

Design of Semantically Interoperable Adverse Event Reporting Framework¹

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Abstract. Patient safety is one of the most significant issues not only to medical providers but also to the general public. Despite the widespread recognition of the adverse event reporting for patient's safety, there is no widely accepted or standardized way to request and report adverse event information. We designed the semantically interoperable Adverse Event Reporting framework. It consists of two components: the Adverse Event Ontology to describe adverse event in semantically interoperable way and the Adverse Event Reporting Schema (AERS) to envelope and deliver the content of adverse event report request and report. The Adverse Event Ontology was built upon existing adverse event taxonomies. The AERS was designed for common adverse event messaging interface in the form of XML Schema. The adverse event reporting framework is expected to allow semantic interoperability in sharing and exchange of patient safety information within and among various healthcare information systems.

1. Introduction

Patient safety is one of the most significant issues not only to medical providers but also to the general public in many aspects of healthcare because *adverse events* threatening patient safety occur frequently and even trivial often result in severe harm. Adverse event is any event that we do not wish to have happened again[1]. The notion of *adverse event reporting* is that when a reportable adverse event occurs, then it should be reported to the designated recipients. The purpose of adverse event reporting is to understand their origin, predict their occurrence, draw out corrective and preventive actions, and implement quality improvement strategies[2]. There are numerous adverse event reporting systems for specific information need. They collect data on medication errors[3-5], adverse events involving medical products[6], reactions[7, 8], or data solely at specific domain or organization[9].

Despite many reporting systems have been implemented, the ability to learn from these systems is limited because they do not *talk* to each other. Data are not combined or aggregated in the same manner because there is no standardized system for

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classifying and categorizing patient safety problems[10]. The terminologies meaning adverse event vary and nomenclatures are discordant among vocabularies. And it makes difficult to share and exchange adverse event information among different healthcare information systems. In addition, no global standard provides formal messaging format for adverse event reporting. The methods used to record adverse events vary among report requesters, aggregators, and investigators.

The main goal of our study is to provide semantically interoperable adverse event reporting framework. To this end, we built the Adverse Event Ontology, which provides a mechanism to resolve coding disagreement between healthcare agents. Then, we designed the Adverse Event Reporting Schema, which will be used to represent common message interface between adverse event report requesters and reporters. Next, since different principals may have different information needs we designed the Report Item Sets, which function as report item templates for specific user's preference and domain. Finally, we developed a prototype system to demonstrate the proposed framework.

2. Adverse Event Ontology

One of our goals is to develop ontology with logical construction across multiple domains to the detailed level and to capture as many different event types as possible.

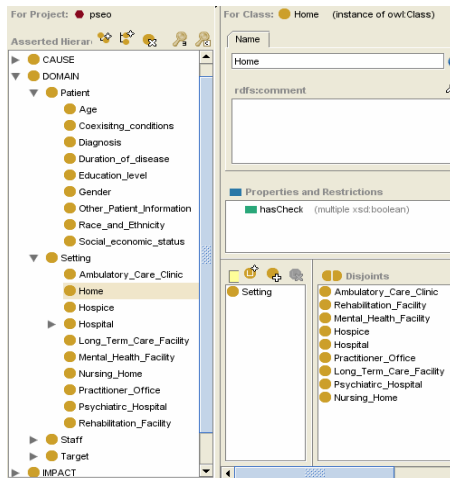


Fig. 1: The Adverse Event Ontology.

to an incident. Prevention & Mitigation is the measures taken or proposed to reduce incidence and effects of adverse occurrences. The Ontology has several properties and disjoints. The properties of the ontology include for example *hasInput*, *hasLevel*, *hasCheck*, and something like that. The structure of the ontology is as Fig.1. and the schema is available at <http://chord.snu.ac.kr/~senator/safety/pseo.owl>.

The Adverse Event Ontology was built upon earlier patient safety taxonomy research conducted by previous works[11-16] and extended them into a more comprehensive ontology. We modeled the ontology in OWL DL plugin. the ontology has five high level primary classifications as in [11, 12]: Impact, Type, Domain, Cause, and Prevention & Mitigation. Impact is the outcome or effects of medical error and systems failure commonly referred to as harm to the patient. Type is the implied or visible processes those were faulty or failed. Domain is the characteristics of the setting in which an incident occurred and the type of individuals involved. Cause is the factors and agents that led

3. Adverse Event Reporting Schema

The very concept of event reporting is that when a specific event occurs at the predefined condition, then it is reported to relevant recipient. As in case of adverse event data, reporting forms differ depending on report requester, aggregators, and investigator in the sense that there is no commonly usable report data interchange interface. To date, however, attempts have been hardly made to build standardized messaging interface across institution boundary. We need a means to exchange information about adverse events between various healthcare principals. Therefore a unified messaging interface for all types of adverse event reporting would be highly desirable. Considering this need we designed the XML based Adverse Event Reporting Schema (AERS). The AERS is intended to become a common messaging tool used by healthcare consumers, providers, regulators, or other principals when they describe whatever they want.

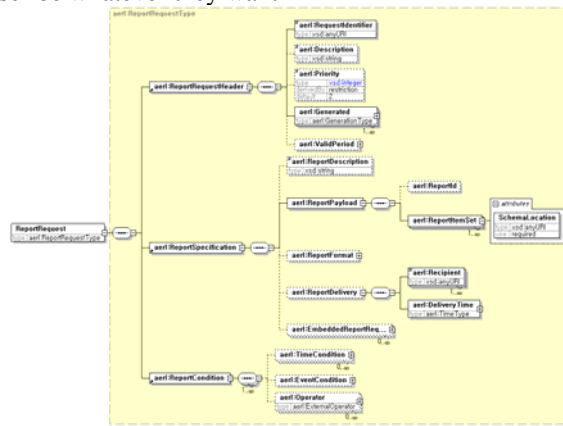


Fig. 2: XML Schema for Adverse Event Report Request.

ReportRequest The AERS comprises of ReportRequest and Report. The purpose of Report Request is to describe the adverse event, which is asked to be reported, designate the recipient, and specify a Report Item Set by which report data payload is included in a report. The ReportRequest is composed of three main sections consisting of several parts as illustrated in Fig. 2. In the ReportRequestHeader the Priority specifies the priority level (0 to 5) for a Report Request to be processed by the system. The ValidPeriod defines the life time of a Report Request. The ReportSpecification allows Report Requesters to specify which report items should be included in report payload, who is its recipient, and when it is delivered. For instance, a Requester can specify an xml schema location of Report Item Set which would be imported by Report Generator. The DeliveryTime in the ReportDelivery allows requestor to specify the time a report is delivered. Using ReportCondition requesters are able to specify report conditions under which Reports are reported: adverse event type, time-span events occur, or combinations thereof.

Report. The Report schema has three main elements. As in Report Request the ReportHeader is used to provide general descriptions of Report. The ReportItemSet provides a place for inclusion of report's payload. It corresponds to the ReportItemSet that is specified in the originating Report Request. The optional element EmbeddedReportRequest contains embedded Event Report Request or reference thereof.

Report Item Set. Information needs may differ depending on communication parties (e.g. healthcare provider, trading partner, patient), communication scope (within or cross organization), healthcare setting (e.g. hospital, ambulatory care setting, home care etc.), and reporting type (e.g. accountability reporting, ad hoc reporting). Some users want simple report data while others want more details applicable to their business domain. Hence, report requesters should be given a set of options to choose a Report Item Set which is deemed to be most qualified to satisfy their information needs. The main purpose of the Report Item Set is to function as reported data template which is filled in by Reporter. Stakeholders might extract report items from the Adverse Event Ontology and build a Report Item Set Schema with help of Report Item Set

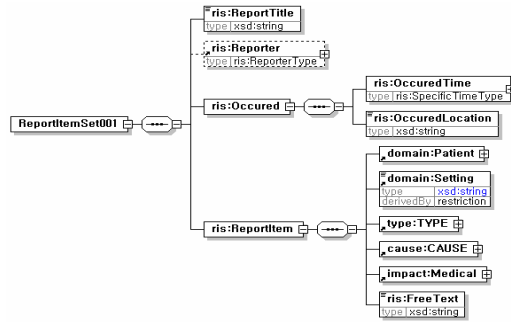


Fig. 3: Exemplary Report Item Set Schema

Generator as shown in Fig.6. For demonstration we designed an exemplary Report Item Set as shown in Fig. 3.

4. The Adverse Event Reporting System

In this section we describe the Adverse Event Reporting System and its use-case scenario. The system consists of four components; The *Report Requester* (public surveillance system manager, individual healthcare quality improvement manager, or agent thereof) who is able to access to the *Report Repository* through authentication; The *Report Generator* who is responsible for generating Report(s); The *Report Repository* which record the adverse event reports specified in a given report request; The *Report Item Set Library* which is referenced to generate Report Request(s) and Adverse Event Report(s). The Library provides Adverse Event Report Item Sets which are extracted from the Adverse Event Ontology and used to specify reported items in a report.

The reporting system operates as numbered sequence illustrated in Fig.4. Using Request Generator the Report Requester selects Report Item Set from the Report Item Set Library to generate a Report Request in which the *Report Time Condition* is set to 'any event occurred during 10 days from January 5, 2006' and Event Condition is 'Death'. In the Report Request two Report Recipients (*SH | PSE-RP-003*)² were designated. Then it is delivered to Request Recipients. A *Report Request* generated by the *Report Request Generator* is as Fig. 6. On receiving Report Request (*GH-RR-001*), the Reporter (*MH*) captures a 'Death' event which had been gone through

² In this use-case, let's say RR is Report Request, R is Report, RP is Report Repository, GH is General Hospital, SH is Smart Hospital, MH is Marine Hospital, PSE-RP is Patient Safety Event.

internal investigation procedures. Next, the Reporter generates an *Adverse Report* (MH-R-001) using the Report Generator which imports Report Item Set xml schema into the Report payload specification and send it to two Recipients who are specified in the Report Request (GH-RR-001). The example of report generated by Report Generator is as Fig.7. The adverse event Repository (PSE-RP) is responsible for consolidating all information which will be offered to requesters. The repository is also used to gather accumulative adverse event statistics. The information may be total adverse events to date, types of events reported ever, and types of providers reporting. report requesters are able to search the repository to retrieve report data which they are interested in.

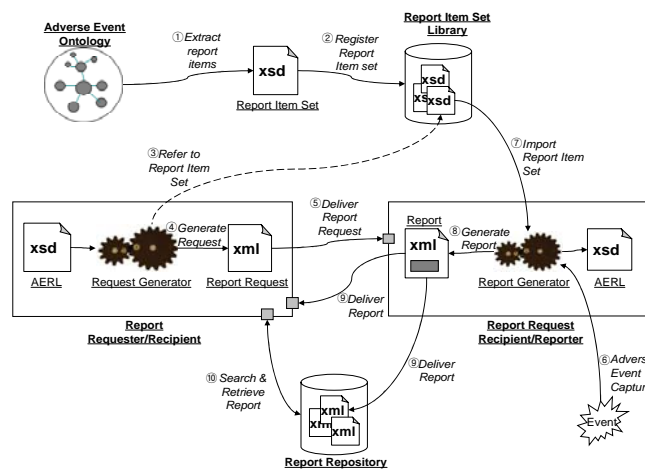


Fig. 4: Ontology-based Adverse Event Reporting System Architecture

An adverse event report should be immediately disseminated to and shared among concerning parties so those who receive report could implement useful prevention strategies. Drastically simplifying the steps and reducing the time is required[1]. Considering these requirements, we designed the reporting system user interfaces so that users can input data entry as easily as possible. The Report Request Generator and Report Generator GUIs were built using XSLT. The system users are able to input data using these generation interfaces as in Fig.5-7.

Fig.5: Report Request Generator's GUI

Fig.6: Report Items generator GUI

Fig.7: Report generator GUI

5. Conclusions and Future work

The purpose of adverse event reporting is to improve patient safety through greater sharing of information about adverse events. We proposed an ontology and xml schema driven methods for semantically interoperable adverse event data communication among geographically distributed and heterogeneous health care information systems.

This paper described the beginning stage of our work on the semantically interoperable adverse event reporting framework. Significant challenges remain to develop sound system to meet various information needs of adverse event reporting community. Above all things, field-test is required to determine plausibility and suitability of the proposed framework. Further, we've just built an exemplary Report Item Set schema by hand. The next stage of the project we will implement the engine which is able to semi-automatically extract elements from the Adverse Event Ontology to construct Report Item Sets depending on user's information need. Still another work to be done is deliberation method of message between Requester (Report Recipient) and Reporter (Request Recipient). In the next stage we explore efficient method for message delivery.

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