

# Minimal Information Model for Patient Safety Incident Reporting and Learning Systems



## USER GUIDE



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## Introduction

Things go wrong in health care with unacceptable frequency for many individuals seeking preventive, diagnostic, curative or rehabilitative health services. When this happens, it is essential to understand the causes and contributory factors, as well as the consequences and possible mitigating actions and solutions that could prevent that type of event from happening again.

One of the major challenges of patient safety incident reporting and learning systems lies in the difficulties of extracting sound and practical information from the vast amount of data collected. For many years, health information systems have focused on classifying occurrences of adverse events in patient safety for statistical and comparison purposes, which can then also provide a basis for policy decision-making.

A large amount of data related to adverse events has been collected in parallel to the growing interest for quality and safety in health care. On the other hand, comparison of data collected from different systems has become extremely difficult due to the lack of universal concepts and definitions to name and report patient safety incidents. Developing and maintaining a classification presents many challenges: agreeing on a common reference nomenclature, aligning to medical progress, cross-cultural implementation, etc.

The World Health Organization (WHO) has been a world leader in examining patient safety incident reporting and learning systems, beginning with its *Draft Guidelines for Reporting and Learning Systems* and the Global Community of Practice in 2005. Then, the *Conceptual Framework (CF) for the International Classification for Patient Safety (ICPS)* [1] was developed in 2009. This CF provided a list of the conceptual instances, or terms, used in adverse event reports, with narrative descriptions of their meaning.

In 2010, a formal representation (categorical structure) of the conceptual framework categories in machine-readable form was generated, based on international standards and using state-of-the-art technologies [2]. This

categorial (information categories) structure had been examined in several countries for a number of years, inputting real data from existing reporting systems. Finally, this information model has been found computable (translatable with an information technology vocabulary) in 2013.

This information model, renamed the Minimal Information Model for Patient Safety (MIM PS) Incident Reporting and Learning Systems was validated in ten European countries, through a joint project of EU and WHO supported financially by the European Commission (Directorate-General for Health and Food Safety – DG-SANTE) in 2014-15. Through this validation process, more than four hundred anonymous data sets were collected from diverse existing reporting systems and the incident types used in those reporting systems were analysed. The results led to the minimal information model format and field guidance presented in this document.

## **Minimal Information Model For Patient Safety Incident Reporting and Learning Systems (MIM PS)**

The purpose of the MIM PS is to provide a list of information categories that should be collected as a minimum, when reporting an adverse event.

The reason for this is that adverse event reporting is nowadays increasingly seen, in the patient safety community, as a tool not only for assessing the patient safety situation at any one point in time, but also to contribute to sharing anonymous safety incident information with others, in a mutually understandable format, as part of a continuous learning process, in order to encourage to policy change.

While an overly strict formatting would not have been ideal for recording softer information, a proper measure of standardization will provide a rigorous framework for the purpose without compromising flexibility. The proposed model is compatible with a number of reporting systems around the world, and so should be easily amenable to mapping from other existing systems, at little cost and effort. It can provide an evolving starting point for those who do not yet have any reporting system in place, but who wish



to implement one, as well as actively participate in the larger international reporting and learning community. National or institutional reporting systems can gather additional information to meet particular needs. The proposed information model is considered a minimum set of data to be collected to meaningfully inform the learning process.

“Model” is the technical term that refers to a systematic representation of knowledge that underpins a given system or structure. That representation is per force interpretive, and is therefore subject to subsequent review as new knowledge emerges. The model presented here, aligned on the results of a wide international consultation, and vetted by its successful mapping with real reporting systems, may be considered as validated, and is expected to have a decent life expectancy.

It has nevertheless been designed as a living document, to be updated in response to evolving needs and growing experience.

## **General description**

As the level of detail in adverse event reports varies from place to place, from no reporting systems at all to elaborated reporting systems used for learning, depending on its intended use and the available resources, it was decided that a tiered, although fully consolidated, system, should be produced, starting with the minimal information model. The upper strata of a more comprehensive information model may be envisaged for the future, as necessary and affordable.

The MIM PS [3] is described as a structured template containing the definition and the rationale for every entity (category or relationship) of a minimal adverse event reporting system.

The range of permissible values for any given category has been established based on standard terminologies and ontologies, in order to facilitate interoperability with other systems.

## **Selected information categories**

### **PATIENT INFORMATION**

**DEFINITION:** Data related to a patient that has been subject to a safety incident.

**RATIONALE:** To anonymously describe the patient to whom the incident occurred.

- The patient must remain anonymous and the data collected should not compromise patients' privacy. The only attributes that can be registered are therefore "sex" and "age".
- If no patient was involved in the incident, these attributes are not required.

### **SEX**

**DEFINITION:** Gender attribute of a patient that refers to the biological and physiological characteristics that define men and women.

**RATIONALE:** To identify possible biological sex categories risks of occurrence of an incident.

### **AGE**

**DEFINITION:** The age or period of life of the patient at which the incident happened.

**RATIONALE:** To identify the paediatric, adult or geriatric risks of occurrence of an incident.

### **TIME**

**DEFINITION:** Date and time of day when the incident occurred.

**RATIONALE:** To describe when the event occurred and understand the timeline of the incident.

## **AGENT(S) INVOLVED**

DEFINITION: Agent with the potential to cause harm.

RATIONALE: To identify the agents used before, during or after the incident without inferring any causal relation with the incident.

- For the purpose of the present information model, the agent category means the product, device, person or any element involved in the incident. The mention of any agent involved in the reported incident may or may not be the cause of the incident.

## **LOCATION**

DEFINITION: Physical environment in which a patient safety incident occurred.

RATIONALE: To describe the place where the event occurred.

- No identifying place names should be mentioned, however.

## **CAUSE(S)**

DEFINITION: Agent that contributed to an incident in a way that this specific incident happened.

- Any agent involved as the cause of the incident should only be indicated after a root cause analysis has been performed and should not be presented at the reporting stage.

RATIONALE: To list the agent(s) that can generate an incident, alone or in combination.

## **CONTRIBUTING FACTOR(S)**

DEFINITION: Any agent thought to have played a part in the origin or development of an incident, or to increase the risk of an incident.

RATIONALE: To list agent(s) involved in generating or enhancing an incident.

## **MITIGATING FACTOR(S)**

DEFINITION: Agent that prevents or moderates the progression of an incident towards harming a patient or to reduce the risk of an incident.

RATIONALE: To list agent(s) considered to reduce incidence occurrence or impact.

## **INCIDENT TYPE**

DEFINITION: A descriptive term for a category made up of incidents of a common nature, grouped according to shared, agreed features.

RATIONALE: To clearly identify the variety of incident.

## **INCIDENT OUTCOME(S)**

DEFINITION: All impacts upon a patient or an organization wholly or partially attributable to the incident.

RATIONALE: To describe all outcomes and consequences of a given incident.

- For the purpose of this information model, outcomes of a patient safety incident are limited to “patient outcomes” and “organizational outcomes”.

## **RESULTING ACTION(S)**

DEFINITION: All actions resulting from an incident.

RATIONALE: To identify immediate or indirect action related to the patient or the organization, resulting from an incident.

- For the purpose of this information model, such actions may aim to improve a situation that emerged as a result of an incident either in terms of patient outcome or of organizational outcome, with a view to preventing the reoccurrence of the same type of incident.

## REPORTER'S ROLE

**DEFINITION:** Role played in the incident by the person who collected and submitted the information about the incident.

**RATIONALE:** To analyse heterogeneous sources of information and the way different people describe a given incident.

## Expansion of the Minimal Information Model

The MIM PS was initially described as an eight-item model. Causative attributes were omitted from the minimal information model based on the consideration that "Causes" can only be completed after elicitation of concomitant factors in the incident. Generally, the factors that contribute to an incident are identified through a systematic iterative process (i.e. root cause analysis) by reconstructing the sequence of events until the underlying root cause has been elucidated.

While retaining the fact that some reports can be recorded without having elucidated all causes and factors, it has been considered beneficial to add three optional characteristics of an agent involved in the incident (e.g. all agents are recorded, and some of them have the property of being a "Contributing factor").

This approach can help ensure compatibility with many vigilance systems (i.e. pharmacovigilance) for which the actual cause is often only known following a long and costly analysis.

Nuances and sensitivities that characterize adverse event reports can be best expressed in free text rather than in check boxes or preselected lists. While free text is not immediately usable for statistical purposes, and is prone to subjective interpretation and valuation, it can nevertheless facilitate the learning component of reporting processes.

## European validation of the MIM PS

The MIM PS was confronted to existing reporting and learning (R&L) systems across the world using a stepwise approach. The European validation of the MIM PS (Figure 1) was part of an EU-WHO collaborative project.

The results of the 2014-2015 European validation process were presented during a two-day international consultation held in Warsaw, Poland, on 12-13 May 2015, with the attendance of experts from European countries, as well as Australia, Canada, India and Japan.

Figure 1: The MIM PS

1. PATIENT INFORMATION
  - Age
  - Sex
2. INCIDENT TIME
3. INCIDENT LOCATION
4. AGENT(S) INVOLVED
  - (Suspected) cause?
  - Contributing factor?
  - Mitigating factor?
5. INCIDENT TYPE
6. INCIDENT OUTCOME(S)
7. RESULTING ACTION(S)
8. REPORTER'S ROLE

A high rate of compliance of the different reports/reporting systems studied with MIM PS [4] content, was confirmed for the reports and reporting systems analysed. With several taxonomies in use, the complex applicability of the International Classification for Patient Safety, and the inclusion of patient safety incidents in the 11th version of the International Classification of Disease under development, further underlined the need for a common simplified approach to recording and reporting patient safety incidents.

The MIM PS was validated as a ground zero tool in patient safety incident reporting and learning by the project participants.

The MIM PS and recommendations for its field application are presented in the next section. All implementation steps require attentive consideration of context. This will ensure integration with technology systems and acceptability of new reporting responsibilities, and support a strong safety culture built on learning and continuous improvement.

## **Validated MIM PS structure and field application**

The MIM PS was validated as follows:

1. The MIM PS should have a structured part (standardized selection of categorial structures) and a free text part, allowing for incident description, which is expected to further enhance the learning component of a simplified format.
2. The basic MIM PS will 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 foreseen, at a later stage, to be part of the accreditation or even certification process of health care institutions, and used as a measure for enhancing patient safety.
3. The advanced MIM PS could prove useful in settings with functional reporting systems already in place. This would entail replacing the one data element "Agent involved" by three data elements: "Causes", "Aggravating factors" and "Mitigating factors".

## BASIC MIM PS

### a) Structured part

#### PATIENT INFORMATION

Age

Sex

#### INCIDENT TIME

#### INCIDENT LOCATION

#### AGENT(S) INVOLVED

(Suspected) cause?

Contributing factor?

Mitigating factor?

#### INCIDENT TYPE

#### INCIDENT OUTCOME

#### RESULTING ACTION

#### REPORTER'S ROLE

### b) Free text part

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## ADVANCED MIM PS

### a) Structured part

#### PATIENT INFORMATION

Age

Sex

#### INCIDENT TIME

#### INCIDENT LOCATION

#### CAUSES

#### CONTRIBUTING FACTORS

#### MITIGATING FACTORS

#### INCIDENT TYPE

#### INCIDENT OUTCOME

#### RESULTING ACTIONS

#### REPORTER'S ROLE

### b) Free text part

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Introducing the MIM PS to general use should allow clustering of information around the categorial structures agreed. Associating a standardized terminology for MIM PS incident types will support comparability between institutions and countries. This could be extracted from existing patient safety reporting and learning systems, to facilitate implementation. Its aggregation at a higher level is expected to help identify, in a quicker way, the key safety issues that need to be addressed, and enhance learning by shared information and updated best practices.

This simple tool has the potential of playing a key role in sharing experience and promoting transparency and improvement of the safety and quality of health care, for all actors involved.



## Privacy concerns

No privacy concerns should be raised through use of the MIM PS. When defining the information categories, any possibility of identification was removed specifically for this reason.

- The “Patient” is described only by gender and age (no name or surname, no ID, no birthdate).
- The “Agents involved”, when referring to a person, are described only by their role.
- The “Location” is only described as the physical environment where the incident occurred (e.g. type of care setting).
- The “Reporter’s role” is described only in terms of his/her role in the incident, removing any indication of the reporter’s identity.

## Proposal for a taxonomy for incident types

Drawing from existing experience, a multi-layered scientific method using upper level ontologies [6] [7] was proposed to build the taxonomy of incident types. It was peer reviewed by experts from the Czech Republic and Norway; however, there was no consensus on the feedback received.

## Conclusions

This guide summarizes the main characteristics of the MIM PS validated during the last expert’s consultation in May 2015, and presents:

- a) Two versions of MIM PS (information categories and organization)
  - A structured part for comparison: basic and advanced versions
  - A free text part for learning (in both basic and advanced versions).
- b) Two scenarios for field applicability:
  - For countries with pre-existing reporting and learning systems for patient safety and/or vigilance systems, it is recommended that the MIM PS be produced by extraction of data from existing systems, with clustering of information according to the minimal information categories agreed.

- For countries without reporting and learning systems and/or vigilance systems in place, or in the very first stages of developing such systems, it is recommended that the MIM PS be used as a basis for developing a reporting system and related information technologies.

The choice of the best option for use will be agreed locally so that application of the MIM PS requires minimal efforts for implementation. Subsequent developments will be determined by the option chosen.

There are still many countries in the European Union without any reporting and learning system in place for patient safety incidents. The MIM PS would provide useful guidance in such cases, while moving forward the development of patient safety monitoring systems and awareness to a wider level.

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