EU Validation of a Minimal Information Model for Patient Safety Incident Reporting and Learning Systems

EXECUTIVE SUMMARY
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Introduction

Patient safety has risen to the frontline of quality management as one of the most vital and strategic topics in health care. The increasing incidence and impact of risks generated by complex health service delivery systems, and continuously emerging technologies, on the patient and the health care professional, have been widely documented. Hence the actions taken at global, regional, national and institutional levels to address safety cultures, and regulate and implement robust reporting and learning systems to improve patient safety.

The restricted ability of established reporting systems to inter-operate and exchange safety-relevant information represents one of the major challenges faced in the development of risk reduction interventions. The reasons for this are manifold and include the lack of an accepted taxonomy and the scarcity of universally applicable standards for collecting, classifying, analyzing and interpreting incident reports.

The European validation of the minimal information model for patient safety (MIM PS) incident reporting and learning project started in December 2013 as a country-driven collaborative undertaking. Within this project, the World Health Organization (WHO) is supporting the European Commission and the EU Member States to advance the development of a common MIM PS, to facilitate comparison, sharing and global learning from the occurrence of patient safety incidents, as they are recorded in reporting systems.

“The primary purpose of a patient safety reporting system is to learn from experience. A reporting system must produce a visible, useful response to justify the resources expended and to stimulate reporting. The most important function of a reporting system is to use the results of data analysis and investigation to formulate and disseminate recommendations for systems change.”

WHO Draft Guidelines for Adverse Event Reporting and Learning Systems, 2005
The MIM PS validation process in EU Member States builds on the experience of the European Union Network for Patient Safety and Quality of Care (PaSQ Joint Action) and of the EU Patient Safety and Quality of Care Expert Group managed by the European Commission’s Health and Food Safety Directorate General (DG SANTE) and its Reporting & Learning subgroup in particular, which was involved in mapping existing practices of incident reporting across the EU, and drawing a set of preferred terms for incident reporting.

Drawing from previous work, international experience and in collaboration with partners, WHO and the European Commission worked together with EU Member States to advance the development of the Minimal Information Model for Patient Safety (MIM PS) reporting and learning systems. The goal of the MIM PS is to be used as a common template by healthcare institutions so that data collection, review, comparison and analysis of incident reports can be performed across institutional borders, and enhance learning practices and safety knowledge. This model will also be a useful template to organize new reporting systems in countries with insufficient development in this field, and further advance the patient safety agenda.

History of the Minimal Information Model for Patient Safety Incident Reporting and Learning Systems (MIM PS)

WHO has been leading work to accelerate and expand patient safety improvements since the launch of its dedicated programme in 2004. The “Draft Guidelines for Adverse Event Reporting and Learning Systems” [1] published in 2005, became a milestone publication in this direction.

To address the need for a common language that would facilitate comparability and aggregated learning from the reporting of patient safety incidents, work continued towards the development of an International Classification for Patient Safety (ICPS) and Conceptual Framework (CF) published in 2009, including a list of terms and definitions of patient safety concepts [2][3]. Many countries have used this framework as a reference
in their reporting and learning systems for patient safety, while international experts have carried out further research to find a simple yet sufficient and useful set of information categories.

Between 2009 and 2012, and drawing from the ICPS, an ontological representation that used the European Committee for Standardization (Comité Européen de Normalisation: CEN) / International Organization for Standardization (ISO) standard for the patient safety categorical structures (PS-CAST) [4] was produced [5,6].

The Minimal Information Model for Patient Safety (MIM PS) Incident Reporting and Learning Systems is a subset of the Patient Safety Categorial Structure (PS-CAST). A historical diagram of MIM PS development is presented in Figure 1.

The concept of MIM PS describes minimal instances of data, and their relations, aiming to provide minimal but sufficient information about patient safety incidents, in a format that is also easily applicable for information technology systems.

**FIGURE 1. HISTORICAL DEVELOPMENT OF THE MIM PS**

The MIM PS provides a minimal common architecture with an agreed list of information categories when reporting patient safety incidents that may be seen as the first layer of a fuller reporting system tailored to a specific context. It could also be seen as the foundation of a more comprehensive common information model that may be envisaged for the future, if such further development is necessary and affordable.

A first evaluation of this format was conducted by analyzing incident reports from Belgium, Canada, Denmark and Japan [7]. The level of detail in incident
reports was found to vary, depending on its intended use and the resources available.

The MIM PS representation, with a set of eight common minimal information categories identified to commonly fit patient safety reporting and learning needs, is presented below.

1. **Patient description** is the characteristics (at least sex and age) of the person who is the recipient of health care and involved directly or indirectly in the patient safety incident.

2. **Time** refers to date and time of day when the incident occurred.

3. **Location** refers to the physical environment in which a patient safety incident occurred.

4. **Agent(s) involved** refers to the product, device, person or any other element involved in the incident, which had the potential to influence it.

5. **Incident type** is a descriptive term for a category made up of incidents of a common nature, grouped because of shared, agreed features.

6. **Incident outcome** refers to all impacts upon a patient or an organization, wholly or partially attributable to an incident.

7. **Resulting action** refers to all actions resulting from an incident.

8. **Reporter** refers to the person who collects and writes information about the incident.

**European validation of the MIM PS (EU MIM PS)**

Advancing a common basic template for sharing information and lessons learned from reporting and learning systems at the EU level was seen to enhance the learning component through comparability, shared and compiled analysis, as well as identification of patient safety priorities at local, regional, national and later, even at global levels.

The second evaluation of MIM PS usability for the European Union was performed in 2014-2015 within the framework of the WHO and EU
collaborative project. The validation process comprised country piloting, regional compliance reviews and guidance to implementation, proposing a layered taxonomy, as follows.

**July to September 2014:** A pilot test investigated to what degree the different reporting systems in participating countries managed to accommodate the MIM PS categories, hence its capacity to represent/be translated into a sample of patient safety actual reports. A total of 407 actual reports were analysed for compliance.

The validation of MIM PS for general use 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.

**November 2014 to February 2015:** A three-step survey concomitantly addressed:

a) The feasibility of adopting the MIM PS in general practice, through regional mapping to national reporting and learning systems.

   The mapping of MIM PS showed general compliance and proposed a two-level approach: a basic eight-item format and then an advanced ten-item format, depending on the local experience.

b) The acceptability and usability of the MIM PS in European countries as a means of enhancing learning.

   The survey showed general acceptability of the MIM PS in participating countries, with minor reservations generated by confusions over the content of information categories used and the choice of structured analysis methods. Different systems, different development levels, different approaches, cultures and legacies are always to be considered in local implementation and/or adaptation of the MIM PS.

c) The terminology used in the region for incident types in view of reaching a common language in reporting procedures.
Analysis of the various incident type terminologies with a view to them being translated into an upper level ontology to facilitate computer processing of data led to the proposed development of a simple multi-layered taxonomy, based on ICPS adaptation.

12-13 May 2015: A two-day international consultation was organized to complete the validation process of the MIM PS in Warsaw, Poland. Forty-five participants, including project participant countries, international experts from Australia, Canada, India and Japan, local experts, and the project research team attended the event.

The results of the research undertaken during the project were discussed and compared with the experience of other reporting and learning systems around the world.

The validation analysis and discussions concluded that MIM PS could be used as a basic reference in countries where reporting and learning systems do not exist, and for clustering information in more developed systems to enhance comparability. A standardized MIM PS incident types terminology extracted from the pre-existing definitions must be associated with MIM PS.

Given the 24 languages used in the EU, very close attention will need to be given to accurately translating, so as to achieve a common template for clustering and sharing information from the different reporting systems.

MIM PS is expected to foster learning by facilitating the aggregation of lessons learned from patient safety incident analysis at higher levels, with the potential of becoming a useful tool to orient future policy decisions concerning patient safety.

The validated MIM PS

The MIM PS was validated as follows:

1. The MIM PS needs to include a structured part (standardized selection of categorial structures) and a free text part, allowing for incident description, and expected to further enhance the learning component of a simplified format.
2. The MIM PS with eight information categories (Basic MIM PS) could serve as a good model for initiating reporting and learning systems, where these do not already exist. It could become a safety standard and eventually be foreseen, at a later stage, to become part of the accreditation or even certification process of health care institutions, as a measure for enhancing patient safety.

3. The MIM PS with ten information categories (Advanced MIM PS) would prove useful in settings with functioning reporting systems already in place. This would entail replacing the one data category “Agent involved” by three information categories: “Causes”, “Aggravating factors” and “Mitigating factors”.

4. “Reporter” became “Reporter’s role” to clarify that the information needed in this element is not the reporter’s information, but only his role.

**BASIC MIM PS**

- **a) Structured part**
  - Patient
  - Time
  - Location
  - Agent(s) involved
  - Incident type
  - Incident outcomes
  - Resulting actions
  - Reporter’s role

- **b) Free text part**

**ADVANCED MIM PS**

- **a) Structured part**
  - Patient
  - Time
  - Location
  - Causes
  - Aggravating factors
  - Mitigating factors
  - Incident type
  - Incident outcomes
  - Resulting actions
  - Reporter’s role

- **b) Free text part**
Introducing the MIM PS to general use should allow a clustering of information around the categorial structures agreed. Associating a standardized terminology for MIM PS incident types will support comparability between institutions and countries. The choice of which of the two options to use will be made locally so that application of the MIM PS requires minimal efforts for implementation.

**References**


6. Souvignet J et al, Standardization of patient safety reports comparison by an international information Model aligned with the upper level ontologies, 2013

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