

International Consultation on European Validation of the Minimal Information Model for Patient Safety Incident Reporting and Learning

12-13 May 2015, Warsaw, Poland

Technical Report



ABSTRACT

The 'International Consultation on European Validation of the Minimal Information Model for Patient Safety Incident Reporting and Learning' represented a milestone in the finalization of the European Union (EU) and World Health Organization (WHO) project on Minimal Information Model for Patient Safety (MIM PS) Incident Reporting and Learning. Forty-five participants, including the countries participating in the project, international experts from Australia, Canada, India and Japan, national experts in Poland, the project research team and WHO staff attended the International Consultation. The compiled results of the research undertaken during the previous 15 months were presented and discussed, while comparing with the experience of other reporting and learning systems. Consensus was reached for MIM PS validation in its extended format, and it was considered extremely useful as a common denominator for the development of reporting systems where these have not yet been established, for their compilation at national level where applied randomly, and for collating data at the EU level from very developed systems, so that the learning component can be shared and enhanced.

Keywords: Quality of care, Patient safety, Health systems, Reporting and learning

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1. Executive summary

The International Expert Consultation on the European validation of the Minimal Information Model for Patient Safety (MIM PS) incident reporting and learning was held on 12-13 May 2015, in Warsaw, Poland. It was organized by the WHO Headquarters Patient Safety and Quality Improvement Unit in the Service Delivery and Safety Department, in close collaboration with the WHO Collaborating Centre on Quality of Care, Krakow, the WHO Country Office for Poland, the WHO Regional Office for Europe, with the support of the European Commission's Directorate General for Health and Food Safety, and hosted by the Polish Ministry of Health.

The International Consultation represents a milestone in the finalization of the EU-WHO MIM PS project. Forty-five participants, including each of the project participating countries, international experts from Australia, Canada, India and Japan, national experts from Poland, the project research team and WHO staff participated in the International Consultation.

The compiled results of the research undertaken during the previous 15 months were presented and discussed, and comparisons with the experience of other reporting and learning systems were made.

Consensus was reached for MIM PS validation in its extended format, and considered extremely useful as a common denominator for the development of reporting systems where these have not yet been established; for their compilation at national level where applied randomly; and for collating data at the EU level from very developed reporting systems, so that the learning component can be shared and enhanced.

The outcomes of the International Consultation were then presented to the EU Patient Safety and Quality of Care Expert Group in Brussels, on 8 June 2015.

2. Introduction

The Minimal Information Model for patient safety incident reporting and learning (MIM PS) was developed by WHO in 2012, drawing from international experience and previous work on reporting and learning¹ and patient safety taxonomy^{2,3}.

The International Expert Consultation on the MIM PS validation process represents an important milestone in rendering this tool acceptable for use in EU and EFTA (European Free Trade Association) countries. Being part of a project launched under a collaborative agreement between the EU and WHO, at the end of 2013, this work builds on several research steps exploring mapping, usability and acceptability for rolling out the MIM PS for general and widespread use.

¹ WHO draft guidelines for adverse event reporting and learning, WHO, 2005

² 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

³ International classification for patient safety, WHO, 2009 www.who.int/patientsafety/implementation/taxonomy/publications/en/

The International Consultation was jointly organized by the WHO Headquarters Patient Safety and Quality Improvement Unit, in close collaboration with the WHO Collaborating Centre (WHO CC) on Quality of Care, Krakow, the WHO Country Office for Poland, the WHO Regional Office for Europe, with the support of the European Commission's Directorate General for Health and Food Safety, and hosted by the Polish Ministry of Health.

It was held on 12-13 May 2015, in Warsaw, Poland, and was attended by 45 participants, including the project participating countries, international experts from Australia, Canada, India and Japan, national experts from Poland, the project research team and WHO staff.

3. Opening session

The International Expert Consultation was opened by the Head of the WHO Country Office, Dr P. Mischiewicz, placing the event in the context of two anniversaries addressing one of the simplest but essential patient safety interventions: the 10th anniversary of the launch of the WHO Clean Care is Safer Care programme, and the 150th commemoration of the death of Dr I. Semmelweis, the pioneer of hand hygiene and antiseptic procedures.

Dr I Rdziewicz-Winnicki, Undersecretary of State, Polish Ministry of Health, gave the formal welcome intervention, highlighting the continuous path of change that the Polish National Health Service is going through as it strives to improve quality and safety of service delivery. Areas already addressed include the rationalization of services and pharmaceuticals and implementation of quality standards, with the recently introduced standards for cancer care. The well-established knowledge of safety and quality requires further practical guidance and a common language for comparability and sustained improvement of health services.

The WHO CC host institution extended the welcome, emphasizing the importance of local culture in implementation of which reporting and learning is a part. The role that Poland has played in moving forward the patient safety agenda since 2004, including during the Polish EU Presidency and the Warsaw statement on patient safety were mentioned as setting the scene for the two days of discussions around the MIM PS validation project.

Two chairpersons were elected for the International Consultation: Dr B. Kutryba, WHO CC Krakow, Poland, as chairperson for the first day, and Dr P. Bandura, Ministry of Health, Slovakia, as chairperson for the second day. Dr V. Hafner acted as rapporteur for both days.

3.1 Introduction to the Minimal Information Model and consultation objectives

The new Patient Safety and Quality Improvement Unit in the Service Delivery and Safety Department, within the Health Systems and Innovation cluster supports strategic vision in matters critical to patient safety, and quality of care and promotes best practices to address the alarming global burden of unsafe medical care, which sees an estimated 43 million injuries per year and nearly 23 million DALYs lost.⁴

⁴ Jha AK, Larizgoitia I, Audera-Lopez C, et al, BMJ Qual Saf 2013; 22:809-815

WHO had initiated work on reporting patient safety incidents and learning to prevent reoccurrence of harm by developing the Draft Guidelines for Adverse Event Reporting and Learning in 2005, and the International Classification for Patient Safety (ICPS) Conceptual Framework a few years later, in 2009. The Minimal Information Model for Patient Safety incident reporting (MIM PS) was empirically developed to facilitate and enhance learning from patient safety reports, by simplifying the data categories required for analysis.

The EU–WHO project to validate MIM PS in the European context was initiated in 2014. The assessment of EU reporting systems for MIM PS compliance and for information sufficiency was carried out as part of this project. The work on building a glossary of incident types and current practices for learning is currently in progress. The objectives of the International Consultation were, to:

- Review compiled project results and MIM PS potential for broader use and field adaptation;
- Share and learn from international best practices in reporting and learning for patient safety;
- Agree on the MIM PS content and validate for use or recommend further improvements;
- Identify priorities for enhanced reporting and learning and future strategic directions

3.2 Work on patient safety and quality of care at the EU level

EU action in the field of patient safety and quality of care has so far focused on: a) sharing knowledge and experience through the establishment of the EU Patient Safety and Quality of Care Expert Group (PSQC EG) currently chaired by Poland; and the EU network for patient safety and quality of care (PaSQ Joint Action); b) classifying and measuring patient safety, and c) developing and promoting research. Multiple patient safety initiatives are ongoing, in close collaboration with international partners such as WHO and the Organisation for Economic Co-operation and Development (OECD).

Upcoming EU activities in the field build on the 2nd Commission Report on Implementation of Recommendation 2009/C151/01, Council Conclusions on Patient Safety and Quality of Care of 1 December 2014, PaSQ Joint Action, and the European Parliament's report on safer healthcare in Europe, voted on 19 May 2015.

Discussions towards developing a framework for sustainable EU collaboration on patient safety and quality of care started in the EU PSQC EG, in February 2015. The framework, to be completed by December 2016, aims to facilitate mutual learning and exchange of patient safety good practices and strategies between Member States, and to facilitate their implementation.

3.3 WHO Collaborating Centre (WHO CC), Krakow work on quality and safety of care

The WHO CC for developing quality and safety in health systems that hosted this event is part of the National Centre for Quality Assessment (NCQA) in Poland. The WHO CC

(established in 2005) has implemented WHO biennial collaborative agreements, and dedicated quality and safety projects and interventions (PATH secretariat, translation and adaptation of WHO hand hygiene guidelines, surgical Safety checklist adapted for seven surgical specialties and work on medication reconciliation).

The NCQA, which hosts the WHO CC, was established in 1994. Its main area of work is the accreditation of health-care settings, while building and supporting local capacity in safety approaches and the application of quality standards.

The programme of accreditation in Polish Health Care (developed with USAID support and based on JCAHO and Canadian models) started with hospital accreditation in 1998, and extended to primary care accreditation in 2004, and addiction centers accreditation in 2013. Law 6 of November 2008 on accreditation in health care regulates this voluntary process based on three-year accreditation cycles. There are 221 standards grouped into 15 sections, of which one part is dedicated to safety, and includes reporting systems. Implementation has been supported by two consecutive EU-funded projects as part of the operational programme, Human Capital. The number of health-care settings participating has increased exponentially over the years, reflecting directly on the quality and safety of delivered care. The national ranking of hospitals started in 2004, and EU support for accreditation came as an incentive for active hospital enrolment in this programme.

4. The MIM PS project – research results

The project entailed several research steps based on report analysis and targeted surveys to participating countries, to explore and document usability and acceptability of the MIM PS format for extended use as part of the validation process. For easy reference, the research steps presented during the event are summarized below.

4.1 Analysis and results of the survey for MIM PS mapping to national systems for safety reporting and learning

The ICPS conceptual framework, published by WHO in 2009, was the starting point for MIM PS development, so that Patient Safety Categorial Structures (PS-CAST) could become more suitable for computer modelling. The PS CAST complex domain (160 concepts) was tested with patient safety reporting systems in Australia, Belgium, Canada, Denmark and Japan, to define the MIM PS - the simplest set of information necessary to satisfy basic needs for patient safety monitoring. MIM PS contains eight data categories, with a more comprehensive format available for countries experienced in patient safety, and will be accompanied by an incident reporting guide.

The validation of MIM PS with European reporting systems (pilot sites) reviewed 30 reporting templates submitted by 10 participating countries against the eight MIM PS information categories. The over 90% average compliance rate confirmed that MIM PS contains common basic information categories present in most existing reporting and learning systems and that it is possible to complete the MIM PS locally to satisfy hospital or national requirements.

The mapping of MIM PS (six-question survey) reflected the heterogeneity of responders. These were subsequently split into a 'practical experience group', an 'early experience group', and an 'Others' group, closely linked to reporting systems development. The conclusions pointed towards a structured MIM PS extended to 10 data categories as level one, with additional free text reporting for the incident types, aggravating/mitigating factors and causes identified through analysis. This strategy will allow basic comparison with all MIM PS and provide material to develop terminology that could be introduced in a stepwise manner in this format.

4.2 Analysis of the general survey on MIM PS applicability

The general survey (44 questions) conducted between November 2014 and February 2015 analysed the applicability and acceptability of the draft MIM PS in European countries, and how reporting systems can enhance learning practices, and the role of MIM PS in this process. Responses were collected through the electronic survey platform developed for the purpose, and 31 complete responses (out of 88 received) from twelve countries were analysed.

Reporting systems appeared to be largely operational at national level in most of the countries surveyed, with additional layers of reporting at regional/local or/and institutional levels present in some countries. But for some countries, information was received from institutional levels only.

The validation analysis showed general compliance with MIM PS (conformance was based on compared information content in the submitted reports with the MIM PS information categories). This was seen as a useful and acceptable tool, and its inclusion in the reporting systems deemed feasible. The additional information categories proposing ICPS for an intermediate extended MIM PS, depending on context, were positively evaluated. MIM PS was considered particularly valuable where reporting systems are not yet established. Where patient safety reporting systems are already in place, the efforts required for MIM PS adaptation would need to be further evaluated.

The learning component of patient safety reports was unanimously recognized, however the extent in terms of content and coverage of the learning process varied in the systems surveyed. Root cause analysis and simple analysis were most commonly used to identify the sources of error. Resulting information was disseminated to health-care workers, with less than expected outreach to the education and research sectors. Analysis showed that information is shared, but not used to its full potential, hence the need to foresee MIM-PS use in strengthening the learning component was recognized.

4.3 Methodology for analysing the patient safety incident types

Sustained work to define patient safety classifications crystalized in the ICPS conceptual framework (2009/ 13 incident type categories) and later the PS CAST (2010-2012/ around 30 ontological entities for incident type), highlighted the need for a common taxonomy

adaptable to existing patient safety systems and starting with incident types. Furthermore, the 13 countries surveyed as part of MIM PS validation exercises reported a limited use of ICPS.

The reference incident type definitions of ICPS, JCAHO, AHRQ, ICD-10 CHADx (Australian adaptation of ICD-10) and ICPS-be (Belgian adaptation) were reviewed as part of the methodological approach to define a standardized terminology for MIM PS Incident Types. Variations in the terminology of definitions were analyzed to develop the related ontology components for computerization. These aspects are presented in detail in the analysis of incident type taxonomies used in MIM PS under development.

A multi-layered approach to developing a standardized terminology was proposed, encompassing several levels: the basic formal ontology (BFO) as upper level ontology (ULO), and the PS-CAST, the ICPS, the ICD-11 chapter 23 and ICD-10 CHADx. This would be a combination of the simplest components of every layer. The standardized terminology for MIM PS incident types could therefore align with an upper level ontology (BFO2). The PS CAST is compatible with BFO2. ICPS and PS CAST alignment would require reorganization of incident types into three main categories. At level 4, ICPS would be aligned with ICD-10 CHADx and ICD-11 chapter 23 (under development).

Several options were proposed: to maintain the ICPS, to use ICPS-be level 4, the four-level approach (BFO, PS CAST, ICPS, ICD), develop a glossary of incident type terms based on information from the project participating countries, or create a new taxonomy for incident types from scratch. This work is in progress.

5. International experience in reporting & learning systems for patient safety

Several case studies of existing reporting and learning systems from Europe and other continents were presented, to complement the research component with national experiences from the field, in the process of finalizing the validation process of the MIM PS.

FIRST ROUND TABLE: EUROPE

5.1 Case study from Denmark: The Danish patient safety database

A patient safety law passed in 2003 determined the establishment of a national system of incident reporting for both public and private hospitals from 2004. It expanded in 2010 to include municipalities (other health services) and then in 2011, also general practices, patients and families. The number of reports received has been constantly increasing since 2004, with especially high levels of reporting from the municipality levels.

The Danish reporting system is mandatory, confidential and non-punitive. It uses a classification with 18 types of incidents, 117 process levels and 138 problem levels. All reports are centralized in one national database for patient safety. The municipal council analyses the primary care reports, the regional council - the public and pre-hospital care reports, and private hospitals analyse their own reports. The resulting information is

translated into various publications (alerts, newsletters, annual reports, etc.) and local patient safety initiatives.

The system, with 10 years' experience, efficiently supports patient safety interventions, but requires strengthened cooperation to improve information flow and enhance the learning component and positive outcomes.

5.2 Case study from Hungary: Software-based reporting and learning

The pilot programme for a national adverse event reporting and learning system started in 2006 and developed into a hospital-based reporting system. Reporting is voluntary, anonymous, and non-punitive, with a system oriented feedback. Software for automatic analysis, structured forms, and trend analysis are all part of the new solutions to enhance feedback to the reporter and promote learning for patient safety.

The event report sheets are useful for exploring systematic errors, enhance organizational learning, system and process management and planning, but cannot be used for incidence analysis or epidemiology research. New data collection forms (structured questionnaires) follow the logic of earlier formats expanding reportable events from six to 21 categories (with event-specific data collection forms). A statistical module with predefined statistics supports users in defining required analysis.

The national reporting for patient safety (NEVES) programme, hosted by the Semmelweis University, has 54 registered institutions and 230 registered users. Reporting systems for patient safety adverse events are part of the accreditation standards.

5.3 Case study from Italy: The Italian monitoring system

The National Observatory of Sentinel Events was established by the Ministry of Health as an alert system for clinical care conditions prone to higher risk of error. Reporting is confidential, non-punitive, independent, responsive and system oriented. The reported adverse events are forwarded to the National Health Information System through the Information System Monitoring Sentinel Events (SIMES). SIMES was established by Ministerial Decree 11 Dec 2009. It follows a standardized protocol and operates with a list of 16 sentinel events.

Data is validated and centralized from local (hospitals and health facilities) to regional, and from regional (Regions and Autonomous Provinces) to national (Ministry of Health) levels. Root cause analysis and auditing are the main methods of analysis. Emerging recommendations are disseminated to regions, organizations and operators.

The number of reports received between 2005 and 2013 increased twenty-fold. Five steps for quality improvement have been defined: site visit (informal inspection where sentinel event occurred), analysis (expert review of the reported case), recommendations, data collection on sentinel event, and monitoring (health-care system performance indicators linked to financial grants).

5.4 Case studies from Poland

Accreditation of hospitals has been the major transformation tool for bringing about change in patient care. The main focus of the national accreditation system is patient safety, reporting and learning and analysis of clinical performance. Updating experience and knowledge of hospital staff runs in parallel with hospital performance monitoring. The concept of teamwork introduced with the accreditation process further enhances clinical performance and patient provider communication.

5.4.1 The 15th year of the quality journey in Elblag provincial hospital

The provincial hospital has 610 beds, 23 hospital departments, 341 physicians, 595 nurses and midwives, and over 40 300 admissions per year. It has been engaged in the accreditation programme for hospitals since 1999.

The 'Improvement of Quality and Patient safety in Hospital Departments' analysis chart was introduced following changes in the accreditation programme (2009). The chart has 12 areas for monitoring, completed every quarter by the department coordinator. The quality specialist prepares a report on quality and patient safety as recorded by each department, for hospital management. Patient safety data is analysed twice a year, complications discussed after each event, and reports of infections presented every quarter to the Medical Director. The register of adverse events with conclusions and defined improvement activities is presented to the heads of each department and to the Medical Director of the hospital.

5.4.2 Fifteen years after the first accreditation certificate of Lublin University Hospital

The University Hospital has a mean turnover of 34 842 patient admissions per year and 15 361 surgeries per year. Following sustained education on patient safety, the 'Adverse Events Register Book' was introduced in 2005. A mean of 35 reports of adverse events have been recorded between 2005-2013, predominantly patient falls.

The institution has a sustained focus on strengthening the safety culture for health-care professionals and patients. As such, particular attention is being given to continuous medical education and patient safety promotion. Education programmes for students are considered the basis for building a patient safety culture and a positive attitude towards reporting and learning.

5.5 Case study from Portugal: The Portuguese reporting and learning system

The national reporting and learning system for patient safety was launched in 2012 (Orientation no. 25/2012) and is regulated by the Directorate-General of Health guideline no.15/2014. Developed using the WHO ICPS, it does comply with a majority of MIM PS listed categories. Reporting is mandatory, anonymous, covered by full confidentiality, and promotes a learning and blame-free culture. Both health-care professionals and citizens are encouraged to report adverse events.

The System Manager, designated by each health-care organization, has the obligation to perform root cause analysis for each notification, maintain the board of directors informed and ensure that corrective actions are implemented. The National Coordinator must perform the national analysis of reports, spread learning experiences, organize the training of health-care professionals, and publish newsletters with national results for patient safety.

A number of 1081 patient safety notifications (960 from health-care professionals and 121 from the general public) have been received up to April 2015.

SECOND ROUND TABLE: OTHER CONTINENTS

5.6 Case study from Australia: Surveillance, monitoring and response to infrequent incidents at the population level

Well-established policy frameworks regulate the local electronic reporting systems that manage and investigate patient safety incidents. The systems are run by the States, leading to standardized approaches in information technologies, education, classification and definitions. Resources available for clinicians, education and information products are part of an integrated transformational programme.

A large responsive incident system enables aggregation of data of locally significant risks, characterizing clusters of information with similar features, to propose corrective and preventive strategies and national recommendations. The rapid response process aims to provide proportionate, evidence-based and action-based solutions. The infrastructure requirements include information technologies (software to manage the incident response process), criteria for identifying patient safety risks that require a population response, supported by a structured decision-making process (multi-disciplinary team), response formats and mechanisms to disseminate and track recommendations.

Rapid response reports (RRR) are issued regularly, and follow a standardized format with supporting information. Other outputs include clinical audit implementation tools, and detailed evidence. Compliance mechanisms with recommendations for hospitals are in place. The system works efficiently but needs to be supported by an education continuum and monitoring for RRR threshold to ensure further improvement of timeliness and performance.

5.7 Case study from Japan: Patient safety national reporting and learning system

In the Western Pacific Region, several collaborative patient safety initiatives have been developed through joint inter-regional projects and with the OECD. The ICPS is used in a few countries in the region, such as Australia (for national definitions), China and Hong Kong, SAR (for the electronic Advanced Incident Reporting System) and the Republic of Korea (used in some hospitals).

In Japan, a series of serious medical incidents and increasing numbers of medical lawsuits prompted national patient safety measures. A legal and regulatory framework for patient safety was developed following the report on coordinated comprehensive patient safety measures presented by the Patient Safety Promotion Office to the Review Committee for Patient Safety. Three ministerial ordinances on patient safety in hospitals and consultation services (2002 and 2003), the reporting of medical accidents (2004) and a law (2006) to support administrative patient safety structures at the local level were issued. The Council for Quality in Health Care (JCQHC) manages the national reporting system. Reporting is mandatory, with results published as monthly alerts (medication safety information), as well as in the form of quarterly and annual reports.

An inspection system for medical accidents and a planned medical accident review system are part of a new initiative to be launched in October 2015. Supporting patient safety implementation is a priority of the Ministry of Health, Labour and Welfare, which fosters a multi-stakeholder participative approach.

5.8 Case study from India: Patient safety in the South-East Asian Region

The South-East Asian Region covers eleven countries, India being the largest. Regional initiatives to address the lack of safety culture and patient empowerment have focused on hand hygiene, patient safety checklists and the education of health-care professionals and patients. A Regional Patient Safety Strategy with six strategic objectives has also been developed.

India has 1.37 million hospital beds and 15 393 hospitals (public and private sector). Quality and safety of care are matters of serious concern (with a mean of 34% estimated medical errors), which the draft national health policy under preparation aims to address.

Patient safety interventions have included the National Accreditation Board for hospitals and health-care providers (2006) which requires mandatory reporting of sentinel events; the Clinical establishment act 2010, which regulates registration according to minimum standards; the National Coordination Centre for Pharmacovigilance, working with individual case reporting forms. Patient safety target interventions promote hand hygiene, safe surgery, and other patient safety solutions, with the Association of Health Care Providers and Hospital Infection Society being deeply involved in the patient safety education and training of health-care professionals.

6. ICD revision for quality and safety

The current review and update of the ICD-10 to ICD-11, is looking at how to better incorporate quality and safety aspects of care in reporting. The safety and quality of care is a theme that spreads across chapters, and as such its measurement is central to health system accountability and improvement. ICD-11 creates new opportunities for recording quality and safety data with greater reliability and efficiency.

Ideally, all key concepts from ICPS and the conceptual framework should map to ICD-11 codes. This could lead to a new chapter dedicated just to patient safety incidents, or a complete mapping virtual chapter. The Technical Advisory Group (TAG) working on the development of ICD-11 has started, in this respect, a horizontal review across chapters, coding rules, volume 2 of ICD-11, and applicability of ICD-10 indicators in the updated version. Revision of chapters 19 and 20 (injury and external causes) and especially code ranges T80-88 and Y40-84 is of particular relevance for the topic. Four sources of harm (and for each the cause, mechanism and actual harm) are identified: medication and substances, procedures, devices and other aspects of care.

Field trials, stakeholder surveys, clinical episode coding trials, and code-recode trials have been initiated as part of the validation process of definitions and reviewed recoding for the area of quality and safety. The results are published by the TAG in academic journals, as part of disseminating findings and ensuring that validation process results are known and progress is monitored. Knowledge exchange, dialogue and collaboration with international leaders in patient safety, WHO and partners are expected to support the process of ICD enhancement, and handling of data potential in monitoring the quality and safety of care.

7. Validating the MIM PS for general use

The validation of MIM PS for general use was aimed to establish the format as a reference framework to enhance learning from reporting systems through shared information. The quantitative and qualitative analysis of surveys performed, covered various operational levels of reporting systems: national, regional, local and institutional.

The mapping of MIM PS to national reporting and learning systems showed general compliance and proposed a two-level approach: a standard eight item format and an extended ten item model depending on the local experience.

The MIM PS applicability survey showed general acceptability, with minor reservations generated by confusions over information category levels and the choice of reporting and learning analysis methods for inclusion. Further structuring of the information categories (e.g. ICD coding, SAC, ICPS) were suggested for developed reporting systems, being already used in medication safety reporting. The main challenges to implementation were reported to be: existing policies and practices, information technology and cost, and last but not least, safety culture.

Reporting and learning systems are used as a source of knowledge in setting patient safety priorities, ministerial recommendations, theme reports, warning and attention notes, information bulletins, updated good practices, teaching sessions and statistical analysis – but never in all settings nor in all countries. The main obstacles to retrieving learning from report analysis relate to existing systems, data handling and outreach, as well as staff awareness and openness to change.

Enhancing the learning component would require faster and wider access to information, quicker feedback to frontline workers and sustained education and team training.

Participants recommended reporting and learning as a top priority for hospitals, with more disclosure of information to the public needed also.

The validation analysis and discussions concluded that MIM PS could be used as a basic reference tool where reporting and learning systems do not yet exist, and for the clustering of information in more developed systems, to enhance comparability. As such, it would support learning by facilitating aggregation of lessons learned at a higher level, with the potential to become a useful tool for orienting policy decisions to improve patient safety.

8. Priorities for enhanced reporting and learning systems for patient safety

Agreeing on a basic framework for sharing information and lessons learned from reporting and learning systems at the EU level is expected to enhance the learning component through comparability, shared and compiled analysis, as well as identification of patient safety priorities at local, regional, national and eventually at global levels.

The research results and subsequent discussions confirmed that MIM PS can be used as planned, once there is a clear understanding of what the information categories contain. Participating countries have different systems, different levels of development, different approaches/cultures and different legacies to be considered in the local implementation/adaptation of this tool. The 22 languages existing in the European Union will also require close attention being given to the translation aspects of a common template for clustering information from different reporting systems.

There is a strong need and clearly stated interest to enhance the learning potential of reporting systems, but this is hindered by limited resources, limited time and work overload. In such instances, even basic statistics can become a useful source for identifying alerts, with further structured analysis, when capacity allows, being used for remedial actions.

Breaking resistance to change and enforcing a safety culture requires knowledge, patient-provider involvement and patient safety leadership. Dedicated training of health-care staff and leaders (e.g. via the WHO Patient Safety Curriculum Guide) is required to build the necessary level of awareness to implement fully operational reporting and learning systems. The development of national programmes to support safety practices and incident reporting are part of the emerging priorities.

9. Conclusions and next steps

The participants of the International Consultation concluded that there is a recognized need to define a common approach to reporting and learning across the different EU countries and beyond.

The MIM PS with 10 elements was accepted and consensus reached for its usability in settings with functional reporting systems already in place. The eight data element format could still serve as a good model for initiating reporting systems in settings and countries

where these do not already exist. In both cases, the MIM PS should have a structured part (data categories) and a free text part.

The eight data categories of the Minimal Information Model for Patient Safety are:

1. Patient information
2. Incident time
3. Incident location
4. Agent(s) involved
5. Incident type
6. Incident outcomes
7. Resulting actions
8. Reporter's role

The ten data categories of the Extended Minimal Information Model for Patient Safety are:

1. Patient information
2. Incident time
3. Incident location
4. Cause(s)
5. Aggravating Factor(s)
6. Mitigating Factor(s)
7. Incident type
8. Incident outcomes
9. Resulting actions
10. Reporter's role

A standardized MIM PS Incident Types terminology extracted from the definitions already in use must be associated with MIM PS to support comparability across countries (even if free text is allowed to describe the incident, to ensure comparability of the collected data).

Support for implementing the MIM PS at national and institutional levels should be considered for the countries that have already expressed interest. Further consideration will need to be given for implementing the finalized MIM PS in the additional interested countries that could not participate in the earlier exercise.

Next steps will need to focus on the finalization of the project deliverables by the end of June 2015:

1. The report of the international consultation
2. The standardized incident type terminology to be associated with MIM PS
3. The development of a user guide to support countries in implementing MIM PS.

The outcomes of the event were presented and discussed further at the meeting of the PSQC EG in Brussels (on 8 June 2015) following the consultation in Warsaw.

Annex 1: Concept note for the international consultation

Background

Drawing from the WHO draft Guidelines for Adverse Event Reporting and learning Systems (2005), work on the International Classification for Patient Safety, and international expertise from its Member States, WHO developed, in 2012, the draft prototype of the Minimal Information Model (MIM) for Patient Safety Incident Reporting and Learning Systems. The concept of the MIM defines minimal instances of data expected to provide sufficient information on patient safety incidents to enhance learning, which would be applicable to information technology systems.

Project summary

The project concerned with a European validation of the MIM was signed in December 2013 and launched under a collaborative agreement between the European Union (EU) and WHO. It builds on the previous experience of EUNETPAS, the Joint Action for Patient safety and of the DG SANCO Working Group for Patient Safety and Quality of Care, Reporting & Learning subgroup, to map existing practices of incident reporting across Europe, highlighting gaps, challenges and drawing a set of preferred terms for incident reporting. This country-driven project aims to test, adapt and validate the MIM draft template developed by WHO for field use and to explore methods of extracting a common data set from existing patient safety reporting systems. The project has already completed several stages in its implementation. A Sharepoint platform has been set up to support data collection and project communication.

Fifteen EU Member States registered to participate as pilots in the MIM project. Over 400 reports (national, regional or hospital) on patient safety incidents were submitted for analysis from 10 pilot sites. This work is being complemented by a feasibility assessment of MIM field adaptation and by building a library of the most preferred terminology for the types of patient safety incidents used in existing European reporting systems.

International expert consultation

The international expert consultation represents the international platform for presenting and discussing project deliverables to date, validating MIM as an interface to which reporting systems could be meaningfully mapped, and to develop best practices to enhance useful learning from patient safety reporting systems.

This event is being organized in collaboration with the EU's DG SANCO and the WHO Collaborating Centre for quality and patient safety, in Krakow, Poland, which will also be hosting the upcoming event. This will bring together representatives from all EU and EFTA countries (including the 10 pilot sites which participated in the MIM field validation process) along with international experts from beyond the EU as well.

The objectives of the consultation are, to:

- Review the compiled results of the MIM pilot project and the concordance of the MIM template as a tool for broader use and field adaptation;
- Agree on the common items to be used in completing the MIM form so that the learning component is enhanced through comparability of results;
- Validate the tool in its current format or recommend further improvements that might be required, especially concerning local adaptation;
- Use the lessons derived from this exercise and provide recommendations on future directions to further enhance reporting and learning for patient safety across the EU.

Annex 2: Programme of work

 World Health Organization		International Expert Consultation European validation of the Minimal Information Model for Patient Safety Incident Reporting and Learning 12-13 May 2015, Warsaw, Poland
Tuesday 12 May 2015		
08:30 – 09:00	Registration	
09:00 – 09:15	Opening Session ▪ Welcome and opening remarks ▪ Introduction of participants ▪ Election of chairs and rapporteurs	Dr Igor Radziewicz-Winnicki, Undersecretary of State, Ministry of Health, Poland Dr Paulina Miskiewicz, WHO Country Office, Poland Dr Jerzy Henning, NCQA, WHO Collaborating Centre, Krakow Dr Basia Kutryba, NCQA, WHO Collaborating Centre, Krakow
09:15 – 09:45	The Minimal Information Model for Patient Safety (MIM-PS) Incident Reporting and Learning ▪ Objectives of the International Expert Consultation ▪ Overview and achievements of the EC-WHO MIM Project	Dr Neelam Dhingra, WHO
09:45 – 10:05	EC work on patient safety and quality of care	Dr Aurelien Perez, DG SANTE, European Commission
10:05 – 10:30	WHO CC POL work on quality and safety of care	Dr Basia Kutryba, NCQA, WHO CC
10:30 – 11:00	Break & group photo	
11:00 – 11:40	Analysis and results of the survey for MIM-PS mapping to national systems for safety reporting and learning	Professor Jean-Marie Rodriguez, Medical informatics Lab, Université Jean Monet, Saint- Etienne, France Mr Julien Souvigner, INSERM, Hôpital Nord, Saint-Priest-en-Juarez, France
11:40 – 12:10	Plenary discussion on MIM PS mapping results	Moderator: Dr Aurelien Perez, DG SANCO
12:10 – 12:30	Analysis of the general survey on MIM PS applicability	Ms Maki Kajiwara, WHO
12:30 – 14:00	Lunch	
14:00 – 14:20	Plenary discussion on MIM PS applicability	Moderator: Dr Peter Bandura, Ministry of Health, Slovakia
14:20 – 15:40	1 st Round table on international best practices in patient safety reporting and learning: Denmark, Hungary, Italy, Portugal	Moderator: Dr Ken Taneda, Japan National Institute of Public Health Presenters: Dr Lena Graversen (Denmark) Dr Judit Lam (Hungary) Dr Lucia Guidotti (Italy) Dr Anabela Coelho (Portugal)
15:40 – 16:10	Break	

16:10 – 16:55	Presentation of Polish path towards improving quality of hospital care – Hospital accreditation programme ▪ Accreditations, benefits, challenges – 15 years after the first accreditation certificate in the 1st university hospital, Lublin, Poland ▪ 15th quality journey of the Provincial Hospital in Elblag	Dr Stanislaw Ostrowski, University Hospital Lublin, Poland Dr Marek Pietruszka, Provincial Hospital, Elblag, Poland
16:55 -17:10	Summary and closure day 1	Dr Basia Kutryba, NCQA, WHO CC
17:30	Welcome reception	
Wednesday 13 May 2015		
09:00 – 09:45	Methodology for analysing the patient safety incident types used in safety reporting	Professor Jean-Marie Rodriguez, Medical informatics Lab, Université Jean Monet, Saint-Etienne, France Mr Julien Souvigner, INSERM, Hôpital Nord, Saint-Priest-en-Juarez, France
09:45-10:30	Plenary discussion on the patient safety incident types categories	Moderator: Dr Peter Hibbert, Macquarie University, Australia
10:30 – 11:00	Break	
11:00 – 12:00	2 nd Round table on international best practices in patient safety reporting and learning Australia, India, Japan	Moderator: Dr Lucia Guidotti, Ministry of Health, Italy Presenters: Dr Peter Hibbert (Australia) Dr Geeta Mehta (India) Dr Ken Taneda (Japan)
12:00 – 12:30	ICD-11 for quality and safety	Dr Bill Ghali (Canada) on line
12:30 – 14:00	Lunch	
14:00– 14:30	Validating the MIM PS for general use	Dr Valentina Hafner, WHO
14:30– 15:30	Priorities for enhanced Reporting and Learning Systems for Patient Safety (guided plenary discussion)	Dr Neelam Dhingra, WHO Dr Basia Kutryba, NCQA, WHO CC
15:30 – 16:00	Conclusions and next steps	Dr Neelam Dhingra, WHO Dr Aurelien Perez, DG SANTE Dr Paulina Mischiewicz, WHO Country Office, Poland Dr Basia Kutryba, NCQA, WHO CC
16:00	International Consultation close	

Annex 3: List of participants

Anamaria Corca

EU Policy Advisor, Standing Committee of European Doctors (CPME), Belgium

Paul Garassus

President, European Union of Private Hospitals (UEHP), Belgium

Hilde Peleman

Quality and Patient Safety Belgian Federal Public Service Health, Belgium

Jasna Mesaric

Assistant Director Department for Quality and Education, Agency for Quality and Accreditation in Health Care and Social Welfare, Croatia

Zdeněk Hřib

Leading specialist Institute for Applied Research, Education and Healthcare Management, Czech Republic

Lena Graversen

Head, National Agency for Patients' Rights and Complaints, Denmark

Heli Paluste

Head of Health Care Unit, Ministry of Social Affairs, Estonia

Michèle Perrin

Chargée de mission, Bureau Qualité et Sécurité des soins, Ministère des affaires sociales, de la santé et des droits des femmes – DGOS, France

Judit Lám

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Senior researcher, Norwegian Knowledge Centre for the Health Services, National Patient Safety Unit, Norway

Basia Kutryba

National Centre for Quality Assessment in Health Care (NCQA), Poland

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Head of Division, Department of Quality in Health, Directorate General of Health, Portugal

Guna Jermacane

Senior Expert, Division of Treatment Quality Ministry of Health, Latvia

Carmen Angheluta

Senior Expert Public Health and Management, Department Health Research and Development
National School of Public Health and Management, Romania

Peter Bandura

Expert on Patient safety and quality of care, Ministry of Health, Slovak Republic

INTERNATIONAL EXPERTS**Australia****Peter Hibbert**

Program Manager, Centre for Healthcare Resilience and Implementation Science
Australian Institute of Health Innovation
Macquarie University, Australia

Canada**William Ghali**

Professor, Departments of Medicine and Community Health Sciences, University of Calgary, Canada

India**Geeta Mehta**

Advisor and Consultant for Infection Control and Patient Safety, India

Japan**Kenichiro Taneda**

Chief Senior Researcher, Department of Health and Welfare Services, Japan National Institute of Public Health, Japan

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Directorate-General for Health and Food Safety, Healthcare systems Unit Workforce, Safety & Quality Team, European Commission, Belgium

NATIONAL EXPERTS IN POLAND**Igor Radziewicz-Winnicki**

Minister of Health

Anna Leśniewska

Ministry of Health

Michał Bedlicki

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Halina Kutaj- Wasikowska

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Romuald Krajewski

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Marek Pietruszka

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Grażyna Wójcik

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