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INFORMATION SYSTEMS AND HEALTH CARE XIII: EXAMINING THE CRITICAL REQUIREMENTS, DESIGN APPROACHES AND EVALUATION METHODS FOR A PUBLIC HEALTH EMERGENCY RESPONSE SYSTEM

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ABSTRACT

Research pertaining to emergency response systems has accelerated over the past few years, particularly since 9/11 events, and more recently due to Hurricane Katrina and concern over a potential of an avian flu pandemic. This study examines the requirements that are the most demanding with respect to software and hardware, and the associated design strategies for a public health emergency response system (ERS) for electronic laboratory diagnostics consultation. In addition, this study illustrates ways to evaluate the design decisions.

An important goal of a public health ERS is to improve the communication and notification of life-threatening diseases and harmful agents. The system under study is called Secure Telecommunications Application Terminal Package or STATPack. STATPack supports distributed laboratories to communicate information and make decisions regarding biosecurity situations. The intent of the system is to help hospital laboratories enhance their preparedness for a bioterrorism event or other public health emergency.

The practical nature of this research concerns how an ERS diagnostic and consultation system was designed to alert and support first responders and Subject Matter Experts (SMEs). The academic nature of the research centers on the critical requirements of an ERS and how these unique needs can be met through careful design. Understanding the critical requirements will assist developers to better meet the expectations of the users. Specifically, I conducted a thirteen month study analyzing the requirements, design, and implementation of the system.

Keywords: Emergency Response Systems, System Design, Public Health Systems

I. INTRODUCTION

The rapid movement of the West Nile virus (WNV) in the United States underscores the ease with which emerging infectious pathogens can move into new geographical areas. Mechanisms for chemical-induced, radiological-induced, or infectious air-borne and water-borne diseases affecting humans, animals, and agriculture are serious ongoing health, environmental, and economic concerns in the United States and throughout the world. Emergency preparedness and response systems are emerging to addresses these concerns [Baker, 2001].

The spread of infectious air- and water-borne diseases affecting humans, animals, and agriculture remains a serious environmental and economic concern. The World Health Organization's coordinator for avian and human influenza warned citizens on September 20, 2005 that the "range of deaths could be anything between 5 and 150 million" from a new pandemic. This death toll will depend on the lethality of the virus and how easily it is transmitted from human to human. Neither of these variables will be known until the virus emerges. Experts across the world are monitoring the avian flu as it makes its way from Asia to Europe. What is feared is that the virus will mutate into one that can be transmitted from human to human. So far the cases of avian flu have been linked to contact with sick birds, but the mortality of this virus is high. As of this writing, 137 human deaths have been reported in 235 laboratory confirmed cases.

Recognizing an outbreak of an infectious disease early is essential to saving lives. Sound techniques in surveillance and identification will enable communities to implement measures to contain and isolate those who are infectious, preventing further transmission. Along with a limited supply of anti-viral medication, these measures will be the only defense until a vaccine can be manufactured. This process may take up to six months, and initially the vaccine will be in limited supply. All of these factors have led to the current emphasis on pandemic flu planning across the nation and around the world. Emergency response systems are one of the ways to address this threat.

An Emergency Response System (ERS) is an emergency information system that can be viewed as a specialized group decision support system that includes a structured group communication system where the protocols and communication structure are provided, but there is little content about a particular crisis except in integrated electronic databases [Turoff et al., 2004]. In the event of a man-made or natural disaster an ERS is specifically designed to assist. Emergency response systems provide the necessary information for decision makers to determine a course of action during an emergency. It may include an alert and notification process. Emergency response systems often require multiple decision makers to work collaboratively in a time sensitive situation where lives are at risk. These systems must be predictable, reliable, and usable. Decision makers must be functional quickly when using the ERS. Ideally, it is critical to design an ERS that can be used on a daily basis for non-emergency events, so that individuals who are familiar with the system can easily transition to an emergency mode as needed. In other words, a helpful emergency response system is a *system that is used.*

State and local Public Health Laboratories (PHLs) are at the core of the United States public health delivery system, linking almost every facet of public health infrastructure: disease control and prevention, maternal and child health, environmental health, epidemiology, and emergency preparedness and response. As a result PHLs interact with a wide range of local/state/federal agencies and individuals, including local hospitals/laboratories/clinics, environmental/agricultural/wildlife institutions, academic institutions/health sciences centers, and law enforcement agencies.

Public health emergency response systems, a type of ERS, are one of the most important components of the national information infrastructure for bioterrorism preparedness and require special attention. The system examined in this study is a public health emergency response diagnostic consultation system. It is an interactive computerized system that utilizes the Internet infrastructure to provide microbiology diagnostic consultation to hospital laboratorians and send alert notifications to hospital laboratories in the case of a bioterrorism event or public health emergency. In the context of this study bioterrorism is defined as: the deliberate use of a biological agent(s), such as B. anthracis, Variloa virus, Coxiella burnettii, or biological toxins such as neurotoxins produced by Clostridium species, to cause illness, disease or death to an animals, plants or humans. Biosecurity refers to the secure handling and containment of such agents or toxins.

In general, ERS systems often have unique and challenging system requirements. Public health ERSs have additional distinctive and critical requirements such as Health Insurance Portability and Accountability Act, HIPAA[1] compliancy, accuracy, privacy, and so forth.   These systems often require real-time immediate responses in a highly secure environment. They must be easy to learn and use. The information presented must not overload the user. These systems require dynamic interaction of data, multi-level statuses and notifications, and real-time up-to-date information.   The systems must be accurate, reliable and process at peak performance.   In summary, the design and development of ERS systems is a complex challenge and there still is much to learn about the best practices.

The purpose of this paper is to illustrate both the critical requirements of a public health ERS and how various design principles must be taken into account to guide the development.   Action research was considered the most suitable research methodology.   To this end, the paper presents research on how an Information Technology (IT) development project team engineered a laboratory diagnostics and consultation system that met the demanding functional, non-functional, and physical requirements of an informational ERS system for the Nebraska Public Health Laboratory (NPHL). The NPHL is a collaborative effort between the Nebraska Department of Health and Human Services (NHHSS) and the University of Nebraska Medical Center (UNMC), with consultation from the Centers for Disease Control and Prevention (CDC) to provide diagnostic services and consultation regarding the potential exposure of the public to infectious organisms.

The remainder of the paper is structured as follows.   The next section presents background information on emergency response systems and their importance. Section 3 discusses the research method. Section 4 provides an overview of the STATPack system. Section 5 presents the requirements, design strategies and evaluation methods. Section 6 is a discussion on ERS design principles that apply to this study and the lessons learned and their implications. The paper concludes with a discussion of key findings, limitations, and directions for future research.

II. STATEMENT OF THE PROBLEM

The increased incidence of infectious diseases and antibiotic resistance are growing threats to public health. Since September 11, 2001 and the following anthrax events, the detection and reporting of bioterrorism, and the ability to maintain disaster preparedness and formulate a response, has grown in importance. The capability to communicate and transfer data securely and efficiently is especially problematic in rural areas due to the lack of computing and telecommunications infrastructures.   Efforts are needed to assess local computing capacity, regional telecommunications resources and barriers, and to design and test emergency response systems sensitive to the computing, economic, and healthcare environment of rural areas.

In a 1988 report, the Institute of Medicine identified three core functions of public health. The core functions are assessment, policy development, and assurance (cited in Nebraska Health and Human Service System, 1999). Public health surveillance provides an ongoing assessment of the health status of populations for the purpose of identifying and solving community health needs [Baker et al., 1994] In recent years, concerns about bioterrorism and emerging infectious diseases such as the West Nile virus, Severe Acute Respiratory Syndrome (SARS), and now avian influenza A/(H5N1) have accelerated the efforts of state public health laboratories to establish better communication networks with private, clinical, and hospital laboratories in an

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[1] HIPAA is a recent US Federal Government legislation known as the Health Insurance Portability and Accountability Act.   This legislation concerns consumers' rights to health care privacy practices.   Specifically, the purpose of HIPAA is to ensure the portability of medical records, protect consumers' health information, streamline the process how doctors process medical reports or payments with insurance companies, and simplify how medical providers do business with health insurance companies and other medical providers.

effort to improve public health surveillance. Since the majority of infectious disease testing in the U.S. is done in private hospital and clinical laboratories, better integration with state public health laboratories is expected to improve both the timeliness and validity of disease reporting. During a health-related event, timely interpretation and dissemination of information are essential to reducing morbidity and mortality.

Most states in the U.S. do not have the capability to efficiently and electronically share critical public health microbiology laboratory information in emergency situations where time is of the essence. This is a critical issue in the Midwestern states which have large geographical areas that are serviced by a single State Public Health Laboratory (SPHL).

A solution to this situation is leveraging information technology in response to a national call to better prepare the nation's citizens, both urban and rural, in case of a biosecurity or bioterrorism emergency [Kun and Bray, 2002]. According to Edward Baker, assistant U.S. Surgeon General, "The best public health strategy to protect the health of civilians against biological terrorism is the development, organization, and enhancement of public health prevention systems and tools, including enhanced communications mechanisms and messages." [Baker, 2001].

Most people are familiar with emergency response systems such as 911, ambulatory services, fire fighters, and so forth. Today, emergency response systems continue to emerge as an integral part of addressing improvements to aid in managing and minimizing the impact of man-made and natural disasters. The federal agency responsible for managing and assuming total control of a crisis or disaster is the Department of Homeland Security (DHS). The Department of Homeland Security replaced the Office of Emergency Preparedness. Both of these offices are in the Executive Office of the President. The Department of Homeland Security provides the capability to anticipate, preempt and deter threats to the homeland whenever possible. When such threats happen DHS is charged with the responsibility to respond quickly. Furthermore, DHS is responsible for assessing the vulnerabilities of the nation's critical infrastructure and cyber security threats, as well as leading the coordination of federal, state, local and private entities to ensure an effective response[2].

An important motive of this research is that there are several unique, often challenging issues applying to ERSs; such as the type of users of such systems and the environment in which the ERS must operate. Individuals dealing with emergencies work long hours around the clock and have no tolerance or time for distractions or information overload. Often these individuals are the first responders in an emergency and are the main users of the systems. During a crisis situation, hundreds of people from different organizations need to freely exchange information, delegate authority, and conduct oversight. The critical problem at the moment is where people focus and what resources are expended [Turoff, 2002].

The environment during an emergency is chaotic and volatile. In many situations, the process of responding to a crisis is unpredictable since almost everything in a crisis situation is an exception to the norm. Managing the exceptions to planned responses is always critical in determining the minute-to-minute operations. [Turoff, 2002] To better manage these exceptions, it is important that the best possible up-to-date information is provided, and that this information instills confidence in decision making where lives and resources are at risk.

Several emergency response management information systems for healthcare initiatives are promoted at the national level. These include the Outbreak Management System (OMS), BioNET, Laboratory Response Network (LRN), Center for Disease Control and Prevention (CDC), Food Emergency Response Network (FERN), National Health Information Infrastructure (NHII), Health Alert Network (HAN) and National Electronic Disease Surveillance System (NEDSS). Table 1 lists the mentioned emergency response management information systems and their missions.

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[2] http://www.dhs.gov/dhspublic/theme_home6.jsp.

Table 1. Selected International and National Emergency Response Management Information Systems and Agencies

System	Mission
Outbreak Management System	OMS is a complete application that can be used to respond to a public health emergency. The software provides public health partners with a suite of tools for capturing standard data; configuring outbreak-specific vocabularies; performing analyses; and creating dynamic questionnaires, reports, and outbreak-specific packages. The application also manages case and contact investigations, records epidemiological data, allows for relationship management and captures follow-up activities for managing exposed contacts. http://www.cdc.gov/phin/software-solutions/oms/index.html
BioNET	BioNET is an international not-for-profit initiative dedicated to promoting taxonomy, especially in the biodiversity rich but economically poorer countries of the world. Working via local partnerships (LOOPs), BioNET's goal is to provide a forum for collaboration that is equally open to all taxonomists and to the other users of taxonomy. http://www.bionet-intl.org/opencms/opencms/whoWeAre
Laboratory Response Network (LRN)	LRN is charged with the task of maintaining an integrated network of state and local public health, federal, military, and international laboratories that can respond to bioterrorism, chemical terrorism, and other public health emergencies. The LRN is a unique asset in the nation's growing preparedness for biological and chemical terrorism. LRN is the first network to link state and local public health laboratories, veterinary, agriculture, military, and water- and food-testing laboratories. http://www.bt.cdc.gov/lrn/
Centers for Disease Control and Prevention (CDC)	CDC's mission is to promote health and quality of life by preventing and controlling disease, injury, and disability. Further, CDC seeks to accomplish its mission by working with partners throughout the nation and the world. Specifically, CDC, monitors health, detects and investigates health problems, conducts research to enhance prevention, develops and advocates sound public health policies, implements prevention strategies, promotes healthy behaviors, fosters safe and healthful environments, and provides leadership and training. http://www.cdc.gov/about/mission.htm
Food Emergency Response Network (FERN)	The mission of FERN is to integrate the nation's food-testing laboratories for the detection of threat agents in food at the local, state, and federal levels. This requires a comprehensive effort including chemical, biological, radiological disciplines involving full range of food commodities. Specific objectives are 1.) Prevention – federal/state surveillance sampling programs, 2.) Preparedness – strengthening lab capabilities/capacities, 3.) Response – surge capacity and 4.) Recovery – provide assurance to the consumer. http://www.fbi-isa.org/library/McCaskey_files/frame.htm#slide0027.htm

System	Mission
National Health Information Infrastructure (NHII)	The National Health Information Infrastructure (NHII) is an initiative set forth to improve the effectiveness, efficiency, and overall quality of health and health care in the United States. It includes a comprehensive knowledge-based network of interoperable systems of clinical, public health, and personal health information that would improve decision-making by making health information available when and where it is needed. It utilizes a set of technologies, standards, applications, systems, values, and laws that support all facets of individual health, health care, and public health. However, NHII is NOT a centralized database of medical records or a government regulation. NHII operates on a voluntary basis. http://aspe.hhs.gov/sp/nhii/FAQ.html
Health Alert Network (HAN)	HAN is a national program, providing vital health information and the infrastructure to support the dissemination of that information at the state and local levels. The HAN Messaging System directly and indirectly transmits Health Alerts, Advisories, and Updates to over one million recipients. The current system is being phased into the overall PHIN messaging component. http://www.phppo.cdc.gov/han/
National Electronic Disease Surveillance System (NEDSS)	NEDSS is an initiative that promotes the use of data and information system standards to advance the development of efficient, integrated, and interoperable surveillance systems at federal, state, and local levels. It is a major component of the Public Health Information Network (PHIN). NEDSS' wide-ranging initiatives are to detect outbreaks rapidly and to monitor the health of the nation, facilitate the electronic transfer of appropriate information from clinical information systems in the health care system to public health departments, reduce provider burden in the provision of information, and enhance both the timeliness and quality of information provided. The vision of NEDSS is to have integrated surveillance systems that can transfer appropriate public health, laboratory, and clinical data efficiently and securely over the Internet. NEDSS will revolutionize public health by gathering and analyzing information quickly and accurately. This will help to improve the nation's ability to identify and track emerging infectious diseases and potential bioterrorism attacks as well as to investigate outbreaks and monitor disease trends. http://www.cdc.gov/nedss/

All of these initiatives focus on the national level and are accessible in most states at various capacities. State public health laboratories are independent of each other and vary on their information technology abilities to transmit data to and from the national systems. There are gaps in the availability of emergency health response systems at local levels. This is a serious problem, especially in rural communities. Most states in the U.S. do not have the capability to share critical, real-time public health microbiology laboratory information among each other and within their state at the local levels, especially in rural communities where laboratorians serve as the front line of disease recognition. The need for rapid communication and exchange of data during an emergency is essential. Currently, there is no single comprehensive system that provides the solutions to all needs of a state in terms of response to and detection of a bioterrorism event or any other emergency.

"According to the National Committee on Vital and Health Statistics (NCVHS), the nation's primary external advisory group for health information policy, the national information infrastructure (NII) can be an essential tool for resource in promoting the nation's health. However, it is a largely untapped resource. The health sector has not applied information and

communication technologies as effectively as have other sectors; and, health is under-represented in the NII relative to the scale of the national health enterprise and its importance to the American public." [Kun and Bray, 2002]

Designing and developing dynamic distributed emergency response systems for health care is an emerging field and calls for further study. There are some notable studies: using telemedicine applications for disaster situations [Garshnek and Burkle, 1999]; an overview of informatics response to disaster, terrorism, and war [Teich et al., 2002]; and recommendations on using tele-health to improve disaster response [Myers, 1997]. However, there is limited research on how to design systems to meet the unique and challenging requirements of Emergency Response Systems. Several questions need further exploration and study:

- What are the challenging design requirements for an ERS?
- How can these design requirements be operationalized?
- What are effective ways to ensure that the design accomplishes the system requirements?

In this study, a Midwestern SPHL serving rural communities responded to a need to design and develop a networked state-wide computerized public health ERS. The ERS needed to provide electronic laboratory diagnostics consultation capable of quickly, efficiently, and electronically sharing critical microbiology and pathological health information in emergency situations. The health information consisted of photographic and microscopic images of specimens and descriptive text. In addition, the ERS required a systematic method of alert notification and escalation, a repository of the data, and microbiology protocols and treatment regimens.

The contribution of the study is as follows. First, understanding critical system requirements can help future developers better project the effort required to design and develop new emergency response systems. Second, a fundamental decision confronting all societies concerns the security and privacy of consumer health information, and this study can serve as input for designing systems that support HIPAA guidelines. Third, researchers have often studied the assessment of system requirements, but their findings may have been over-generalized. This research demonstrates new ways to assess software, hardware, and technical requirements for a public health emergency response system. Lastly, this study presents several system design strategies that have proven to be effective in this case.

III. METHOD

For this study, a qualitative approach was considered to be most appropriate because qualitative research methods allow researchers to gain a rich understanding of people and the context in which they live and work [Myers, 1997]. Myers identifies four approaches to qualitative inquiry: action research, case study, ethnography, and grounded theory.

Action research has the dual intention of improving the practice and contributing to theory and knowledge [Argyris et al., 1982], [Checkland, 1981]. I followed the model proposed by Zuber-Skerritt [1991] which states that an action research study may consist of four activities that can be carried out over several iterations. 'Plan' concerns exploration of the research site and the preparation of the intervention. 'Act' refers to the actual intervention made by the researcher. 'Observe' concerns the collection of data during and after the actual intervention to enable evaluation. Finally, the 'Reflect' activity analyses the collected data and infers conclusions that may feed into the 'Plan' activity of a new iteration.

Action research was selected as my research approach for several reasons. First, action research is especially appropriate to address 'how to' research questions. My research aimed to explore and identify what are the critical requirements with respect to software and hardware for the development of an ERS and how to design and evaluate these requirements.

Second, action research was selected because of the relevance of this research to the real world. Baskerville et al. [1998] argue that action research is the most scientifically legitimate approach available where specific new information system development methodology or an improvement to a methodology is being studied. Third, action research is very well suited for continuous learning. It allows researchers to continuously evaluate and improve their problem solving techniques or theories during a series of interventions.

DATA SOURCES AND ANALYSIS

I collected data from both quantitative and qualitative sources. Table 2 displays how each of these data sources mapped to the four activities of action research.

Table 2**.** Data Sources for Action Research Activities

Data Sources	Methods	Action Research Activities
Direct Observation	The researcher's notes of incidents, participants' remarks, and events that conveyed critical information.	Observe/Reflect
User Feedback	The researcher held weekly status meetings with the project team that provided an open forum to discuss what was going well on the project and where adjustments were needed.	Plan/Reflect
Usability Evaluation	After the release of three key prototypes at different points in time, full-system usability evaluation was done.	Act
System Documentation	Test plans and release notes were stored electronically for each prototype. User scenarios, release notes, prototype requirements, meeting minutes were kept in an online blackboard for all team members to share. All team members, developers and users, contributed to the online blackboard.	Reflect
GSS Workshops	Workshops using GSS systems were conducted to brainstorm, synthesize and prioritize system requirements. Data from these workshops were captured electronically for further analysis.	Plan
System Monitoring Reports	Data on the system network availability, system performance, and usage were gathered.	Reflect

The variety of data sources gave a rich representation, enabling comparison and contrast of the collected data. Given the exploratory nature of the study, I analyzed the requirements as the system development process progressed, researched design solutions, and identified appropriate evaluation methods. I monitored the feedback from the users, and reviewed the test plans and outcomes in which I identified areas of improvement and refinement. In particular, I investigated user satisfaction through usability testing, and project team satisfaction through informal one-on-one meetings with the project manager.

ROLE OF THE RESEARCHER

The role of the researcher was one of observer and participant at the same time, as the researcher also served as the project manager. This included assigning development tasks, coordinating meetings, budget oversight, as well as technical guidance. Additional experts assisted the researcher in facilitating strategic planning sessions and system assessment.   The

strategic planning sessions were led by a professional collaboration facilitator.   Information assurance experts assessed the security of the system.   Additionally, a public health graduate student, who is a veterinarian working in a microbiology laboratory, did an independent survey on user satisfaction.

IV. STATPACK SYSTEM

The Secure Telecommunications Application Terminal Package, STATPack™ project is an effort to address critical health communication and biosecurity needs in Nebraska [Fruhling and Sambol, 2003]. To date, 20 STATPack systems have been placed in key laboratory locations throughout greater Nebraska, including the Nebraska Department of Agriculture (NDA) food testing laboratory, the NHHSS water and environmental testing laboratory, and the University of Nebraska-Lincoln (UNL) Veterinary Science diagnostic testing laboratories.   Another 20 STATPack™ systems are planned to be deployed in two additional Midwestern states.

The preliminary STATPack meeting to discuss the requirements was September, 2002. During the next nine months STATPack prototypes were designed and developed by computer science and management information system students with the guidance of Information System faculty and microbiology laboratorians. In June, 2003, the first STATPack prototype was deployed for field evaluation.

The over-arching goal of this pubic health ERS was to establish an electronic infrastructure, largely using web technology to allow secure communication among smaller Nebraska Laboratory Network (NLN), "Level-A" hospital laboratories, larger NLN "Level-B" hospital laboratories, and electronically make available services provided by the NPHL located at the University of Nebraska Medical Center (UNMC). The project focused on linking UNMC's state-of-the-art technology approaches to identifying emerging infectious diseases, tracking sources of antibiotic resistance, and detecting bioterrorism agents to the rural public health infrastructure throughout greater Nebraska.

The project began with the investigation of enabling technologies through research and development to design a low cost "medical information appliance" intended for use in clinical hospital laboratories that would facilitate laboratory data collection and two-way communication between local regional medical centers and the NPHL. The appliance device requirements were based on open standards and open source software with the intent that support would be independent of vendor reliability and technological obsolescence.

Both the hardware and software were engineered for this project. The STATPack™ system consists of a computer terminal which includes a flat screen monitor, a small, virtually indestructible keyboard that can be sanitized, speakers, a high-resolution digital camera that can capture images of culture plates housed in a biosafe container, and a hardware interface to a microscope as depicted in Figure 1.

The system architecture uses client/server technology, and operates in a distributed environment connecting regional and rural health laboratories.   This connectivity allows for immediate communication and data transfer of urgent health information by transmitting images and text. For example, when a rural laboratory is processing a "suspicious" organism growing from a culture, the STATPack™ serves as a means for providing immediate diagnostic consultation with the NPHL (Figure 2). Should a serious situation need to be communicated to the laboratories, the STATPack™ system enables NPHL to send notices to each lab including an audible computer alarm.

Figure 1. STATPack Hardware

Figure 2. STATPack Capturing Image

V. REQUIREMENTS, DESIGN STRATEGIES, AND EVALUATION METHODS

The STATPack project had many challenging critical requirements that demanded innovative design solutions. The following sections present the critical software, hardware and technical requirements, the design strategies, and the evaluation processes used to assess if the requirement was met. A summary table concludes each section.

SOFTWARE

An important consideration of the development of the STATPack was that it could potentially save lives. Therefore, the system must be available 24 hours a day, seven days a week, and be extremely accurate. The user interface was designed to limit the possibility of data entry errors. It must be easy to learn and use since the laboratorians may use the system only sporadically. The interface was designed to provide real-time interactive information to the user in a format that would not be overwhelming, especially in an emergency situation. The organization of the interface was compartmentalized so that the system could be used by a variety of first responder public health agencies (i.e. NPHL, NFA, NHHSS Water, UNL Vet). It also was designed to be scalable and to allow new clients to be added with minimal programming effort.

The delivery methods of the alert notifications were designed to accommodate various users' needs. Alert messages at the hospital laboratories are signaled to the technicians, both visually and audibly. Therefore, they can continue their day-to-day work and still be notified when

needed. The NPHL SMEs have responsibilities that require them to travel. Consequently, they often needed to be notified using additional telecommunication delivery modes such as pagers and e-mail.

Another highly sought function was the ability to have real-time electronic consultation where the hospital laboratory technician could interact using a text messaging system with NPHL experts. The cost-effective solution to implement this function was using open source instant messenger software.

For security reasons the system was designed to go into screen saver mode after five minutes of inactivity. The screen saver also was designed to visually notify the hospital laboratorians if a new alert notification was sent.

Another complex requirement was the image repository. This feature provided a library of stored images that could be accessed and searched by the NPHL for future reference. The images were categorized by location and could be attached to new alert notifications as needed. Open source software was selected to accomplish this requirement.

The requirements and design decisions were evaluated using a host of methods (see Table 3). Some of the methods are common in systems develop projects; such as, system walkthroughs, system testing, user acceptance testing, and so forth. Additional specialized evaluation methods included Group Support Systems usability (GSS) evaluation using collaboration engineering [de Vreede et al., 2005; Fruhling and de Vreede, 2006a], key stakeholder feedback from rapid prototyping, full project team strategic planning sessions, and face-to-face feedback from laboratorians in the field.

Table 3. Software Requirements, Design and Evaluation Methods

Critical Software Application Requirements	Design Strategies	Evaluation Methods
Serve Several Venues – Microbiology in: Private Hospital, Food, Water, Veterinary Laboratories	Client Categorization Interface Design	Usability Evaluation GSS Workshops
Scalability	Interface Design and System Architecture	Amount of Effort for Developers to Add New Clients
High Usability of Interface Design	Multiple Usability Evaluations by Different Key Stakeholders	GSS Workshops
Three-tier Alert Prioritization: Routine, Urgent, Emergency	Routine Urgent Emergency	User Feedback Rapid Prototyping
Three Notification Venues STATPack, E-mail, Pager	Client – Messages, Audio, Visual Server – Messages, Pager, e-mail	User Feedback Rapid Prototyping
Real Time Electronic Consultation	Instant Messenger Open Source	GSS Workshops Rapid Prototyping System Testing
Screen Saver Security	Programmed by Project Developers	User Feedback
Image Repository	Open Source	User Feedback

HARDWARE

Another important function of the system was the ability for the laboratorians to capture macroscopic and/or microscopic images and then request diagnostic consultation services from NPHL laboratorians. The quality, clarity, and color of the image were carefully evaluated by the NPHL laboratorians to determine if the representation was acceptable to make a diagnosis. Camera selection was done with care, balancing cost, and image quality. The system was designed to easily interface with off-the-shelf cameras, and to allow NPHL laboratorians to access and control remote cameras at each of the regional laboratories. The system also connects to a hardware interface that pulls images from a microscope and populates the image into an alert notification to be shared among all laboratories in the network.

Minimizing the cost of the system hardware was important. System analysts researched the latest technology and found the most reliable and stable "micro" size components to build the STATPack appliance. The goal was to build a robust client with the minimal amount of hardware specifications, and to design the system so that the client was very thin. The unit cost was determined to be sufficiently affordable so that it would be possible to place as many systems in hospital laboratories as needed.

The "footprint" of the STATPack needed to be minimal, as most hospital laboratories are limited in space. Through diligence and persistence all the components of the system were configured in a footprint size of 12" x 14" x 10".

One other notable requirement was the need to design an airtight biosafe container that could house potentially bioharzardous specimens and the digital camera. The system analysts worked with local plastic specialists to design a small biosafe container, as shown in Figure 3.

Figure 3. STATPack Biosafe Specimen Container

Hardware requirements were evaluated several ways. First, field tests of the camera and the bio-safe containers were completed by laboratorians. Second, the cost of the hardware was critiqued. Third, the dimensions of the system were assessed by the laboratorians. Table 4 summarizes the critical hardware requirements, design strategies and evaluation methods.

Table 4. Hardware Requirements, Design and Evaluation Methods

Critical Hardware Requirements	Design Strategies	Evaluation Methods
Camera Feature - Quality, Clarity, Color - Panning, Zooming Functions	Research Best Off-the-shelf Product that Met Standards	User Feedback in Field Tests
Low Cost	Build System Hardware Internally Thin Client	Cost of Hardware
Minimal Physical Size	Micro-hardware	Dimensions of the System Space Available in Laboratories.
Biohazardous Airtight Plastic Container for Specimens and Camera	Small Footprint, Plexiglass, Airtight	User Feedback in Field Tests

TECHNICAL

The STATPack project also had the complex challenge that the technical requirements of the system were as important, if not more important, than the functional requirements. The project team communicated with the Medical Center HIPAA compliancy officer several times. Health care applications need to be extremely secure and must follow HIPAA guidelines. The STATPack project followed UNMC's HIPAA policy statements. Several provisions were put into place to ensure the system was HIPAA-compliant, such as data encryption, login authentication, and deidentification of patient demographics; as well as not storing patient identification information in the system. Using Secure Shell (SSH) and Secure Socket Layer (SSL) technology further secured the system. The screen saver function of the system also had built-in security features, such as requiring the user to re-login when the system was in screen saver mode.

The design decision to use Linux as the operating system and to utilize as much open source code as possible was driven by system requirements relating to performance, remote maintenance in a distributed environment, security and cost. Linux outperforms other operating system environments when there is limited need for graphical user interfaces on the server and when the system can use clients that have slower processors and less memory. In the case of this system, it, used mini-processors and minimized the memory (RAM) and hard drive size. The goal was to have a small, compact unit, and to reduce the hardware cost as much as possible yet have the necessary performance.

Because the STATPack has the potential of being placed in 85 hospital laboratories across the State, some in very remote locations, it was decided the STATPack system would be designed for a distributed environment using client-server architecture.   The telecommunications infrastructure and information technology experts in most rural communities are minimal, so the requirements of the telecommunications infrastructure were unclear and sometimes unknown.

A key technical requirement was to be able to efficiently and effectively support the maintenance of the system with a limited IT staff. Several of the STATPack systems are physically located hundreds of miles from the IT staff. So, updates to the system must be able to be distributed remotely. Linux provides an efficient means to upgrade the system in a distributed client/server environment where updates to the system require remote administration abilities.

Also, this design decision leveraged the built-in security of the Linux OS, as well as the selected open source packages. Lastly, as is the case in most health care organizations, resources are scarce to purchase hardware and software. Therefore, the low costs of Linux and open source were attractive.

Peak performance and fast response time of the system are vital in an emergency situation where information needs to be shared in a matter of minutes. The STATPack system does depend on the speed of data being sent across the Internet; however, the processing speed of the hospital laboratory client, as well as the processing speed of the server, is also significant. For this reason, the design focused on a very thin client and a fat server.

Performance of the time it takes to capture an image was also taken into consideration, and the programming algorithms to store and send alert notices were carefully designed and tested. The quality of the image that was captured by the camera needed to be at high resolution and have accurate color representation so that NPHL laboratorian experts could confidently provide diagnostic consultation. In addition, the system provided image magnification capabilities that were coded by the developers.

The project manager employed several methods to ensure that the critical requirements were adequately developed. Such methods included rapid prototyping, user scenario validation, internal and field testing, GSS-support usability evaluation [Fruhling et al., 2006a, deVreede et al. 2005], key stakeholder system evaluation, strategic planning sessions, face-to-face feedback from users in the field, meetings with the Medical Center HIPAA officer, and a system security audit.

The eXtreme Programming (XP) methodology which emphasizes rapid prototyping was employed. Since this was a new application, and because of the nature of open source, the developers were truly working in a R&D environment, i.e. researching and evaluating various open source and hardware technologies. This created a dynamic development environment. Having system prototypes available for user inspection of new requirements ensured that the development effort was on track and accurate [Fruhling and deVreede, 2006b].

One other critical decision was to have independent information assurance experts conduct a security audit. The security audit consisted of an independent analysis of the code and system design and several sessions where various security evaluation tools were run against the test and production systems. Table 5 summarizes the technical requirements, design strategies and evaluation methods.

Table 5. Technical Requirements, Design and Evaluation Methods

Critical Technical System requirements	Design Strategies	Evaluation Methods
Security	SSH, SSL Encryption One Port Access Screen Saver	Security Audit
HIPAA Compliance	Encryption Login Authentication Screensaver Lock Out HIPAA Statement Reminder on Data Entry Screen De-identification of Patient ID SSH Technology SSL Technology	UNMC HIPAA Policies Meetings with HIPAA Compliancy Officer
Distributed	Client-Server Platform	Multi-clients Installed
Open Source	Jabber	Open Source Research

Critical Technical System requirements	Design Strategies	Evaluation Methods
	Yappa Linux Whitebox	
Performance	Thin Client Linux OS State-of-the-art Micro Processor on Client	User Inspection of Prototype Unit, System, Field Testing User Feedback
Maintainable in a Distributed Environment	Open Source Distributed Technology for Remote Updates	Number of Analysts Required to Support the System Timeline to Update System
Image Quality at a Level the Diagnostic Consultation Could Occur	AXIS Camera, Panasonic Camera	Early Prototype
Color Correct on Images	Camera Selection	User Feedback Early Prototype
Image Magnification	Digital Magnification	User Feedback Early Prototype

VI. DISCUSSION

One of the most intriguing challenges of the STATPack project was for the team to define the requirements and design the system solely based on a conceptual idea of one of the senior users. There was no existing hospital microbiology laboratory system to evaluate or re-engineer. However, the senior user was aware of national systems that were similar and had a vision as to how these might be adapted to the public health microbiology laboratory environment. Clear and accurate communication between the developers and users was essential in determining what system functions were envisioned and how they might work. Rapid prototyping helped clarify both of these issues.

The system was developed to provide adaptiveness, flexibility, and the ability to electronically respond to situations that were currently being handled without a dedicated computerized system to support them. In the course of this process, a number of critical design decisions were made. Below I discuss how these decisions align with a number of key ERS design principles, and the lessons learned from my experiences.

DESIGN PRINCIPLES

Turoff et al. [2004] proposed a set of general and supporting design principles for designing flexible, robust, and dynamic emergency and crisis response systems. The design decisions for the STATPack system are compared with Turoff et al.'s proposed principles. However, the initiation of this research occurred before Turoff et al.'s article appeared.

Design Principle 1: System Directory

The system will provide a hierarchical structure for all the data and information in the system as well provide a complete text search. The STATPack application is menu driven and has hierarchical structure for each main function in the menu. In addition, alerts are categorized three ways: messages sent, messages received, and messages for local use only. Messages are color coded and have an envelope icon to visually allow the user to know whether the message (alert) is an emergency, urgent, or routine; as well as, whether it has been opened. Search capabilities

of the information stored on the system continue to be enhanced to provide more complex queries.

Design Principle 2:   Information Source and Timeliness

All data dealing with the emergency should be identified by its human or database source, time of occurrence, status, and location. The datapoints in the STATPack alert messages include similar attributes of this principle (e.g. location source, date and time stamp, specimen attributes, and alert notification level).   In addition, the STATPack system has a rich source of data by having image (visual) information included with detailed text information.

Design Principle 3:   Open Multi-Directional Communication

The system should have a non-hierarchical communication process. The STATPack system to date has a one-to-many communication process. In other words, NPHL can communicate with all the hospital laboratories, and NPHL determines who receives what information and if a state-wide alert should be sent. There have been some discussions regarding multi-directional communication allowing all hospital laboratories to interact via a community forum. However, NPHL states that issuing state-wide alerts needs to be carefully monitored and should this feature be implemented there would be a filter mechanism in place to prevent the spread of misinformation. Multi-directional communication is available via another application.

Design Principle 4:   Content as Address

The system will decide when the content of a piece of information is the determining factor as to where to send the information. This design principle did not apply. The system was designed to send all emergency alerts and messages from the clinical laboratories to the SPHL. The SPHL determined which clinical laboratories would receive messages and alerts.

Design Principle 5:   Up-to-date Information and Data

The system will have up-to-date data and information. This design principle is fully implemented in the STATPack system. The system constantly refreshes the information in the system. In fact, all alert notifications are visible within five seconds or less of the client receiving them, and the feeds from the camera and microscopes are also constantly refreshed.

Design Principle 6:   Link Relevant Information and Data

The system should be designed so that an item of data and its semantic links are linked to other data and treated as one unit of information that is simultaneously created or updated. This design principle has been implemented in a limited format. Alert notifications and their associate specimen images are linked and are also linked to a separate repository that can be searched.

Design Principle 7:   Authority, Responsibility, and Accountability

This principle reinforces the need for authority in an emergency, and that authority flows down to where the action is taking place. The state public health experts have the authority to send out system-wide alerts in the event of a national, state, or local event or emergency through the CDC's Health Alert Network (HAN). This HAN typically utilizes phone, fax, email, and page. The STATPack system can be used to further compliment these notifications by NPHL directly transmitting alerts to public health labs serving rural communities. Additionally, local hospital laboratories have the authority to send emergency alerts to the SPHL if they discover a biothreat agent in their locality.

Design Principle 8:   Psychological and Sociological Factors

The ERS will encourage and support the psychological and social needs of the crisis response team. The STATPack provides the platform for laboratorians to interact, work together as a team by sharing information, and support each others' analysis.   A director of a clinical hospital

laboratory in a rural community made the following comment "I feel more secure having the technology. If something were to occur, communication with the NPHL would be immediate." [Omaha World Herald, 2006]

Overall, the design principles introduced by Turoff et al. are applicable. The Psychological and Sociological Factors and the Authority, Responsibility, and Accountability principles are the more abstract principles. It was less clear how they might be operationalized.

LESSONS LEARNED

Several lessons were learned from this research, each representing an interesting avenue for future research. The design of an ERS that is intended for specialized applications, such as telemedicine, pubic health, etc., requires that the system analysts and developers work closely with the end users and subject matter experts in defining the requirements and evaluating the design. In this study I found that the analysts and developers involved did not have a good understanding of the barriers to information flow in public health laboratories and had even less knowledge of the medical terminology being used. In the case of this system, key feedback from the users evaluating the multiple prototypes was valuable. From each prototype iteration, I learned how to better meet the needs of the users. For example, initially the system only captured *macroscopic* images. Users expressed the importance of the additional functionality of capturing *microscopic* images, saying this was a mandatory function to make the system useful during an emergency.

Given the requirement for the system to be available 24 hours a day and 7 days a week, monitoring the system availability status became one of the more important non-functional requirements. I learned that the hospital internet access networks were not as reliable as business internet access networks and so I designed the system to closely monitor the network availability in 15 minute increments. Should the system be down longer than 15 minutes, the System Network Administrator immediately looked into the problem. In many cases, I found that the hospital organization has scheduled power outages, so to remedy this I installed UPS units for each location. This improved the stability of the system.

Three lessons learned extend Turoff et al.'s design principles. First, ERS systems should be designed so that there is redundancy of alert notifications. Initially, the system was designed with only one type of communication notification path. It soon became apparent that multiple formats of communication were needed. Redundancy of functionality is not something that most IT systems recommend as a high priority in requirements and design principles.

Second, it is best if the system is designed to be used for some routine activities as well as in emergency situations, so that it will be positioned to be better utilized during an emergency. This ensures first responders and SMEs will be familiar with the system and its capabilities. Also, it helps them use the system quickly and efficiently without having to remember how to use the system in-between emergencies. I found that the more the first responders used the system for routine matters, the more confident they were using the system during an emergency.

Third, I learned that it was important to prioritize the alert messages and put protocols in place for expected response times. Thus, I propose the following three additional principles.

Design Principle 9:   Provide Alert Notification Redundancy
An ERS should be designed so that there is redundant alert notification. This is especially important when using electronic notification. The STATPack system notifies the SMEs via the STATPack system (audible and visible), e-mail, pagers and text messages.

Design Principle 10:   Include Non-emergency Usefulness
The system should also be useful for non-emergencies. This principle goes back to the adage that a good ERS system is a system that is used. The STATPack provides communication and

information-sharing capabilities for non-emergency events. This is important so that users do use the system and therefore, are familiar with the system and can easily and quickly use the system during emergencies.

Design Principle 11:   Prioritize Alerts

The system should have a method that prioritizes the messages (alerts) it sends and receives. Even though the STATPack system was originally intended for emergency situations, it was found after further user feedback that the system would also be beneficial for teaching and consultation on routine day-to-day events. Therefore, the system design included a prioritization level of alert notifications. The three levels are routine, urgent, and emergency. System policies were put into place as to the expected response time to the alert notification. In an emergency situation, the laboratorian first responders can expect a response from the SPHL in 15 minutes or less.

VII. CONCLUSION

In this study, a Midwestern State Public Health Laboratory serving rural communities responded to a need for a state-wide networked computerized public health ERS for electronic laboratory diagnostics consultation that was capable of quickly, efficiently, and electronically sharing critical microbiology and pathological health information in emergency situations. The health information consisted of photographic and microscopic images of specimens and descriptive text. In addition, the application provided a systematic method of alert notification and escalation, a repository of the data, and microbiology protocols and treatment regimens.

The purpose of this research was to examine the critical requirements for an ERS that had multiple stakeholders with different priorities, to better understand the critical design considerations of the ERS, and to provide insightful suggestions on how to successfully evaluate an ERS for state public health laboratories.

A limitation of this research is that the ERS this study examined was specifically developed for electronic laboratory diagnostics consultation and responding to public health emergencies. Therefore, generalizing the research results is restricted.

There were several key findings. First, it was found that the technical requirements of an ERS system were the most demanding as well as critical to the system success. System developers and analysts maximized the capabilities of the client/server architecture using the Linux operating system and took advantage of several open source products. Second, analysis of design principles proposed by Turoff et al. [2004] correlated well with the design of the STATPack system. However, further evaluation of these principles needs to be done, and three new principles were proposed. Third, the results of this study also support that iterative prototypes were an efficient and effective way to discuss with users whether the system was meeting requirements. Lastly, the action research presented here is a valuable example of the intricate issues involved in the design of an ERS, especially given the new and emerging nature of the field of public health emergency response systems.

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Editor's Note: The following reference list contains hyperlinks to World Wide Web pages. Readers who have the ability to access the Web directly from their word processor or are reading the paper on the Web, can gain direct access to these linked references. Readers are warned, however, that

> 1. these links existed as of the date of publication but are not guaranteed to be working thereafter.
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