A Patient Safety (PS) Information Model for Interoperability.

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1. Starting point: Knowledge ICPS Conceptual Framework
2. Double refinement approach:
   - Semantic top down (PS-CAST aligned with Biotop and BFO 2)
   - bottom up based on R&L Systems for Patient Safety and international and national vigilance system
3. MIMPS and Incident types Terminology
In 2009, the WHO published reports for a so-called “International Classification for Patient Safety (ICPS)” . Its representation includes:

- a list of terms and ‘key concepts’
- a conceptual framework

But... this CF is not suitable for computer modelling
ICPS Issues

- Schulz et al. (2009) made an appraisal of ICPS
  - [ICPS] “is neither a classification nor a taxonomy” [but] “presents properties for modelling […] an ontology”

- Ceusters et al. (2011) wrote:
  - “some ambiguous definitions” within ICPS such as “class” or “semantic relationship”
  - “additional efforts must be provided, using an ontological methodology”
2 PS Semantic modelling and bottom up testing

- 21 PS CAST and ULO

- 22 Bottom up
  - Reporting and learning systems
  - Vigilance systems
<table>
<thead>
<tr>
<th>Item</th>
<th>Categorial Structure Definition Model</th>
</tr>
</thead>
<tbody>
<tr>
<td>Place of occurrence</td>
<td>Incident hasLocation some Care_Setting</td>
</tr>
<tr>
<td>Patient</td>
<td>Incident hasPeopleInvolved some Person</td>
</tr>
<tr>
<td></td>
<td>Person hasRole some Patient</td>
</tr>
<tr>
<td>Sex of patients</td>
<td>Person hasGender some Gender</td>
</tr>
<tr>
<td>Who found this incident?</td>
<td>Incident hasDetection some Detection</td>
</tr>
<tr>
<td></td>
<td>Detection hasPeopleInvolved some Person</td>
</tr>
<tr>
<td>Years of experience</td>
<td>Staff hasWorkExperience some DurationDescription</td>
</tr>
<tr>
<td>Level of damage</td>
<td>Incident hasConsequence some Outcome</td>
</tr>
<tr>
<td></td>
<td>Outcome hasSeverity some Severity</td>
</tr>
<tr>
<td>Clinical examination</td>
<td>Incident hasSituation some Action</td>
</tr>
<tr>
<td></td>
<td>Diagnostic_Action is a Action</td>
</tr>
<tr>
<td>Cause of incident &gt; system</td>
<td>Incident HasCause some Circumstance</td>
</tr>
<tr>
<td></td>
<td>System_Deficiency is a Circumstance</td>
</tr>
<tr>
<td>...</td>
<td>...</td>
</tr>
</tbody>
</table>
PS-CAST incident Model

Toward a Patient Safety Upper Level Ontology
Souvignet Julien
May 2015 - MIE Madrid
Upper level ontologies

- Top level ontology:
  - BFO (Basic Formal Ontology)
- Top-domain ontology
  - BioTop (a biomedical top-domain ontology)
## Alignment with BFO2

<table>
<thead>
<tr>
<th>PS-CAST Concepts</th>
<th>(link) BFO2.0</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incident</td>
<td>(subClassOf) Process</td>
</tr>
<tr>
<td>Incident_Type</td>
<td>(subClassOf) Dependant Continuant</td>
</tr>
<tr>
<td>Outcome</td>
<td>(subClassOf) Disposition</td>
</tr>
<tr>
<td>Action</td>
<td>(subClassOf) Process</td>
</tr>
<tr>
<td>Circumstance</td>
<td>(subClassOf) Disposition</td>
</tr>
<tr>
<td>Detection</td>
<td>(subClassOf) Process</td>
</tr>
<tr>
<td>Care_Setting</td>
<td>(subClassOf) Site</td>
</tr>
<tr>
<td>Agent</td>
<td>(subClassOf) Material Entity</td>
</tr>
<tr>
<td>Role</td>
<td>(subClassOf) Role</td>
</tr>
<tr>
<td>hasType</td>
<td>(subRelationOf) hasContinuantPartAtAllTime</td>
</tr>
<tr>
<td>hasConsequence</td>
<td>-</td>
</tr>
<tr>
<td>hasSituation</td>
<td>(subRelationOf) hasOccurentPart</td>
</tr>
<tr>
<td>hasCause</td>
<td>-</td>
</tr>
<tr>
<td>hasDetection</td>
<td>(subRelationOf) hasOccurentPart</td>
</tr>
<tr>
<td>hasLocation</td>
<td>(equivalentTo) HasLocationAtSomeTime</td>
</tr>
<tr>
<td>hasAgentInvolved</td>
<td>(equivalentTo) HasContinuantPartAtSomeTime</td>
</tr>
<tr>
<td>hasRole</td>
<td>(equivalentTo) HasRoleAtSomeTime</td>
</tr>
</tbody>
</table>
Remark expressivity (PS-CAST) versus formal logic (BFO 2)

- “hasCause” and “hasConsequence” relationships involve causality. This refers to a trigger-and-realization process pair.
- We use the relation of temporal relatedness PrecededBy, which does not express causation. The reason is that although much of those events are of causal nature, the proof of this is often impossible.
22 Bottom up validation

- R and L national systems
  - Australia, Japan, Belgium, Denmark, British Columbia (Canada), U.S. AHRQ

- Vigilance systems

- EU
3 Results
31 MIMPS 10 items definitions

- **1** The **PATIENT** is the person who is a recipient of healthcare and involved (NO IDENTIFICATION only age and gender).
- **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** **CAUSE WITH FREE TEXT**
- **5** **CONTRIBUTING FACTORS WITH FREE TEXT**
- **6** **MITIGATING FACTORS WITH FREE TEXT**
- **7** **INCIDENT TYPE** is a descriptive term for a category made up of incidents of a common nature, grouped because of shared, agreed features.
- **8** **INCIDENT OUTCOMES** refer to all impacts upon a patient or an organization wholly or partially attributable to an incident.
- **9** **RESULTING ACTIONS** refers to all actions resulting of an incident.
- **10** **REPORTER’S ROLE** refers to the person who collects and writes information about the incident. (NO IDENTIFICATION)
Vigilance systems high Compliance score with MIMPS

<table>
<thead>
<tr>
<th>Reporting System</th>
<th>Patient</th>
<th>Date of incident</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>
<th>Items present/9</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1) ADR CIOMS</td>
<td>YES</td>
<td>YES</td>
<td>NO</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>NO</td>
<td>6</td>
</tr>
<tr>
<td>(2) GENERIC ADR UPPSALA</td>
<td>YES</td>
<td>YES</td>
<td>NO</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>7</td>
</tr>
<tr>
<td>(3) SAFRON RADIATION ONCOLOGY IAEA</td>
<td>NO</td>
<td>YES</td>
<td>NO</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>NO</td>
<td>5</td>
</tr>
<tr>
<td>(4) AEFI POST IMMUNIZATION</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>8</td>
</tr>
<tr>
<td>(5) SOUTH AFRICA HAEMOVIGILANCE</td>
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<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>NO</td>
<td>YES</td>
<td>7</td>
</tr>
<tr>
<td>(6) NEEDLE STICK INJURY CDC</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>NO</td>
<td>YES</td>
<td>7</td>
</tr>
<tr>
<td>(7) BODY FLUID EXPOSURE CDC</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>NO</td>
<td>NO</td>
<td>YES</td>
<td>6</td>
</tr>
<tr>
<td>(8) MEDICAL DEVICES NCAR</td>
<td>NO</td>
<td>NO</td>
<td>NO</td>
<td>NO</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>4</td>
</tr>
<tr>
<td>(9) MEDICAL DEVICES DG SANCO annex3</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>8</td>
</tr>
</tbody>
</table>

TOTAL /9: 7 8 5 8 9 8 6 7
3 Results
32 Terminology of Incident types
BFO 2 top level entities

- Continuant
  - Independent Continuant
    - bearer
  - Specifically Dependent Continuant
    - disposition
- Occurrent
  - Process of realization

realizable
Incident types: complex entities

- An incident occurred to a patient during the past, is documented in a database and there is an expectation of some future happening that can be prevented.
- It is a complex entity which corresponds to an occurrent event or process as well as to an independent continuant as a physical object or to a dependent continuant as a wrong drug prescription by a physician.
- Inherent polysemy arises only when there are dependence relations involved, such as between components, and that such complex objects are mereological sums of their aspect components.
BF0 based Incident types Terminology 1

- **bfo:** *Occurrent* (incident unrelated to any healthcare intervention)
  - ICPS Patient accidents; Behaviour.
  - CHADx: Accidental injuries.
  - ICD11 beta Chapter 23: "External causes of morbidity and mortality: Unintentional causes"

- **bfo:** *Occurrent* and **PrecededBy** some *HealthCareIntervention* (incident happening in relation with an health care intervention )
  - ICPS Health care associated infection, Problems in the management of Clinical process, Medication, Blood/Blood products, Nutrition, Medical fluids, Medical devices.
  - CHADx: Post-procedural complications; Adverse Drug Event and codes Not Present On Admission (NPOA)
  - ICD11 beta Chapter 23 External causes of morbidity and mortality: causes of healthcare related harm or injury
BF0 based Incident types
Terminology 2

- **bfo:** *IndependentContinuant*: incident related to a permanent entity as a structure or organization
  - ICPS Infrastructure/building /Fixtures;
  - CHADx: none
  - ICD 11 beta none

- **bfo:** *GenericallyDependentContinuant*: Information entities:
  - ICPS Documentation; Human resource management (plan)
  - CHADx: none
  - ICD 11 beta none
Conclusion and outlook

- Top down semantic approaches CAST and ULO and bottom up validations across countries can be associated for semantic interoperability.
- MIMPS is presently tested in four countries (Morocco, Afghanistan, Sri Lanka and India) having no national PS or specific vigilance reporting systems.
- 2 main issues are pending:
  - Structured(mimps) vs free text analysis
  - Cause vs precededby ontology
Vielen Dank für Ihre Aufmerksamkeit

! Any Questions ?

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Questions?

Muito obrigado
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Thank you
Grazie
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Merci

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