Integrated care: an Information Model for Patient Safety and Vigilance Reporting Systems

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Abstract. Quality management information systems for safety as a whole or for specific vigilances share the same information types but are not interoperable. An international initiative tries to develop an integrated information model for patient safety and vigilance reporting to support a global approach of health care quality.

Keywords. Information model, Patient Safety, Vigilance, Integrated care

Introduction

Quality and safety management has become one of the most vital and strategic topics within the health care domain. Central to any effort to improve quality is the question of measurement and comparison.

The effectiveness of the risk management systems established by vigilance systems is clearly mitigated by the inability to interoperate between them and prevent the systematic exchange of much safety-relevant information.

Since 2004, the World Health Organization (WHO) Patient Safety (PS) Programme, aspirates to turn failures of health care into global learning opportunities to accelerate and expand vigilance on patient safety.

A structured representation of safety vigilance information is essential for comparison, trend detection and learning in patient data by reporting incidents that often lead to adverse healthcare events.

In 2009, the WHO Department of Patient Safety published the first report on a conceptual basis for an International Classification for Patient Safety (ICPS). The report contained a conceptual framework including a list of terms and definitions of patient safety concepts used in national PS reporting systems \[01\] \[02\].

In 2010, based on the conceptual framework of ICPS, an ontological representation using the CEN/ISO standard for categorial structure \[03\] method is published: PS-CAST (Patient Safety Categorial STructure) \[04\] .

In 2012, WHO requested the creation of an International Information Model for Patient Safety (2IMPS) based on the previous PS-CAST representation to ensure the comparisons of PS data among countries and institutions.
In 2014 WHO decided to test if this 2IMPS can be used as an integrated tool between the generic national reporting systems and the main specific vigilance systems in the world. This paper aims to present the results of this test to integrate different Quality Management information systems [05].

1. Material

We extracted the 8 items of MIMPS and their definitions.

1. The patient is the person who is a recipient of healthcare 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 occurs.
4. Agent involved refers to product, device, person or any element involved in the incident with 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 outcomes refer to all impacts upon a patient or an organization wholly or partially attributable to an incident.
7. Resulting actions refers to all actions resulting of an incident.
8. Reporter’s role refers to the role of the person who collects and writes information about the incident.

The World Health Organization Patient Safety Department (WHOPSD), with the help of their taskforce members, has selected 9 international or national Vigilance templates forms.

These forms have been selected for their exemplary and the domains they cover: 2 from Pharmacovigilance, 1 from Patient Safety in Radiotherapy (Radiation Protection, 1 from Patient Safety following Immunization (Adverse Events Following Immunization), 1 from Haemovigilance, 2 from Injection Safety (Occupational Health) and 2 from Medical Devices Vigilance. They are listed here.

1. Suspect Adverse Reaction Report Form I by CIOMS (Council for International Organizations of Medical Sciences)
2. Generic Adverse Drug Reaction Report Form by WHO Collaborating Centre for International Drug Monitoring: Uppsala Monitoring Center (UMC)
4. Reporting Form for Adverse Events Following Immunization (AEFI) by WHO. Draft version, cleared by WHO Global Advisory Committee on Vaccine Safety (GACVS) in June 2014
5. Haemovigilance Adverse Event Report Form from South Africa haemovigilance reporting system by South African National Blood Service (SANBS)
8. National Competent Authority Reporting (NCAR) Form by Global Harmonization Task Force
9. Report Form from the Manufacturer’s to the National Competent Authority by DG Health and Consumers (SANCO) extracted from Guidelines on Medical Devices Vigilance System (MEDDEV), Annex 3.

2. Methods

We defined the criteria to certify whether an element is present or not. They are presented in Table 1:

<table>
<thead>
<tr>
<th>MIM item</th>
<th>Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patient information</strong></td>
<td>Data (anonymized name, age, sex) about the recipient of healthcare involved in the incident</td>
</tr>
<tr>
<td><strong>Date of incident</strong></td>
<td>Date (and time) when the incident occurs. (day or week day, exact time, etc.)</td>
</tr>
<tr>
<td><strong>Location of incident</strong></td>
<td>Data about the physical environment in which the incident occurred (typically a health care setting, de-identified but individualised).</td>
</tr>
<tr>
<td><strong>Agent(s) involved</strong></td>
<td>List of agent with the potential to cause harm (object, substance, anonymized person, etc.)</td>
</tr>
<tr>
<td><strong>Incident type</strong></td>
<td>Category of incident</td>
</tr>
<tr>
<td><strong>Incident outcomes</strong></td>
<td>Data about any impact attributable to an incident (upon a patient or an organization)</td>
</tr>
<tr>
<td><strong>Resulting actions</strong></td>
<td>Data about any actions taken after an incident</td>
</tr>
<tr>
<td><strong>Reporter’s role</strong></td>
<td>Data about the role the reporter played in the incident (not his/her name)</td>
</tr>
</tbody>
</table>

*Table 1 – MIM items criteria*

The validation was performed manually by two Patient Safety Experts from our team. The task consisted of an alignment attempt between each item of the MIMPS and
an element (a box, a form fields or text information) present on a vigilance form and/or the templates guidance instructions to test.

We scored the 8 items for the 9 selected templates in a table using Yes/No and a free text comment. This field is used to keep trace of the expert mapping but also to justify mapping when there were uncertainties on the answers (e.g: rather YES but not fully, rather NO but not fully).

The experts’ tasks were carried out separately, and the results were compared and approved consensually at a meeting conducted internally.

The validation is ongoing with institutions responsible of the templates.

3. Results

The results show in Tab 2 that 5 out of 9 vigilance templates have at least a compliance ratio of 7/8 (87.5%). The most compliant templates are: (#4) post immunization, (#9) Medical device DG Sanco, (#2) generic ADR, (#6) needle stick and (#5) South Africa haemovigilance.

One template (#8) (medical devices NCAR) look a long way from the compliance, with 4 out of 8 items present.

The raw results are presented here: (present=YES, absent=NO)

<table>
<thead>
<tr>
<th>Template</th>
<th>Patient</th>
<th>Date</th>
<th>Location</th>
<th>Agent(s) involved</th>
<th>Incident type</th>
<th>Incident outcomes</th>
<th>Resulting actions</th>
<th>Reporter’s role</th>
</tr>
</thead>
<tbody>
<tr>
<td>#1) ADR CIOMS</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>Y Y Y Y Y N</td>
<td>6/8</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>#2) GENERIC ADR UPPSALA</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>Y Y Y Y Y Y Y</td>
<td>7/8</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>#3) SAFRON RADIATION ONCOLOGY IAEA</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>Y Y Y Y N N</td>
<td>5/8</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>#4) AEFI POST IMMUNIZATION</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y Y Y Y Y Y Y</td>
<td>8/8</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>#5) SOUTH AFRICA HAEMOVIGILANCE</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y Y Y Y Y N Y</td>
<td>7/8</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>#6) NEEDLE STICK INJURY CDC</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y Y Y Y N N N</td>
<td>6/8</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>#7) BODY FLUID EXPOSURE CDC</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>Y Y Y Y N Y Y</td>
<td>4/8</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>#8) MEDICAL DEVICES NCAR</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y Y Y Y Y Y Y</td>
<td>8/8</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>#9) MEDICAL DEVICES DG SANCO annex 3</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y Y Y Y Y Y Y</td>
<td>8/8</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 2 – Vigilance templates Compliance with MIMPS

The different MIM items are present: 100% for Incident types, 88 % for Date of Incident, Agent Involved and Incident outcome, 77 % for Patient characteristics and Reporter role, 66 % for Resulting actions, 55 % for Location.
4. Discussion

These results show that the different quality management information systems overlap for most of the items even if they have different goals and different reporting procedures. The MIMPS designed from the generic national or institutional reporting systems from Australia, Belgium, British Columbia, Denmark, Japan and USA AHRQ is nearly fulfilled by 7 out of 9 international vigilance information systems. Only the NCAR Medical Device template fulfils half the MIMPS (4 items out of 8), but it corresponds to a use-case very different: the conformance to regulations. The limitation of the study is due to be based on vigilance empty templates and guidance instructions and not on actual data as for the reporting systems. The MIMPS can be seen as the framework to Quality and Security of Care integrated management.

5. Conclusion

This paper shows that the integration of the different quality management information systems based on MIMPS seem rather easy since 78% (7 out of 9) of tested templates fulfill at least 75% (6 out of 8) of the MIMPS items.

During the international WHO expert consultation organized for the presentation of the report [05] experts from developing countries having no generic national reporting systems and/or not use of the specific international vigilance templates have decided to recommend to their government an integrated quality management information system based on the MIMPS which can reduce the workload and ease international comparison and learning process on health care quality.

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The views expressed are those of the authors only.

References

[05] EU-WHO MIMPS Pilot Test final report.(2014). To be published