Review

WHO efforts to promote reporting of adverse events and global learning

Itziar Larizgoitia, Marie-Charlotte Bouesseau, Edward Kelley

Service Delivery and Safety, World Health Organization, Geneva, Switzerland

Significance for public health

Understanding the causes and consequences of incidents is cornerstone for patient safety improvement. Likewise, setting up systems to facilitate such understanding and communicate the learning across all healthcare actors is crucial. Over the past decade, the World Health Organization has convened an area of work, with the support of a growing number of collaborating agencies, institutions and experts worldwide to facilitate the identification of global directions aiming to facilitate the development and management of patient safety incident reporting systems as well as the extraction and communication of useful learning. Exchange and sharing of best practices and experiences has been at the essence of this work. This paper describes such efforts and also reflects on other areas of work which are essential to enhance patient safety by learning from the failures of the health care.

Abstract

Despite the importance of reporting systems to learn about the casual chain and consequences of patient safety incidents, this is an area that requires of further conceptual and technical developments to conduce reporting to effective learning. The World Health Organization, through its Patient Safety Programme, adopted as a priority the objective to facilitate and stimulate global learning through enhanced reporting of patient safety incidents. Landmark developments were the *WHO Draft Guidelines for Adverse Event Reporting and Learning Systems*, and the *Conceptual Framework for the International Classification for Patient Safety*, as well as the *Global Community of Practice for Reporting and Learning Systems*. WHO is currently working with a range of scientists, medical informatics specialists and healthcare officials from various countries around the world, to arrive at a Minimal Information Model that could serve as a basis to structure the core of reporting systems in a comparable manner across the world. Undoubtedly, there is much need for additional scientific developments in this challenging and innovative area. For effective reporting systems and enhanced global learning, other key contextual factors are essential for reporting to serve to the needs of clinicians, patients and the healthcare system at large. Moreover, the new data challenges and needs of organizations must be assessed as the era of *big data* comes to heath care. These considerations delineate a broad agenda for action, which offer an ambitious challenge for WHO and their partners interested in strengthening learning for improving through reporting and communicating about patient safety incidents.

Introduction

Since the influential 1999 IoM *To Err is Human* report,[1] patient safety has been positioned as a core public health issue of concern to the public, professionals, institutions and agencies involved in healthcare. Over the past fifteen years, since that seminal document was published, the ubiquitous occurrence of adverse events has been unveiled with clarity and determination,[2] and a greater understanding of the burden due to unsafe care, its characteristics and circumstances is more clear today.[3] Similarly, the science of patient safety, together with a range of specific solutions to relevant patient safety problems have been developed and implemented widely.[4] But, even if adverse events occur with alarming frequency, there is still a large gap in understanding the particular chain of events and the weaknesses, lapses and errors that lead to their occurrence, as well as their specific consequences to patients, clinicians and the organizations. There are still many areas that require particular attention to achieve greater levels of safety in healthcare. One that yet needs to be strengthened and further developed is related to disclosure and reporting of adverse events. This paper attempts to review progress internationally in this area and map potential priority next steps for the global safety community in reporting, monitoring and learning from adverse events in health care.

Progress to date: why reporting and learning efforts have stalled

The systems, sciences, mechanisms and procedures that could facilitate the systematic reporting of adverse events and, moreover, the related learning which could lead to effective practice and behaviour change are yet not sufficiently advanced in healthcare.[5] The potentials of systematic reporting to identify and tap on the underlying system gaps and latent failures that lead to safety incidents has been demonstrated in numerous hazardous industries over the past decades.[6] In these high risk industries, reporting has led to remarkable improvements in safety through the systematic investigations of events and the understanding and correction of their original failures. These successes triggered significant developments in various healthcare systems including the creation of national agencies charged with tracking adverse events and had inspired global recommendations to promote reporting and learning.[7] But, while some institutions have been relatively effective in building reporting systems that respond to their needs, others have found more difficulties.[8]

The reasons that prevent successful reporting practices are numerous and varied.[9] For reporting to be effective, there needs to be a clear awareness of its relevance and purpose across healthcare institutions and societies.[10] Clinicians and all those potentially involved in providing reports, including patients and relatives, need to share a culture of safety and improvement to boost their willingness to describe the circumstances and consequences that led to a harmful event.[11] In parallel, healthcare institutions and patient safety agencies must analyse the data on a timely fashion and more over return the learning back to those who reported in the first place, to the rest of the system and to the society at large with proposals, and actions for improvement.[12]

However, it is not always evident how to distil meaningful lessons

from patient safety reports. Many institutions are confronted with inherent difficulties to successfully analyse the growing quantity of often unstructured accounts of adverse events. To date, there is not a set of universal standards for data collection and storage, nor an agreed set of terminologies for incidents and their related factors and consequences. Most reports are provided by healthcare workers or patients, each having a partial understanding of a particular event and their circumstances, thus often lacking essential data to facilitate a complete analysis of the incident. Moreover, many reports are provided in natural language or narrative format. Despite the recent innovations in data mining and natural language processing, there is still a long way until these techniques could be applied routinely to the analysis of incident reports. Other techniques to extract learning from reports need as well to be streamlined and expanded. But, opportunities for sharing experiences, understanding and moreover effective and practical solutions from reporting systems are less than optimal.[13] Despite the parallelism underpinning the occurrence of adverse events across different institutions, learning does not easily cross the walls of organizations; less it crosses national and regional borders.

More fundamentally, the fear of blame and retaliation, the sense of guilt, underpinned by the lack of supportive structures and legal frameworks to protect the disclosure of events and reporting in confidential and blame-free environments are too often too powerful to deter meaningful reporting.[14] In many instances, reporters and the healthcare staff involved in the occurrence of events are not sufficiently protected from disclosure, perpetuating as a result a culture of occultation and self-blame, and, what is worse, the underlying conditions that led to patients' harm.

Once discovered, adverse events become an uncomfortable reality; but, as all other dark sides of reality, one that needs to be understood and confronted, in order to recover from it and comfort the victims, and in order to prevent the events from happening again. Studying, analysing, and therefore unveiling and documenting the facts when they occur is paramount

The WHO programme for reporting and learning

WHO is an intergovernmental organization of 194 Member States with the mandate to provide leadership on matters critical to health; shape the research agenda and stimulate the dissemination of valuable knowledge; set norms and standards and articulate ethical and evidence-based policy options; provide technical support for change, and monitor the global health situation [World Health Organization. About WHO: The role of WHO in public health. Available from: http://www.who.int/about/role/en/index.html]. In 2004, WHO set up the Patient Safety Programme aiming to catalyse and accelerate international action around patient safety interventions. As part of an ambitious programme of work, the Patient Safety Programme adopted as a priority the objective to facilitate and stimulate global learning through enhanced reporting of patient safety incidents.

The reasons that were present at that time are still valid. The occurrence of patient safety incidents go for the most part unnoticed by lack of effective notification, extraction of learning and adequate communication and exchange. The absence of a common language to name incidents in a manner that can be shared and understood across organizations and countries, and the lack of shared principles in which to base and root that communication, and share knowledge about common risks, hazards and patient safety events led to adopt a vision for the WHO programme.[15] The goal was to foster global learning through strengthening opportunities for exchange and sharing, by reinforcing the foundations for reporting systems.

Draft guidelines for adverse event reporting and learning systems

In 2005, WHO invited Lucian Leape, physician and professor at Harvard School of Public Health and world known expert in the field of patient safety, to help the Patient Safety Programme identifying some of the core and essential principles that healthcare institutions might wish to consider to strengthen reporting systems. The *WHO Draft Guidelines for Adverse Event Reporting and Learning Systems* synthesized those principles.[16] Stemming from a literature review and complemented by a survey of existing national reporting systems, together with the vast experience of the author, the publication objectives were to provide guidance on the core functions and principles for reporting as well as on the mechanisms for effective learning cycles. Their spirit was to provide general advice which could undergo modification over time as experience accumulated. Some of the core principles highlighted by the *Draft Guidelines* are as relevant today as when they were published. As such, the document highlights the importance of embedding reporting practices within a culture of safety and improvement, preserving blame-free environments to protect reporting, as well as the need for timely feed-back and for articulating effective responses, including recommendations for changes in processes and systems of health care, through the analysis of reports. The guides also covered criteria for setting, using and managing reporting systems. They have been and still are an important referent by many institutions worldwide.

International reporting and learning systems community of practice

The fundamental role of reporting systems is to enhance patient safety by learning from the failures of health care. Health-care errors are often provoked by weak systems and often have common root causes and solutions, which can potentially be generalized. Although each event is unique, it is also likely that there are similarities and patterns in the sources of risk that may be common across different institutions, organizational cultures, and communities. By facilitating exchange and sharing of experiences across organizational boundaries, it is possible that some of the existing and recognized problems in individual sites might be better understood, and that some of the solutions might be even more effectively formulated through the convergence of various complementary perspectives. In July 2008, WHO launched an *International Reporting and Learning Systems (RLS) Community of Practice* at a conference at Johns Hopkins University, in Baltimore, USA. Since its inception the RLS Community has grown to include hundreds of patient safety and adverse event experts from around the world working together.[17] Since 2012, the RLS Community was hosted by the Canadian Patient Safety Institute. The RLS Community charged itself with the purpose of sharing learning, innovations, solutions and best practices, and also to validate interventions and work to enhance awareness of reporting and learning systems issues globally. In addition to organizing online discussions, periodic webinars and occasional face to face meetings, one of the most relevant products developed so far is the *Concise Event Analysis* methodology for the rapid analysis of adverse events, based on the Canadian Concise Analysis Method [for further information see: http://www.slideshare.net/PatientSafety Canada/cpsi-incident-analysis-learning-series-module-05-2013-0131; and http://www.patientsafetyinstitute.ca/English/research/commissioned Research/IncidentAnalysisMethod PilotStudy/Pages/default.aspx]. In partnership with the Canadian Patient Safety Institute and the Johns Hopkins' Armstrong Institute for Patient Safety and Quality, WHO is now starting a global piloting of this tool.

The conceptual framework for the international classification of patient safety

One of the major obstacles to enable global exchange of lessons from reporting systems lies in the absence of a universally agreed taxonomy to define, name and categorize the range of possible incidents, their contributing factors and their consequences.[18] The pursuit of a common language for patient safety has driven much scholar effort and debate to these days. For about 3 years, WHO assembled an international expert panel, the *Drafting Group*, comprised of experts in patient safety, classification theory, health informatics, consumer/patient advocacy, law and medicine, with the task of defining, harmonizing and grouping core patient safety concepts as an initial step to set up a common terminology. The Drafting Group understood that the most crucial task was to agree and clarify a core set of conceptual definitions, while in a second instance, they will assign terms or labels to these concepts.[19] As a consequence, they defined 48 key concepts and labelled them with agreed preferred terms.

The most relevant definition that was proposed by the Drafting Group was the notion of *Patient Safety Incident as an event or circumstance that could have resulted, or did result, in unnecessary harm to a patient*. A patient safety incident can be a reportable circumstance, a near miss, a no harm incident or a harmful incident (adverse event). Incidents could be of different types, depending on their nature and other agreed features.[20] The group provided initial categorization for incident types, whose further validation and sub-categorization was left to be further developed by new academic work.

The Drafting Group also organized the basic concepts into meaningful categories, applicable to the full spectrum of healthcare settings in developing, transitional and developed countries. The set of meaningful categories organized around distinct relationships with the concept of the patient safety incident at its core, depicted the conceptual framework for the knowledge domain of patient safety. Both, the key concepts and conceptual framework were iteratively improved through a two-stage web-based modified Delphi survey and consultations with international stakeholders and safety experts, publishing the final versions in 2009 and 2011.[21,22]

In total, the Conceptual Framework is comprised of 10 high-level classes that together depict the universe of the concepts that are related to the occurrence and consequences of an incident. Gravitating around the *Incident type*, the framework recognizes the contributing factors, patient characteristics, and the set of outcomes the incident caused to both the patient and the organization. The framework ends with a cycle provided by the different actions that might be done to detect the incident, mitigate its impact, and prevent it from happening again (Figure 1). The categories related to the detection, mitigating

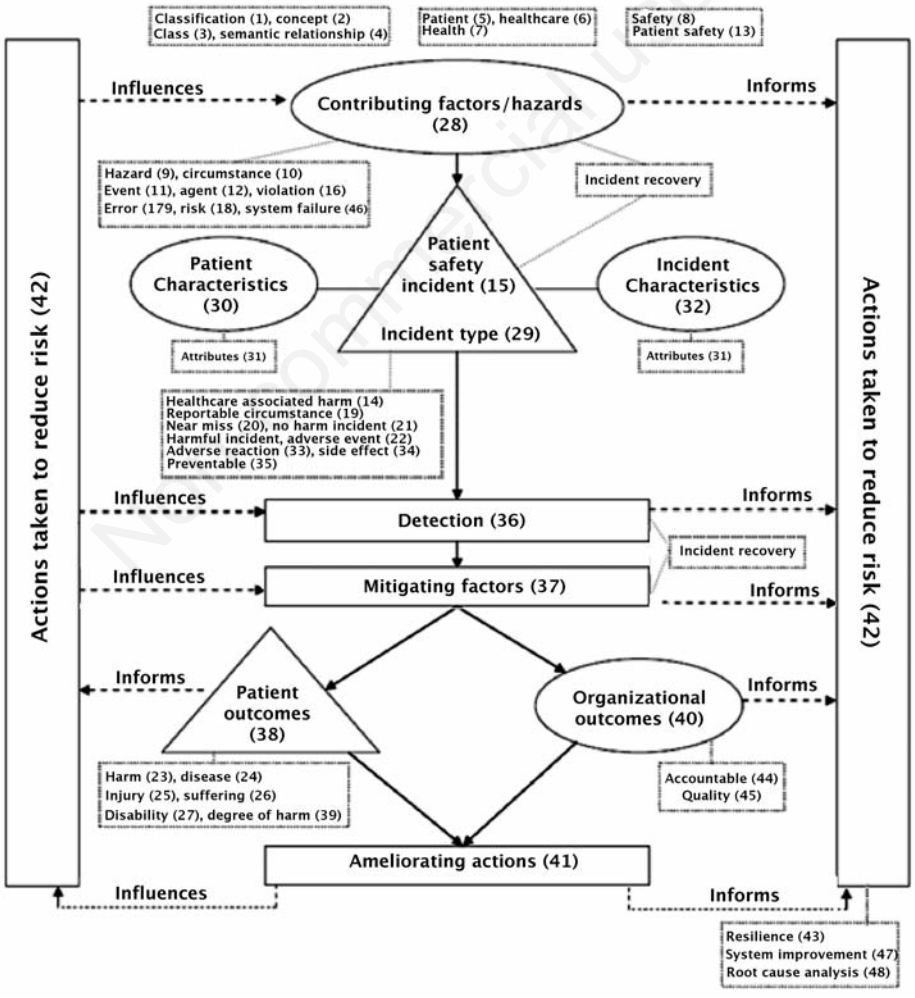

Figure 1. Conceptual framework for incident reporting. Rectangles: System resilience (proactive and reactive risk assessment). Triangles: clinically meaningful, recognizable categories for incident identification and retrieval. Circles: descriptive information. Dotted lines: relevant key concepts with preferred terms. Reproduced with the permission of the World Health Organization.

factors, ameliorating actions and actions taken to reduce risk were inspired in innovations from the hazard industry, bringing to the field of patient safety the notions of prevention, error recovery and system resilience, all of them particularly important to draw learning.

At the time the Conceptual Framework was published, it was regarded as the first step to a new Classification for Patient Safety. This understanding has matured over time as the intrinsic properties of the framework have become more clear. For example, there is need for academic research to populate the various categories of the Framework, such as the incident types or the detection factors. But while these and some other classes may require of new and specific taxonomies, for other classes, such as patient outcomes, there are fully developed taxonomies, such as the ICD. Therefore it may be likely that the steps to populate the Conceptual Framework would need to be mixed bringing together in an organized way, possibly various existing terminologies for some of the classes, while perhaps developing new taxonomies for additional categories. Therefore the framework may be better conceptualized as a relational entity, or as it is also defined, an information model, rather than as a fixed classification. Academic scholars having analysed the framework in the light of classificatory principles concluded its value as an information model, with clear advantages as a standard reporting instrument for change management and process improvements.[23]

The minimal information model for patient safety reporting

A *model* is a technical term that refers to a systematic representation of a knowledge domain, that is, a series of related concepts and the particular relationships across these concepts. The Conceptual Framework represents one information model which can be used to structure reports of patient safety incidents. It describes the key data categories that are of interest to understand what happened, why, and what were the consequences and reactions to it. It describes the key concepts and its relations; that is, an information flow.

One practical challenge posed by any model relates to its fit and application to particular settings. The scope and level of detail required by reporting systems may vary from place to place, depending on its intended use, the resources available and other context specific characteristics. Producing a unique information model may risk falling short or too ambitious.

A possible solution to provide the flexibility required to use the model in various contexts may be found by producing a tiered system, starting with what it could be considered as a Minimal Information Model. That is, a model containing the set of data categories that should be populated as a minimum when reporting patient safety incidents. This Minimal Information Model may be seen as the first layer of a more complete reporting system tailored to its own specific context. It could also be seen as the upper strata of a more comprehensive Common Information Model that may be envisaged for the future, if such further development proved necessary and affordable. Such efforts could potentially, be expanded if considered appropriate across different technical areas, such as haemovigilance, pharmacovigilance or other specific domains where particular developments have taken place over time.

WHO is currently working with a range of scientists, medical informatics specialists and healthcare officials from various countries around the world, to explore opportunities and eventually arrive at a minimal model that could serve as a basis to structure the core of reporting systems in a comparable manner across the world. This ongoing work is expected to advance by 2015. It is envisaged that through harmonizing a core data set, sharing and global learning across reporting systems will be largely facilitated.

An overview and next steps

WHO has worked over the past 10 years trying to promote global learning through encouraging the principles for reporting, facilitating opportunities for debate, exchange, and shared developments, and strengthening the information structure of reporting systems. The objectives were to accelerate reporting, build a global community of practitioners and also some of the fundamental aspects of its science. Nonetheless, the stage of reporting these days is far from being satisfactory. Despite its intrinsic advantages due to its higher potentials for providing contextual information about the circumstances of patient safety incidents and its relative lower costs as compared to other data extracting mechanisms, such as case note reviews, various studies have demonstrated the large underuse of routine reporting systems;[24] along with their limited sensitivity to identify harmful incidents as compared with medical records reviews or other mechanisms.[25,26] As a consequence, research also suggests the advantages of triangulating the evidence obtained from various data sources, including routine reporting systems, case note reviews and others, given the different and partial perspective about incident identification that each of these sources tap on.[27,28] Nevertheless, there are also some reporting systems that claim success in hosting a growing number of reports and in their ability to extract useful knowledge to prevent new incidents and build safer systems.[29] The success factors in some settings as well as the barriers to successful learning from reporting, from some other environments need to be understood in order to distil recommendations that could be helpful to a broad range of countries and systems. All of these factors will only become more important as health care organizations struggle to manage both greater amounts of data being generated from automated patient monitoring, often within a context of electronic health records systems. Undoubtedly, there is much need for additional scientific developments in this challenging and innovative area, including overcoming the technical and conceptual difficulties to analyse and make effective use of the data.[30] All of these areas may become renewed focused priorities for the academia to take on forward this direction of work.

But for effective reporting systems and enhanced global learning there is much more than sophisticated research and data systems. Other key contextual factors are essential for reporting to serve to the needs of clinicians, patients and the healthcare system at large. Reporting needs to be integrated in an enabling environment that facilitates and protects the disclosure of failures and of unintended harm to patients; and that also protects the healthcare professionals involved.[31] An environment with a strong and determined culture of safety and improvement, which include a positive attitude towards recognizing and sharing their own failures and which promote improvement through understanding the failures and speaking about them. Enabling environments for effective reporting also necessitate of operational and timely feed-back systems, and therefore of healthy, cohesive and constructive teams ready to change and improve through learning.[32] Strengthening the patient safety culture of organizations is one of the most important directions of travel for safer healthcare systems. Although there is not a single solution, there is increasing evidence about the effectiveness of interventions that encourage teamwork and professional engagement around the pursuit of meaningful clinical goals, such as the reduction of catheter led sepsis, which together with active error identification lead to reinforced patient safety culture and behaviour change.[33,34]

Table 1. Ethical principles underpinning reporting and learning.

Beneficence, non-maleficence	Collection and analysis of information related to patient safety incidents are pivotal in improving the risks-benefit ratio of medical interventions. As long as systems of reporting are effective in providing such learning, they might also help health care providers to be more efficient in their practices and to improve risk prevention. This responsibility is clearly expressed in professional policies.* How disclosure and reporting are exerted is key.
Governance: transparency, accountability, responsiveness	Based on the principles of transparency and accountability, health services should be prepared to disclose information about adverse events; mechanisms of compensation for patients potentially harmed may need to be in place. Appropriate responses to prevent the repetition of such events would be in consonance with these ethical principles.
Respect for dignity, autonomy, privacy	Patients are entitled to be informed in order to make free and informed decisions; the communication of potential risks is consistent with the information needed by the patients to make choice. Improving access to reliable information about potential adverse events could help fulfilling this ethical principle. A written informed consent is usually not requested for surveillance activities, however a general disclosure informing patients about the existence of reporting systems might be beneficial.° Due to the difficult delimitation between surveillance and research, specific guidance could be developed to define when a full informed consent process is required. People suffering harm due to an adverse event have a fundamental right to receive transparent information. It is the responsibility of health care providers to inform them and their relatives. Health professional may need to be trained to improve their communication skills. Reporting systems must prevent breaches of confidentiality and protect all personal data. Anonymous disclosure may be preferred for this reason, however this may need to be balanced with the need to come back to the patient if needed in some instances.
Empowerment	Good reporting and learning systems may facilitate more equitable access to key information and thus may empower stockholders, including patients organizations and the public and they may contribute to build a common culture of safety.
Integrity, responsibilities	In order to maintain integrity, and facilitate trust, with the public, health systems and health professionals have an ethical duty to disclose information related to adverse events as well as to try limiting their consequences. Health systems should protect health care workers from unjustified denunciations and retaliation; whereas responsibilities and their share need to be identified and fairly allocated.

*See for example World Medical Association, Declaration on Patient Safety adopted by the 53rd WMA General Assembly, in October 2002 and reaffirmed by the 191st WMA Council Session, in April 2012: *National medical associations should cooperate with one another and exchange information about adverse events, including errors, their solutions, and lessons learned to improve patient safety.* (http://www.wma.net/en/30publications/10policies/p6/). °In cases where individual informed consent from patients will not be sought, general disclosure to patients about patient safety research is highly recommended. WHO Ethical issues in Patient Safety Research Guidance point 6 http://apps.who.int/iris/bitstream/10665/85371/1/9789241505475_eng.pdf.

Above all, reporting needs of a protective environment for professionals, avoiding undue blame and retaliation, by providing and appropriate legal framework based on a systems-approach to understanding failures in healthcare, while also preserving as appropriate due individuals' accountability.[35]

Reporting about patient safety incidents cannot be disentangled from the notion of disclosure and respect to patients and their families. Reporting systems in principle look at learning for improvement or at providing public accountability, whereas disclosure looks at recognizing the incident and informing and communicating about it to the patients and relatives who suffered it. Both reporting and disclosing bear important ethical connotations that are necessary to understand in order to adequately frame the appropriate responses at the individual and systems level.[36] Table 1 shows an overview of some of the ethical principles that are questioned by the principles behind communicating and reporting of adverse events.

To be consistent with these ethical principles, reporting and learning systems require specific measures to be taken: a clear legal framework has to be developed to establish modalities of confidentiality, define liabilities and responsibilities; educational programs and capacity strengthening activities are needed for the different stakeholders to help them understand better how reporting tools should be used. Healthcare professionals need to strengthen their skills of communication with patients, especially when adverse events have to be disclosed. It is also fundamental to develop clear mechanisms to really learn from errors and put in place prevention strategies to avoid their repetition in a timely manner. Reporting and learning systems have to be considered as part of person centered care, aiming to empower patients and enable them to take part in decision making processes. A number of concrete questions should be addressed by all the relevant stake holders with an aim to build systems useful to all. For example mechanisms of peer review and analysis of the information should be agreed by all. It may be also useful to explore what is done in other domains such as health research where reporting systems are strictly defined by a number of common standards of procedures to report adverse events and analyse them in efficient and timely manner (see for example Data Safety Monitoring Boards).[37]

Over the past two decades, numerous calls have been made to facilitate reporting of medical errors and to strengthen a culture of safety based on lessons learnt.[38] To the opposite of a culture of blame, this cultural change allows patients as well as health care workers to build trust, improve safety and quality of care. High quality and person centered care are embedded on the exchange of transparent information between health professionals and patients; this open communication has to be promoted *outside the courtroom* and within a clear ethical framework.[39]

These considerations delineate a broad agenda for action, which together with the more technical aspects related to the data infrastructure and research methodologies, conform an ambitious challenge for WHO and their partners interested in strengthening learning for improving through reporting and communicating about patient safety incidents.

Acknowledgements

The work described here has only been possible thanks to the support of an impressive number of professionals and their institutions who very generously have collaborated with WHO over these past years offering

their knowledge and expertise. Among them, it is our honor to recognize the leadership, vision and strategic advice of Sir Liam Donaldson, WHO Envoy for Patient Safety and former Chief Medical Officer of England and Wales; Prof Lucian Leape, who graciously provided his wisdom to the development of the Draft Guidelines for Reporting and Learning; Peter Pronovost, Christine Goeschel, Albert Wu, Julius Pham and Sebastiana Gianci from the Bloomberg School of Public Health and the Armstrong Institute at Johns Hopkins Medicine; and Hugh Mc Leod, Paula Beard, Caroline Hoffman, and Erin Pollock from the Canadian Patient Safety Institute, who all contributed to the design, shaping and management of the R&L Community of Practice; as well as Noel Eldridge, Peter Goldschmidt and William Munier from the Agency of Health Care Research and Quality. The ICPS Drafting Group, included Martin Fletcher, now with the Australian Health Practitioner Regulatory Agency; Heather Sherman, the late Jerod Loeb, Richard Koss and Gerry Castro all with The Joint Commission; Martin Hatlie with Partnership for Patient Safety; Pierre Lewalle and Robert Jakob with the World Health Organization; Thomas V. Perneger with Geneva University Hospitals; Richard Thomson with Newcastle University Medical School; Tjerk van der Schaaf with Eindhoven University of Technology; Martti Virtanen with STAKES (Nordic Centre for Classifications in Health Care); and Peter Hibbert, Prof William Runciman, University of Adelaide and Joanna Briggs Institute and Tim Schulz from the Australian Patient Safety Foundation. The Australian team also contributed to the subsequent early developments in the population of the ICPS. In addition, Oscar Corcho from Universidad Politécnica de Madrid; Stephan Schulz; Medical University Graz, Jean Marie Rodriguez and Julien Souvignet from St Etienne University and Prof Masanori Akiyama from University of Tokyo, contributed to the development of the Categorial Structure and the ontological basis for the Minimal Information Model. Advisors to the development of the Minimal Information Model include Zafar Ahmed, National University of Malaysia; Mark Etienne and Luc Van Looy, GZA Ziekenhuizen Belgium; William Ghali, University of Calgary; Joergen Hansen, National Agency for Patients Right's Denmark; Farah Magrabi, University of New South Wales; Annemarie Taylor, British Columbia Patient Safety & Learning System; Terri Jackson University of Melbourne; Futaba Kaneyasu and Toshie Murakami, The University of Tokyo; and Kenichiro Taneda, Regional Office for the Western Pacific of WHO. Bedirhan Ustun and Nenad Kostanjsek, Najeeb Al-Shorbaji and Marie-Paule Kieny from the World Health Organization provided guidance, alignment with the WHO Family of International Classifications and the conditions to facilitate this work. Many more academics, medical informatics specialists, clinicians, patient safety experts and have provided their insights and relevant contributions in the developments described in this paper, to them we are indebted and thankful.

Correspondence: Itziar Larizgoitia, Service Delivery and Safety, World Health Organization, 20 Ave Appia, Geneva 27, 1211-CH, Switzerland.
E-mail: larizgoitiai@who.int
Key words: patient safety, taxonomy, reporting systems, information systems, safety management, communication.
Contributions: the authors contributed equally.
Conflict of interests: the authors declare no potential conflict of interests.
Received for publication: 1 November 2013.
Accepted for publication: 1 November 2013.

Journal of Public Health Research 2013; 2:e29
doi:10.4081/jphr.2013.e29

References

1. Kohn L T, Corrigan J M, Donaldson MS. To err is human: building a safer health system. Washington, DC: National Academy Press; 2000.
2. Stelfox HT, Palmisani S, Scurlock C, et al. The 'to err is human' report and the patient safety literature. Qual Saf Health Care 2006;15:174-8.
3. Jha AK, Larizgoitia I, Audera-Lopez C, et al. The global burden of unsafe medical care: analytic modelling of observational studies. BMJ Qual Saf 2013;22:809-15.
4. Pronovost PJ, Holzmueller CG, Ennen CS, Fox HE. Overview of progress in patient safety. Am J Obstet Gynecol 2011;204:5-10.
5. Pronovost PJ, Holzmueller CG, Young JB, et al. Using incident reporting to improve patient safety: a conceptual model. J Patient Saf 2007;3:27-33.
6. National Reporting and Learning Service. Lessons from high hazard industries for healthcare. National Patient Safety Agency, 2010. Available from: http://www.nrls.npsa.nhs.uk/resources/patient-safety-topics/.
7. National Patient Safety Agency. Building a memory: preventing harm, reducing risks and improving patient safety. The first report of the National Reporting and Learning System and the Patient Safety Observatory. National Health Service. 2005. Available from: http://www.nrls.npsa.nhs.uk/EasySiteWeb/getresource.axd?AssetID=60016&.
8. Mahajan RP. Critical incident reporting and learning. Br J Anaesth 2010;105:69-75.
9. Harper ML, Helmreich RL. Identifying barriers to the success of a reporting system. AHRQ Publication No. 05-0021-3. Available from: http://www.ahrq.gov/professionals/quality-patient-safety/patient-safety-resources/resources/advances-in-patient-safety/vol3/Harper.pdf.
10. Parrella A, Braunack-Mayer A, Gold M, et al. Healthcare providers' knowledge, experience and challenges of reporting adverse events following immunisation: a qualitative study BMC Health Serv Res 2013;13:313.
11. Neuspiel DR, Guzman M, Harewood C. Improving error reporting in ambulatory pediatrics with a team approach. In: Henriksen K, Battles JB, Keyes MA, Grady ML, eds. Advances in patient safety: new directions and alternative approaches. Vol. 1. Assessment. AHRQ Publication No. 08-0034-1. Rockville: Agency for Healthcare Research and Quality; 2008. Available from: http://www.seguridaddelpaciente.es/contenidos/castellano/Volumen_1_Assessment.pdf.
12. Pronovost PJ, Morlock LL, Sexton B, et al. Improving the value of patient safety reporting systems. In: Henriksen K, Battles JB, Keyes MA, Grady ML, eds. Advances in patient safety: new directions and alternative approaches. Vol. 1. Assessment. AHRQ Publication No. 08-0034-1. Rockville: Agency for Healthcare Research and Quality; 2008. Available from: http://www.seguridaddelpaciente.es/contenidos/castellano/Volumen_1_Assessment.pdf.
13. Walshe K, Shortell M. When things go wrong: how health care organizations deal with major failures. Health Aff (Millwood) 2004;23:103-11.
14. Howard J, Levy F, Mareiniss DP, et al. New legal protections for reporting patient errors under the Patient Safety and Quality Improvement Act: a review of the medical literature and analysis. J Patient Saf 2010;6:147-52.
15. World Alliance for Patient Safety. Forward programme 2008-2009. Geneva: World Health Organization; 2008.
16. World Alliance for Patient Safety. who draft guidelines for adverse event reporting and learning systems: from information to action.

Geneva: World Health Organization; 2005.
17. Pham JC, Gianci S, Battles J, et al. Establishing a global learning community for incident-reporting systems. Qual Saf Health Care 2010;19:446-51.
18. Donaldson L. An international language for patient safety: global progress in patient safety requires classification of key concepts. Int J Qual Health Care 2009;21:1.
19. The World Alliance For Patient Safety Drafting Group: Sherman H, Castro G, et al. Towards an international classification for patient safety: the conceptual framework. Int J Qual Health Care 2009;21:2-8.
20. Runciman W, Hibbert P, Thomson R, et al. Towards an international classification for patient safety: key concepts and terms. Int J Qual Health Care 2009;21:18-26.
21. Thomson R, Lewalle P, Sherman H, et al. Towards an international classification for patient safety: a Delphi survey. Int J Qual Health Care 2009;21:9-17.
22. World Health Organization. Conceptual framework for the international classification for patient safety. Version 1.1. Final technical report. WHO, Geneva. 2009. Available from: http://www.who.int/patientsafety/implementation/taxonomy/icps_technical_report_en.pdf.
23. Schulz S, Karlsson D, Daniel C, et al. Is the 'international classification for patient safety' a classification? In: Adlassnig KP, Blobel B, Mantas J, Masic I, eds. Medical informatics in a united and healthy Europe: proceedings of MIE 2009, volume 150 studies in health technology and informatics. Amsterdam: IOS Press; 2009.
24. Sari AB, Sheldon TA, Cracknell A, Turnbull A. Sensitivity of routine system for reporting patient safety incidents in an NHS hospital: retrospective patient case note review. BMJ 2007;334:79.
25. Naessens J, Campbell C, Huddleston J, et al. A comparison of hospital adverse events identified by three widely used detection methods. Int J Qual Health Care 2009;21:301-7.
26. Williams DJ, Olsen S, Crichton W, et al. Detection of adverse events in a Scottish hospital using a consensus-based methodology. Scott Med J 2008;53:26-30.
27. Kessels-Habraken M, Van der Schaaf T, De Jonge J, et al. Integration of prospective and retrospective methods for risk analysis in hospitals. Int J Qual Health Care 2009;21:427-32.
28. Levtzion-Korach O, Frankel A, Alcalai H, et al. Integrating incident data from five reporting systems to assess patient safety: making sense of the elephant. Jt Comm J Qual Patient Saf 2010;36:402-10.
29. Smith AF, Mahajan RP. National critical incident reporting: improving patient safety. Br J Anaesth 2009;103:623-5.
30. Vincent CA. Analysis of clinical incidents: a window on the system not a search for root causes. Qual Saf Health Care 2004;13:242-3.
31. Wu A. Medical error: the second victim. BMJ 2000;320:726-7.
32. Evans SM, Berry JG, Smith BJ, et al. Attitudes and barriers to incident reporting: a collaborative hospital study. Qual Saf Health Care 2006;15:39-43.
33. Pronovost PJ, Goeschel CA, Colantuoni E, et al. Sustaining reductions in catheter related bloodstream infections in Michigan intensive care units: observational study. BMJ 2010;340:c309.
34. Dixon-Woods M, Bosk CL, Aveling EL, et al. Explaining Michigan: developing an ex post theory of a quality improvement program. Milbank Q 2011;89:167-205.
35. Wachter RM, Pronovost PJ, Balancing no blame with accountability in patient safety. N Engl J Med 2009;361:1401-6.
36. Hannawa A. Principles of medical ethics: implications for the disclosure of medical errors. Medicolegal Bioethics 2012;2:1-11.
37. World Health Organization. Ethical issues in patient safety research: interpreting existing guidance. Geneva: World Health Organization; 2013.
38. World Medical Association. Declaration on patient safety. 53rd WMA General Assembly and 191st WMA Council Session, 2012. Available from: http://www.wma.net/en/30publications/10policies/p6/.
39. Clinton HR, Obama B. Making patient safety the centerpiece of medical liability reform. N Engl J Med 2006;354:2205-8.