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Working Paper

PRELIMINARY VERSION OF

MINIMAL INFORMATION MODEL FOR PATIENT SAFETY

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The Minimal Information Model for Patient Safety Incidents Reporting described in this document is the result of a project conducted by the World Health Organization (WHO) Patient Safety Programme in 2011 and 2012. This project builds on a longer-term programme of WHO with important milestones, starting with the Draft Guidelines for Reporting Systems followed by the Conceptual Framework for the International Classification of Patient Safety.

The project presented in this report has been possible through a grant of the **Ministry of Health, Labour and Welfare of Japan**, who trusted and demonstrated support to the vision of the Patient Safety Programme in its efforts to advance the groundwork for effective patient safety incidents reporting and learning. WHO thanks the essential contribution of the Government of Japan in this important area of work.

The Minimal Information Model for Patient Safety presented here is the result of applying innovative and rigorous scientific methodologies derived from medical informatics and information processing techniques to the relatively new field of patient safety incident reporting. Two world recognized academic institutions in the area of medical informatics have led the scientific developments. **Professor Masanori Akiyama** led the Policy Alternatives Research Institute at The University of Tokyo, Japan, and was responsible for customizing and applying ground-breaking Natural Language Processing to patient safety data, providing a solid empirical base to this analysis. **Professors Katsuhide Fujita** and **Yingzi Jin** of the School of Engineering at The University of Tokyo collaborated with Professor Akiyama in this effort, as well as **Dr Etsuko Nakagami-Yamaguchi** from Osaka City University Hospital. **Professor Jean-Marie Rodrigues** is the head of the Department of Public Health and Medical Information at the University of St Etienne, France. Under his leadership, **Professors Julien Souvignet**, **Cédric Bousquet** and **Pierre Lewalle** built on the developments of the Tokyo University team and the experience of other patient safety incident reporting systems, to draft the knowledge engineered Minimal Information Model for Patient Safety Incidents Reporting systems as is described in this document.

International experts in patient safety, incident reporting, medical informatics, health information systems, standards, terminology and classification, provided expert and critical advice at different steps of the process. The overall project plan and its conceptual basis were discussed at the international expert consultation held in September 2012 in Tokyo, Japan. Participants at the consultation, **Dr Zafar Ahmed,** National University of Malaysia; **Mr Mark Etienne,** GZA Ziekenhuizen Belgium; **Dr William Ghali,** University of Calgary, Canada; **Dr Joergen Hansen**, National Agency for Patients Right's, Denmark; **Dr Farah Magrabi**, University of New South Wales, Sydney Australia; **Dr Annemarie Taylor**, British Columbia Patient Safety & Learning System, Canada; **Dr Luc Van Looy,** GZA Ziekenhuizen Belgium; **Dr Terri Jackson** University of Melbourne Australia; **Ms Futaba Kaneyasu** and **Ms Toshie Murakami,** The University of Tokyo; and **Dr Kenichiro Taneda,** Regional Office for the Western Pacific of WHO, provided relevant contributions that shaped the project plan and the interpretations of results.

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THE DRAFT Minimal Information Model for Patient Safety

One of the long standing aspirations of the World Health Organization (WHO) Patient Safety Programme, since its start in 2004, was to turn the failures of health care into global learning opportunities to accelerate and expand patient safety improvement. As Sir Liam Donaldson, WHO Envoy for Patient Safety, expressed, "*the belief that one day it may be possible for the bad experience suffered by a patient in one part of the world to be a source of transmitted learning that benefits future patients in many countries, is a powerful element of the vision behind the WHO initiative*." Yet, health players are still struggling to build effective learning systems based on the reporting of patient safety incidents. Weak patient safety cultures, together with the fear of punishment, prevent to some extent the reporting of adverse incidents. In addition, the scarcity of universally applicable and common standards for collecting, storing, classifying, analysing and interpreting incident reports as well as other clinical data is a significant barrier to effective reporting and learning.

The first version of the "Minimal Information Model (MIM) for Patient Safety Incident Reporting" that is described in the following pages is an attempt to overcome some of these limitations. Building on the previously developed Conceptual Framework for the WHO International Classification of Patient Safety, WHO intended to address the scarcity of standards for patient safety incident reports by proposing developing a core template or a core model that could expectedly satisfy the most basic information needs of reporters and users of such reports, and that could be universally applicable. As it is described in these pages, the first output of this effort was an empirically designed draft model based on analysis of incident reports and reporting systems and experts' consultation. This draft model needs to be validated and further advanced.

Key concepts

An Information model is a technical term that refers to "an organized structure of information requirements for a knowledge domain that underpins a given system or structure"[1]. It involves a representation concepts and their relationships. "Minimal Information model" refers to a minimal common architecture for the core concepts considered to be essential for information and comparison purposes of patient safety incident reports, while additional concepts can be included and customized based on every context. As a consequence, incident reports would expectedly be more homogenously structured and amenable to national and international aggregation and comparison.

The purpose of such MINIMAL INFORMATION MODEL FOR PATIENT SAFETY is to strengthen effective reporting by identifying the key data features that can provide minimal meaningful learning.

National or institutional reporting systems are encouraged to collect additional information to meet their particular needs.

The level of details in adverse event reports varies from place to place depending on its intended use and available resources. Producing a unique information model may risk falling short or too ambitious, depending on the particular circumstances and needs of reporting systems. A possible solution to allow flexibility in various contexts would be to develop a tiered, although fully consolidated, system, starting with what could be considered a **MINIMAL INFORMATION MODEL,** and continuing by other levels of intermediate and/or full Models. This Minimal Information Model may be seen as the first layer of a fuller local reporting system tailored to its own 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 is necessary and affordable

In general, reporting systems aim to satisfy three main objectives

- ***DESCRIPTION*** (What happened): this can be accomplished by a mix of ***patient characteristics*** (such as age, sex, etc.), ***incident characteristics*** (observations, measures, clinical features, tentative disease categories), the ***location*** where the incident occurred (hospital, clinic, etc.), ***people involved*** (attending physician and other health personnel), indications about the ***discovery*** of the incident (how, when and by whom the incident was noticed), the possible harm (direct and consequential) and the ***immediate action*** taken to remedy the situation.
- ***EXPLANATION*** (Why it happened): a set of known risks associated with the ***patient's condition*** (according to the pathology or the patient physical status), ***causes*** of the event, ***contributing factors*** or ***mitigating factors***.
- ***REMEDIAL MEASURES*** (what were the reactions): for example, the identification of weak links in the care-chain, review of clinical and supervisory processes and procedures, as well as administrative, educational and other requirements to prevent the re-occurrence of similar incidents and to minimise the impact on the patient (sequels) and on the care organisation (direct and indirect costs), if re-occurs.

The Minimal Information Model includes these categories in the following scheme as shown in Table 1. For details of how it was developed, please see Annex 1 at the end of this report.

Table 1. Minimal Information Model for Patient Safety data categories

THE DATA CATEGORIES OF THE DRAFT MINIMAL INFORMATION MODEL FOR PATIENT SAFETY ARE:

- Incident identification
  - Patient
  - Time
  - Location
  - Agent(s) involved
- Incident type
- Incident outcomes
- Resulting actions
- Reporter

DEFINITIONS AND RATIONALE FOR THE ELEMENTS OF THE MINIMAL INFORMATION MODEL FOR PATIENT SAFETY

This section aims to introduce the definitions, rationales and value sets for each category in the Minimal Information Model for Patient Safety. Suggested definitions and value sets for the Intermediate and Full Information Model are not included in this version of the document.

Value sets refer to the range of permissible values for any given category. Some elements of the Minimum Information Model may use value sets based on standard terminologies and ontologies in order to facilitate interoperability, including the International Classification of Disease (ICD), International Classification of Functioning, Disability and Health (ICF), and International Classification for Patient Safety. For other categories such as 'location' and 'incident type', there are currently no universal standards; therefore, identifying the most appropriate value sets will require additional research and consultations.

INCIDENT IDENTIFICATION: *aims to describe an incident specifically*

Patient/Person

Definition: a person who is a direct or indirect recipient of healthcare and involved directly or indirectly in the patient safety incident.

Rationale: to describe the person to which the incident occurs.

- *The patient/person must remain anonymous and the data collected should not compromise patients' privacy. The only attributes that must be registered are: sex and age.*
- *If no patient is involved, these attributes are not required.*

Sex

Definition: gender attribute of a patient that refers to the biological and physiological characteristics that define male and female

Rationale: to identify biological sex categories risks of occurrence of an incident. If no patient is involved, the value is "no patient involved"

Value set: *male*, *female* or *unknown*

Age

Definition: the age or period of life of the patient at which the incident happened.

Rationale: to identify paediatric, adult or geriatric risks of occurrence of an incident.

Value set: age breakdowns

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.

Value set: Timestamp

- *Use standard date format: YYYY-MM-DD and HH:mm in 24-hour format (e.g. 2014-01-01, 16:00)*

Location

Definition: physical environment in which a patient safety incident occurs.

Rationale: to describe the place where the event occurred.

Value set: health care setting type

- *No identifiable place name should be mentioned.*
- *Select only one type of health care setting.*
- *If an appropriate setting is not listed, choose "*Other*".*

Agent(s) Involved

Definition: agent with the potential to cause harm. It refers to the product, device, person or any elements involved in the incident with the potential to influence it.

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.*

Value set: List of medical devices

INCIDENT TYPE

Definition: a descriptive term for a category made up of incidents of a common nature, grouped because of shared, agreed features.

Rationale: to clearly identify the type of an incident.

Value set: Pre-defined set of Incident Types as described in the ICPS report

INCIDENT OUTCOMES

Definition: all impacts upon a patient or an organization wholly or partially attributable to an incident.

Rationale: to describe all kinds of outcomes and consequences of an incident.

For the purpose of this information model, outcomes of a patient safety incident are:

- Patients outcomes
- Organisational outcomes

Patient outcomes

Definition: the impact upon a patient which is wholly or partially attributable to an incident.

Rationale: to describe the consequence of an incident for the patient in details

Value set: Already existing international classifications codes, such as ICD and ICF codes.

Organizational outcomes

Definition: the impact upon on organization which is wholly or partially attributable to an incident.

Rationale: to describe in detail the consequences for the organization of an incident.

Value set: *to be discussed*

RESULTING ACTION

Definition: all actions resulting of an incident.

Rationale: to identify immediate or indirect action related to the patient or the organization resulting of an incident.

Such actions may aim at:

- Improving a situation that emerged as a result of an incident, either in terms of patient outcome or of organizational outcome;
- Preventing the reoccurrence of the same incident.

Ameliorating action

Definition: an action taken to compensate any outcome after an incident.

Rationale: to describe any action that was taken to mitigate the effects of an incident on the patient or on the organization

Value set: to be discussed

Preventing action

Definition: actions taken to reduce manage or control any future incident, or probability of incident.

Rationale: actions taken to control any future incident, or probability of incident.

Value set: to be discussed

REPORTER

Definition: person who collects and writes information about the incident.

Rationale: to identify the reporter.

Profession

Definition: role of the reporter when the incident occurred.
Rationale: to analyse the way different healthcare professionals describe an incident.
Value set: to be discussed

Advanced Information Models

Based on the internal logic of the Minimal Information Model and the experience of selected real life reporting systems, it would be possible to suggest advanced Information Models by adding more detailed circumstances of the incidents.

Intermediate Information Model

The additional concepts included in this model are described in the box below:

Table 2. Data categories for the Draft Intermediate Information Model for Patient Safety

Data Categories for the DRAFT Intermediate Information Model for Patient Safety

1. **Incident identification**
   - Patient
   - Time
   - Location
2. **Incident circumstances**
   - Agent(s) involved
   - **Leading actions**
   - **Ongoing actions**
   - **(Causes)***
   - **(Contributing factors)***
3. Incident type
4. Incident outcomes
5. Resulting actions
6. Reporter
   - **Role in the incident**

* Causes and Contributing Factors are handled as a property of every action and agent involved

Circumstance is the context of an incident.

Leading actions are all actions that were made before the incident.

Ongoing actions are all actions performed when the incident occurred.

A **contributing factor** is an element thought to have played a part in the origin or development of an incident or to increase the risk of an incident.

The **cause** is the main element triggering an incident. Without it, the incident would not take place.

Role is the role played by the reporter in the incident.

Full Information Model

Similarly, a Full (complete) Information Model is suggested as well to represent more detailed elements related to an incident. The additional concepts included in this model can be described as follows:

Table 3. Data categories for the Complete Information Model for Patient Safety

Data Categories for the Complete Information Model for Patient Safety

1. Incident identification
   - Patient
     - **Initial condition**
   - Time
   - Location
2. Incident circumstances
   - Agent(s) involved
   - **Process involved**
   - Leading actions
   - Ongoing actions
   - (Causes)
   - (Contributing factors)
3. **Incident detection**
   - **Time**
   - **Location**
   - **Person**
4. **Incident type**
5. Incident outcomes
6. Resulting actions
7. **Report**
   - **Time**
   - Reporter
     i. Role in the incident

Initial condition describes the condition of the patient before the event.

Process involved identifies if circumstance actions were part of defined processes (and should be questioned)

Incident detection is the instant of discovery of an incident. It can be described with a **date/time**, a **location** and the **person** who made the discovery.

Report is the actual report of the incident; it is described by a **date/time** and a reporter.

Whilst the introduction of these advanced (Intermediate and Full) information models is not the main purpose of this paper, it is hoped that a brief overview of the advanced models demonstrates that the Minimal Information Model provides the *core components* of more advanced or comprehensive models. In addition, this may provide insights for those countries that adopt the MIM and wish to develop it into a more advanced reporting system according to their specific context.

For details of how these models have been developed, please see Annex I at the end of this report.

WHAT IS NEXT?: A TEMPLATE TO GUIDE REPORTING AND LEARNING SYSTEMS

The Minimal Information Model presented here is an initial step to facilitate harmonisation of patient safety incident reporting systems, and as a consequence, enhance comparison and learning across various reporting systems. The Model relies on the logic and coherence of the Conceptual Framework for the International Classification of Patient Safety, drawing directly from its structure to which empirical analysis and experts' opinions have been added to arrive at the suggested data categories for the Minimal, Intermediate and Full models.

The expectations are that the Data Categories of the Draft Minimal Information Model satisfy the core information requirements posed to an incident report, while at the same time provide flexibility to the system to include additional items if required and to suit various contexts across different healthcare institutions. Based on the adoption of the suggested data categories by individual reporting systems, it is hoped that the Minimal Information Model will promote commonality among different healthcare reporting systems, and therefore allow comparisons and information sharing for global learning.

It is important to remember that the Draft MIM does not aim to omit any important elements of information required for effective incident reporting or overlook the information needs of particular healthcare systems. It is rather an attempt to provide a common and essential architecture which could be further developed with additional layers of categories, depending on the different needs of reporting systems in various institutions.

The models presented here are, as indicated, first drafts, delivered through empirical research. The next step is to confirm its validity as an informative useful model, as well as the feasibility and practicality of using it as part of the reporting function of healthcare institutions and agencies involved in patient safety incident reporting. The goal is then to test those aspects in a range of reporting systems of various socioeconomic settings and organisational environments and estimate how well the model meets the information needs of the various potential users, including clinicians, patients and the general public, administrators and managers of institutions, and various other agencies at subnational, national or supranational levels. As part of this evaluation, it is also important to understand how this Minimal Information Model may be integrated into broader reporting systems, as well as into particular thematic fields of health care such and existing reporting mechanisms such as it could be for haemovigilance or pharmacovigilance .

Many other important aspects are necessary for functioning effective reporting systems, which have not been covered by this report. For example, it is essential to identify common values for the data categories included in the Minimal Information Model. Likewise, it is essential to develop effective learning mechanisms to enable the extraction, dissemination and use of effective, timely and pertinent information for practice and policy change and improvement. The optimal use of reporting systems also needs of an enabling environment promoting the patient safety and learning cultures, as well as regulatory and ethical frameworks to facilitate the just assumption of responsibilities and the protection of the persons involved in the occurrence of incidents, with the recognition and disclosure of incidents. These exciting and important areas work require attention in order to meaningfully enhance the reporting of patient safety incidents and moreover its use for effective change.

As a first step, it is expected that the Minimal Information Model for Patient Safety will serve as a unifying model for patient safety reporting systems, after the evaluation and refinement by many stakeholders in the months to come.

Annex 1

HOW THE MINIMAL INFORMATION MODEL FOR PATIENT SAFETY INCIDENT REPORTING WAS DEVELOPED

Among the WHO's priorities in the area of patient safety is to facilitate cost-effective mechanisms suitable in most countries and institutions to allow sharing, aggregation, comparison and, hence, learn about the causes of and solutions to patient safety incidents.

This minimal information model or template presented here is an attempt to produce a commonly acceptable architecture minimally informative of the nature and consequences of incident reports. Such template could be used to organize incident reporting systems based on the core set of data categories proposed as a full information model for incident reporting, and could also be used as a core module of broader reporting systems, where additional customisation or more sophisticated information of incident would be required. Hence, it could ideally be adapted to existing reporting systems or could be used to build a new reporting system.

The steps that had been taken so far to arrive at the Minimal Information Model is described as follows:

PROJECT CONCEPTUALISATION

Following the publication in 2009 of the WHO Conceptual Framework for the International Classification of Patient Safety,[2] [3]WHO initiated work to advance an architecture or template for a "Patient Safety Information Model" with the goal to provide effective and useful guidance to agencies interested in developing or modifying reporting systems in alignment to a common architecture. The task would be to define a *model* under certain principles; firstly, it should be minimal whilst it should be informative enough about the particular incident being reported, its application should be as universal as possible, it should have the potential to be used as a module or component of broader and deeper reporting systems; it should allow relative customization while preserving its common architecture for comparison.

The conceptualisation and the design were based on recent technical advances in the area of biomedical terminology and related information models recommending ontological engineered methodology[4] to define the "Categorial Structure of the Patient Safety Conceptual Framework"[5] of which the Minimal Information Model for Patient Safety Incident Reporting should be a subset.

On the other hand, most reporting systems in the world use natural language and free-unstructured text to describe incidents. Current research through Natural Language Processing (NLP)[6] also shows that unformatted narrative reports include critical content of the incidents, which is rarely captured in formatted reporting (i.e. through selection boxes, choices, etc.). During the conceptualization of this project, it became evident that researches should combine a mapping of the ontology-driven hierarchy[7] with the reality of reporting systems in the world. As a result, an analysis of the formatted and unformatted reports was conducted.

The Key partners in this process were the Department of Public Health and Medical Informatics at the University of Saint Etienne in France, a lead expert institution in the application of ontological engineering[8] in the biomedical field and the developer of the Categorical Structure for Patient Safety, and the Policy Alternatives Research Institute at the University of Tokyo, one of the world leading research centres in developing and applying the methodology of Natural Language Processing and Neural Network Analysis in patient safety incident reporting systems. Head professors from both centres and their respective teams designed the project plan.

In summary, the research project consisted in establishing a cross-mapping of formatted and unformatted real reports (using ontological analysis and natural language Processing) against the hierarchy defined by the full Categorial Structure. Through this mapping process, it was expected to identify a minimum essential set of concepts from the Categorial Structure that are compatible with all analysed reports in order to define the core information model.

INTERNATIONAL EXPERT CONSULTATION

The project designed was discussed at an International Expert Consultation organized by WHO in September 2012, where the challenges and directions for the analysis of patient safety incident data and reports were discussed. About 20 international experts, including managers of national and subnational patient safety incident reporting systems, academics and researchers with expertise in the analysis of patient safety related data, specialists in medical informatics, health classifications and terminologies, participated this consultation which was hosted by the Policy Alternatives Research Institute at the University of Tokyo in Japan. The list of participants is included below. As a result, the project plan was finalized with the inclusion into the analysis of reporting systems from Japan, Belgium, British Columbia in Canada, and Denmark. Experts in the consultation also recommended to consider the enabling and contextual factors that are necessary for the effective use of reporting systems in additional phases of the project.

PROJECT EXECUTION

The research took place in the second half of 2012 and 2013. It involved various steps.

(I) TOP-DOWN ANALYSIS

This step, conducted by the University of Saint Etienne, analysed the formal structure of various reporting systems as described above, and compared them with the formal ontology-based Categorical Structure, which served as a theoretical reference. The initial analysis corresponded to the format used at the Japanese Osaka City University Hospital, after its translation into English. The form included 105 items, 101 of which were with value sets and the remaining 4 were in free text. Through this first analysis, it was possible to establish a first delimitation of the full Categorical Structure into the knowledge domain used in Osaka Hospital for incident reporting. The comparison also suggested adding several concepts and unfolding existing ones into distinct new concepts, whilst others that seemed irrelevant were flagged for possible elimination. This analysis was later repeated against the formats of Belgium, Denmark and British Columbia in Canada. The original Categorial Structure which served as the framework for this analysis, included in its development an analysis of the structure of the Australian Incident Monitoring System (AIMS).

(II) BOTTOM-UP APPROACH

The University of Tokyo analysed unformatted free texts from a large sample of about 20,000 real incident reports from the Saitama Medical Center and ichi Medical University in Japan. These reports were analysed and pre-structured through an innovative and well-established analytical method known as Natural Language Processing (NLP). Through this methodology, first, it was possible to detect the most relevant characteristic keywords in the text (a function of frequency and relationships) and in the second step, to detect networks or preferred relationships between the keywords. A further step was taken by conducting Network Clustering Analysis on the identified data such as keywords and relationships, and then the underlying networks formed by those key words and their relations were identified. Subsequently, a panel of clinical specialists, including medical doctors, nurses, pharmacists and medical administrators reviewed and interpreted the results of the Natural Language Processing and Network Clustering Analysis, to assess whether they were able to recognize and agree on the semantic meaning of the networks and structure that emerged from the analysis.

Following this analysis, both teams were able to match the resulting emerging structure from the Natural Language Processing analysis against the top-down hierarchy suggested by the team from St Etienne derived from the mapping of formatted reporting systems against the Categorial Structure. The results of this final step provided the basis for the proposed Minimal Information Model for Patient Safety

Results and Next Steps

The combination of both analysis through this iterative process, complemented with feedback and discussions by the core research team, led to the proposed Minimal Information Model for Patient Safety Incident Reporting that is described in this report. This template should thus be considered a prototype, or a pilot version, which requires extensive testing and evaluation for its fit for purpose, feasibility, acceptability and effectiveness.

Additional work will be also required to identify and suggest value sets as well as additional key system features to implement reporting systems successfully.

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