WHO Inter-regional Consultation on Patient Safety Incident Reporting and Learning Systems in Africa and the Asia Pacific Regions

22-24 March 2016, Colombo, Sri Lanka

Jointly organized by WHO headquarters and WHO SEARO, with support from the Governments of Japan and Sri Lanka

Meeting Report
WHO/HIS/SDS/2016.21

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1. Executive Summary

The Inter-regional Consultation on Patient Safety Incident Reporting and Learning Systems in Africa and the Asia-Pacific Regions, was held on 22-24 March 2016 in Colombo, Sri Lanka. The consultation was jointly organized by WHO headquarters and the WHO South-East Asia Regional Office (SEARO), in collaboration and with the support of the Governments of Japan and Sri Lanka.

The event was attended by representatives from 18 countries: Afghanistan, Bangladesh, Canada, Ethiopia, Ghana, India, Italy, Japan, Malaysia, Morocco, Nigeria, Oman, Philippines, Poland, South Africa, Sri Lanka, Thailand and Vietnam, and two WHO Regional Offices (Eastern Mediterranean and South-East Asia). This was organized as a platform for presenting international experiences and discussing the role of reporting and learning systems (RLSs), considered essential for improving patient safety and the quality of health care. Particular attention was given to resource-limited settings and how RLSs could become operational, for improved patient outcomes and economies of scale.

Structured in four parts, the consultation a) reviewed patient safety success stories at global, regional and national level, b) provided input for the revision of the WHO Implementation Guidelines on Patient Safety Incident Reporting and Learning Systems, through structured discussions, c) reviewed the results of the Minimal Information Model for Patient Safety Incident Reporting and Learning Systems (MIM PS) regional pilot exercise, and d) examined best practices to analyse collected data and enhance useful learning from reporting safety incidents.

The lessons derived from this exercise were formulated into strategic recommendations to develop, implement, support and strengthen patient safety RLSs, as quality and safety surveillance tools and a source of shared knowledge for better care, which is foundational to patient safety strategies.

Recommendations formulated by participants from national health authorities requested the establishment of effective and sustainable national RLSs, drawing on a strong safety culture, increased awareness of a patient safety and quality improvement approach, and well-trained staff. The legal and regulatory framework in force, national dedicated guidelines, standards and tools, should help to ensure feasibility and support implementation.

Leadership and training at all levels is needed, including appropriate training for reporting, data collection, analysis and dissemination.

Global and regional level recommendations stressed the importance of leadership, policy development and partnership in moving forward the patient safety agenda.

WHO’s role was seen as vital in this process by producing and providing specific guidance and support to reporting and learning systems (RLS) development and implementation. This work includes finalization of the WHO Draft Guidelines for Adverse Event Reporting and Learning Systems currently under development, continued use of the MIM PS as a simple tool for RLS and the WHO multi-professional Patient Safety Curriculum Guide, as well.

Participants proposed initiating a new World Health Assembly resolution on achieving universal health coverage with a special focus on quality of care and patient safety, with the establishment of a World Patient Safety Day.
2. Introduction

Improving access to meaningful care is closely dependent on how the health care system performs in terms of safety and quality of services. Patient safety incidents resulting from health care system deficiencies continue to bear an important toll on health outcomes and expenditure. RLSs are an important surveillance and awareness-raising tool which assess how health systems are performing. They provide the necessary information to develop corrective actions and prevention strategies. Additionally, they serve as a good educational tool for building a better understanding on the team approaches and coordination required to protect the safety of patients. Implementation and adherence to RLS depend on many local factors, in which legal and regulatory aspects as well as the existing safety culture play a vital role.

The inter-regional consultation was organized as an international platform for presenting and discussing experience and role of reporting and learning systems for patient safety and quality of care, and examine the best practices to enhance useful learning from patient safety reporting systems, with emphasis on resource-limited settings. The consultation brought together representatives from countries participating in the MIM PS field piloting, countries with RLS in different stages of development, and other local and international experts in the field of patient safety and quality improvement. Representatives from 18 countries: Afghanistan, Bangladesh, Canada, Ethiopia, Ghana, India, Italy, Japan, Malaysia, Morocco, Nigeria, Oman, Philippines, Poland, South Africa, Sri Lanka, Thailand and Vietnam, and two WHO Regional Offices (EMR and SEAR) attended the event.

3. Meeting Proceedings

The inter-regional consultation was part of a global project focused on strengthening patient safety and quality of care, through shared experience, and the development and implementation of efficient reporting and learning systems, co-funded by the Government of Japan. The meeting was structured in seven parts, with an inauguration session and six technical sessions.

3.1 Inaugural Session

The event opened with the Sri Lankan National Anthem, and lighting of the traditional burner. Participants were welcomed by the representative of Sri Lanka Ministry of Health, Dr L. Siyambalagoda, Deputy Director-General, Public Health Services, who underlined the long-standing and successful collaboration between Sri Lanka and WHO.

The representative of the Japanese Ministry of Health, Labour and Welfare, Dr Shin Ushiro, Japan Council of Quality for Healthcare, in his welcome address, similarly underlined the long history of support and collaboration between the Japanese Government and WHO in the field of quality and safety improvement. He emphasized that the experience brought and shared by attendees of the meeting would add valuable insights towards implementation of national RLS.

The WHO Representative for Sri Lanka, Dr Arturo Pesignan, in his welcome note, reflected on the magnitude of the problem, and the fact that most countries share common quality and safety challenges, even if the scale may differ. The shared experiences and the expert input from meeting participants in the finalization of WHO dedicated RLS guidelines would fall on fertile ground for building on previous WHO work and support inter-country collaboration.
Dr Neelam Dhingra-Kumar, Coordinator of the Patient Safety and Quality Unit at WHO headquarters, stressed the importance of RLS in correcting the breakdowns of the system and strengthening patient safety and quality of care, and introduced the objectives of the event. The inter-regional consultation aimed to foster information exchange on field experience in implementing reporting and learning systems, obtain input for the WHO Implementation Guidelines on Patient Safety Incident Reporting and Learning Systems under development, review the results of the minimal information reporting format (MIM PS) usability as a tool for broader use and field adaptation, and review methods of data analysis pending on context and investigation capacity. Stemming from the three days discussions, a number of strategic recommendations will be developed to further enhance reporting and learning for patient safety.

The event was chaired by Dr L Siyambalagoda, Deputy Director-General, Public Health Services, Sri Lanka Ministry of Health. Each technical session had a dedicated Chair (see Annex 1: Programme of Work).

**Keynote speech: The patient safety journey in Sri Lankan hospitals**

Sri Lanka spends 3.4% of its GDP on health, which corresponds to yearly health expenditure of US$ 119 per person (2014 data). Health care facilities are spread across the country to ensure access within a 3 km radius for every inhabitant. Historically, work focusing on health care quality and safety in Sri Lanka started in 1989 and was strengthened in 2000. Progress was steadily recorded and the policy of health care quality and safety was developed 2012. The Care Quality Improvement programme is centrally driven, locally led, clinically oriented and patient centered. The roadmap for quality improvement (total quality management) went through five phases, with deep roots in stakeholders’ attitudes. Strategic directions have been developed around seven key result areas: patient satisfaction, managerial systems and process improvement, clinical effectiveness, risk management and safety, establishing a culture for quality improvement, staff development and welfare and research for quality and safety. The institutionalized programme was supported by clinical and national guidelines for quality and safety and sustained work on developing a quality and safety culture. The manual for master trainers in health care quality and safety advanced local capacity. Surveillance mechanisms including reporting of adverse events and 23 mandatory indicators were established. As a result, infection rates were reduced, and quality of care was improved, including a reduction in waiting times. The accreditation council was recently formed. Several low-cost initiatives to strengthen patient safety (e.g. visual control scene, colour coding system) were implemented. An environmentally-friendly initiative was started to ensure clean hospital environments. Sri Lanka has provided training for staff in 35 countries in Asia and Africa on these initiatives. The motto in use has been ‘Patients are safe in our hands’.
3.2 Session 1: Advancing the patient safety and quality of care agenda across the world

Roundtable – Global and regional overview on patient safety and quality improvement, and reporting and learning systems

The session provided an overview of current progress in patient safety and quality of care globally, through WHO’s lens.

Global overview on patient safety and quality improvement journey

The magnitude of the patient safety problem (e.g. 1 in 10 patients harmed, 14 out of 100 patients affected by health care associated infections) promoted action at global level. WHA55.18 resolution on Quality of Care: patient safety prompted the initiation of the World Alliance for Patient Safety and WHO patient safety programme. WHO has provided leadership and strategic directions in matters critical to safety, by enhancing global awareness, developing guidance and tools, fostering collaboration and best practice networks to support translation into practice of this work. The first Global Patient Safety Challenge ‘Clean Care is Safer Care’ focused on hand hygiene and preventing health care associated infections. The second Global Patient Safety Challenge ‘Safe surgery saves lives’ promoted the WHO Surgical Safety Checklist. The next Global Patient Safety Challenge dedicated to medication safety will be launched in 2017. Multiple interventions were designed and supported in their field implementation, through political and technical advice, supported by effective collaboration. The best practice for patient safety and quality network that was initiated following the Oman hosted meeting earlier in February is a good example of fostered information exchange and cooperation. The Patient Safety Global Summit organized by the United Kingdom in March, and the WHO Global Consultation on Patient safety to follow in Italy in September are awareness raising mechanisms for enhanced commitment to the global patient safety movement. Empowered patients receiving safe and quality care from competent professionals in conducive environments with measured outcomes constitute the vision of WHO’s dedicated work.

Patient safety in the Eastern Mediterranean region: Current situation and perspectives

The regional patient safety strategy is being developed around five axes built around the quality improvement cycle, to enhance the safety of patients and services. The 22 countries of the region are highly diverse, and each intervention has to be customized to context. Up to 80% of hospital admissions are associated with harm, with a 62% preventability rate, based on a recent prospective study. Medication safety is also a real problem in the Region. The Patient Safety Assessment manual and toolkit is one of the tools developed to help identify the causes of the problem. The Patient safety friendly hospital initiative is promoting harmonized standards (updated to cover patient safety) and a team approach for improvement. Implemented in three phases, it reached 14 hospitals, in both the public and private sectors. It is not yet institutionalized (due to equivocal commitment). Work on the institutionalization of patient safety and quality improvement interventions appears to have the required legal and regulatory background in place, but supportive structures (including staff) lag behind. A tool to assess quality and safety and primary care level (34 core indicators) was developed and piloted. A meeting on health care accreditation will follow in December 2016. Work on patient engagement and education is progressing, particularly through the WHO Patients for Patient Safety network. Interventions are developed and deployed transversally between technical areas to support in a sustainable manner patient safety and quality of care as a cross-cutting theme.
Regional overview on patient safety: South East Asia Region

The Region counts 11 countries, many with dense populations, more than 20 official languages (over 700 dialects in India) and an average spending on health of 3.7% of GDP (between 1.4 and 11.4) reflected in a wide diversity of health systems. Several resolutions were issued over the last 10 years, promoting quality and safety in health care, and SEA/RC/RS Patient safety contributing to sustainable universal health care was endorsed in 2015. Major regional initiatives focused on building capacity of human resources for health. The WHO Patient Safety Multi-Professional Curriculum Guide was tested and adopted in Bangladesh, India, Sri Lanka and Thailand. The SEAR Medical Council Network recently endorsed the curriculum to be introduced in all medical schools. A dashboard patient safety assessment tool developed for regional purposes was recently piloted in Sri Lanka. The Regional Strategy for Patient Safety was developed and adopted during the Regional Committee in 2015. The Regional Plan 2016-2020, including cross sectional approach to patient safety and quality of care, is being developed for universal access to health care through people centered integrated health services. Prevention of health care associated infections is an important focus area. The regional framework covers all levels of care, and has four pillars: service delivery infrastructure, human resources, information and evidence, and experience sharing and network, with multiple interventions planned for each pillar.

Discussion: Several issues were raised following the three presentations, and comments were grouped according to topic, for a better overview of emerging considerations.

A fair safety culture was considered a critical issue for establishing effective RLS and ensuring staff adherence to reporting procedures. Building trust between partners is important, through documentation support and assistance for improvement. A non-punitive approach is required to foster RLS and to ensure that the system is used for learning purposes and not for retaliation. Without leadership commitment, the system will reduce learning and focus on reporting only. The primary care level and the private sector also require increased attention for implementing effective RLS. To ensure these issues are correctly addressed in context, wider consultation at national level should be foreseen.

The multi-professional Curriculum Guide in the South-East Asia Region underwent a step-wise process of endorsement. The Councils are the strongest regulatory body of medical professionals responsible for licensing; there are also several nursing councils. The curriculum was already endorsed for medical schools. The WHO Multi-Professional Patient Safety Curriculum Guide was adapted to local requirements. This process was undertaken by several countries/regions and does not necessarily require many funds. Innovative approaches, shared knowledge and collaborative centers can help in shaping the existing materials to local needs. The use of networks, as an information sharing lucrative mechanism should be maximized. There are several networks operating at various levels in EMR and SEAR, as well as in other WHO regions.

Ministries of Health must provide leadership to ensure that key initiatives building required levels of awareness and knowledge for patient safety and quality improvement are implemented.
3.3 Session 2: Importance and relevance of patient safety incident reporting and learning systems

WHO Guidelines for Adverse Event Reporting and Learning Systems An introduction to the WHO Guidelines for Adverse Event Reporting and Learning Systems under development was provided, starting with the fact that RLS represents a corner stone of safe health care practice. By helping to identify hazards, RLS targets improvement, and can lead to harm reduction and more efficient use of health expenditure. WHO has been considering the relevance of RLS to safer systems and patient experience. Specific guidance for RLS, which builds on the 2005 draft guidelines for adverse event reporting and learning systems for patient safety is currently being developed by the WHO Envoy for Patient Safety, Sir Liam Donaldson. The guidance is complemented by a minimal information model (MIM PS) for reporting systems, which builds on the 2009 WHO Conceptual Framework for the International Classification for Patient Safety. The guidance under development responds to Member States’ interest and need to implement effective patient safety measures, and aims to advance RLS implementation and improvement irrespectively of setting or context. Successful RLS are built around four core principles: enhanced learning, protection of reporter from retaliation, meaningful analysis of collected data, extraction of learning and dissemination. The country experiences in the field and the dedicated group work session that follow will provide direct input to this important work in progress.

Key findings and recommendations on RLS across Europe

The European Union (EU) promotes a value-based approach to health, committed to universality, good quality care, equity and solidarity. There are major differences in terms of health status and effectiveness of health care systems across its 28 member states. The Expert Group on Patient Safety and Quality of Care of the European Commission brings together representatives from the 28 countries, representatives from major health care organizations and groups of experts in health. It has several sub-groups. Its sub-group on RLS issued, in 2014, a report on the state of RLSs in Europe.

The report reviewed mandatory and voluntary reporting systems co-existing in the EU. It recognized the challenges raised by weak safety culture and the need for regulations to promote and ensure sanction free reporting and clear rules of confidentiality. It recommended for RLS to be separated from formal complaints and disciplinary actions, so that learning from error and system improvement are enhanced. A mechanism to capture data, defined reporting forms and a consistent taxonomy to facilitate comparison between providers were considered to be part of an effective RLS. Reports should be systematically reviewed with feedback mechanisms in place, to promote learning and preventive recommendations. All staff should understand the benefits of reporting and be able to report. Patients and families should be encouraged to contribute in RLS and system improvement processes. Establishing effective RLS requires technical infrastructure hence adequate resources and the training and education of users. The development of web based platforms to share data and knowledge gained were recommended. The EU Joint Action for PSQC that developed into the EU network for PSQC are such information sharing mechanisms.

Country experiences/initiatives: National, subnational or institutional patient safety incident reporting and learning systems

National representatives from Japan, Malaysia, Oman, Poland, South Africa, and Thailand presented short case studies on RLS initiatives (various levels of data aggregation). A private sector experience on
implementing RLS in India, the launch of a macro-vigilance programme, complemented these presentations.

A report from Japan

Japan has developed a nationwide investigation and prevention system for medical accidents of a (quasi) public nature, coordinated by the Japan Council for Quality of Health Care (JQ). The chronology of development and implementation includes an adverse event reporting system for medical institutions (2004), a reporting system for community pharmacies (2008), the Japan obstetric compensations system (2009) and the recent investigation system of accidental deaths (2015). The WHO Draft Guidelines for Adverse Event Reporting and Learning Systems were used as a baseline in the development of these initiatives. The hospitals are mandated by the Ministry of Health, Labour and Welfare to have internal reporting systems, and reporting (web based and/or on-site voluntary surveys) is mandatory for teaching hospitals, and voluntary for other health care institutions. Reports are collected and aggregated for statistical analysis at national level by the JQ. Cases deemed particularly important are evaluated individually. JQ produces annual and quarterly reports that are released with a press conference and disseminated to health care providers and the public. Medical safety information is produced as monthly alerts with nationwide dissemination. JQ conducts training programmes for the understanding of patient safety and RLS. Facebook is also used as a means for distribution of knowledge. As a result of the growing patient safety culture, the nationwide adverse event reporting system is widely utilized in the Japanese medical society (an increasing number of reports recorded in the national database), serving as a valuable resource for health care services and quality of care improvement.

The Malaysia Ministry of Health incident reporting and learning systems

RLS development started in Malaysia with local initiatives that evolved nationally. RLS started in 1998 in Ministry of Health hospitals. Dedicated policies (1998) underwent subsequent revisions in 2013 and 2016. The private sector regulations enforcing RLS were issued in 2006. Incident reporting is part of the 13 national patient safety goals since 2013, and part of the fourth edition of the Malaysian Accreditation Standards. The national RLS subsequently applies to all health care settings with a standardized approach. Public hospitals abide to 29 mandatory reportable incidents, while health clinics, public or private, have 10 mandatory reportable incidents. Reporting is confidential, non-punitive and independently assessed. Electronic reporting was introduced in June 2015. Root cause analysis (RCA) is performed using a system approach to improvement, and standardized template. Periodically, feedback is provided to implementers through the National Report available on the Patient Safety Council Malaysia website. Dedicated training and tools (Incident RLS manual and Incident Reporting RCA manual) are in use. Limited resources, limited awareness on incident reporting and weak patient safety culture are part of the challenges faced in implementing RLS. The lack of information technologies in some private health care facilities makes reporting more difficult.

Strengthening the sharing and learning component is part of the strategy to support RLS implementation, training and more comprehensive information technology systems that include the private sector. A series of national investigation reports, safety alerts and seminars are foreseen as part of the awareness raising mechanisms with wider coverage, aiming to build understanding and increase adherence to RLS as a system improvement mechanism.

Adverse event reporting and learning systems, Oman

The Sultanate of Oman has a national RLS that aims to foster an environment for safety; a system that is non-punitive and focused on preventing and correcting system failures. The policy and procedural system set up were developed in 2009, using the WHO Draft Guidelines for Adverse Event Reporting and Learning Systems. An updated taxonomy for incident reporting was made available in 2012. Reports are anonymous and submitted electronically. Information submitted is comprehensively analysed to identify actions to minimize reoccurrence of risks. Safety alerts are being issued periodically resulting from the
analysis of the reports. The development of a web-based portal to facilitate monitoring of compiled data might be considered.

There are several layers of responsibility in the system that include the reporter (knowledgeable of the event), the system administrator (agreed by the quality manager and patient safety department), the event manager (appointed quality assurance staff responsible for report review) and the supervisor that follows on the occurrence of reported incidents. The introduction of the electronic RLS (fostering confidentiality) led to an increase of reports received. The challenges to consider include the need for a more structured approach to data analysis, sustained follow up on the development of preventative action plans in the system as well as supporting better knowledge of the medical and public communities on the role of RLS, fostering the just culture for safety and quality of care.

**Reporting and Learning Systems in Poland**

Poland has a long history of solidarity movements, which began in 1980. The National Centre for Quality Assessment in Healthcare (NCQA), founded in 1994, currently in the process of re-designation as a WHO Collaborating Centre, provides technical support both on national and international level. Its main function is the accreditation of health care facilities. Its work includes evaluation of high specialty procedures and assessment of emergency departments, patient and staff opinion surveys and the national ranking of hospitals ‘Safe hospital’. It also runs patient safety programmes (surgical safety checklist, hand hygiene), quality indicators projects and organizes education and training in quality for healthcare professionals, managers and teams. Its ‘Quality in Healthcare’ conference is an important annual event. The Polish accreditation system started in 1998 regulated by law. It is based on the Joint Commission International healthcare standards, and is voluntary. It follows a three year accreditation cycle (based on min 75% compliance with standards), endorsed by the Ministry of Health. Adverse event reporting is part of the accreditation standards, hence mandatory in accredited institutions. Recorded adverse events include patient falls, equipment failures, patient aggression, suicide, and elopement. Only few incidents relating to clinical practice and almost no medication errors are reported, reflecting a lack of confidence of health care staff in the system, and weak leadership for patient safety.

The new law on quality and safety includes accreditation, the development of clinical registers and the implementation of national and hospital reporting and learning systems. Sustained efforts should be focused on developing an informed reporting and learning culture that is just, and promotes continuous improvement of patient safety and quality of care.

**Developing a national policy to manage patient safety incident reporting for the public sector in South Africa**

Access to health care is stated in the Constitution of the Republic, and the health system framework is regulated through the National Health Act 61/2003. The Office of Health Standards Compliance (2013) monitors quality of care nationally. The National Health Insurance supports universal health coverage. The development of a national policy to manage patient safety incident reporting was initiated following the audits performed by the Office of Health Standards Compliance showing an average score of 35% conformity on standards relating to management of patient safety incidents, and a lack of a uniform RLS. The development of the national policy drew from collected information on practices for patient safety incident management in the nine provinces of the country, used WHO guidelines and documents for RLS (including the MIM PS) as technical references, and several consultation processes with stakeholders were held to build ownership and agreement. Convincing the provinces that a national RLS is needed, and the RLS culture in general, were the main challenges to overcome in this process.

The first draft version of the national RLS policy for was submitted to wide consultation, including WHO and inputs received incorporated. The second draft was also widely reviewed, (including WHO) and will be completed following the present workshop. This will be submitted for approval to the National
Health Council. Implementation will be supported by the development of guidelines for standard operating procedures for hospitals and primary care facilities and a web based software, and will be rolled out in all nine provinces of the republic.

**Thailand’s experience: Patient safety incident reporting and learning systems**

Studies of adverse events reviewed by the Quality Committee showed that report analysis is limited to whether a standard of care is given or not, without properly identifying the system gaps to be corrected. Hence the establishment of the Thai patient safety goals and the work led by the Healthcare Accreditation Institute (established as an independent government agency in 2010). The institute works as change catalyst in quality improvement of the health care system, using self-assessment, external surveys, recognition and accreditation, and knowledge sharing as leverage mechanisms. A three-phase implementation strategy initiated by the Healthcare Accreditation Institute led to 75.96% of hospitals being covered by an accreditation system. Hospitals have a coordinated risk/safety and quality management system, including an integrated approach for patient care quality improvement. Accreditation is being used to drive patient safety RLS.

The safe hospital model was developed, by integrating patient safety, safe hospital and safe health care service. A total of 112 volunteer hospitals participate in the health care risk management system (HRMS) hospital centre and results are centralized by the Healthcare Accreditation Institute in the HRMS centre database. A patient engagement framework project was also initiated, to enhance health literacy and the just culture fostering effective RLS.

**Patient safety incident reporting and learning: The private sector experience**

India hosts the largest private health sector. Close to 85% licensed physicians are working in the private sector which includes 93% hospitals and 80% outpatient clinics. It is estimated that only few citizens are covered by health insurance (public 1%, and private 10%), the system being financed mainly through out-of-pocket payments.

Reporting for patient safety in private hospitals is not yet fully implemented. Pharmacovigilance, haemovigilance, and reporting for notifiable diseases are in place. A guidance document for spontaneous adverse drug reaction reporting has been developed. The haemovigilance programme connects Blood Transfusion Centres through the Haemo-Vigil software and 1716 transfusion reaction reports are stored in the database. Patient safety reports are linked to voluntary accreditation, and the 64 quality indicators defined. Tools available include reporting forms (incident reporting form, medication error reporting form, transfusion reaction form), quality score-cards (clinical excellence score card, maternal and child health score card), checklists (surgical safety checklist), and monitoring of process compliance and clinical outcomes. An infection control and anti-microbial resistance programme have been developed. The learning component draws from failures identified and third tier analysis by supervisory committees. Findings are discussed through online forums between accredited hospitals, but there is a need for a peer review system of information that is shared. The use of information technology (where available) facilitates reporting and the quality of the medical act.

The multiple unstructured regulatory bodies and agencies and the lack of a unified reporting system, altogether with the lack of legal support to transparent reporting and weak safety culture are main barriers to be considered in establishing effective and integrated national RLS. WHO advocacy and support is needed for promoting and establishing RLS for patient safety.
3.4 Session 3: Developing WHO guidelines on patient safety incident reporting and learning systems (Group work)

The WHO Draft Guidelines for Adverse Event Reporting and Learning Systems were developed in 2005 under the guidance of Professor Lucian Leape. The document is currently being updated under the guidance of Sir Liam Donaldson, to reflect progress achieved in the field. The aim of the session was to facilitate the identification of perceptions, structures, challenges, and interventions that could support development and implementation of RLS nationally and gather practical knowledge for the document under development. The input of experts and country representatives (five working groups that presented in plenary) compiled around the 10 questions discussed is summarised below.

**Q1: What do you expect from a patient safety reporting system?**

A patient safety reporting system should be able to record and analyse system failures and enable corrective actions to prevent further reoccurrence of safety incidents. It should be simple, reliable, anonymous, confidential, user-friendly, structured, and focused on the learning component. A standardized format for reporting should be used, and the reporting process should be widely known. Each hospital should have a reporting system and reporting should be encouraged with various incentives. A blame-free culture is a prerequisite to increase adherence to incident reporting. RLS should create trust of medical staff and society in the health system.

Reporting should take into account the cultural context and effectively disseminate results. A national system to identify specific areas of concern to ensure systemic improvement could be developed. This should increase awareness of patient safety issues, and foster cost savings in the long run with a reduction of litigation cases. Countries should share the information and outcome of their RLS.

**Q2: How often do you feel that such a system meets expectations and where does it fall short?**

Patient safety RLS very rarely meet expectations. Not all stakeholders are engaged, including leadership, and the system, where in place is usually under-utilized, with slow feedback and difficulties in communication. Health care staff are often scared to report due to fear of reprisals. When reporting happens, the lack of proper feedback leaves reporters discouraged. Patient engagement in reporting faces cultural barriers that require additional efforts to be overcome. Initiatives like patient calling centres (e.g. in Oman and Bangladesh), community centre and complaint boxes, SMS services, could be used. Data from public and private providers must be included/integrated within the same system. There is often a lot of missing data from primary care and patients, and lack of integration between hospital and national level in reporting. Staff are insufficiently trained on the systematic analysis of reported events, and the bureaucratic burden to validate the data and sharing experiences between organizations hinder effective RLS.

RLS also fall short in relation to lack of transparency, lack of consistent leadership and sustainability. The system should foresee clear description of reporting and analysis processes, as well as dissemination of results, that is usually lacking. An annual review could be performed to monitor and document progress achieved.

**Q3: In your experience, can patient safety incident reporting data be used to judge health care organizations’ performance?**

A number of participants agreed on the value of incident reports as a way of evaluating performance in the organizational context, after the data is validated, or until the systems were very mature, with low rates of non-reporting. Additional contextual factors must be used to judge health care organization performance.
Risk adjustment of the data should consider the potential of under-reporting bias, and continuously review the reporting rate in order to map resulting improvements (e.g. reduction in occurrence of one type of incident). Data quality requires close monitoring and the evaluation of reports has to be integrated with clinical indicators.

Both qualitative and quantitative data must be considered. Incidents based on number and type can also indicate the level of the patient safety culture. Once an RLS has been embedded in the organization for a long time, it can support benchmarking between specific departments. It will also show how transparent the organization is.

Q4: How often do you find that the analysis of an incident leads to a solution that reduces risk of recurrence?

Very often, and depending on the type of event, the analysis of an incident can lead to rapid prevention solutions. This is always supported by in depth comprehensive analysis that accompanies the event description, and evidence-based decisions. The analysis may act like a flag in one department, representing a signal for other departments to reflect on the problems and help leaders to generalize solutions. When it integrates other sources of information it may become effective at the health system level to redesign the structure and the process of care. Proper monitoring and timely feedback systems are essential after the analysis of an incident to show results and maintain motivation to report and implement (e.g. Malaysia example: national level analysis showed high number of wrong side surgery that led to implementation of WHO Safe Surgery Checklist).

In a safety culture environment, RLS must collect important events, analyse, and give solutions to reduce risks, followed by learning from error to close the reporting loop for improvement.

Q5: What are the main problems with patient safety incident RLS as they are currently designed and operated?

Under-utilization, limited acceptability of the system (not user friendly), low level awareness, lack of training, weak policy and leadership support are some of the main problems encountered with RLS efficiency.

RLS aims to identify system failures and in particular preventable system failures, not the individual, and the persistence of the blame culture and fear to be sanctioned are demotivating factors to reporting. Additionally, variability of local reporting systems often prevents aggregation of data. Labour intensive reporting systems reduce effectiveness (e.g. paper based report is difficult to analyse, and so are forms not fully completed). IT systems are a prerequisite for effective RLS, and this requires additional sustained funding and knowledge, for both local and national operability.

Q6: What would help to reduce the almost universal problem of under reporting?

Ownership, awareness among stakeholders, understanding the benefits for the system of RLS (dissemination of success stories), leadership at every level, use of patient safety language can help addressing under reporting, tailored to context. The ‘no blame’ principle should be applied, while ensuring confidentiality of information. Staff should be made aware about the importance of reporting and have confidence in the institutional reporting system. Incident reporting should be embedded within staff performance appraisal. Units reporting well should be given priority to improve their systems (reporting data compared to the volume of activity and expected rate of incidents could be used to assess adherence to procedure). Reporting could be encouraged through different and easy channels of communication, including user friendly online forms, and feedback to help understand the benefit of reporting, continuous training after reporting and conducive environment for change.
Research to show the effectiveness of the solutions identified for the patient population should be conducted.

Make it simple to report. Policy framework and legislation should ensure that the scope of reporting is improvement. Effective leadership will ensure that action is taken on reporting. External stimulation by society can trigger the establishment of RLS. Education in patient safety directed to all professional groups and provided by dedicated leaders of patient safety should enhance the reporting and safety culture. It was considered that reporting should be a mandatory procedure.

Q7: How engaged are frontline health care staff with discussing and analysing patient safety incident reports?

Frontline engagement is a reflection of absence/presence of a national framework in quality and safety improvement, but the actual level of frontline staff engagement throughout the healthcare system is not clear.

Hospital committees along with national commission can support staff to discuss and analyse the incident. Engagement must not be reduced to the quality improvement team and should be cascaded to frontline staff with discussing and analysing patient safety incident reports is variable across health systems, informal discussions and interviews can supplement RLS. In some countries, focal points/patient safety officers (health care worker, usually nurse) are established in each department to follow on the report and actions taken.

Q8: What sources of data in addition to incident reports can help to measure the safety of health care?

There are multiple additional sources of information that can contribute to accurately measure/evaluate safety of health care services. The key elements identified during the working group and plenary discussions include:

- National patient safety indicators used for benchmarking purposes (e.g. cancellation rate of surgery, falls reported on quarterly base), key performance indicators used to measure the application of patient safety goals, performance measurement (quality indicators), medical record review, clinical review audits and external assessment

- Hospital survey reports, internal quality and safety improvement projects, surveillance data, data on infection control, data on near misses and non harmful reporting, mortality rates and morbidity registers, health care associated infections registry, waste management, and other non-clinical data, haemovigilance, pharmacovigilance and risk assessment data

- Patient opinion experience surveys, exit interview, data on patient feedback and patient experience, feedback from patient compliance system, patient complaint systems and patient reported outcomes measurement

- Media reports, parliamentary debates in some countries, medical claims and research

Q9: What should be the scope and nature of patients and families involvement in patient safety incident reporting and learning systems?

Patients should be educated and motivated to report (e.g. web based systems, part of the routine discharge). If properly applied, they can bring an important added value. Patients should get engaged in the process of reporting and learning, without overruling health care staff. Autonomy, privacy, confidentiality, should be fundamentally accepted and maintained.
There is a need to recognize patient fear to report and partly take share of healthcare responsibility, and help them distinguish between complaints and reports. Patients should be given the option to choose their treatment, get second opinions for medical advice and get support of patient and families in decision making process.

Patients and family awareness to understand safety incidents should be enhanced through transparent communication. The patient rights charter could be introduced in focus group discussions to build understanding on rights and responsibilities and make communities aware of the patient safety agenda and the potential of their contribution to improve health care.

Q10: Which locally reported patient safety incident data should be shared at national and international level and how should this be organized?

All locally reported patient safety incident data could be shared at national level, but preferably adverse events that led to death and disabilities, medication errors common for all regions, problems with drugs and medical devices, and adverse events related to blood and blood products. Critical incidents should always be reported nationally. At the international level, mandatory reporting to WHO for key events could be established. A common classification between countries to report and share lessons learnt after the analysis and actions taken should be available.

Creating public domains with filtered data for anonymous incident reports could facilitate sharing of information and best experiences on addressing adverse events locally, regionally and internationally. Forums could be established for interest groups to share and learn on patient safety related matters, exchange meetings and sustain horizontal partnerships. A platform for sharing and learning developed with support from WHO will further assist in the identification, investigation and prevention of safety incidents.
3.5 Session 4: Application of the Minimal Information Model for Incident Reporting and Learning Systems

The Minimal Information Model for reporting patient safety incidents – progress review

The Minimal Information Model for patient safety (MIM PS) presents a core set of data elements of a reporting system. It was developed in response to the lack of standards for patient safety incident reporting and processing, to facilitate data comparison and aggregation for better learning across different reporting systems. It builds on existing WHO work in reporting and learning, and extensive expert consultation and input. The patient safety categorial structures stemmed from the International Classification for Patient Safety conceptual framework, and developed further to constitute the first MIM PS draft. The process was led by the Universities St Etienne, France, and Tokyo, Japan, and externally reviewed by four countries across the world. The second draft of MIM PS was piloted in ten European countries (2014-2015). The validated tool (eight or ten data elements) was found to be a good tool for the development of RLS and to facilitate comparison between collected data between various levels and countries. MIM PS underwent further validation in other regions (2015-2016) and result will be presented shortly.

MIM usability was also explored as a common reporting template for reporting and vigilance for safety in health care (cross-cutting MIM). Potential future directions of MIM development include piloting of the template in cross-cutting areas (e.g. blood safety, pharmacovigilance, radiation safety, vaccine safety, medical device safety etc.), and extended applications to patient and family reporting for safer better health outcomes.

Adverse event reporting in a microbiology laboratory and infection prevention and control unit at SJGH

The Ministry of Health adverse event/ incident reporting form was piloted at the microbiology and infection control unit at Sri Jayewardenepura General Hospital (SJGH), Sri Lanka. Several problems were identified with the form’s design and content. This was reviewed in line with the feedback received during piloting, and a new form was introduced.

In the microbiology laboratory adverse event reports are filled manually, and a root cause analysis is performed by a microbiologist consultant with assistance from other staff. Preventive and corrective actions are defined and taken. All the adverse events related to infection prevention and control are reported to the infection control unit and discussed during monthly meetings. Major decisions taken are highlighted and the minutes of the meeting are presented to the management committee of the hospital. The number of reports, initially very low, are steadily increasing as result of continuous communications and preventive and corrective actions taken following analysis of reported incidents.

Experience of adverse event and incident reporting in a secondary care hospital

The experience of reporting safety incidents was related to a situation of local conflict. Kilonochchi, Sri Lanka was heavily mined, and the Government began conducting a demining process, that is expected to take about 15 years. The outpatient department had to change location several times. Implementing reporting safety incidents was an additional challenge in context.
Enhanced adverse event and incident reporting in a tertiary care hospital

The vision that guided this experience resulted in the development of the safest tertiary hospital in Sri Lanka. Patient centred services, competent human resources, reliable physical resources, continuous process improvement and regular supervision and reviews were considered complementary approaches in achieving the highest safety outcomes. There were 34 wards selected to participate in the pilot implementation of the adverse event and incident report and two awareness programmes were conducted for the staff of the selected wards. The fear of litigation, inadequate systems for data analysis and the lack of a ‘learning from mistakes’ approach had to be overcome. An agreed classification stemming from the ICPS and a standardized form for reporting were made available (introduced and discussed).

A quality management unit was established, which conducted the implementation. Guidelines were developed in line with WHO recommendations and the ministry and forwarded for use. Initially there were only few incident reports recorded, but the numbers grew slowly based on improvement results. For example, the solution implemented to reduce patient falls from bed drastically reduced fall incidence. The safe surgery checklist was also part of the safety tools introduced. Reviews were conducted on a quarterly basis to monitor progress, and the quality manager performed daily visits. A meeting with the coordinating team and the ministry representatives provided the opportunity for discussions and reporting on the implementation process.

Presentation of MIM PS regional mapping results

The MIM PS defines minimal categories of data, to provide sufficient information on patient safety incidents to enhance learning and future prevention. It was successfully piloted in Japanese hospitals and subsequently validated in the European Union in 2015. The European validation concluded that the MIM PS could be used for establishing reporting systems and to support comparability and learning where reporting systems are in place. Four countries (Morocco, Oman, Philippines and Tunisia) participated in this mapping exercise and submitted original reports and reporting templates, and/or reporting registries to WHO online. Submitted documents were analysed for structure, content and fitness with MIM PS requirements. The content of available documents was very heterogeneous. Results showed that the structure of the data sets is slightly coherent with the MIM PS and the classification of the incident type is diverse following local practices. The most important missing elements are the agent involved and reporter’s role, that are valuable to understand the nature of the event or find additional information. The level of compliance in the present mapping exercise is rather similar to the earlier European mapping process.

Conclusions underlined the need for a shared classification of incident types, considered essential for MIM PS integration with existing reporting systems. Corrective and preventive actions should be developed for all recorded reports, in a no blame environment, and actions should be implemented and sustained by trained staff. Where specialty registries are available (for example maternal deaths, haemovigilance, infections), incident analysis through MIM PS could be considered for learning purposes. Reporting close calls and unsafe acts should be promoted in the areas where registries are available. It is also important to understand the human factors in order to create an environment where human error is safely and confidentially reported.

Presentation of MIM PS feasibility regional results

The MIM PS, developed to bring incident reporting systems to a common denominator, was developed to simplify and facilitate implementation of RLS, while providing a computer-friendly interface. Several piloting exercises explored MIM PS feasibility and adaptability in hospitals, in various countries. In 2014-
2015 it was validated in the European Union countries. Piloting was extended to other WHO regions in 2015-2016, and these results are summarized.

A feasibility survey (questionnaire based) was implemented to validate MIM PS applicability and compatibility with reporting systems in countries explored, focused on resource limited settings. Four countries completed the survey: Oman, Philippines, Sri Lanka and Thailand. Results showed high-level compliance of MIM PS information category content with existing RLS. Adaptation to context was considered feasible, not difficult or requiring moderate effort due to the existing high degree of content compliance. Additional MIM PS information categories (causes, contributing and mitigating factors) were considered equally useful and implementable. Main challenges to implementation included: laws and institutional regulations, increased workload, information technology setups and resistance to change. Using reports as sources of knowledge is not yet common practice in all institutions. Information is disseminated through various means, for example, newsletters, discussions, reports to executive management, regular pledges to patient safety. MIM PS was considered to provide sufficient information for analysis and learning, with training required. The extended use of the MIM PS prototype was supported. It was considered that MIM PS has a clear learning component closely linked to the quality of the analysis performed, communication and dissemination mechanisms in place, and the local safety culture.

**Plenary discussion on wide field applicability of the MIM PS in establishing operational RLS**

The results of the current MIM PS piloting, in which several countries attending the meeting participated, were further discussed. The various RLS operating in a country often work in isolation and there is a need to enhance communication and scale up the system at national level. Raising awareness, education and training to build the common understanding for patient safety and support implementation of effective RLS for safe quality of care were repeatedly mentioned. An assigned person should be dedicated for the task.

Participants stated that a minimal standard package that could facilitate generation of actionable knowledge from RLS is needed. Such simplified user-friendly systems, with harmonized definitions should be applicable in both public and private healthcare settings.

MIM PS could provide the basic package solution for countries that have no reporting at all, and serve as a reference for national RLS, to facilitate comparability, aggregation of information and enhance learning for improvement. MIM PS could be considered for integration in the good reporting system where these already exists, such as reporting systems for disease management and outbreak; medication adverse event reporting and other registries. Considering the similarities in terminology, the process should not be difficult. The examples of web based incident reporting made the case for faster pace in implementation and rapidly increasing number of reports, if the system is covered by confidentiality and empowerment. Some countries already decided to adopt MIM PS, such as Oman, Philippines and Sri Lanka. A number of countries initiating RLS implementation requested WHO support in this process: Bangladesh, Jordan, Nigeria, South Africa, Thailand and Vietnam. WHO e-network for patient safety and quality of care could already be used for sharing available information.
3.6 Session 5: Exploring data analysis and use to enhance the learning component

International perspective: Canada

Established by Health Canada in 2003, the Canadian Patient Safety Institute (CPSI) works with governments, health organizations, leaders, and health care providers to inspire improvement in patient safety and quality. Patients for Patient Safety Canada provides advice and directions to both all CPSI work but also across Canada at the local, regional, provincial and national level (creating alignment across the system and transferring knowledge across the provinces). For over five years, in consultation with stakeholders, CPSI developed a patient safety vocabulary that was steadily adopted by many pan-Canadian organizations provinces and territories, for a common language in many areas of patient safety including RLS. A system perspective, patient centred care, safety culture, and shared responsibility, are key principles guiding CPSI’s work.

Reporting does not exist in isolation, and should be considered in context, with a system perspective. Knowing system factors (legislation, policies, culture, people, resources and processes) is important to understand the multiple interconnections that make the big picture work. The Patient Safety and Incident Management Toolkit deliver resources that “help anticipate, monitor, prevent and plan for expected and unexpected safety issues”. It includes recommendations for establishing RLS. Advice on immediate response to the incident, disclosure process, structured analysis and follow up are provided in the incident management section. Analysed reports and aggregated data, formulated in alerts, advisories and recommendations for patient safety and quality from Canada and various countries/health care organizations across the world, are gathered in the Global Patient Safety Alerts database.

WHO Reporting and Learning Community of Practice e-platform was part of the global information and experience sharing mechanisms fostering real time learning and knowledge dissemination.

Reporting and learning: analysis and use of data

The research conducted by the Italian Centre for risk management, known as the Centro Gestione Rischio Clinico, in 2007 (randomized sample of 942 health care workers in 18 hospitals) identified the lack of response to reporting and the fear of losing professional credibility as the main barriers in safety reporting. Reporting is of value only if it generates a constructive response. The benefit stems from the information gained through incident analysis and effective change can be driven only by feedback to frontline staff and recommendations for improvement. Statistics on valid reports contribute to regular updates of the safety profile of the organization, or department/unit concerned. It is why under-reporting creates a bias that limits the validity of collected data (scale of risk vs harm incurred). The four system requirements for transforming data into information are: to report incidents, aggregate them, support and conduct risk surveillance, review, respond, and disseminate recommendations. A multi-disciplinary team (including human factor experts) is needed to ensure that interpretation of data takes into account a range of perspectives. The risk surveillance, review and response process include aggregation of data from various sources, including patient safety champions, analysis, and wide health care sector consultation for the development of corrective strategies for improvement. The system needs to be constantly controlled and monitored to understand the real practice within.

In the region of Tuscany, adherence to reporting of safety incidents steadily increased, as a result of sustained dedicated initiatives including the appointment of patient safety officers in every ward, establishment of RLS budget goals, credit systems for professional development, release of a digital reporting system and guidance review.
A good example of scaling up the reporting and dissemination of safety information internationally is the global vigilance and surveillance database for medicinal products of human origin (also known as the Notify library) that also provides real time information on safety concerns.

**Case study: structured analysis – adapting method to context**

The reporting of safety incidents can be used to reduce and prevent future similar hazards and create a safer health system. To become useful, reported data has to be properly analysed. The report of a wrong procedure performed on a patient was presented as an example of contextual adaptation of structured analysis to context. Analysis of the incident was performed in a systematic and detailed manner to extract the recommendations for change and ascertain the learning component. A clinical audit (a process of quality improvement that reviews care processes against explicit criteria) was used to analyse the case and draft the improvement strategy. The classification and systematic analysis of the process allowed identification of a series of ameliorating actions to prevent similar events occurring in the future. Each ameliorating action was described, indicating level of application, person in charge, application time, evaluation measures, time and frequency of measurement, and the degree of management involvement in the process. The clinical manager in collaboration with the working group led the implementation of ameliorating actions. An alert report was developed and monitoring and evaluation of the improvement strategy initiated. Based on the results of monitoring implementation effects on risk levels, the working group reviewed regularly the priority areas for intervention.

The learning component resulting from reported data analysis (qualitative analysis vs statistics) is part of the mechanism for developing and disseminating changes in policy and practice to improve safety and quality of health care, and must be shared. Feedback to the reporter (related to the learning component) is a strong motivating factor for health professionals and also patients to report future safety incidents for system improvement.

**Enhancing the learning component of reporting systems: Elaborating on data dissemination mechanisms for extracted learning**

Reporting systems are a safety monitoring mechanism used to identify, document, prevent and reduce the occurrence of risks, hazards and failures of the health care system. RLS used as a knowledge source can take the form of defined patient safety priorities, ministerial recommendations, theme reports, warnings, attention notes, information bulletins, newsletters, reports, teaching sessions, checklists, or other means, as listed by countries participating in the MIM PS piloting. Retrieving lessons learned from incident reports is often a difficult task due to structures in place, quality of records, and staff awareness and openness to change. It all depends on how data is collected, analysed and corroborated with alternative sources of patient safety information, and how it is perceived and used by decision makers, health staff and patients.

There is a documented need to strengthen the RLS learning component and safety culture, which can be done in multiple ways: wider and faster access to information, rapid feedback to frontline workers, involvement of both health professionals and patients in defining solutions, clinical safety standards and accreditation procedures, data flow integration and computerization, and more information transparency and disclosure to the public. The WHO Global Patient Safety Network is an example of a global information dissemination mechanism, providing a platform for shared experience and lessons learnt, fostering international collaborative healthcare system and patient safety improvement.
3.7 Session 6: Implementation of reporting and learning systems for patient safety

The group work session aimed to facilitate the development of country, regional and global action plans building on the knowledge and awareness acquired during the event which could strengthen patient safety culture and support establishing simple, harmonized RLS on a national scale. Participants were distributed into four regional groups to ensure that country needs to locally implement RLS could be supported at regional level. A health system standpoint was considered, looking at leadership and governance required for implementation, resources (infrastructure and staff), funding available and services to be covered. Working groups reported on their deliberations, and provided input in establishing key priorities and recommendations for establishing and strengthening RLS for patient safety.

RLS were seen as a cornerstone of patient safety strategies that should be implemented at all levels of health care by all working groups. It was noted that all reporting systems, irrespective of complexity, need: clear objectives, clarity about who should report and what gets reported, mechanisms for receiving reports and managing the data, expertise for analysis, capacity to respond to reports, method for classifying reported events, capacity to disseminate findings, technical infrastructure and data security.

The development of national patient safety incident RLS adapted to local circumstances was considered a priority.
4. Recommendations

The outcomes of the working groups were summarized and used as input to the following recommendations, addressing the national, regional and global/WHO level.

**National level**

Countries should establish national RLSs that are effective and sustainable, drawing from a strong safety culture, increased awareness and trained staff. Work can start at any level: institutional, regional or national, and developing simple and user-friendly step-wise reporting and learning systems.

Policy framework and legislation must be supportive to RLS and can be either mandatory or voluntary, and regulations to ensure that the system is non-punitive and failures are accurately reported and corrected. Leadership, national action plans for patient safety, national guidelines, standards, tools, national focal points, are all key elements that need to shape and/or support RLS development and strengthening.

Training at all levels is required to ensure the system functions, and in particular training for reporting as well as data collection, analysis and dissemination are a must. Academic institutions can help build the skills and the will for system improvement. The WHO multi-professional Patient Safety Curriculum Guide could be transposed into health care professional training curricula and in continuous professional education schemes.

Strengthening the learning component of RLS must be considered from the start, and encouraged with incentives and rewards for reporting and better quality data. Data should be linked into broader health information systems, and patient safety indicators used to monitor the resulting progress.

Campaigns, social media and networking at the institutional and professional level are part of the communication mechanisms that can act as levers for RLS. The role of patients and the public at large to increase adherence to RLS as improvement mechanisms should not be overlooked.

**Regional and global levels**

The regional/global level recommendations stressed again the importance of leadership, policy development and partnerships in advancing the patient safety agenda. Strategic advice should provide linkages with larger goals, such as universal health coverage and the Sustainable Development Goals.

Research based advocacy for RLS should be widely disseminated to provide evidence on the key constructive role that RLS can play in the process of improvement.

Guidance documents and tools to be used in establishing RLS should include an open source software and tools for data collection, analysis and dissemination of results; common minimum standards for reporting and patient safety; guidance on developing systems for disclosure to patients and families and guidance on establishing a medical liability system.

Shared experiences, information exchange and training schemes are part of regional and global learning mechanisms. The existing databases (e.g. Global Patient Safety Alerts) and networks (e.g. the Network for Medical and Nursing Educational Councils and Universities, or the Patients for Patient Safety network) should be used to increase access and availability of knowledge in this field. International training and capacity-building courses to countries through fellowships, twining and online training programmes should be foreseen.
WHO’s role was seen as vital in this process by producing and providing specific guidance and support for the development and implementation of reporting and learning systems. This work includes the finalization of RLS guidance under development, the extended use of the MIM PS as a simple tool for RLS and wider implementation of the WHO Multi-Professional Patient Safety Curriculum Guide. Development of a WHO web-based reporting system was also recommended.

5. Conclusions and next steps

The event concluded, with widespread agreement, on the importance of strengthening patient safety and quality of health care irrespective of resources available. Field efforts, tailored to match needs, need strong leadership, knowledge and evidence for change to support the development and/or strengthening of RLS. Participants were invited to further explore and share all technical resources made available during the event, and to work on the draft plans for better RLS in their countries.

Next steps include the finalization of the WHO guidance for patient safety incident reporting and learning systems document, to which all meeting participants contributed through structured discussions and sharing their own experiences.

The MIM PS, complementary tool to this guidance, has already been made available to participant countries. Piloting results will be finalized and shared, and guidance for MIM PS field adaptation will be followed with the support of WHO and its Collaboration Centre for Clinical Risk Management, in Florence, Italy.

The WHO Patient Safety and Quality Network will post meeting presentations and documents, and participants will be invited to register as active community members on the electronic information exchange platform.

The next meeting, to monitor progress, will be organized in 2017.
6. Annexes

6.1 Annex 1 - Programme of Work

<table>
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<tr>
<th>Inter-Regional Consultation</th>
<th>Patient Safety Incident Reporting and Learning Systems in Africa and Asia Pacific Regions</th>
<th>22-24 March 2016, Colombo, Sri Lanka</th>
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Jointly organized by WHO HQ/Geneva and WHO-SEARO in collaboration and support from the Government of Japan and Sri Lanka

Programme of Work

**Day 1 - Tuesday, 22 March 2016**

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<th>Activity</th>
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<td>8:30 – 09:00</td>
<td>Registration at Room Galle Face 6 (in Galle Face Hotel)</td>
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<td><strong>Inauguration Session: MC</strong></td>
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<td>09:00 – 10:00</td>
<td>Welcome Address, Ministry of Health, Sri Lanka – Dr L. Siyambalagoda, Additional Secretary</td>
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<td>Welcome Address, Ministry of Health, Labour and Welfare, Japan – Dr Shin Ushiro</td>
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<td>Welcome Address, World Health Organization – Dr Arturo Pesigan, A/C WR, Sri Lanka</td>
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<td>Introduction of participants</td>
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<td>Objectives of the event – Dr Neelam Dhangra, WHO-HQ</td>
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<td>10:00 – 10:30</td>
<td>Key Note speaker: The Patient Safety Journey in Sri Lanka hospitals</td>
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<td>Group photo &amp; Break</td>
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**Session 1: Advancing the Patient Safety and Quality of Care agenda across the World**

**Chair:** Dr Arturo Pesigan

11:00 – 12:00

- Roundtable - Global and Regional Overview on Patient Safety and Quality Improvement, and Reporting and Learning Systems
  - Structured 10’ presentations followed by guided discussion on global and regional achievements and challenges

**WHO/HQ** – Dr Neelam Dhangra

**WHO/SEARO** – Dr Sunil Senanayake

**WHO/EMR** – Dr Mondher Letaief (Remote)

**Session 2: Importance and Relevance of Patient Safety Incident Reporting and Learning Systems**

**International and National Experience/Initiatives/Status**

**Chair:** Dr Lakshmi Somatunga

12:00 – 12:15

- WHO Guidance on Patient Safety Incident Reporting and Learning Systems
  - Dr Neelam Dhangra

12:15 – 12:30

- EU- Reporting and Learning Systems for Patient Safety Incidents across Europe: Key Findings and
  - Dr Basia Kutryba
### Session 1: Overview of Patient Safety Incident Reporting and Learning Systems

**12:30 – 13:00**
**Country Experiences/Initiatives: National, Subnational or Institutional Patient Safety Incident Reporting and Learning Systems**
- Japan
- Malaysia

**13:00 – 14:00**
Lunch

**14:00 – 15:30**
**Country Experiences/Initiatives: National, Subnational or Institutional Patient Safety Incident Reporting and Learning Systems - Contd.**
- Oman
- Poland
- India
- South Africa
- Thailand
- Private sector

**15:30 – 16:00**
Break

### Session 3: Developing WHO Guidance on Patient Safety Incident Reporting and Learning Systems

**16:00 – 18:00**
Group Work (Five small groups)
- Introduction – Ms Katherine Hayes
- Moderated structured discussion around 10 question to provide input for the upcoming WHO Implementation Guidelines on Patient Safety Incident Reporting and Learning Systems

**18:00**
Conclusions of the Day

### Day 2 - Wednesday, 23 March 2016

**09:00 – 09:15**
Summary of Day 1
Ms Katherine Hayes

**Session 3: Developing WHO Guidance on Patient Safety Incident Reporting and Learning Systems (Contd.)**

**Chair: Dr Sunil Senanayake**

**09:15 – 10:30**
Reporting from the Group Work
Group Rapporteurs

**10:30 – 11:00**
Break

**11:00 – 12:00**
Reporting from the Group Work (Contd.)
Group Rapporteurs

**12:00 – 12:45**
Outcome of the Group Work Session
Plenary discussion

**12:45 – 13:00**
Summary of input for the upcoming WHO Guidance on Patient Safety Incident Reporting and Learning Systems
Chairperson

**13:00 – 14:00**
Break

### Session 4: Application of the Minimal Information Model for Incident Reporting and Learning Systems

**Chair: Dr Basia Kutryba**

**14:00 – 14:20**
The Minimal Information Model for Reporting Patient Safety Incidents – progress review
Ms Maki Kajiwara
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<td>Dr Ratnayake</td>
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<td>Experience of piloting Adverse Event Form in a secondary care hospital</td>
<td>Dr Karthikeyan</td>
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<td>Experience of piloting Adverse Event Form in a laboratory setting</td>
<td>Dr Jayathilake</td>
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<td>15:00 – 15:30</td>
<td>Presentation of MIMPS regional mapping results</td>
<td>Dr Tommaso Bellandi</td>
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<td>15:30 – 16:00</td>
<td>Break</td>
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<td>16:00 – 16:30</td>
<td>Presentation of MIMPS feasibility regional results</td>
<td>Dr Valentina Hafner (Remote)</td>
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<td>16:30 – 17:30</td>
<td>Wide field applicability analysis of the MIMPS in establishing operational reporting and learning systems</td>
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<td>17:30</td>
<td>Conclusions of the Day</td>
<td>Chairperson</td>
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**Day 3 - Thursday, 24 March 2016**

**Session 5: Exploring Data Analysis and Use to Enhance the Learning Component**  
**Chair: S. Sridharan**

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<td>Summary of Day 2</td>
<td>Ms Katherine Hayes</td>
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<td>09:15 – 09:30</td>
<td>Learning and resources from the Canadian Patient Safety Institute, a long-term WHO collaborator</td>
<td>Ms Ioana Popescu (Remote)</td>
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<td>09:30 – 09:50</td>
<td>Reporting and learning – analysis and use of data</td>
<td>Dr Tommaso Bellandi</td>
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<td>09:50 – 10:20</td>
<td>Case study: structured analysis – adapting method to context</td>
<td>Dr Michela Tanzini</td>
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<td>10:20 – 10:45</td>
<td>Enhancing the learning component of reporting systems: Elaborating on data dissemination mechanisms for extracted learning</td>
<td>Dr Valentina Hafner (Remote)</td>
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<td>10:45 – 11:15</td>
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**Session 6: Implementation of Reporting and Learning Systems for Patient Safety**  
**Chair: Dr Thushara Ranasinghe**

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<tr>
<td>11:15 – 13:00</td>
<td>Development of draft country, regional and global action plans for establishing/ supporting the strengthening of Reporting and Learning Systems for Patient Safety</td>
<td>Regional working groups</td>
</tr>
<tr>
<td>13:00 – 14:00</td>
<td>Lunch</td>
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<tr>
<td>14:00 – 15:30</td>
<td>Round table on priorities and recommendations for establishing/ strengthening Reporting and Learning Systems for Patient Safety</td>
<td>Round table structured around the reports of the 4 regional working groups</td>
</tr>
<tr>
<td></td>
<td>Reporting on draft country, regional and global action plans – 3 key priorities, and recommendations and next steps</td>
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<tr>
<td>15:30 – 16:00</td>
<td>Break</td>
<td></td>
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<tr>
<td>16:00 – 16:30</td>
<td>Conclusions and Next Steps</td>
<td>DGHS, Sri Lanka</td>
</tr>
<tr>
<td></td>
<td>Closure of the Technical Consultation</td>
<td>WR, Sri Lanka</td>
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<tr>
<td></td>
<td></td>
<td>Dr Sunil Senanayake</td>
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<td></td>
<td></td>
<td>Dr Neelam Dhingra</td>
</tr>
</tbody>
</table>
### Annex 2 - List of Participants

#### Provisional List of Participants

<table>
<thead>
<tr>
<th>Country/Region</th>
<th>Name</th>
<th>Position and Department</th>
</tr>
</thead>
<tbody>
<tr>
<td>Afghanistan</td>
<td>Dr Karima Mayar Amiri</td>
<td>Coordinator Improving Quality in Health Care (IQHC) Department</td>
</tr>
<tr>
<td></td>
<td>Mohammad Salem Asghar Khil</td>
<td>Patient Safety and CDC Officer Improving Quality in Health Care (IQHC) Department</td>
</tr>
<tr>
<td>Ethiopia</td>
<td>Mr Abiy Dawit Tantu</td>
<td>Officer, Federal Ministry of Health</td>
</tr>
<tr>
<td></td>
<td>Mr Gabone Gudina Boku</td>
<td>Federal Hospital Case Team Leader, Federal Ministry of Health</td>
</tr>
<tr>
<td>Ghana</td>
<td>Mr Emmanuel Owusu-Ansah</td>
<td>Acting Policy Planning Monitoring and Evaluation, Ministry of Health</td>
</tr>
<tr>
<td>Indonesia</td>
<td>Dr. Nani H. Widodo, Sp.M, MARS</td>
<td>Head, Medical and Nursery Services Sub-Directorate</td>
</tr>
<tr>
<td></td>
<td>Prof. Dr. Herkutanto, Sp.F(K), SH, LL.M, FACLM</td>
<td>Member of Patient Safety Committee</td>
</tr>
<tr>
<td>Malaysia</td>
<td>Dr Nor’Aishah bt Abu Bakar</td>
<td>Senior Principal Assistant Director, Medical Development Division, Ministry of Health Malaysia</td>
</tr>
<tr>
<td></td>
<td>Dr Farahdina bt Abidin</td>
<td>Senior Principal Assistant Director, Medical Practise Division, Ministry of Health Malaysia</td>
</tr>
<tr>
<td>Morocco</td>
<td>Dr Riad Mohammed</td>
<td>Director of the Provincial Hospital, El Jadida, Ministry of Health</td>
</tr>
<tr>
<td></td>
<td>Mme Zouatni Bahija</td>
<td>Chief Engineer, Quality Unit, Direction of Hospitals and Ambulatory Care, Ministry of Health</td>
</tr>
<tr>
<td>Nigeria</td>
<td>Dr Yagana Iman</td>
<td>Director, Specialty Hospitals, Department of Hospital Services</td>
</tr>
<tr>
<td></td>
<td>Mrs A Jones</td>
<td>Assistant Director, Nursing Division, Department of Hospital Services</td>
</tr>
<tr>
<td>Oman</td>
<td>Mrs Samra Salim Al Barwani</td>
<td>Staff Nurse, Directorate General of Quality Assurance</td>
</tr>
<tr>
<td></td>
<td>Ms Asma Mohammed Al Hadifi</td>
<td>Staff Nurse, Department of Quality &amp; Patient Safety, Khoula Hospital</td>
</tr>
<tr>
<td>Philippines</td>
<td>Dr Antonio Roque Paradela</td>
<td>Chief Medical Professional Staff, Vicente Sotto Memorial Medical Centre</td>
</tr>
<tr>
<td>Country</td>
<td>Name</td>
<td>Position/Title</td>
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</tr>
<tr>
<td>South Africa</td>
<td>Ms Ronel Steinhobel</td>
<td>National Deputy Director, National Department Of Health, Directorate: Quality Assurance, DD Complaints Management</td>
</tr>
<tr>
<td>Sri Lanka</td>
<td>Dr Lakshmi Somathunga</td>
<td>Deputy Director General (Medical Services) - 1, Ministry of Health and Indigenous Medicine</td>
</tr>
<tr>
<td>Dr Sathasivam Sridharan</td>
<td>Director / Quality Healthcare &amp; Safety, Ministry of Health and Indigenous Medicine</td>
<td></td>
</tr>
<tr>
<td>Thailand</td>
<td>Mrs Somphorn Kampan</td>
<td>Registered Nurse, Senior Professional level, Rajavithi Hospital, Department of Medical Services, Ministry of Public Health</td>
</tr>
<tr>
<td>Dr Piyawan Limpanyalert</td>
<td>Deputy Chief Executive Officer, Healthcare Accreditation Institute (Public Organization)</td>
<td></td>
</tr>
<tr>
<td>Vietnam</td>
<td>Dr Nguyen Trong Khoa</td>
<td>Vice Director, Medical Service Administration, Ministry of Health</td>
</tr>
<tr>
<td>Dr Phan Thi Hang</td>
<td>Head, Quality Division, Hung Vuong Hospital and Vice Chairwomen, Committee of Patient Safety, Department of Health of Hochiminh City</td>
<td></td>
</tr>
<tr>
<td>Canada (Via Skype)</td>
<td>Ms Ioana Cristina Popescu</td>
<td>Patient Safety Improvement Lead, Canadian Patient Safety Institute</td>
</tr>
<tr>
<td>India</td>
<td>Dr Jitendra Kumar Sharma (Via Skype)</td>
<td>Head-Division of Healthcare Technology &amp; Director, WHO CC for Priority Medical Devices &amp; Health Technology Policy, National Health Systems Resource Centre, Ministry of Health &amp; Family Welfare, Govt. of India</td>
</tr>
<tr>
<td>Dr Narayan Pendse</td>
<td>Patient Safety Expert</td>
<td></td>
</tr>
<tr>
<td>Italy</td>
<td>Dr Tommaso Bellandi, PhD, Eur.Erg.</td>
<td>Laboratorio per le attività di studio e ricerca applicata, Centro Gestione Rischio Clinico e Sicurezza dei Pazienti, Patient Safety Research Lab</td>
</tr>
<tr>
<td>Dr Michela Tanzini</td>
<td>Laboratorio per le attività di studio e ricerca applicata, Centro Gestione Rischio Clinico e Sicurezza dei Pazienti, Patient Safety Research Lab</td>
<td></td>
</tr>
<tr>
<td>Japan</td>
<td>Dr Shin Ushiro</td>
<td>Director, Japan Council for Quality Health Care</td>
</tr>
<tr>
<td>Poland</td>
<td>Ms Basia Kutryba</td>
<td>WHO Collaborating Centre, Krakow</td>
</tr>
<tr>
<td>Sri Lanka</td>
<td>Dr Gamini Senevirathna</td>
<td>Director, Castle Street Hospital for Women</td>
</tr>
<tr>
<td>Dr Asela Gunawardhane</td>
<td>Director, Colombo South Teaching Hospital</td>
<td></td>
</tr>
<tr>
<td>Dr S. Ratnayake</td>
<td>Director, Teaching Hospital, Kandy</td>
<td></td>
</tr>
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27
<table>
<thead>
<tr>
<th>Country/Region</th>
<th>Name</th>
<th>Role</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sri Lanka</td>
<td>Dr Kushlani Jayathilake</td>
<td>Consultant Microbiologist, Sri Jayawardhanapura Hospital</td>
</tr>
<tr>
<td></td>
<td>Dr P. Karthikaeyan</td>
<td>Ex Director, DGH Kilinochchi</td>
</tr>
<tr>
<td></td>
<td>Dr G.S.K. Dharmaratne</td>
<td>Director, Respiratory Disease Hospital, Welisare</td>
</tr>
<tr>
<td></td>
<td>Dr Ashok Perera</td>
<td>Ex. Med. Siperintendent, BH Puttalan, Registrate in Directorate of Healthcare Quality and Safety of Ministro of Health and Indigenous Medicine, Sri Lanka</td>
</tr>
<tr>
<td></td>
<td>Ms Christine Perera</td>
<td>Patients for Patient Safety Champion, Colombo</td>
</tr>
<tr>
<td>South Asia</td>
<td>Dr Preethi Wijigoonewardene</td>
<td></td>
</tr>
<tr>
<td>WHO/HQ</td>
<td>Dr Neelam Dhingra</td>
<td>(Organizing Secretary), Coordinator, Patient Safety and Quality Improvement</td>
</tr>
<tr>
<td></td>
<td>Dr Valentina Hafner</td>
<td>(Via Skype), Consultant, Patient Safety and Quality Improvement</td>
</tr>
<tr>
<td></td>
<td>Maki Kajiwara</td>
<td>Technical Officer, Service Delivery and Safety</td>
</tr>
<tr>
<td></td>
<td>Ms Katherine Hayes</td>
<td>Consultant, Patient Safety and Quality Improvement</td>
</tr>
<tr>
<td>WHO-SEARO</td>
<td>Dr Sunil Gunasena Senanayake</td>
<td>Regional Adviser, Health Systems Management</td>
</tr>
<tr>
<td>WCO-Sri Lanka</td>
<td>Dr Jacob Kumaresan</td>
<td>WR, Sri Lanka</td>
</tr>
<tr>
<td></td>
<td>Dr Thusara Ranasinghe</td>
<td>NPO, Sri Lanka</td>
</tr>
<tr>
<td>WCO-Bangladesh</td>
<td>Dr Murad Sultan</td>
<td>NPO, Bangladesh</td>
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WHO INTER-REGIONAL CONSULTATION
PATIENT SAFETY INCIDENT REPORTING AND LEARNING
SYSTEMS IN AFRICA AND ASIA PACIFIC REGIONS

JOINTLY ORGANIZED BY WHO HQ/GENEVA AND WHO-SEARO
IN COLLABORATION AND SUPPORT FROM THE GOVERNMENT OF JAPAN AND SRILANKA.
22-24 MARCH 2016, COLOMBO, SRILANKA