

BRIEF REPORT

A Real-time Tracking, Notification, and Web-based Enrollment System for Emergency Department Research

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Abstract

The authors describe the development of a real-time tracking, notification, and Web-based enrollment system designed specifically to facilitate emergency department research. The system was developed in a cooperative arrangement between an emergency medicine researcher and a medical information software company. The system design and utilization are

described as well as the security measures to ensure compliance with Health Insurance Portability and Accountability Act (HIPAA) regulations and database security. **Key words:** patient enrollment systems; research; emergency medicine; software; Web-based systems. *ACADEMIC EMERGENCY MEDICINE* 2004; 11:1245–1248.

The emergency department (ED) is a fertile place to do research. It is the primary entry point for most patients who enter the health care system and, in some institutions, the ED is responsible for up to 30% of admissions.¹ However, the ED is also a chaotic environment; patients present with a large number of complaints, care and therapy have constant time pressures and urgencies placed on them, and, for the majority of caregivers, performing clinical research is not their primary duty and motivation. This makes identification, recruitment, and enrollment of patients a challenging endeavor. To meet these challenges, we have developed a real-time research tracking, instantaneous notification, and Web-based enrollment system to develop an efficient method to deal with the barriers to clinical research in the ED.

THE SYSTEM

When patients register in the hospital, the hospital sends out a Health Level-7 (HL7)* message, which is a standardized broadcast of data used by most hospital information systems (HIS). The broadcast contains patient registration data that consist of patient demographics, insurance information, and visit information, including chief complaint. The system we developed is designed around and uses this information in real time. The hardware requirements of the

system include an entry-level server with a redundant array of backup drives (RAID) and nightly backup for data storage and redundancy that can also act as a Web and database server. In addition to the Microsoft Windows server software (Microsoft Corp., Redmond, WA), the system includes a receiver to receive HL7 broadcasts of patient registration data, a parser to put the data into a robust database such as a Microsoft Structured Query Language (SQL) server, thus building a data repository of real-time information on all patients who register in the ED, and Microsoft Access to house individual study databases. For research purposes, we have set up secure Web pages to receive the real-time patient data and to initiate transactions with the real-time data repository. The Web server is located on the hospital local-area network (LAN) that is hidden from the Internet by a firewall. The Web server cannot respond to any outside intruder. Users inside the LAN cannot access Web pages without prior authentication. After the authorized user logs on to the Web site via Microsoft Internet Explorer, a list of patients currently registered in the ED along with the time of registration, time waiting, and chief complaint is presented on a Web page. The Web page is updated every 30 seconds and can serve as a patient-tracking system for the entire ED, although we currently use it only for research purposes. From the list of patients, one can select a patient and launch a research Web page. From the research Web page, one can choose from a number of ongoing studies. Once the desired study is chosen for that patient, he or she is enrolled into that study and the

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James Quinn is an unpaid consultant for KDH Systems Inc. and receives product and support for his consulting efforts. Kris Durski is the founder and a major equity holder in KDH Systems.

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doi:10.1197/j.aem.2004.08.020

*Health Level Seven, Inc. is an American National Standards Institute (ANSI) Accredited Standards Developer (ASD) committed to developing and publishing a comprehensive framework and protocol specifications for health data interchange, integration, storage and retrieval among diverse data acquisition, processing, and handling systems. HL7 V.2.3.1 has been an approved ANSI standard since April 1999.

requested demographic, insurance, and visit data for that study are automatically sent to the research database for that study and the appropriate fields are populated. Simultaneously, a secure Web page is produced with customized and patient-specific information. This is a specific Web page for that study and serves as the study data form. The physician or study coordinator fills out the data form online and electronically submits the data to that study's specific research database, and by doing so further populates the fields of the research database for that study. The data that are sent online during the interactions are double-protected by first encrypting sensitive information and then using Secure Socket Layer (SSL) (https://) that further encrypts the entire message, which can then be sent to local and/or central databases for multicenter trials. The Web-based data forms can be simple or complex to allow one to print consent forms and discharge instructions, and even to randomize medications. They are user-friendly and can be completed all at once or in stages, allowing physicians to return to where they left off. The Web-based data forms can also provide prompts and queries to ensure that consent forms are completed before enrollment and to prompt audits of potentially erroneous data entry.

To further enhance compliance and enrollment into research studies, we developed a notification system that screens the chief complaint on the tracking system. The chief complaint is a free-text entry of the patient's complaint by the registration clerk. The system searches for key words or elements of key words and then simultaneously sends a real-time notification, through either a paging system or a short message service (SMS) message, to the investigator or study coordinator to inform him or her of potential study patients in the ED. A telephone call can usually ensure that physicians enroll the patient; alternatively, a study coordinator can come down and enroll the patient. A page is sent at individually defined intervals, e.g., every hour for a specified period of time or until a patient is enrolled, at which time the submission of data stops further pages. We have used the notification system not only for studies using our Web-based enrollment, but also to help our colleagues in other specialties with recruitment problems.

CURRENT STUDIES

We have had experience running several types of studies, with great success. A prospective observational study to develop a clinical decision rule to predict serious outcomes in patients who present with syncope has used the system to enroll more than 1,300 patients in the derivation and validation sets.² Using the notification system, investigators are paged instantaneously when the ED receives patients who have a presenting complaint of interest to the investigators and whom they wish to screen. They call in to discuss

the eligibility of the patient with the physician caring for the patient, and that physician logs in and enrolls the eligible patients online by completing a simple Web-based form. The notification system pages every hour until the patient is enrolled, at which time it is programmed to automatically stop when data are submitted.

We also run a multicenter prospective randomized dog bite study. With this study, the research coordinator or investigator is paged when a patient comes in with "dog" or "bite" in the complaint. The coordinator or investigator calls in to ensure it is a dog bite. The study involves patient consent, and the Web-based study or case report form is more complex. However, the system is easy enough that most physicians are willing to enroll patients into the study or at least willing to be shown how to do it. The form does not allow enrollment or randomization unless the consent form is printed and complete. The form also randomizes medications used with the study and prints customized study discharge instructions for the patients. If the physician is too busy or uncomfortable, the coordinator will enroll the patient himself or herself, although we have found that physicians are willing to complete the process themselves more than 80% of the time.

Overall, four other studies are supported by the system. The tracking, screening, and notification components ensure that all patients are considered and allow us to ensure the generalizability of all studies.

SYSTEM SECURITY

The real-time research database described above utilizes the KDH Electronic Data Collection and

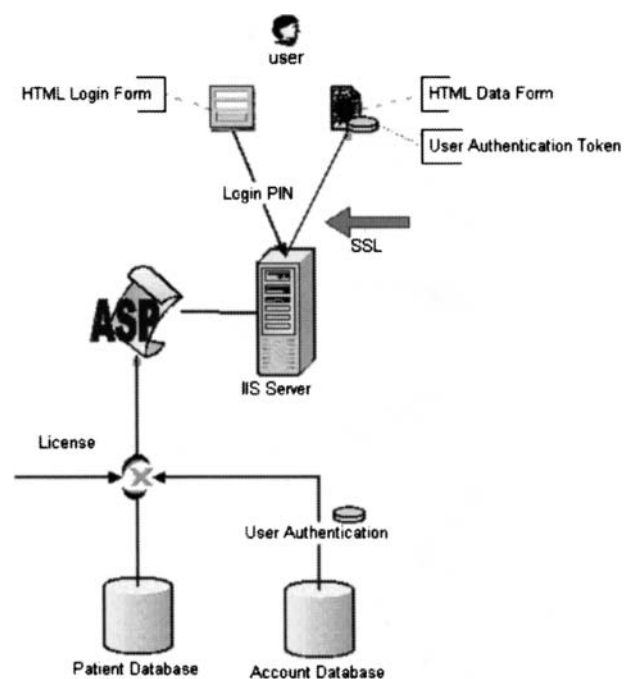


Figure 1. Security features.

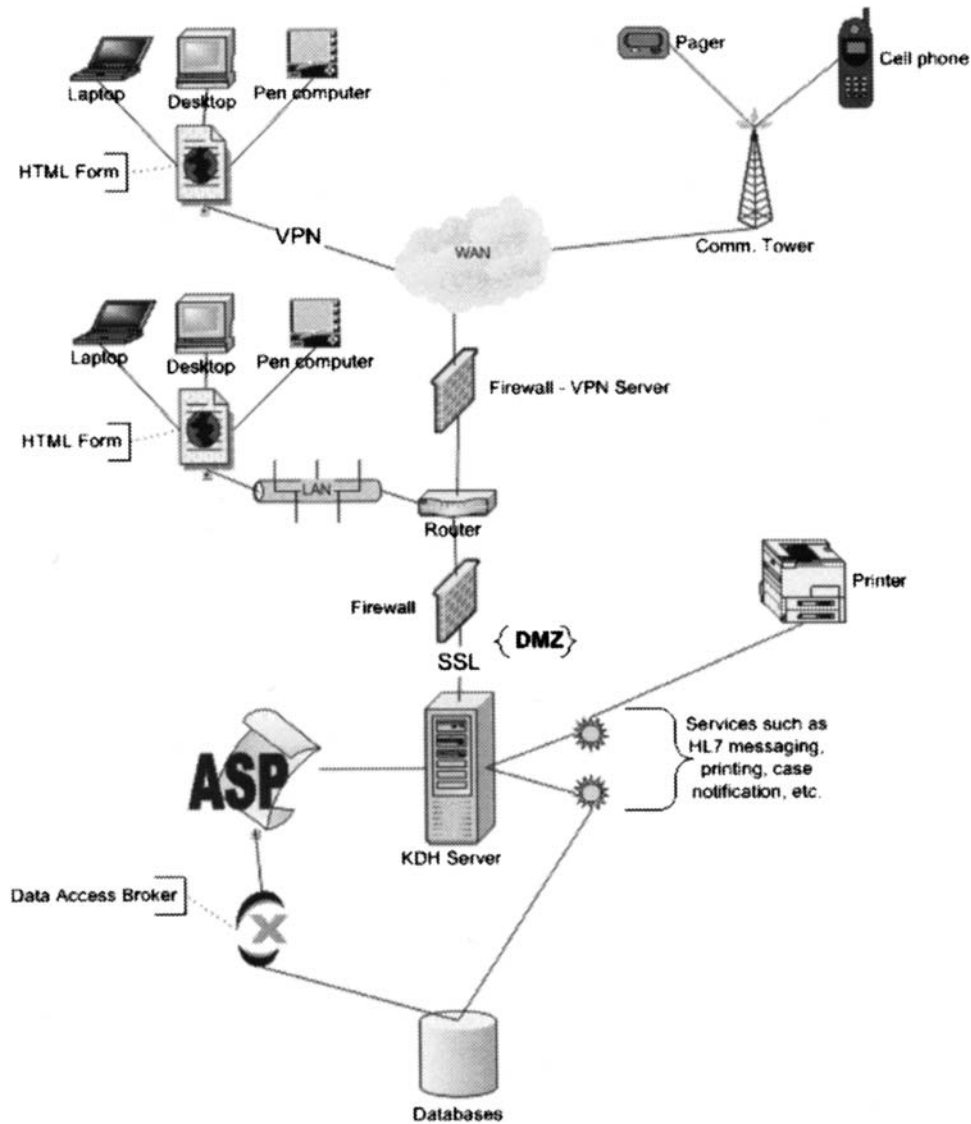


Figure 2. System architecture.

Distribution system (KDH Systems Inc., El Cerrito, CA) that was designed to satisfy or even exceed the requirements set by Health Insurance Portability and Accountability Act (HIPAA) regulations.² Communication with outside world (both intranet and Internet) is secured with 128-bit encryption or better, either with Secure Socket Layer (SSL) for active service pages (ASP) Web forms or with KDH Secure Channel for service-to-service component data exchange. Critical data are encrypted and stored on a database. Optionally, entire databases can also be encrypted for greater security, but at the cost of performance. The system does not use cookies for obvious reasons and terminates Web server sessions after each transaction for added protection. The Secure Channel passes encrypted token-containing information necessary for user identification and reauthentication with each Web form (Figure 1). A new token is generated for each transaction and its acceptance is limited by timeout (default is 10 minutes).

To gain access to a system for the first time or after timeout, users must authenticate themselves either with a personal identification number (PIN) or with a login name and password (Figure 1). Subsequent transactions are authenticated automatically with a token. In addition to login timeout, each submission of a form is also controlled by a separate submission timeout (default is 30 seconds). Besides authentication, users can access only functionality or data that are relevant to their roles. Roles are controlled during each login whether directly via PIN or indirectly via token. ASP pages are configured dynamically according to user roles.

For better protection against intruders, the system uses KDH Node Locked Component Licensing model and KDH Node Locked Registry Settings for critical data. Registry settings cannot be copied from one computer to another without being invalidated. Optionally, the system provides full audit trail and logging

of system activity, such as transactions, accessed data, and modifications to the data. The operating system provides basic Windows security, which is used to protect the filing system as well as to control direct access to a machine with local or remote logins that include Web server permissions. User logins to all Web pages is controlled by the KDH authentication system that enables or disables specific functionality of a current Web server thread based on authenticity of login data, including tokens and user roles.

To avoid dependency on network outages, the system relies on its own resources located on the same computer or servers connected to a dedicated subnet except for collaboration with other vendors' systems. All KDH components performing services have built-in proactivity and recovery intelligence that allow them to respond to network outages by automatically resuming operation after network restoration, repeating actions on errors, rebooting, etc.

CHALLENGES

Our biggest challenges to date have been to get hospitals to allow us to install a server on their network and use software with which they are not familiar. Hospitals are concerned about information technology (IT) resources, HIPAA, and security issues. The security of the system far exceeds HIPAA requirements and can satisfy large institutions. While institutional approval has taken time, we have been able to convince two large institutions to allow us to install our server and software on their networks. Installation takes less than half a day and require minimal hospital resources. Institutional review board (IRB) and HIPAA issues have been presented to their institutional review boards. The data used for screening purposes are being collected for purposes other than research (HL7 data), and no hypothesis or research questions are being generated on this tracking data set, which is being used only to identify potential patients. Given the security of the system, the minimal risk involved to patients, and the fact that researchers require some mechanism to identify potentially patients eligible for research, the

tracking data set and screening process has been granted a waiver of consent and individual authorization. However, each study making use of the tracking data set requires its own individual IRB approval specific to that study before any data can be used. As part of their approval, individual studies need a limited waiver of individual authorization for the use of the tracking data set for recruitment in addition to addressing the consent and HIPAA issues specific to that individual study. The uniqueness of the system with the advent of new HIPAA and IRB regulations has presented challenges that have been addressed. It is hoped that this will improve the efficiency with which similar systems can be implemented in the future.

CONCLUSIONS AND FUTURE DIRECTIONS

The research system described has been implemented as an integral part of research at our institution. The system architecture can support operations for more than just clinical research (Figure 2). The future will see the research product expand and be integrated with clinical documentation to avoid "double documentation." This would be an electronic medical record (EMR) that would be designed to populate research databases and utilize multiple sources of data entry to make physician charting and research data entry seamless. A totally electronic research record including an electronic patient signature and allowing easier storage and retrieval will be more secure than paper and improve the efficiency of clinical research. As more institutions move toward the EMR, a research electronic record will be easier to implement and integrate.

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