Date : 22/06/2006

Ontology based Adverse Event Reporting System Architecture

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Meeting:	**148 Health and Biosciences Libraries**
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20-24 August 2006, Seoul, Korea

http://www.ifla.org/IV/ifla72/index.htm

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 the information of adverse events. We proposed the Ontology-based adverse Event Reporting System (ONTERS) Architecture. In ONTERS, the adverse event ontology describes adverse event in semantically interoperable way. The ontology was built based on existing adverse event taxonomies. The Adverse Event Reporting Schema (AERS) is designed for common adverse event messaging interface in XML Schema. The ONTERS is expected to provide semantic interoperability in sharing and exchange of adverse event information within and among various healthcare information management systems.

Introduction

Patient safety is one of the most significant issues not only to medical providers but also to the public in many aspects of health care because adverse events threaten to 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(Fernald et al. 2004). 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 identify and understand their origin, predict their occurrence, draw out corrective and preventive actions, and implement quality improvement strategies(Makeham et al. 2002). There are numerous adverse event reporting systems for specific information need. They collect data on medication errors(United States. Food and Drug Administration. 1994), adverse events involving medical products, reactions(BLAKE et al. 1999; Zhou et al. 2003), or data solely at specific domain or organization(Mekhjian et al. 2004). The reporting forms vary from a simple request for a free narrative through to a series of complex forms.

Despite there are many adverse event-reporting systems implemented, the ability to learn from these systems is limited because they do not talk to each other. To the authors' knowledge, it's hard to find the authoritative common language capable of representing or coding the adverse event, though the WHO's *International Patient Safety Event Taxonomy* is embarked on the development(WHO 2004). The terminologies meaning adverse event are discordant among vocabularies. It makes hard to share and exchange adverse event information among different healthcare information systems. Moreover, no global standards provide formal messaging format for adverse event reporting. The methods used to record adverse events vary among report requesters, aggregators and investigators.

The main objective of our study is to facilitate adverse event information sharing and exchange among healthcare information systems. To this end, we constructed the Adverse Event Ontology, which provide a means to resolve coding disagreements. Second, we designed the Adverse Event Reporting Schema, which can be used to specify an adverse event content and format to satisfy Report Requester's information need regardless of their domain. Third, because 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, Ontology-based Adverse Event Reporting System (ONTERS). This paper provides overall system architecture of the ONTERS.

Adverse Event Ontology

The Adverse Event Ontology was built upon earlier patient safety taxonomy research conducted by previous works(Chang et al. 2005; WHO 2004) and extended them into a more comprehensive ontology. We modeled the ontology using protégé OWL DL plug-in. The ontology has five high level primary classifications: 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 to an incident. Prevention & Mitigation is the measures taken or proposed to reduce incidence and effects of adverse occurrences. Under the five primary axes there are secondary, tertiary, quaternary classes, and narrative fields.

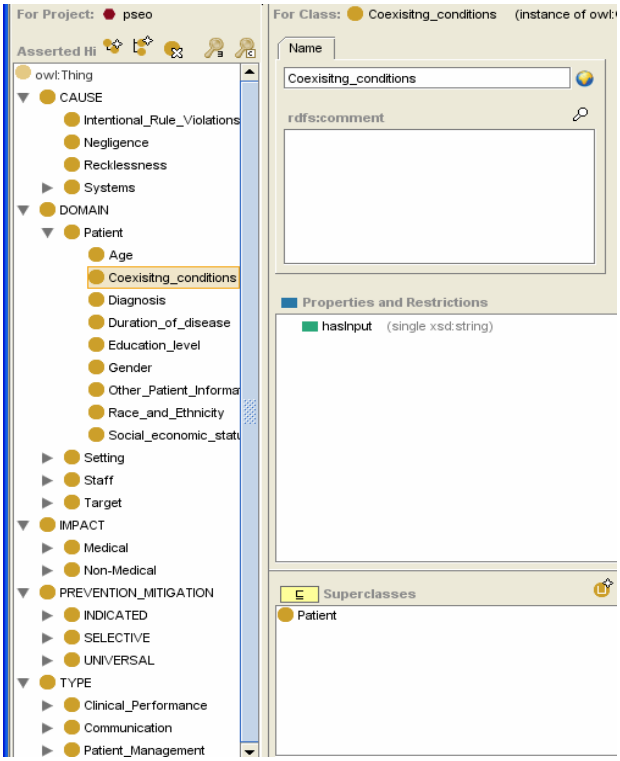

Figure 1. The adverse event ontology

Adverse Event Reporting Schema

The very concept of adverse event reporting is that when a specific adverse event occurs at the predefined condition, then we are expected to report that. As in case of adverse event data, reporting forms differ depending on report requestor, 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 a standardized messaging interface across institution boundary collaboration. 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, policymakers, or other principals when they describe their information needs, report quality requirements, or other purposes.

The AERS comprises of *ReportRequest* and *Report* element. 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 to be included in a Report.

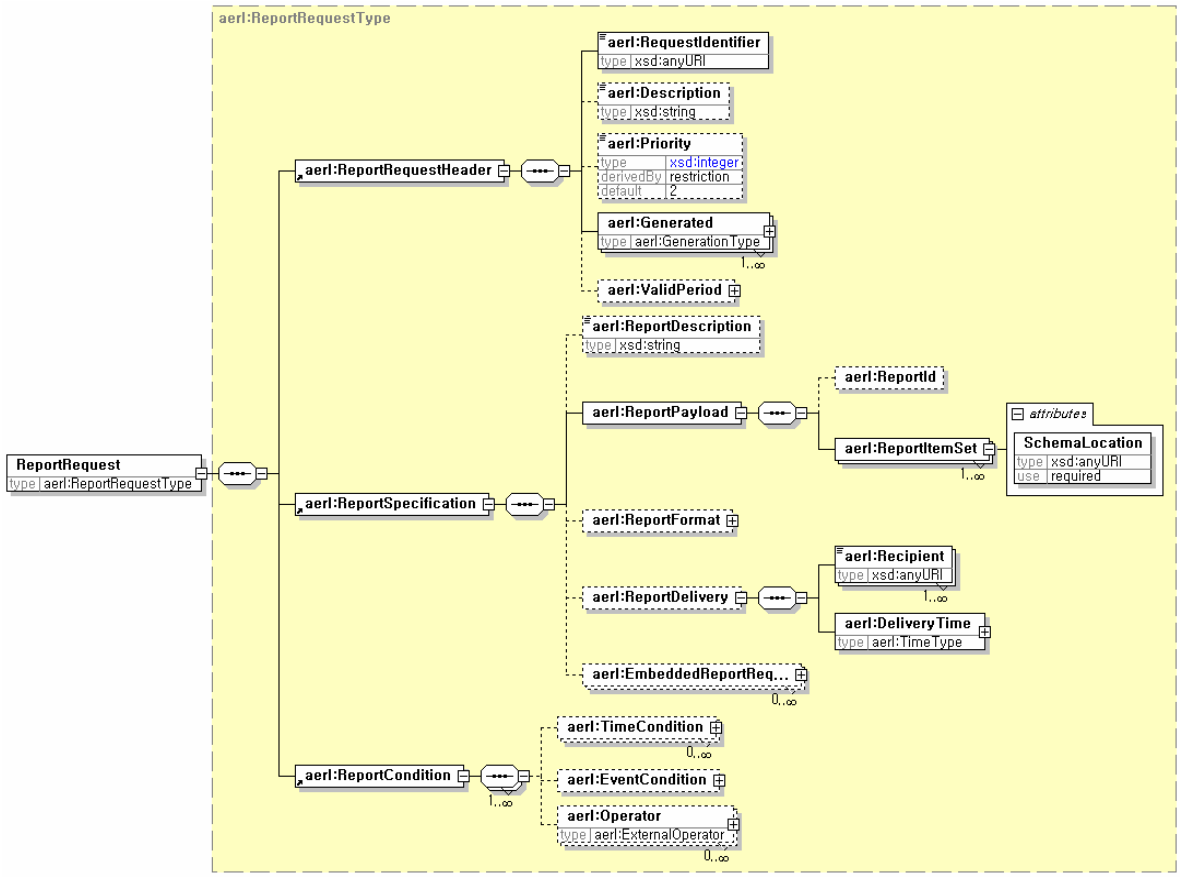

Figure 2. XML Schema for Report Request

1. ReportRequest

The *ReportRequest* is composed of three main sections consisting of several parts which are specified as Figure 2. The *ReportRequestHeader* provides general parameters of a Report Request. For example, 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 and also who is its recipient, and when it is delivered. For instance, a Requester can specify an xml schema location of Report Item Set which will be imported by Report Generator. The *DeliveryTime* in the *ReportDelivery* is to allow Requestor to specify the time that Report is generated. Using *ReportCondition*, Requesters are able to specify report conditions under which Reports are reported: the adverse event type, time-span events occur, or combinations thereof.

2. Report

The Report schema has three main elements. As in Report Request *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.

3. ReportItemSet

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 only minimal 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 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 Generator as shown in Figure 7. For demonstration we designed an exemplary Report Item Set as shown in Figure.3.

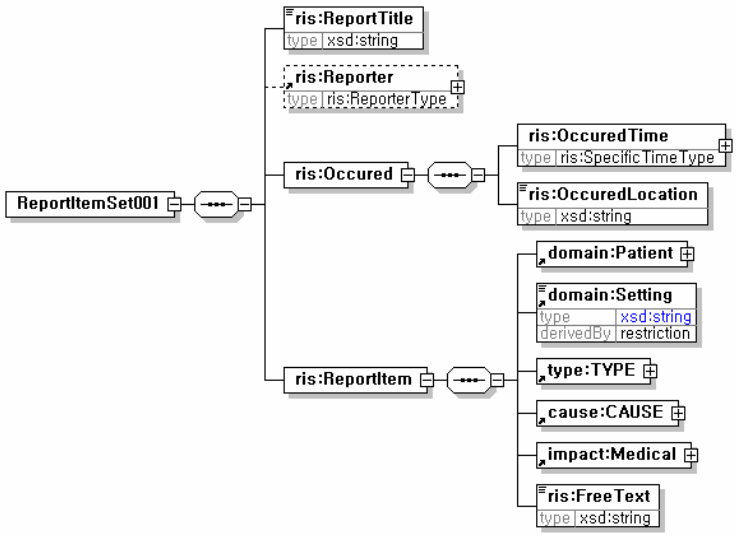

Figure 3. Exemplary Report Item Set Schema

The Adverse Event Reporting System

In this section we describe the Adverse Event Reporting System (ONTERS) and its use-case scenario. The ONTERS 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 records 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.

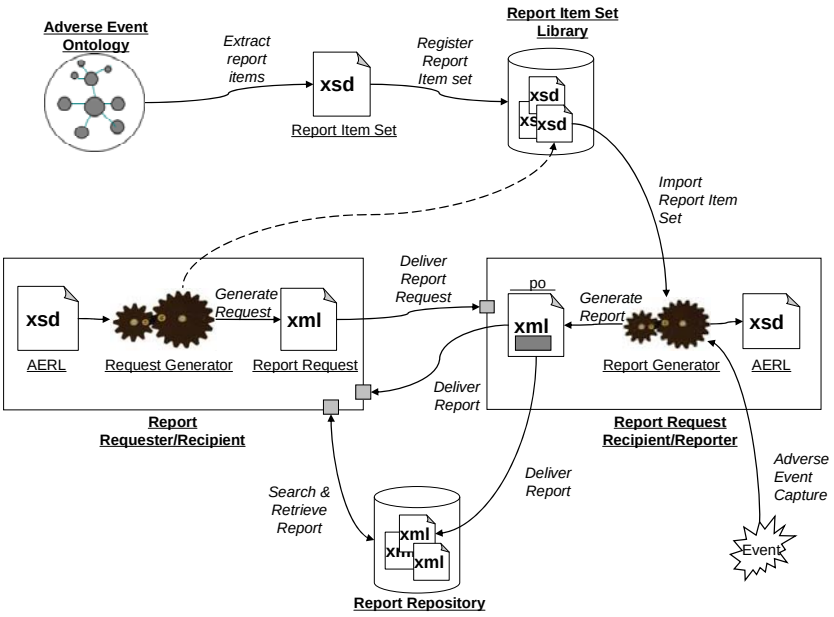

Figure 4. Architecture of Adverse Event Reporting System

The ONTERS operates as numbered sequence illustrated in Figure 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 *Adverse Event Condition* is '*Death*'. In the Report Request two Report Recipients[1] (*SH* | *PSE-RP-003*) were designated. Then it is delivered to Request Recipients. A Report Request generated by the Report Request Generator is as Figure. 6. On receiving Report Request (*GH-RR-001*), the Reporter (*MH*) captures a '*Death*' event which had been gone through 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 Figure.7. The Adverse Event Report 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.

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(Fernald et al. 2004). Considering these requirements, we designed the ONTERS user interfaces so that system 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 Figure.5-7.

[1] 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.

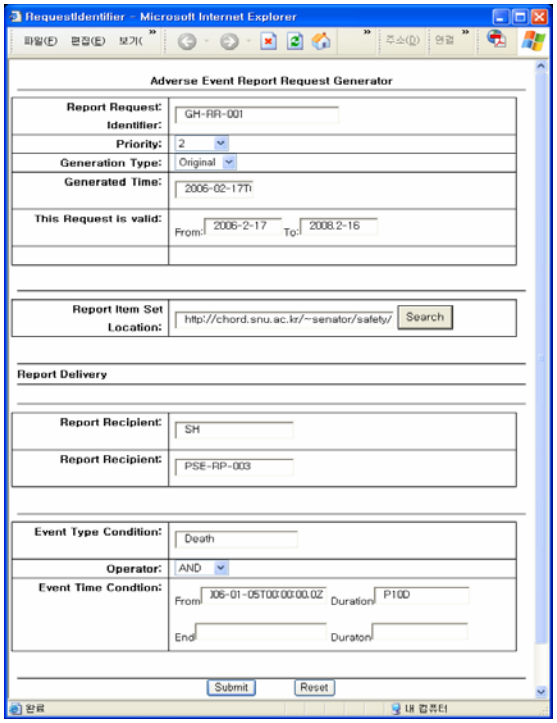

Figure 5. Report Request Generator's GUI

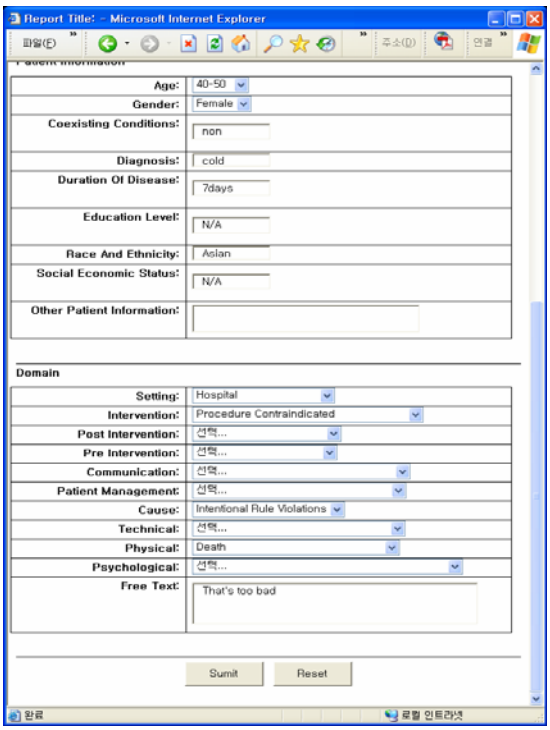

Figure 6. Report Items generator GUI

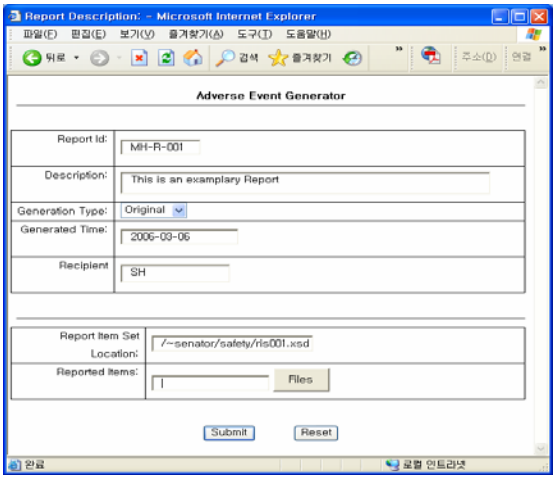

Figure 7. An exemplary report generator

Conclusion

The purpose of event reporting is to improve patient safety through greater sharing of information about adverse events. We've built the adverse event ontology to share adverse event among various users and designed reporting schema to exchange adverse event data among distributed and heterogeneous healthcare information systems. Then we proposed the Adverse Event Reporting System (ONTERS) which is expected to allow semantic interoperability among various healthcare information systems. The ONTERS can be associated with medical bibliographic knowledge base upon which reported adverse event related scholarly information can be collected.

However, significant challenges remain to develop sound models to reflect the various aspects of Adverse Event and Reporting. Among other things field-test is required to determine suitability of the framework and to bring it to the full maturity.

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