth Hecker is a passionate advocate for health care quality with a particular focus on patient safety. She begun her career as a nurse and then studied medicine; after working many years in the field of anaesthesia, she earned a University degree in health science. Ruth Hecker is currently Head of Quality and Clinical Risk Management.

Patient safety should be the top priority for all healthcare organisations and the health industry; it should be the ultimate goal of all legislative procedures in healthcare.

Patient safety is a high priority for every member of staff working at all levels in the health service; for those working at the political, organizational and practical domain. Anyone who contributes to healthcare should always pay attention to patient safety when making decisions. In recent years, economic arguments have often been at the forefront of decisions, resulting in outcomes that infringed upon patient safety. Here we demand a paradigm shift.
Political Core Messages
to the Ministers
In various workshops the patient safety experts elaborated the following key messages for the ministers.

**Workshop 1 – Economy and Efficiency of Patient Safety**

1. **Reduce failure cost and invest in failure prevention**
   - Failures are costly: personally to patients, financially, politically, morally – investments can be profitable and are much needed
   - Requires adequate data on performance

2. **Patient Safety strategies need to be founded in an evidence-based approach and the total set should create value**
   - To be effective, efficient, appropriate, transferable, and sustainable
   - Individual strategies should be implemented and evaluated in the broader context of sectors, settings, systems, states, and organizations, and aligning clinical and corporate risks

3. **Patient Safety requires strong leadership and communication competence at all levels**
   - Interaction of infrastructure, clinical levels, patients, caregivers, organisations, legislation, payment methods and fundamentals (education, reporting, standards) is key to establishing a safety culture
   - Safe communication, support of staff and partnering with patients and care companions are important and helpful factors when building a sustainable patient safety culture
   - Health system leaders should invest in supporting

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**Workshop 2 – Global Patient Safety – Perspectives from Low- and Middle-income Countries**

1. **Patient safety is a universal issue, but poses special challenges for LMICs**
   - Inadequate allocation and use of resources, infrastructure and human resources, lack of respect for patients rights, compliance with patient safety standards
   - Dedicated investment and a comprehensive policy on patient safety is needed

2. **Patients, families and communities are a powerful resource for patient safety**
   - Increase health literacy, empower patients to ask questions
   - Patient-reported experiences and outcomes should be part of country data approaches

3. **Strengthening data concerning patient safety is crucial for**:
   - Motivating a culture of change to inform policy and programming, identify capacity-building gaps, increase accountability and involve leaders, based on evidence
**Workshop 3 – Patient Safety and mHealth, Big Data, and Handheld Devices**

1. Improve the digital health literacy of patients, professionals, manufacturers and the system
   - The patient has to be in control of his/her data
   - Recognize the need for ongoing changes in training and healthcare education curricula

2. Recognize the primacy of patients’ welfare with regard to data sharing
   - Value and quality of data and algorithms have to be understood and assured
   - Patient-centred approaches/patient engagement are paramount

3. Translating data into effective improvement strategies
   - Develop, support and make transparent the evidence base
   - Use routine data to improve patient safety now

**Workshop 4 – Prevention and Control of Infectious Diseases**

1. There is a significant burden of disease due to HAI (Healthcare Associated Infections). Sepsis is the most severe manifestation. HAI and Sepsis can be reduced by IPC (Infection Prevention and Control Programs).
   - The WHO core components for IPC provide good evidence and recommendations for effective interventions to reduce AMR and HAI.
   - Policy makers have a crucial role in the enforcement and implementation of IPC.

2. Standardised monitoring and feedback of IPC activities is crucial.
   - Surveillance and measuring the burden of HAI and of sepsis as well as the degree of implementation of IPC core components are essential.
   - Self-Assessment on the national and facility level is a valuable tool to evaluate the status of IPC, including sepsis prevention programs, and to identify and focus on gaps in the implementation of core components

3. Effective and modern IPC should be patient-centred and cost effective. Further research is needed.
   - Hand hygiene and the prevention of sepsis are good examples of a need to educate/inform, not only professionals but also patients (patient participation)
   - Increase awareness and knowledge to prevent and detect sepsis earlier (public information about available data, preventive measures and symptoms).
Workshop 5 – Increased Safety of Diagnostics and Treatment – Checklists and Other Tools

1. Continuous improvement of patient safety is only possible by systematically involving patients, their relatives and caregivers as partners.

2. Sustainable implementation of best practices for patient safety requires sufficient resources for clinical staff to lead those efforts.

3. Patient safety requires integrated leadership at all levels – starting at the political top – to lead the culture change.

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Workshop 6 – Safety of Medication Therapy

1. Better information on medication for patients and health-care professionals
   - An up-to-date medication plan (schedule) is necessary for all patients with polypharmacy
   - Ensuring patient comprehensibility of the medication plan (regimen/schedule) is strongly recommended.

2. Creation of a framework for quality assurance and optimal use of the medication plan
   - The complete medication (Rx/OTC) has to be checked regularly for potential safety risks

3. Ensure adequate (human) resources to avoid medication errors
   - In primary as well as secondary care and at transitions in care
   - E.g.: pharmacists can improve medication safety on hospital wards and on admission or discharge from hospital
Global Launch

1. Medication-related harm is a global pandemic that has been documented for 60 years and continues to kill and cause illness amongst patients

2. Patients are harmed because:
   - Medicine naming, packaging and labelling causes confusion
   - Errors are made in prescribing and administering medicines
   - The patient is badly informed and disempowered

3. Today, WHO has launched its third Global Patient Safety Challenge: Medication without Harm
Observations as Moderator of the 2nd Day of the Summit

Egbert M. Schillings, CEO World Innovation Summit for Health (WISH), Qatar Foundation, Germany

Egbert Schillings is a business leader with 25 years’ experience in the global healthcare industry, across payers, provider systems, best practice research, and consulting. Most recently he served as the founding CEO of the World Innovation Summit for Health (WISH) at Qatar Foundation. Previously, Egbert Schillings was SVP of Client Service for McKinsey’s Health Systems Institute in London. He has deep expertise in performance improvement, leadership development, and patient safety in healthcare systems, having worked with systems in over 20 countries.

Medicine performs miracles, heals hearts, mends minds, and even cures certain cancers. Yet medicine also causes harm. We do not know for certain how much harm but, frankly, we should and what we know already is frightening enough. Patient harm during the process of care represents the most fundamental form of waste in healthcare, it violates all ethical codes of the professions involved, destroys lives and along with it trust in the health care system.

Nobody raises their hand when asked upon admission to the hospital: “How many of you would like to acquire an infection during your stay here?” And yet it wasn’t so long ago that infections were seen as part of the bargain, not largely preventable. Much progress has been made since the publication of “To Err is Human” in 1999. And lest one be cynical about the publishing of reports, the IOM report is the birth certificate of a global movement that is still cited today and gave rise to countless national efforts to tackle the issue all over the globe.

Why has this proven to be such a gnarly issue? I have been asking famous leaders that question all around the world: Peter Pronovost will point to the myth of human perfectibility in medicine, the heroic individual who thinks they must simply work harder at their job.

In our work together for the 2015 WISH conference, we also explored the sheer complexity of healthcare delivery: A patient with chronic disease with multiple morbidities in the hospital is not a risk for one harm; they are probably at risk for 12 or 15. Every one of those harms might have 5 or 10 evidence-based practices that you need to do to prevent that harm and every one of those practices may need to be done three or four times a day. You do the math and we expect our clinicians to do 150 things every day and there is not a single EMR on the market right now that gives you any visual
display if you have done those things. No decision-support or task management tool that does justice to the complexity of the situation. Despite spending billions of dollars, it still requires about 150 clicks to tell even the most basic story about the patient and their care.

Never mind the Tower of Babel created by vendors across all the equipment in an average ICU – no linked up system to connect the infusion pump to the heart monitor, the EHR with the ventilator, etc., each creating a cacophony of alarms and data-points with the lowest possible noise-to-signal ratio. This is a systemic failure and the whole sector – including HIT vendors, providers and policymakers have a lot to answer for.

New drive for the topic of Patient Safety in Bonn 2017

In 2017 in Bonn, it really felt like we were turning a corner: Margaret Chan exhorted the ministers present to put patient safety in every speech, every conversation. Viktor Dzau mapped out just how the movement has grown since 1999 and gave due credit to IOM, IHI, the WHO and others. Kudos to Hermann Gröhe and Jeremy Hunt for linking arms on this crucial issue so publicly.

The safety model that we use in healthcare came largely from manufacturing and with ideas meant for smoothing rough edges, not for building from the ground up. Healthcare then cherry picked ideas from aviation and other industries but has not yet committed to designing a system that is explicitly safe. The Five Most Dangerous Words in Healthcare: “It could not happen here!” This is how Sir Liam Donaldson, former CMO of the NHS and today the WHO’s global envoy for patient safety, summed up the dilemma for policymakers as they seek to reduce harm at a system level. He was addressing the 2nd Global Ministerial Summit on Patient Safety in Bonn, Germany, a follow-up to the previous year’s inaugural summit in London. I was hugely energized by the 2016 London summit, so what did more than 40 country delegations, the OECD, the WHO, the EU and other luminaries add in Bonn?

For one, the ethical and moral case for action was supplemented by a comprehensive economic case. As a follow-up to the London summit, the German Federal Minister for Health Hermann Gröhe commissioned the OECD to study the economics of patient safety. Their report is outstanding and should serve nicely as ammunition for any leader seeking to make the business case: For instance, 15 percent of hospital expenditure and activity can be attributed to safety failures. The annual cost of common adverse events in England is equivalent to 2,000 GPs or 3,500 hospital nurses! There are 80,000 bloodstream infections in the US and the cost of these largely avoidable infections tops $2.3 billion annually. We know that central line infections can be eliminated because Peter Pronovost and the leaders of the Keystone ICU project have shown us that a simple checklist can reduce the infection rate to almost zero. Billions saved along with lives and life years not lost to disability, at almost no added cost. What blockbuster drug can claim a rate of return of this magnitude?

But it seems to be not enough to move the system. A most likely apocryphal remark attributed to George Bernard Shaw tells us that “It is the mark of a truly intelligent person to be deeply moved by statistics.” If he said it, I am sure he was being sarcastic. I for one was more inspired by the incredible stories from patient safety leaders working in resource constrained settings, who have moved mountains with ingenuity and single-minded leadership. Take Nor’Aishah Abu Bakar who has led the creation of an incident reporting system in Malaysia, using Google Docs and frugal innovation. Or take public health leader Ayda Taha from Sudan whose presentation on reducing infant and maternal mortality in Sudan was one of the most moving and compelling moments of the Summit.
How far have we come?

Whenever more than two people get in a room anywhere in the world to talk about patient safety, inevitably the IOM’s “To Err is Human” will be mentioned. I think of it the birth certificate of the global patient safety movement. It gave the world the framework, the numbers, and the metaphors needed to craft a powerful narrative for change. Usually that reference is followed within minutes by “Crossing the Quality Chasm”.

Going back almost 18 years now, they both still seem fresh. A cynic might say that this is because we have moved so little since then. But we have and the IOM/NAM tradition of intellectual leadership in this space was demonstrated impressively once again by 2015’s report on diagnostic error (http://www.nationalacademies.org/hmd/Reports/2015/Improving-Diagnosis-in-Healthcare.aspx) – something all of us will encounter at least once in our lifetime. As Moderator of the Summit’s Day 2, it was my privilege to welcome Dr Victor Dzau, President of the US National Academy of Medicine, for his keynote address to the delegates. He charted the course for us, how far we have come and how much further we have to go in light of increasing technological complexity and highly multi-morbid patient populations.

One cannot help but feel impatient about the pace of progress in this space. Both Jeremy Hunt and Margaret Chan channelled that sense of impatience in their remarks. The State Secretary for Health in his keynote replayed the horrors of the Mid Staffs scandal and put the names and faces of bereft family members up on screen. Dr Chan reminded everyone that 2/3 of patient harm occurs in the developing world where the majority of incidents lead to death or permanent disability.
Ultimately, patient safety is not a project. It’s an integrated system where interventions at the meta-level (such as no-fault medical negligence, EHRs, mandatory reporting etc.), and those at the organizational (institutional) level (safety culture, clinical governance systems for safety, patient centred design, monitoring of PSIs), all serve to support and reinforce the crucial clinical level interventions such as medication reconciliation, VTE protocols, surgical checklists and many others. Those at the sharp end should not be asked to do 80 percent of the safety work. The system should support them so that the human at the bedside is responsible for no more than 20 percent of the fail-safes and double checks. That is how all other high-risk sectors build their systems. In healthcare we have allowed the reverse to be the norm.

After reviewing the evidence of best practices (check out the handy compendium created for the Summit: https://www.bundesgesundheitsministerium.de/fileadmin/Dateien/3_Downloads/P/Patientensicherheit/Best-Practice_Patient_Safety_Web_plusWHO.pdf) and moderating the ministerial portion of the Bonn Summit, one thing is clearer to me than ever: We are not waiting for a breakthrough in safety.

What we need is a break-away from these piecemeal solutions that have not served us – piecemeal solutions that rely on the heroism of clinicians and nurses every day. The whole system solution we need has to begin with thought leaders at all levels. It was good to see policymakers beginning to rally around that idea in Bonn. We need to change what we declare to be important and my hope is that all 300+ delegates at Bonn will make safety part of their agenda, right at the top – where it belongs.
Workshops
Workshop 1: Economics of Patient Safety

Niek Klazinga, MD, PhD, Senior Economist/Policy Analyst, OECD, France (Dutch Nationality)

Niek Klazinga, MD, PhD is coordinator of the Health Care Quality Indicator project at the OECD in Paris since 2005. He combines this work with a professorship in Social Medicine at the Academic Medical Centre at the University of Amsterdam.

Dr. Ingo Härtel, Senior Science Advisor, German Federal Ministry of Health, Germany

Dr. Ingo Härtel holds a doctorate in medicine from the Charité, Berlin and an MA in bioethics from the Kennedy Institute of Ethics, Georgetown University, Washington, DC. His current position is Deputy Head of the Health Law, Patient Rights & Patient Safety Division at the German Federal Ministry of Health. Prior to his current post, he worked for the office of the Study Commission “Law and Ethics in Modern Medicine” at the German Bundestag.
Expert statements on Economy and Efficiency of Patient Safety

Introduction

On the one hand, the aim of the workshop was to analyse the economic effects and the efficiency of procedures for the improvement of patient safety at the international level. In preparation of this topic, OECD has conducted an international study on economic consequences of patient safety, which regards longer-term and indirect consequences of improved patient safety. On the other hand, the efficiency of patient safety measures should be examined with special attention being paid to safety culture and the influence that leadership style and patients’ involvement have in this respect.

Workshop Summary

Presentations and discussions during the workshop highlighted the substantial economic impact of patient safety. The OECD report “Economics of Patient Safety” states that patient harm is number 14 on the global list of burden of disease. The considerable financial losses resulting from errors in the provision of healthcare are a problem for industrialised and developing countries alike. Approximately 15 percent of total hospital activity and expenditure is a direct result of adverse events. In the political economy, the cost of safety failure includes loss of trust in the health systems, in governments, and in social institutions. At the same time it became clear, that many adverse events are preventable through better policy and practice, with the cost of prevention typically much lower than the cost of harm.

Presentations exemplified how on a national level governments can choose a mix of safety strategies that contribute best to increase the overall value. These “best buys” address a mix of strategies to be applied on clinical, organisational and system level.

Speakers convincingly demonstrated that measures addressing problems in safety cultural – such as care for the “second victim” – are wise investments in healthcare systems from an economic perspective. An example from Italy demonstrated that partnering with patients is possible and how successful solutions found at a local level can be upscaled, spreading therewith safety culture improvements and multiplying desired economic effects. Emphasis was put on presenting patient safety in positive terms, shifting from merely identifying shortcomings to presenting successes of applied modern safety strategies. The importance of communication as a universal tool that is essential to all kinds of care cannot be underestimated. This is true for the individual patient-provider-communication as well as for communicating concepts and policies. Beyond the presentation at the Summit, communication became the motto of the International Day of Patient Safety on 17 September 2017.

Discussions emphasized the need to look at the improvement of patient safety measurement in combination with actual improvement activities. Patient Safety strategies need to be founded in an evidence-based approach and the total set should create value. On the health system level, apart from supportive legislation (no-blame systems) and national programs, leadership from ministers is essential to create a culture in health care where safety is a “conditio sine qua non“. While emphasizing patient safety through specific strategies and policies should be a top priority of each health care system, these efforts should be considered in the broad context of quality improvement and health system performance.
Expert statements on Workshop 1

Tommaso Bellandi, Deputy Director, Centre for Clinical Risk Management and Patient Safety, Department of Health of the Tuscany Region – WHO Collaborating Centre, Italy

An integrated system for patient safety management can contribute to improved patient outcomes, as well as quality and efficiency of the clinical processes. Within such a system, clinical risks should be handled jointly with financial risks associated with adverse outcomes, so to have a fair and timely compensation system, and a return of experience to inform process redesign that can help to reduce direct and indirect costs.

The national legislations should include patient safety as a fundamental right, like in Italy, along with a safe space for reporting and learning, a safe harbour for clinicians who respect the evidence based practice and open communication and engagement of patients and their families.

Prof. Jeffrey Braithwaite, Founding Director, Australian Institute of Health Innovation, Macquarie University, Australia

In this talk we discussed the implications of the OECD report, The Economics of Patient Safety: Towards a Value-Based Approach of Reducing Patient Harm at National Level, which argues the importance of tackling harm to patients in a range of key areas; infections, venous thromboembolism, pressure ulcers, medication error and wrong or delayed diagnosis. The basis for this is that these are major contributors to the burden of harm and cost to health care systems.

We also advanced implementation strategies that can be tailored for different kinds of health systems. Low-, middle- and high-income countries have differing infrastructure, resources, and capacities to mitigate harm. We recognised the importance of understanding when things go right (Safety-I) as well as when things go wrong (Safety-II) as a way of developing implementation strategies tailored to circumstances in different countries.
Diplom-Kaufmann (FH) Ingo Gurcke, Managing Director, Marsh Medical Consulting GmbH, Germany

Big data is a chance for hospital management. The goal is to use standard, common datasets to monitor outcomes and reduce variation as well as to identify avoidable problems and root causes. This has to be done with minimal impact on clinical time. The web-based software solution “Copelands Risk Adjustment Barometer” is a peerless benchmarking application. It serves as a safety and quality monitoring system, designed to give doctors, nurses, hospitals and external assessors detailed visibility on clinical performance from patient-level data. It helps to identify good practice and danger zones based on clinical variation in practice that would not appear in statistical analysis and review underlying issues of morbidity and avoidable harm. The tool offers an Individual risk prediction of risk of mortality and complication for each patient having an operation as well as improving effectiveness of mortality and morbidity review. It helps to identify those deaths where improvements in care potentially could have been made. It takes a focus at complications to the find the underlying causes of avoidable deaths.

Prof. Dr. Annegret Hannawa, Associate Professor; Director, Center for the Advancement of Healthcare Quality and Patient Safety (CAHQS), Università della Svizzera italiana, Switzerland

Safe interpersonal communication is not a soft skill that enhances patients’ care experiences, but a core skill that constitutes the vehicle to overcoming prevalent safety challenges in healthcare. My investigations pose two clear implications for reducing the burden of preventable patient harm:
1. We must urgently install five core “safe communication” competencies (encapsulated in the acronym “SACCIA”, see www.saccia.info) into medical and nursing practice via basic and continuing education.
2. We must activate all care participants (i.e., providers, patients and care companions) with these five “SACCIA safe communication” practices to effectively enhance the safety of patient care.

Doing so will transform the causes and contributing factors of many patient safety events into resilient processes, and optimize interpersonal competencies in response to patient harm – as an important process to reducing preventable repetitions of unsafe care.
Niek Klazinga, MD, PhD, Senior Economist/Policy Analyst, OECD, France (Dutch Nationality)

Patient Safety is a critical policy issue; patient harm is number 14 on the global list of burden of disease, implying it has a similar impact as malaria or tuberculosis. The majority of this burden falls on developing countries. In developed countries the cost burden to acute care is estimated to be comparable to the one from multiple sclerosis and several types of cancer. The cost to patients, healthcare systems and societies is considerable; approximately 15 percent of total hospital activity and expenditure is a direct result of adverse events. The most burdensome adverse event types include venous thromboembolism, pressure ulcers, and infections. Greater investment in prevention is justified because effective preventive approaches are available and the costs of prevention are dwarfed by the costs of failure. Solid foundations for patient safety need to be in place such as the appropriate legislation and reporting systems but also safety culture and safety leadership. Active engagement of providers and patients is critical because ultimately safety needs to be built in the working processes but national leadership from ministers to enhance a safety culture in health care is essential.

Luke Slawomirski, Health Economist, OECD, France

Patient safety is a critical policy issue. Safety lapses resulting in patient harm exert a considerable cost on patients, communities and the health system. The global morbidity burden of patient harm can be compared to that of tuberculosis or malaria. We estimate that 15 percent of hospital care activity in OECD countries is a direct consequence of treating harmed hospital patients. More research is needed in non-acute settings. The broader social and economic costs run into the trillions of dollars. Many safety lapses are preventable, and the costs of implementing effective prevention strategies are miniscule compared to the costs of harm.

A national value-based approach to safety should begin with fundamental system-level initiatives such as professional education and training, safety standards and a solid information infrastructure. Organisational-level initiatives such as clinical governance frameworks, patient-engagement and building a positive safety culture also form an important part of a safety strategy. With these structural reforms in place, micro-level interventions to prevent specific adverse event types at the clinical practice level can be implemented to minimise harm. Emphasis should broaden from safety in hospital settings to primary care and long term care.
Stress and burnout are universal problems that increasingly threaten both the well-being of health care workers and the safety of patients. Studies worldwide suggest the prevalence of burnout is greater than 30 percent. Nurses, physicians and other providers can be traumatized by patient adverse events, becoming “second victims”. Their clinical performance may be impaired, and some develop long term adverse consequences similar to post-traumatic stress disorder. Some leave their professions and a few even commit suicide. Despite this, health care institutions have paid little attention to helping health care workers cope with adverse events.

Recently, programs have been developed to help support health care workers after adverse patient events. One such program is the RISE (Resilience in Stressful Events) peer support program at Johns Hopkins, which provides timely psychological first aid to staff members who encounter stressful patient-related events. This program has been demonstrated to save hospital costs. Hospitals should consider implementing institution-wide support programs for medical staff, based on the high demand for this type of service, and the potential for cost savings and improve the quality of care.
Workshop 2: Global Patient Safety – Perspectives from Low- and Middle-income Countries

Prof. Sir Liam Donaldson, WHO Envoy for Patient Safety, World Health Organization, Switzerland

Liam Donaldson was the foundation chair of the World Health Organization’s World Alliance for Patient Safety, launched in 2004. He is the World Health Organization’s Envoy for Patient Safety, Chairman of the Independent Monitoring for the Global Polio Eradication Programme, as well as Chairman of the Transition Monitoring Board of this Programme.

Dr. Edward Kelley, Service Delivery and Safety, World Health Organization, Director, Geneva, Switzerland

Edward Kelley is Director for the Department of Service Delivery and Safety at the World Health Organization. In this role, he leads WHO’s efforts at strengthening the safety, quality, integration and people centeredness of health services globally and is the lead for WHO’s work on strengthening health systems and security.
Workshop Summary

This workshop explored innovative, cost-effective patient safety solutions conceived in settings with limited resources in low- and middle-income country (LMIC). The workshop focused on the following themes: organizational leadership, safer primary care, patient, family and community engagement, education and training, national patient safety systems, policy implementation and safer maternal and neonatal care (agenda enclosed). Experiences from countries were shared across all world regions. The key messages and discussions are summarized below:

**Start small.** In the Sudanese experience, lessons extracted from implementing the WHO Safe Childbirth Checklist in one of the largest hospitals proved that any strategies to improve patient safety should be piloted in a small-scale setting before they are scaled-up, like a small facility or a department in a larger hospital. This can help facilitate a better understanding of the local needs and conditions in which successful implementation can occur.

**Focus on behaviour change.** A large-scale patient safety impact evaluation conducted by the World Bank in Kenyan primary care settings in 2012 revealed that knowledge and resources are not enough to improve compliance with patient safety standards. Incentives may be necessary to facilitate the behaviour change needed for sustainable and effective improvements.

**Get creative.** Engaging patients in their own care and improving health literacy can be extremely effective strategies if deployed meaningfully. In the Ugandan example, community engagement techniques such as local dance events, SMS text messaging and open discussions based in community settings have proved an effective patient empowerment strategy, with the latter as the most effective.

**Legislative frameworks are necessary.** An enabling political environment needs to be created, through empowering regulatory and legislative mechanisms for improving, reporting, and minimising patient harm.

**Data is a key driver.** To be effective, countries are encouraged to devise comprehensive plans based upon an in-depth understanding of the patient safety issues specific to their context. Effective health policies and strategies can then be developed based upon the baseline data collected. These policies must also be developed in conjunction with other quality improvement initiatives, like infection prevention and control.

**Convene enthusiasts.** Based upon the Thai experience of scaling-up a nationwide patient safety education and training initiative, bringing together networks of interested groups has proved to be a powerful advocacy tool.

The discussions explored more of an in-depth understanding of how to begin implementing patient safety strategies effectively at a national level, exploring the important role of patients and sharing success stories. Core political messages for the ministers of health were summarized into:

1. **Patient safety is a universal issue, but poses special challenges for LMICs:**
   - Inadequate allocation and use of resources, infrastructure and human resources, lack of respect for patients’ rights, compliance with patient safety standards
   - Dedicated investment and a comprehensive policy on patient safety is needed

2. **Patients, families and communities are a powerful resource for patient safety:**
   - Increase health literacy, empower patients to ask questions
   - Patient-reported experiences and outcomes should be part of country data approaches

3. **Strengthening data concerning patient safety is crucial for:**
   - Motivating a culture of change to inform policy and programming, identify capacity-building gaps, increase accountability and involve leaders, all based on evidence.
Incident reporting and learning systems is one of the earliest patient safety programmes in Malaysia. One of the main challenges is to establish a policy and system which can be implemented efficiently, effectively, and meet the needs of the stakeholders. In order to overcome this challenge, Malaysia has used “Leadership, Engagement and Creativity” as the strategy. This involves:

1. Creating more leaders to champion patient safety and incident reporting at various levels and disciplines.
2. Engaging with relevant stakeholders to get feedback and improve the system.
3. Creating enablers such as using free online web-based systems to facilitate incident reporting directly from hospital to Ministry and to make the complicated process of reporting shorter and more user friendly.

After one year of implementation, a total of 2,769 incidents were reported in 2016. This is the highest number being reported so far. More detailed epidemiology of incidents can now be captured. In summary, policy should be dynamic and responsive to meet the need of stakeholders. “Leadership, Engagement and Creativity” is the key.
Patients, families and communities are powerful resources for improving patient safety and quality. This requires for patients, families and health professionals to work together, to engage and empower patients to effectively manage their own care and make behavioural changes, through health literacy and patient information. It is also critical that they are recognized as equal partners in their health care. They should be treated with care, respect and also listened to.

Other key components of patient safety are infrastructure, equipment and training, as well as high quality and affordable medicines. When receiving care in low- and middle-income countries, many patients and their families suffer every day from preventable adverse events due to challenges. These are: low government prioritization and spending on health, inadequate human resources for health, poorly maintained health facilities without functioning equipment, inadequate drugs and supplies, as well as weak medicine regulatory and pharmacovigilance systems. It is therefore critical that these issues are addressed to ensure patients receive safe care.

In Thailand the Healthcare Accreditation Institute (HAI) has initiated the “Engagement for Patient Safety Project”, aiming at improving healthcare service systems that provide safe and high-quality care with active participation of all key stakeholders. In order to be successful in this area, the following experiences are important. Engagement of all key stakeholders, including multi-professional, regulators, producers, and students is essential to integrate the WHO Multi-professional Patient Safety Curriculum Guide into undergraduate and postgraduate training for healthcare professionals. Also training of the trainers is vital and should start with an interest group that has a mindset on patient safety. Last but not least, a long term evaluation is needed to assess whether health professionals are more competent on patient safety.
Patient Safety is a high priority on the Croatian healthcare quality agenda and it is integrated in the respective legal framework and “National Health Care Strategy 2012–2020” document. Patient safety activities are mostly focused on hospital setting (surveillance of sentinel events, patient safety indicators, compliance with mandatory quality and patient safety standards, health professional training, WHO surgical check list, medication reconciliation, national policy for antibiotic resistance control, safety culture survey). In primary healthcare, patient safety activities are in early stage development.

In developing patient safety system for the last five years we have acquired useful experience and knowledge through the international collaboration. Sharing knowledge, exchange of good practices and building relationship between experts and practitioners are very useful for initiative patient safety activities at local and national level. To enforce patient safety the focus should be on continuous education and training to achieve respective competences, patient safety skills of healthcare providers and to increase awareness of the issue among stakeholders involved. Adequate resources and leadership capacity are essential for successful patient safety implementation.

Maternal and neonatal health (MNH) is a global priority. In many parts of the world, efforts put into reaching the targets of Millennium Development Goals have fallen short. Because of this, the WHO developed a Checklist to help bridge the gap between healthcare providers’ knowledge and practice. Since MNH is a national priority in Sudan, our team decided to participate by conducting a pre- and post-intervention study to determine the applicability of the Checklist and its effect on healthcare provider practices.

Our findings: The Checklist significantly improved the delivery of best practices in 20 out of 25 practices. Furthermore, it unexpectedly was found to reflect weaknesses in the hospitals’ system. So the Checklist can be used to assess the healthcare facility setting and to deliver best childbirth practices. To obtain better results with implementation, leadership engagement followed by provision of a conducive environment is critical by, e.g. developing required guidelines. Starting small, using key figures and the best training modalities such as coaching and videos is of the utmost importance. Lastly, empowerment of quality managers and slow implementation over at least a 6 month period is crucial for sustainability.
Dr. Jeremy Veillard, Program Manager, Primary Health Care Performance Initiative, World Bank Group, Canada

The World Bank presented the results of the largest study of non-compliance with standards of infection prevention and control. This research was carried out in partnership between the government of Kenya and the World Bank in 1,000+ facilities where 1,700 healthcare workers were followed in their interaction with 15,000 patients.

What did we find? That knowledge and supplies are not sufficient to ensure compliance with standards, but that the combination of knowledge, supplies, and right incentives related to inspection, consequences and transparency make a huge difference. The government is now developing new exciting policies to leapfrog more consistent compliance with infection and prevention control standards. As part of the patient safety movement, we need to put more effort into understanding patient safety in primary healthcare. We need to collect more data, carry out more research and share what we know more systematically.
Workshop 3: Patient Safety and mHealth, Big Data, and Handheld Devices

Dr. Mike Durkin, NHS National Director of Patient Safety, United Kingdom

Mike Durkin is NHS National Director of Patient Safety. He is the Senior Advisor on Patient Safety Policy and Leadership at the Institute of Global Health Innovation at Imperial College London. He previously held National Executive Director positions at Strategic Authorities and at Gloucestershire Royal Hospital. He is a Consultant in Anaesthesia and Critical Care having first qualified at the Middlesex Hospital and has held research and teaching appointments in London, Bristol and Yale University.

Introduction

Mobile technologies (mHealth, handheld devices) and also technologies to process big datasets (Big Data) are gaining worldwide importance in the field of health, and in a tremendously fast manner. With the aid of mHealth, patient safety may be strengthened, especially by improved patient information and adherence as well as by increasing self-determination. Big Data applications hold the promise of more efficient methods of successful treatment by evidence-based and personalised procedures in health care. Opposed to this are the risks concerning data safety and product quality. Although patient safety is quoted as the key reason and goal of capital investment in those technologies, the purposeful application and analysis of the latter to reach the established goals of patient safety have not yet been sufficiently developed and networked at the international level. In this regard, the workshop was supposed to provide solutions. Against this background, one of the key points of emphasis was patient safety in connection with non-medical health apps, and attention was paid to the necessary information of customers/patients, transparency and the role of web stores.
Workshop Summary

This workshop on mHealth, Big Data and Handheld Devices brought together truly global and national experts from the fields of clinical and public health, patient advocacy, digital and devices technology, academic and applied research, improvement science and innovation. As Dr. Margaret Hamburg notes: “...in the context of medicine and public health, innovation only really matters if it benefits patients and consumers...” This workshop succeeded in bringing to the foreground the opportunities and the challenges that clinicians, designers, inventors, and patients are presented as they all strive to develop and safely use new, emerging, and innovative digital technologies for the improvement of clinical outcomes.

The competing worlds of digital technological advance and knowledge acquisition and application come together in an often unregulated digital market place where the use of disruptive marketing techniques continues to place the patient in an increasingly vulnerable position. The use of artificial intelligence methodologies is at the forefront of improving safety in delivering healthcare in all sectors, and settings from the critical care unit and operating rooms, to the private office and general practice. However, they also rely on sophisticated algorithms and platforms where simple errors in application and use can lead to unintended harm, which if unchecked and unregulated can bring about severe implications to patients, staff and manufacturers.

Key outcomes that emerged from the presentations and debate within the workshop which were presented to Ministers at the Summit are the following:

We must improve the digital health literacy of the patients, professionals, manufacturers, and the system within which digital technologies are used. There is no doubt that the unregulated use of mHealth applications will place our patients in an increasingly vulnerable position. The patient must be allowed to be in control of his or her data, and the digital developers and related clinicians and innovators must understand their responsibilities and ethical duties in this regard.

There is an urgent need for all providers and regulators of undergraduate and postgraduate healthcare education to recognize the need for ongoing changes of training and healthcare education curricula, to reflect not only the implications of the use of mHealth and Big Data, but also to understand the importance of incorporating patient safety and improvement science as vital components of interprofessional training and education.

We must always recognize the primacy of patients’ welfare with regard to data sharing and that patient-centred approaches and thorough patient engagement are paramount if we are to really gain the advantages brought about by sharing and using data sources. In discussing the use and application of multiple data sources, it is important that innovators, developers and improvement scientists understand and assure the value and quality of data and algorithm development.

This is equally vital if we are to be productive in translating data into effective improvement strategies. For this to be possible it is important that all parties should work together to develop, support and make the evidence base transparent. A recurring theme that emerged from the assembled experts was that the time to use routine data to improve patient safety was now and should not be delayed.

Finally, and with implications for all governments, healthcare regulators, providers and commissioners, we should now work together to develop a global ethical governance framework to enable the usage of data on a much larger scale than currently employed. Key elements within this framework will be to define appropriate data sets and incentivise data sharing, and that work should be across disciplines, sectors and borders such that there is a targeted approach to support the development of smarter and effective regulators.
Margaret A. Hamburg, MD, Foreign Secretary,
U.S. National Academy of Medicine, USA

Advances in science and technology are combining with new insights into the nature of disease management, prevention, and health promotion to offer a remarkable new array of opportunities for health and health care. Mobile technologies, including hand held devices and mobile apps, represent a particularly exciting new arena of activity, enabling patients to have direct access to/control of their own health information, while also supporting doctors ability to diagnose and manage care outside of the healthcare setting. New capabilities in bioinformatics and “big data” provide further opportunities to improve health care and deepen our understanding of disease and wellness. Moving forward, however, these potential advances must be aligned with efforts to adequately assess safety, efficacy, quality and performance of these approaches. In the context of medicine and public health, innovation only really matters if it benefits patients and consumers. New mobile and/or software driven technologies can span a broad range of health issues, many carrying minimal risk. Yet others may pose considerably more concern, and could be truly harmful to patient safety and consumers if they do not work properly. We must work together to strike the right balance.
Consumers and patients are confronted with a multitude of products and apps when they want to use e-health. There has to be feature or label, that reliably distinguishes between safe, useful and privacy-protecting products and those are not, otherwise cheap products will dominate and discredit the whole field of e-health.

Networked care is a key for patient safety and should be conceived as a paradigm shift in care. “Digital and analogue companions for an ageing population (digilog)” is a joint research and development project in the German State of Brandenburg, testing a multitude of IT-assisted tools, digital companions, mainly external, some internal (implanted) made-to-measure for subgroups at risk. The objective is to build a mobile, virtual drop-in clinic.

The technique brought to the patient must not interfere with everyday life, and at best, should not even be perceptible. As data available from mHealth is increasing on a large scale, not only by volume but also by type, the challenge is to process the data overload and at the same time linking data of different types in a medically meaningful manner. This will require an artificial intelligence approach. The boundaryless hospital is made real by networked care. mHealth and big data, combined with "old-fashioned", "analogue" companions (either in the shape of a district nurse or physicians controlling the implications of automated analyses), could pave a sheltered way in community-based care.

Patient Safety is an ethical requirement for the development and application of digitally supported healthcare in terms of diagnosis/monitoring, therapy and prevention. This pertains especially to the ethical principles of autonomy, beneficence and nonmaleficence, privacy and data protection as well as non-discrimination and justice.
Workshop 4: Prevention and Control of Infectious Diseases

Prof. Dr. Petra Gastmeier, Head of the Institute of Hygiene and Environmental Medicine, Charité – University Medicine Berlin, Germany

Petra Gastmeier is certified in Hygiene and Environmental Medicine. Following several years working as a senior physician at the Institute of Hygiene of the Free University Berlin, she became associated professor at Hanover Medical School. Since 2008, she is Head of the Institute of Hygiene and Environmental Medicine Charité – University Medicine Berlin. She is coordinating the work of the German Nosocomial Infection Surveillance System and is responsible for the German national hand hygiene campaign.

Prof. Dr. Lindsay Grayson, Austin Health, University of Melbourne, Director, Infectious Diseases & Microbiology, Director, Hand Hygiene Australia, Australia

M. Lindsay Grayson is Director, Infectious Diseases & Microbiology Department at Austin Health; Professor of Medicine, University of Melbourne and Professor (Hon) in the Department of Epidemiology & Preventive Medicine, Monash University, Melbourne, Australia. Professor Grayson is also Director of Hand Hygiene Australia, the national body responsible for improving and assessing rates of hand hygiene compliance among healthcare workers in Australian hospitals, and for the regular reporting of these results on the Australian Government’s national MyHospitals website.
Introduction

One central issue of the workshop was the discussion of measures to prevent infections, in particular in the context of nosocomial infections and sepsis, but also to reduce the use of antibiotics, thus avoiding antimicrobial resistance. On this occasion, it was examined to which extent national recommendations on infection prevention can also be applied at the international level, and particularly in low- and middle-income countries. Along with the discussion of strategies for implementing recommendations for action, aspects such as costs incurred by nosocomial infections, and the involvement of patients within the scope of infection prevention were covered.

Workshop Summary

Healthcare-associated infections (HAI) are one of the most common adverse events in care delivery. They are a major public health problem, and antimicrobial resistance is one of the biggest global threats today. HAI are associated with a high burden of disease and sepsis is one of the most important consequences of healthcare associated infections because it is associated with a substantial mortality. It is possible to reduce HAI and sepsis by appropriate Infection Prevention and Control (IPC) programmes.

In November 2016, WHO issued its first guidelines on what comprise the core components of IPC programmes at the national and acute health care facility level. The guidelines are based on scientific evidence and provide useful recommendations to reduce HAI and antimicrobial resistance. The target audience of the guidelines is manifold, but at the national level these recommendations are of particular relevance to policy makers responsible for IPC, reduction of antimicrobial resistance and patient safety.

Standardised monitoring and feedback of IPC measures is crucial. It is important to perform surveillance of HCAI and sepsis locally, on a national level and globally. In addition, monitoring the implementation of IPC core components is necessary. Self-assessment forms are a very valuable tool to assess the implementation of IPC programmes on a national level and on the level of the individual facility to identify deficits of implementation and to overcome them. WHO will provide appropriate IPC self-assessment forms.

Hand hygiene and sepsis prevention are excellent examples of the need for better information, not only among health care workers, but also patient groups. Patient involvement was therefore a major issue during the discussions of this workshop. In addition, rising awareness and useful control measures for antimicrobial resistance and sepsis were discussed intensively. Finally, useful and modern IPC programmes have to be patient centred and cost effective. Further research is necessary to increase the evidence for infection control measures and to identify the most effective implementation strategies.
Expert statements on Workshop 4

Alessandro Cassini, Expert Antimicrobial Resistance and Healthcare-associated Infections (ECDC), European Centre for Disease Prevention and Control, European Union

Estimating the impact of healthcare-associated infections (HAIs) is challenging due to the need for good quality data on the incidence of HAIs and on the co-morbidities of hospitalised patients. We estimated the burden, expressed in disability-adjusted life years (DALYs), of six common HAIs included in the 2011-2012 ECDC point prevalence survey (PPS) accounting for more than 2.5 million cases of HAI occurring in acute care hospitals in the European Union and European Economic Area (EU/EEA). The estimated cumulative burden (501 DALYs per 100,000 general population) was higher than the total estimated burden of 31 communicable diseases under surveillance at ECDC (BCoDE 2009-2013, 260 DALYS per 100,000 general population). The results were based on a subset of HAIs and only in acute care hospitals; when considering long-term care facilities, HAIs may double in number and consequently DALYs would also increase. Considering that half of the cases would be preventable through properly implemented infection prevention and control measures, the study indicates the need for increased efforts for their prevention and control.

Dr. Maryanne McGuckin, FSHEA, President, McGuckin Methods International, USA

Patient empowerment is increasingly recognized as an important component of hand hygiene empowerment strategies. Organisations must realize that patients and families are an important part of the healthcare team, and their involvement in hand hygiene campaigns should be encouraged. Healthcare providers should not see patient participation as a threat, but instead as another tool to improve patient care. Our research over the last 15 years showed that patient empowerment can lead to an increase in hand hygiene adherence. Patient empowerment encourages a safer health care environment and improves patient outcomes. Patients do not require extensive medical knowledge to successfully remind healthcare providers to perform hand hygiene. Patients can be empowered only after having gathered enough information, understanding how to use the information, and being convinced that this knowledge gives them shared responsibility with their healthcare workers. The single most important factor that must be included in empowerment models is “explicit permission” that is giving patients permission to ask their healthcare worker about hand hygiene. We should work to make patients and families more comfortable in participating in their care.
Permanent infection prevention and control (IPC) programs in hospitals in Chile can document impact in consistent reduction of the rates of infections between 18 and 70 percent, depending on the type of infection, in the last ten years. Targeted infections are those associated with invasive procedures (i.e. surgery), the use of permanent invasive devices (i.e. indwelling catheters) or are outbreak prone (i.e. C. difficile diarrhea). The hospital programs include: a) staffing of the IPC teams with trained doctors and nurses; b) an active surveillance system; c) IPC evidence-based guidelines; d) access to training resources and e) a system of external evaluation of the compliance of the local programs.

The Ministry of Health (MoH) generates the regulations for the mentioned components, disseminating national evidence based guidelines, and monitoring the local programs through several processes, mainly the results of surveillance and the results of the external evaluations that are performed under the instruction of the MoH.

Some aspects that we consider key to the success of the National IPC Program are: the leadership of the health authority, clear goals and targets, use of evidence for recommendations, focus on local needs, use of local data for interventions and the documentation of impact.

Sepsis is a response to infection and the final common pathway to death from most infectious diseases. Sepsis continues to cause more than 6 million deaths worldwide, every year. The majority of sepsis deaths are community acquired. Sepsis has a unique and time-critical clinical course which in the early stages is highly amenable to treatment through early diagnosis and timely and appropriate clinical management. Infections which may lead to sepsis can often be prevented through appropriate hand hygiene, access to vaccination programmes, access to improved sanitation and water availability and other infection prevention and control best practices. Its ill effects in terms of mortality and long term morbidity can be mitigated through early diagnosis and appropriate and timely clinical management. This makes sepsis the number one cause of preventable deaths. Therefore the 70th World Health Assembly adopted a resolution on sepsis that urges member states to develop training for all health professionals on infection prevention and patient safety, and the importance of recognizing sepsis as a preventable and time-critical condition with urgent therapeutic need and of communicating with patients, relatives and other parties using the term “sepsis”.
Workshop 5: Increased Safety of Diagnostics and Treatment – Checklists and Other Tools

Prof. Dr. Matthias Rothmund, Philipps University Marburg, Professor of Surgery emeritus, Germany

In 1975, Matthias Rothmund became Assistant Professor and later Associate Professor at the University Hospital Mainz, Germany. From 1987 until 2008, he was Chair of Department of Surgery at Philipps University Hospital in Marburg. Afterwards he served as Dean of the Medical School at the same University until 2013.

Prof. Dr. Tanja Manser, University Hospital Bonn, Director Institute for Patient Safety/Professor for Patient Safety, Germany

Tanja Manser is Full Professor for Patient Safety and Director of the Institute for Patient Safety at the University Hospital Bonn, Germany. She is a leading expert in Europe on team performance in healthcare and its relationship to patient safety.
Introduction

The key point of emphasis of this workshop was the topic of safety culture. In this context, examples – as they have been included in the brochure on best practices which was published in preparation of the summit – were used to show in a practice-oriented manner how safe action can be applied in medical care. In addition to international models of success (e.g. High 5s) and their adaptation to national health care systems, the implementation of checklists, the dissemination of recommendations for action and patients’ information, as well as the integration of the topic of patient safety in curricula of medical education were used as good examples.

Workshop Summary

This workshop focused on the safety culture. Ways to implement safe practices in healthcare were imparted through a mix of theory and practice. The focal point of the morning was on leadership and education, in the afternoon, on patient for patient and participation.

In general, it was noted that patient safety is not an “add-on” but has to be viewed as a “by-the-way” – in other words, it must be considered always and everywhere. Patient safety is not only important for inpatient treatment in the hospital. The importance of patient safety extends to all aspects of healthcare, therapeutic and diagnostic measures, and also to nursing. There are no generally applicable solutions to improve patient safety. Tailor-made, local measures always have to be defined. In the implementation of all measures, it is important to note that patient safety must have a positive connotation.

Professor Manser introduced the definitional framework of the patient safety culture in her opening speech and described the evidence linking the patient safety culture to treatment results. Here it became clear that to create and manage a safety culture is a leadership challenge.

Various learning approaches, all of them justified, exist for the development of patient safety: learning through feedback from colleagues, best-practice examples, or influences outside of healthcare, for instance from aviation or the energy sector. Regardless of the method, patient safety has to be implemented even more so in the syllabuses and curricula of all healthcare occupations.

The afternoon session began with three vantage points of integrating patient experiences and perspectives in the improvement of patient safety: patient participation in designing the legal frame-work of a healthcare system, patient participation in the organisation of healthcare facilities, and patient participation in the individual care process. The result unified these approaches: a comprehensive improvement of patient safety is only possible when patients, with their family members are systematically included as partners. Patients contribute aspects that health professionals do not recognise, and are the sole continuum in the entire treatment process.

The workshop ended with the presentation “Participation promotes culture” and the call to action:

Do not be satisfied with small successes – achieving a lot is not enough!
Expert statements on Workshop 5

Sonja Barth, Head of the Department of Health Policy, Berlin Chamber of Physicians, Germany

Patient safety, the prevention of adverse events, and strengthening safety culture is a common goal of all who are involved in healthcare. A key element in achieving this goal is patient safety competence – knowledge, skills and behaviour for patient safety. A whole range of internationally available curricula and frameworks provide concrete assistance in this regard.

Victor J Dzau, MD, President, National Academy of Medicine, USA

Getting the right diagnosis is fundamental to the delivery of high-quality health care: a diagnosis explains a patient’s health problem and it sets the stage for subsequent health care decisions. Unfortunately, diagnostic errors (inaccurate and delayed diagnoses) persist throughout all settings of care and continue to harm an unacceptable number of patients, sometimes with devastating consequences. Post-mortem examination research has shown that diagnostic errors contribute to approximately 10 percent of patient deaths. Diagnostic errors can be costly – unnecessary office and hospital visits, wrong treatments, unnecessary tests and procedures, readmissions and deteriorating health status. Diagnostic errors are the leading type of paid medical malpractice claims.

To address the problem of diagnostic error, the Institute of Medicine released a report in 2015, “Improving Diagnosis in Health Care”. The report is a serious wake-up call that we still have long way to go to improve patient safety. Urgent change is warranted to address this challenge. Improving diagnosis will require collaboration and a widespread commitment to change among health care professionals, health care organizations, patients and their families, researchers, and policy makers. Without a dedicated focus on improving diagnosis, diagnostic errors will likely worsen as the delivery of health care and the diagnostic process continue to increase in complexity.
Dr. Patrick Fraenkel, Head of Clinical Quality and Risk Management, Uniklinik RWTH Aachen, Germany

As a participant in the WHO High Fives project, the University Hospital RWTH Aachen first started with the implementation of a safe surgery checklist in 2010. In terms of the continual improvement process, an efficiency analysis was conducted after implementation. Here, potential for improvement was identified resulting in a revision of the checklist that mainly concerned a clearer structure and a more distinct assignment of responsibilities. The change process required good preparation, communication and monitoring. In addition it became apparent that the safe surgery checklist does not only affect patient safety, but also contributes to organizational development.
Dr. Peter Gausmann, CEO, GRB Gesellschaft für Risiko-Beratung mbH, Germany

Patient Safety Audits that are based on real-life damage and claims raise awareness among therapeutical teams. The findings of audits create ideal conditions for the insurance coverage of hospitals. The level of patient safety is measurable. Patient Safety Audits enhance the image of a hospital.

Dr. Günther Jonitz, President, Berlin Chamber of Physicians, Germany

Culture is the key! “Culture eats strategy for breakfast” (Peter Drucker). To create a better culture for patient safety it is essential to put patient safety in a positive frame and create an atmosphere of trust and common accountability. The German Coalition for Patient Safety (GCPS) brings people and institutions from everywhere in healthcare systems together. GCPS-working groups are providing tools to improve safety. The GCPS itself prevents scandalization and abuse. Leadership is essential. Therefore all leading institutions beginning from the Ministry of Health to patients’ organizations are taking action within the GCPS.

Solvejg Kristensen, PhD, MHSc, Post Doctoral Researcher, Aalborg University Hospital – Psychiatry & Aalborg University, Clinical Institute, Denmark

Currently most information for improvement of patient safety and quality of care is provided by health care professionals – the voices of the patients are not sufficiently asked for nor listened to. Methods facilitating a more equal balance of power, where patients can increasingly expect to be involved in co-designing and evaluating the functioning and effect of health care services at the individual as well as aggregated level are needed. Examples of ways of involvement are Patient Safety Executive Walk Around, Patient Peer Boards (Board of patients providing opinions, advice and experiences to specific problems and solutions) and use of Patient Reported Outcome Measures and Patient Reported Incidence Measures.
Patients are willing and able to participate in error prevention. Their feedback is reliable and provides additional information that cannot be retrieved from other sources. In order to participate effectively they need information, support and encouragement from health care professionals.

Main areas of concerns from the patients’ perspective are:
- communication, mainly with doctors but also with other health professionals,
- involvement in care,
- and care coordination (especially transitions).
Workshop 6: Safety of Medication Therapy

Prof. Dr. Wolf-Dieter Ludwig, Chairman, Drug Commission of the German Medical Association (DCGMA), Germany

MD and PhD, with degrees for specialisation in Internal Medicine, Transfusion Medicine and Hematology/Oncology. From 2001 until August 2017, Medical Director and Head of the Department for Hematology, Oncology, Tumor Immunology and Palliative Care at the HELIOS Clinic Berlin-Buch. From 2006 to the present, Co-editor of “DER ARZNEIMITTELBRIEF” (ISDB), and Chairman of the Drug Commission of the German Medical Association. From 2013 to the present, member of the Management Board of the European Medicines Agency as a representative of DCGMA.
Introduction

The aim of the workshop “Safety of Medication Therapy” was to consider safety when dealing with medicinal products with particular regard to demographic change. Especially in the elderly, medication errors and adverse drug events are common. Therefore, preventive measures were discussed, to avoid medication errors, particularly among this group of patients.

Workshop Summary

In the first lecture, Professor Ludwig presented the main results of the German Action Plans for Medication Safety. These are provided by the Federal Ministry of Health since 2008. One of the main results of the Action Plans for Medication Safety is the development of the nationwide medication plan. Professor Martin Schulz explained the medication plan in detail and underlined the importance of the plan in context of safety of medication therapy. In her talk on Medication at Transitions in Care, Ms. Ciara Kirke called for a better medication process (e.g. best possible medication history, medication reconciliation), better information (e.g. interoperable electronic systems, shared record, standardised forms), restructure and invest (e.g. investment in human resources, IT and process change). She pointed out that the optimisation of the medicines process lead to benefits to patients in terms of morbidity and mortality in addition to a reduction in healthcare resource utilisation. Dr. Norbert Paeschke referred to risk communication as a tool to minimize associated risks of drug treatment and to avoid medication errors. Finally, Professor Daniel Grandt pointed out that we can only achieve medication safety if we do not consider it as one of several competing priorities, but as a precondition of providing care.

As a result of the discussions, the following core messages were prepared

1. Better information of patients and health professionals about medication therapy. All patients with multi-medication need a current medication list. The medication list must be understandable.

2. Establishment of an organisational framework to ensure the quality of the medication list and the best possible use. All drugs (prescription drugs and non-prescription drugs) taken by the patient should be periodically reviewed for possible medication risks.

3. To avoid medication errors, adequate staff and equipment must be provided. This applies to outpatient and inpatient care as well as to the interfaces of both sectors.
There are several critical success factors for medication safety. Patients suffer harm from preventable adverse drug events. Prescribing errors are most relevant. Contributing factors are (1) missing information on patients, (2) not applying established knowledge on drugs, (3) failure-prone treatment processes. Therefore:

1. Risk-awareness and risk-attitude have to be improved
2. Medication safety must be defined a precondition of care: Preventable harm is often due to competing goals that can only be reached by ignoring safety rules. German law (SGB V) should explicitly state: the patient’s right on medication safety, the healthcare provider’s responsibility to guarantee medication safety, and the health insurance company’s task to support both of them.
3. Drug treatment processes must be analysed to detect uncontrolled risks and to redesign processes for resilience. Failure-Mode-and-Effect-Analysis should be mandatory.
4. A mandatory systematic yearly drug therapy review has to be implemented: The medication plan is necessary but not sufficient for medication safety.
5. Measuring medication safety has to be part of routine quality control measures.
6. National coding systems for drugs, ingredients, dosing, and lab test results have to be defined interoperable.
Every day, a large burden of medication discrepancies and harm affects patients at transitions between healthcare settings. Achieving medication safety at transitions involves:

1. Better processes: Medication reconciliation (med rec) at each transition, i.e. building the Best Possible Medication History (BPMH) by interviewing the patient, verifying with at least one reliable information source and returning to the patient, then reconciling with current prescriptions, changing where necessary and communicating the revised list and changes. Encouraging patients to actively participate and understand their medication and keep a medication list is essential. The strongest evidence base is for med rec with intensive pharmacy involvement.

2. Better information: Up-to-date and accurate shared medication record (patient-held list, paper, electronic) and communication across transitions.

3. Restructuring and investing: Achieve known return on investment and efficiencies by investing in the appropriate skill mix and in process change which may include information technology.

A quality improvement approach, with measurement to track progress, is needed to tailor models to local context and ensure delivery of safe, effective, efficient, timely, equitable and patient-centred improvement.

Identified as a relevant patient safety indicator, a National Medication Plan (MP) was developed within the context of the Action Plans for Medication Safety of the German Federal Ministry of Health. The MP is a printable document for the patient that clearly lists his or her complete medication (Rx and OTC) in a standardized format. It specifies the active ingredient, trade name, strength, dosage form, dosing regimen, application information, and the medical indication for each drug.

Recent studies showed, however, a high potential for discrepancies in the different medication records and evidence for a compromised patients’ comprehensibility of the MP. The MP shall facilitate the correct administration and avoid medication errors with the aim to improve medication safety and effectiveness eventually. A comprehensive approach utilizing prescription, dispensing and claims data, performing a structured medication review, developing a consolidated MP between physicians and pharmacists and counselling, as well as monitoring patients is considered necessary to achieve this goal.
Global Launch: Global Patient Safety Challenge – Medication Safety

Prof. Sir Liam Donaldson, WHO Envoy for Patient Safety, World Health Organization, Switzerland

Liam Donaldson was the foundation chair of the World Health Organization’s World Alliance for Patient Safety, launched in 2004. He is the World Health Organization’s Envoy for Patient Safety, Chairman of the Independent Monitoring for the Global Polio Eradication Programme, as well as Chairman of the Transition Monitoring Board of this Programme.

Dr. Neelam Dhingra-Kumar, Patient Safety and Quality Improvement Unit, Service Delivery and Safety Department, Coordinator, World Health Organization Headquarters, Geneva, Switzerland

As Coordinator for the Patient Safety and Quality Improvement Unit at WHO headquarters in Geneva, Dr. Neelam Dhingra-Kumar leads WHO’s efforts at providing strategic leadership on patient safety and quality improvement and strengthening system for safety and quality of health services globally.
Introduction

Patient harm resulting from unsafe medication practices and medication errors is a universal issue. It can have a profound, life-altering impact on patients, families, carers and health professionals everywhere, from rural pharmacies to urban hospitals. Many countries lack data about medication safety, which makes it difficult to design solutions to prevent harm. High-income countries are more likely to possess robust medication safety systems than low-income countries where resources are scarce. However, errors still occur frequently in areas with sound medication safety infrastructure, indicating that focused efforts to improve medication safety may diminish the threat, but have been unsuccessful at eliminating it. A systems approach is needed to build a safety net to catch errors before they reach the patient and more importantly, prevent them from occurring, rather than relying solely on the actions of individuals.

The expected outcome of this workshop was to illustrate the need for a Global Patient Safety Challenge on Medication Safety, provide an overview of the Challenge and outline intended actions to initiate strengthening of global medication systems. The Challenge serves as an opportunity to concentrate efforts on the development and implementation of safe medication practices with patients and their caregivers, health professionals, international experts, policymakers and key stakeholders in academics and industry in patient safety and medication safety.

Workshop Summary

WHO has successfully led two global patient safety challenges in the past, "Clean Care is Safer Care", followed a few years later by "Safe Surgery Saves Lives". The "Third Global Patient Safety Challenge Medication Without Harm" has the goal to reduce severe avoidable medication-related harm by 50 percent, globally in the next five years, was formally announced at the second Global Ministerial Patient Safety Summit at Bonn, Germany. Many participating countries expressed their commitment to participate in the challenge.

Prof. Phillip Routledge from the All Wales Therapeutics & Toxicology Centre talked about the need to focus on the people, the external environment and the medications when addressing the high-risk situations. He highlighted the 7 C aspects of prescription safety as well as the need to have formal assessment of safe prescribing habits as done by the British Pharmacological Society and UK Medical Schools Council. Similarly, a renewed focus on high risk medications (A-PINCH) – Anti-Infectives, Potassium, Insulins, Narcotics, Chemotherapeutic agents and Heparins & Anticoagulants, should be initiated by standardising many of the processes of medication prescription, dispensing, administration and consumption. Ms Alpana Mair, Head of Prescribing & Therapeutics of the Scottish Government, highlighted the problems of increasing polypharmacy associated with multimorbidities of the aging population. She talked about the need to assess the patient and a multidisciplinary evaluation, and share the six steps of national programme guidance on polypharmacy: What matters to the patient; Identify essential medicines; Does the patient take unnecessary medicines; Are therapeutic objectives being achieved; Is the patient at risk of side effects; and Is therapy cost-effective? Another initiative under trial at ten sites across Europe is the Stimulating Innovation Management of Polypharmacy and Adherence in the Elderly (SIMPATHY) that is joining clinicians and policy makers to adopt and share innovative best practices.

Dr. Allen Vaida from Institute for Safe Medication practices (ISMP) presented the key causes of medication errors and strategies for improvement. He emphasized the need for comprehensive medication history, reducing polypharmacy as well as engaging patients. He shared numerous examples of similar sounding medications with confusing labels. ISMP has helped guide many regulatory
changes across the world by implementing improvement strategies with the involvement of regulatory authorities, government and industry.

Prof. Priyadarshani Galappatthy from Sri Lanka discussed the global burden of unsafe medical care and the lack of systems to promote medication safety in low- and middle-income countries (LMIC). Poor illegible prescriptions, lack of standardizations, counterfeit medicines, poor reporting and learning systems, along with a severe lack of trained clinical pharmacists are some of the major issues faced by providers in LMIC.

Ms. Maryann Murray, a Patient Champion from the Patients for Patient Safety Canada shared a heart-breaking experience about how her daughter succumbed to a medication error because of a system failure. She emphasized the need to understand that there is a human behind every medication consumption and engaging them is one of the most important things, healthcare systems can do. She also encouraged providers and systems to acknowledge the errors and learn from them to improve the system.

Dr. Neelam Dhingra-Kumar presented the WHO’s Action plan of the third Global Patient Safety Challenge on Medication Safety. She focused on the need to provide global leadership, policies and strategies, and facilitate sharing of best practices. She highlighted the need to update and implement medication safety curriculum in undergraduate and postgraduate healthcare workers. Similarly, she drew attention to the recently published WHO Technical Series on Safer Primary Care that discusses the medication errors in the ambulatory setting.

After the presentations, Sir Liam Donaldson, WHO Envoy for Patient Safety, formally launched the third Global Patient Safety Challenge with the goal “to reduce the level of severe, avoidable harm related to medications by 50 percent over five years, across the world”. The global launch created a big momentum in the participants, and was strongly supported by the participating countries during the Ministerial Summit.
Prof. Dr. Priyadarshani Galappatthy, Professor and Head of Department of Pharmacology, Faculty of Medicine, University of Colombo, Sri Lanka

Medication safety is a major concern contributing to patient safety particularly in resource-limited settings (RLS). Absence of reliable estimates of prevalence of adverse drug events, costs involved, causes of medication errors, and evidence of effective interventions in RLS is a major limiting factor. Some key problems identified include lack of safety culture, reporting systems, poor reporting, absence of electronic support systems, limited healthcare professionals to serve large numbers of patients, lack of clinical pharmacy services, availability of counterfeit, substandard and large number of generic products, and poor medication literacy of patients.

A multidisciplinary approach with involvement of all stakeholders is needed in preventing medication errors, with identification of epidemiology and causes of adverse drug events in RLS, their severity, amenability for prevention, implementing a stringent national medicines regulatory framework with routine quality testing of medicines. Developing and implementing an individualized action plan for each country for the problems identified based on local data would be the key to ensuring medication safety in RLS.

Alpana Mair, Head of Prescribing and Therapeutics, Scottish Government, United Kingdom

Polypharmacy is the routine use of four or more over-the-counter, prescription and/or traditional medications at the same time by a patient. Polypharmacy has increased dramatically with greater life expectancy and as older people live with several chronic diseases. Polypharmacy increases the likelihood of side effects, as well as the risk of interactions between medications, and may make adherence more difficult. If a patient requires many medication, they must be utilized in an optimal manner, so that the medicines are appropriately prescribed and administered, to ensure that they produce direct and measurable benefits with minimal side effects. Inappropriate polypharmacy can contribute up to 6 percent of all hospital admissions globally. The standardisation of policies, procedures and protocols is critical to polypharmacy. This applies from initial prescribing practices, to regular medication reviews. Patients can play a vital part if provided with the right information, tools and resources to make informed decisions about their medication. Technology can also serve as a useful aid.
Maryann Murray, Volunteer, Patients for Patient Safety
Canada, Canada

Through the lens of one patient experience, medication safety was examined and gaps in the system were outlined. I spoke of the fatal medication reaction suffered by my 22 year old daughter Martha. Errors and communication failures that led to Martha’s sudden death as well as subsequent cover-ups and eventual actions taken to improve medication safety on a national scale were discussed.

Three steps to improve medication safety were detailed:
1. Changing the culture to one of transparency to allow for better communication and shared learning.
2. Helping patients take a more active role in their medication safety. Patients who understand the importance of communication, like sharing medication lists with providers, knowing how to take medication correctly and understanding potential side effects, can help protect against medication harm.
3. Reporting when harm occurs. Effective reporting systems have high compliance rates, transparency and significant feedback.

Harm statistics represent real people who have been harmed. The WHO Global Medication Challenge, with the help of governments, providers and patients, will reduce these incidents of harm and save lives.

Dr. Allen J. Vaida, Pharm.D, BSc, Executive Vice President,
Institute for Safe Medication Practices, USA

An important cause of medication errors on an international level involves medication nomenclature, labelling, and packaging. This includes ambiguous displays of concentration and strength, lack of warnings on vials and ampoules, and lack of universal bar codes. Additionally, it includes the unavailability of commercially prepared intravenous admixtures or government refusal to obtain such due to cost. This leads to nurses preparing intravenous medication on the patient care units without proper training in less than ideal infection control conditions. There have been some strides made with packaging and labelling in many countries, but there is still more that can be done, especially in the way of harmonization. Parenteral products in many countries are packaged as ampoules versus vials. There is difficulty in reading labels on ampoules with leading to mix-up between drug products. Fifteen children in Syria died in 2014 when a mix-up between ampoules of sterile water and a neuromuscular blocking agent were used to dilute measles vaccine. At a minimum, neuromuscular blocking agents must contain a warning noting “Paralyzing Agent” in accordance with the United States Pharmacopeia (USP) standards. Promoting harmonization between regulators should be one focus of the WHO Global Challenge on Medication Safety.