

The Rapid Syndrome Validation Project (RSVP)

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The Rapid Syndrome Validation Project (RSVP) is a collaboration of several institutions: Sandia and Los Alamos National Laboratories, the University of New Mexico Department of Emergency Medicine, and the NM Department of Health Office of Epidemiology. RSVP is a system that operates at the intersection of individual health care providers, public health and bioterrorism. Physicians quickly enter clinical and demographic information on patients exhibiting symptoms and signs of the syndromes of interest. It provides early warning and response to emerging biological threats, as well as emerging epidemics and diseases. RSVP provides real time clinical information to the provider and any other potential user such as the DOH, about current symptoms, disease prevalence and location. The system also serves as a mechanism for the Department of Health to inform health care providers of health alerts and to facilitate the process of collecting data on reportable diseases.

We describe here the purpose and the architecture of a network-based surveillance system that is currently implemented in an Emergency Department.

INTRODUCTION

The threat to the health and well-being of the general public from infectious disease, whether natural or intentionally induced, is ever increasing. New (or newly recognized) and emerging diseases have appeared in unexpected locations with increasing regularity as geographical boundaries evaporate in our highly mobile society. These diseases, such as HIV, dengue fever or Hantavirus, present unique and significant challenges to our public health infrastructure, both in terms of recognizing their presence as well as limiting their effects. The evolution of other naturally occurring diseases such as influenza also is of concern. Worldwide influenza epidemics-- "pandemics"-- have occurred in recent recorded history in 1889, 1918, 1957, and 1968. International flu experts believe that the world will experience another influenza pandemic sometime in the next decade. Added to this

already significant natural threat is the looming scourge of bioterrorism, whereby man attempts to circumvent nature by introducing virulent biological pathogens into the general population intentionally, with potentially catastrophic results.

Each of these threats represents a potential significant impact to public health. Any proposed solution to the biological threat must seamlessly integrate into a disease warning and response network that addresses all infectious disease public health threats -- natural or man-made. The rationale:

1. Natural disease outbreaks, while expected to be less serious or explosive than a terrorist event, are certainly more frequent and any efforts to minimize their impact will have immediate and tangible benefit to public health;
2. Any disease monitoring and response system based only on responding to rare bioterrorism events will not be sustainable as an operational system, either financially or functionally.

BACKGROUND

Physician awareness of emerging disease and biological weapons threats is limited, indeed even reportable diseases are often missed early in an outbreak. In addition, most of the diseases that are frequently mentioned as emerging (or re-emerging), e.g., hantavirus, Ebola or dengue fever, begin in a non-specific fashion: fever and malaise, followed by cough and muscle aches. One of the most difficult problems in dealing with a clandestine bioterrorist event is determining as early as possible when such an event has occurred. The difficulty is multifaceted and also pertains to the identification of naturally occurring disease.

1. Those affected will present to Emergency Departments with complaints usually caused by common diseases and thus will not be recognized as victims of bioterrorism.

2. Changes in routine illness patterns are not identified in any systematic fashion, as there is no infrastructure allowing practitioners to communicate with each other.
3. Physicians do not receive information on the type and frequency of diseases that occur both in their area and in neighboring regions nor do they receive timely information early in outbreaks of common diseases from public health officials.

In order to succeed in managing an event in an effective manner, this information must be obtained and distributed in a rapid, reliable manner. Thus, even in a terrorist attack involving large numbers of people, it is unlikely that health care providers will be able to distinguish between a natural epidemic (such as from influenza) and a bioterrorist attack. Infectious disease and epidemiology specialists will not be alerted until well into the epidemic, resulting in significant public health consequences that otherwise might be averted. This is because traditional health surveillance depends on disease reporting.

Despite disease reporting being a potentially powerful surveillance tool, practitioners tend not to report even "reportable" diseases. This is due to the inconvenience involved, and the lack of perceived utility to their individual practices and patients. Currently, disease reporting is mostly "diagnosis based", that is, it typically comes from clinical laboratories, which report positive cultures and other tests as mandated by state regulations. Reporting based on this information is incomplete because many practitioners don't order such tests because either they don't suspect the disease or the test may not be perceived to impact on the clinical care of an individual patient. Lab based reporting is also slow, because it some tests or cultures require days or weeks to become positive. Furthermore, providers have no easy or systematic way to report cases that don't seem routine. The provider would not know that other health care professionals were also seeing these non-routine cases. To combat this and other barriers, public health officials and health care providers must have a system in place with the following characteristics:

- Syndrome-based reporting rather than diagnostic-based reporting to facilitate physician participation and identify trends early.
- Reporting that is extremely fast and easy to use in the clinical setting and provided incentive for practitioners to utilize the system.
- Network based reporting to facilitate the rapid automated analysis of information
- Interconnectivity between multiple participants to tie disparate and geographically separated sources of information together to provide a clear understanding of the evolving situation
- Clear understanding of the "natural" background of infectious disease in the general population

- Ability to characterize and trigger responses in a timely manner.

SYSTEM REQUIREMENTS

In order to meet these requirements, we have developed the Rapid Syndrome Validation Project (RSVP). It is designed such that clinical and epidemiological data can be entered by health care providers quickly and easily from a touch screen without the use of a keyboard. Currently, we have chosen six syndromes to monitor (none of which are routine or common) but this is flexible. RSVP can analyze the syndromes and clinical data within and between syndromes to identify changes from the expected baselines that may indicate a bioterrorist event, an epidemic or an emerging disease. It is designed to work in a fully distributed environment, so that the data can be viewed and analyzed remotely as needed from multiple sources. All users can see events occurring over a defined geographic area so that threshold events can more readily be detected. Also, immediate alerts are sent to the local Department of Health Epidemiologists to enable them to immediately initiate outbreak investigation and control.

Just as important, RSVP is designed around international standards for clinical observations in cooperation with the Object Management Group. The standard interfaces being implemented are consistent with those standards designed for clinical information systems in hospitals. Thus the RSVP system could be implemented on any clinical system, which implements those international standards without having to deal with database schema, etc. It is designed to facilitate the collection of anonymous patient information, but in a disaster situation can include patient identifiers to link lab tests, treatment, patient locations and outcome to specific individuals. The distributed architecture enables a variety of deployment strategies, which can depend on the clinical facility requirements, as well as network and security limitations of the facilities.

Because it is designed for standard use in ordinary clinical settings, it can be immediately implemented for complex triage. If security allows, the information can be collated and analyzed from a distance to ensure the most effective management of a bioterrorist event. The system can provide robust state-of-the-art security including the ability to control access to information on a need-to-know basis over a wide-area network. At the same time, it provides for access and data acquisition over the web for very low cost and adaptable deployment.

It is developed in 100% Java for complete platform independence in its deployment. It can run with a standalone Java object database or on top of an already prescribed relational database such as Oracle, or SQL Server without re-coding. The data storage can be readily migrated between these different types of persistent stores for flexible deployment strategies.

In addition, the data input and output can be converted to and from XML for the application of a variety of emerging analysis tools. The system implementing these standards is called OpenEMed and is available as open source on the Internet

The software is developed using CORBA (Common Object Request Broker Architecture)¹ standards including the interface standards of the OMG's Healthcare Domain Taskforce and builds on the OpenEMed² (formerly TeleMed) work of Los Alamos National Laboratory. The data is captured using the CORBA client-server architecture to a central data server, which can be situated in the NM Department of Health Office of Epidemiology using secure, encrypted transmission over the Internet, enforcing strong authentication and authorization. The data server processes the information and, utilizing a standard web-based client-server interface, provides reports to all users.

A major focus of this project is to devise a system that health care providers would use readily. It is well known that in busy health care settings providers are unlikely to participate in a project if there is no perceived value. Therefore, in addition to making the interface easy and quick to use, this system provides value by giving the user epidemiologic information about the syndrome entered, thus aiding the practitioner in patient management. RSVP also provides the opportunity for two-way communication with local epidemiologists about the syndrome in question. Currently the features below are provided.

To the Health Care Provider

- A geographic plot of syndrome reporting that closely matches that reported by the physician.
- A temporal (time-graph) plot of similar syndromes over the past several weeks
- A summary of viral laboratory cultures reported in the community (updated on a daily basis).
- One of several "alert" screens, suggesting the possibility that the syndrome reported by the physician may be one of several State of NM sanctioned reportable diseases.

To the Department of Health, State of NM

- All of the data above, for each of the six syndromes reported by physicians
- The capacity to disseminate information to clinicians regarding local outbreaks and similar health alerts
- Under appropriate conditions of secure data transmission and reliable identification of the person sending the data, a simple and quick method for the clinician to make a standard report of a notifiable condition

Key judgments reflected in the design of the system and interface are:

- Demographic data (age, gender, zip code of residence and work place, high-risk occupation are carried out with touch-screen choices.
- The graphical user interface provides the health care provider the ability to enter data in less than 1 minute, assisted by icons and other visual assistance.
- Reporting of spatial and temporal distributions of similar syndromes are immediately available.
- Additional information from Office of Epidemiology is available on specific web pages with special alerts distributed as appropriate

The spatial and temporal data will also serve to refine disease outbreak models currently under development at Los Alamos National Laboratory (LANL) and Sandia National Laboratories, primarily for respiratory illness (influenza and other communicable respiratory diseases). Such a model may assist public health planners and disaster response officials in responding to public health emergencies of either natural or man-made origin. We also plan to survey physician as to what types of feedback would further motivate them to use RSVP.

SYNDROMES AND EVALUATION

The project is being piloted with six syndromes:

1. Influenza-like illness
2. Fever with Skin Findings
3. Fever and Altered Mental Status
4. Acute Bloody Diarrhea
5. Hepatitis
6. ARDS (Adult Respiratory Distress Syndrome)

Physician judgment determines the syndrome that best represents any given patient and is partially captured by the syndrome selection. These syndromes have been chosen for several reasons: They represent the majority of syndromes by which:

- Bioterrorist infections will present.
- Emerging disease have already presented
- Naturally occurring and expected seasonal epidemics will present.

A more detailed description of the rationale for and the details of these syndromes will appear in a subsequent publication.

The reporting system is designed to assist the physician with appropriate clinical and epidemiologic data. If the syndromes match parameters associated with a "reportable disease" designated by the Department of Health (DOH) Office of Epidemiology, an alert is provided to the physician and automatically sent to the DOH.

We are testing the hypothesis that such a system will provide information of utility in the management of

the individual case as well as the development of public statewide health policy (e.g. vaccination, diagnostic and medical prophylactic strategies, need of disease outbreak investigation, etc.). We expect that the system will evolve to meet needs of health-care providers and other users. Thus, changes in entry screen format, clinical data reported, and other technical items are.

We will test these hypotheses by several methods.

1. Process evaluation tools will be embedded into the reports by soliciting user comments for each screen.
2. Case ascertainment success rates (the proportion of patients entered into RSVP relative to the total eligible) will be measured.
3. The proportion of outbreaks identified more quickly by RSVP as compared to those identified through conventional methods will be measured (sensitivity).
4. "Dummy data" will be inserted into the system to validate the model (sensitivity).
5. Epidemiologists will review syndrome reports on an ongoing basis to identify changes from the established baselines. The proportion of changes that correspond to outbreaks will be measured (specificity).
6. The proportion of automatic reports to the health department that result in actions will be measured (specificity).
7. Changes in reporting patterns of reportable diseases will be monitored. Reports from RSVP will be compared to conventional reports to measure sensitivity, timeliness, completeness and utility.

IMPLEMENTATION

The system consists of a multi-tiered architecture with a pure web client provided to the user. The web server has Java Server Pages for generating dynamic web pages and Java Beans that implement the CORBA clients, as show in Figure 1, much like standard Application Servers³. Those clients can connect to various Clinical Observation Access Service (COAS)⁴ servers, which store the collected syndromic data. These servers can be run as a central service or as a de-centralized set of servers working together in a federated manner. This multi-tiered architecture allows for customization at the web server for local configurations while providing separate maintenance of the clinical information. The patients are not identified, but remain anonymous, so the Person Identification Service⁵ is not required (unless the organization wishes to provide an internal, confidential patient identifier). The COAS interfaces are used to enable the system to be implemented on radically different database systems and still be fully interoperable.

The entire system can be run with SSL security and robust-authentication with digital certificates utilizing CORBA Security to provide sufficient privacy and data integrity. If needed data can be protected by content using the Resource Access Decision Service⁶. An entire data set can be stored as XML for transmission for processing by other organizations that do not implement CORBA-based systems. Likewise, RSVP could receive XML data from other systems.

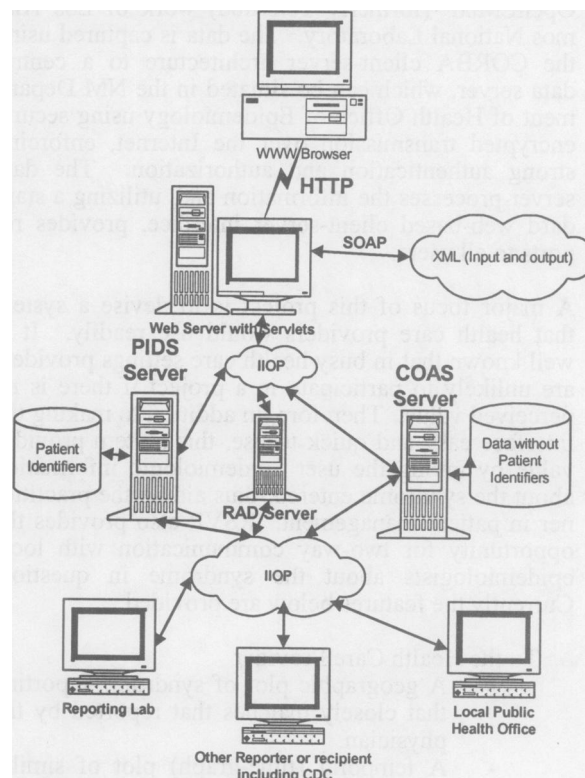


Figure 1. System diagram showing the connectivity between the various components and participants.

At the present time patient confidentiality, anonymity and privacy are maintained because no records contain patient identifiers. A master list of records and patient identifiers does not exist, so reports cannot be tracked through RSVP back to individual patients. This does not impede the collection of data for surveillance or overall epidemiologic purposes. However, reports from RSVP may trigger "auto alerts" to the health department. The health department may then follow up this report through standard epidemiologic methods as required by law. This may include contacting the institution initiating the report and asking the health care provider for clinical information, as is currently the current practice.

The data elements used) do not correspond to any current coding systems, since they are intentionally neither diagnostic nor treatment connected. RSVP is compiling data elements (patient symptoms and physical exam findings) that have not been collected

previously. They are the closest to LOINC⁷ codes, but do not correspond to them, either. We will continue to pursue the use of or standardization of coding schemes used RSVP. These coding schemes should be mediated by a Terminology Query Service⁸ for more widespread use. Such a service could also allow for equivalences in different locations being normalized.

The architecture used here corresponds to the model required to implement a global, extensible electronic health record.⁹ Using open, standard interfaces and data elements used to implement standard services, it becomes possible to integrate multiple data sources to present a unified view of data be acquired from multiple sources. This approach can integrate across multi-vendor platforms without requiring a complex interface engine, because of the presence of the normalizing middleware. We have created a set of secure, Internet services, which provide functionality, and handle standard databases on a rich suite of open, standard services created for the healthcare industry.¹⁰

CONCLUSIONS

We have demonstrated the feasibility of a network-based surveillance system that is easy to use to acquire syndromic reports of illness that may be of public health significance in the detection of natural disease outbreaks or bioterrorism. The surveillance system provides feedback to healthcare providers relating their report to similar cases reported previously. The ease of use and information feedback may increase clinician involvement in disease reporting, which will result in more accurate and timely surveillance. In addition it may be appropriate to remind clinicians of the utility of diagnostic tests, which might provide early differentiation among disease entities responsible for a given syndrome. Further, the exchange among health-care providers of information obtained at virtually every clinical encounter suggestive of a serious communicable infectious disease—age, occupation, sex, location—provides extremely valuable clues to the nature of apparent infectious disease syndromes. These can be utilized for refinement of disease models (including models of transmission), for acquisition of samples for genomic analysis when appropriate, and for generating specific, clinically based requirements for advanced diagnostics (such as early recognition of pathogens) and counter-measures. We have demonstrated the feasibility of this process based on an extensible, open-architecture approach that could be used for a variety of clinical information of value to health care providers, public health organizations and ultimately of value to the patient and community.

References

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