Developing and Integrating an Adverse Drug Reaction Reporting System with the Hospital Information System

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We have developed an adverse drug reaction (ADR) reporting system integrating it with Hospital Information System (HIS) of the University of Tokyo Hospital. Since this system is designed with JAVA, it is portable without re-compiling to any operating systems on which JAVA virtual machines work. In this system, we implemented an automatic data filling function using XML-based (extended Markup Language) files generated by HIS. This new specification would decrease the time needed for physicians and pharmacists to fill the spontaneous ADR reports. By clicking a button, the report is sent to the text database through Simple Mail Transfer Protocol (SMTP) electronic mails. The destination of the report mail can be changed arbitrarily by administrators, which adds this system more flexibility for practical operation. Although we tried our best to use the SGML-based (Standard Generalized Markup Language) ICH M2 guideline to follow the global standard of the case report, we eventually adopted XML as the output report format. This is because we found some problems in handling two bytes characters with ICH guideline and XML has a lot of useful features. According to our pilot survey conducted at the University of Tokyo Hospital, many physicians answered that our idea, integrating ADR reporting system to HIS, would increase the ADR reporting numbers.

Key words—adverse drug reaction; HIS; ICH; electronic reporting system

INTRODUCTION

The World Health Organization (WHO), in 1968, created the International Drug Monitoring Program for the purpose of collecting information about Adverse Drug Reactions (ADR) that were not observed during clinical drug trials. This program has been exceptional in identifying the early signs of ADRs. In Japan, the International Drug Monitoring Program is represented by the Ministry of Health and Welfare (MHW).

Approximately 150,000 ADR cases are reported to the WHO Drug Monitoring Center yearly. Historically, the number of ADR reports from Japanese medical professionals has been considerably lower than reports from the United States and from developed European countries. For instance, in 1995, more than 10,000 ADR cases were reported from the United States, the United Kingdom, and France, but only 2000 cases were reported from Japan.

Previous study found that reports about ADR from medical professionals was one of the most valuable sources of information, and in countries where a large number of ADR case reports had been submitted, comprehensive and innovative measures had been implemented. Such measures include the intervention by regional centers, and by nurses being allowed to report ADRs.

In 1997, the MHW in Japan launched the revised ADR collecting program: “Reporting System of Safety Information on Drugs etc.” The program simplified the standard ADR report form, and extended the list of professionals who could report ADRs to include hospital and community pharmacists. Also, the concept of the ADR report was defined as “event monitoring” so that ADR cases could be reported without having to identify any cause between drug administration and symptoms.

In October 1997, we conducted a pilot survey at the University of Tokyo Hospital to study the awareness of doctors regarding ADR reports and decided to develop an electronic ADR reporting system.

METHOD AND RESULTS

1. Pilot Survey

We sent a questionnaire to ninety-two associate
professors and chief doctors at the clinical section of the University of Tokyo Hospital. Sixty doctors, or sixty-five percent, responded. The survey indicated that ninety percent of the respondents didn’t know how to obtain a report form for the Pharmaceuticals and Medical Device Safety Information program, and seventy percent had never seen the form. This confirmed our suspicions that Japan had been ineffective in reporting ADRs. Eighty-seven percent agreed that if the ADR reporting system was electronically integrated with the HIS, the reporting process would be easier.

Our challenge was to find an innovative and easy way to increase the number of ADR case reports in Japan. According to a survey conducted by the Hospital Computer Center of the University of Tokyo Hospital, all of the forty-two National University hospitals had the Hospital Information System (HIS) installed. Since many of the other hospitals in Japan used the system, we decided to develop an online ADR reporting system that could be integrated with the HIS system.

2. Development of the Electronic ADR Reporting System

2-1. Development Environment We used a 300 MHz AT-compatible computer with 128 MB of memory running Windows NT version 4.0.

2-2. Programming Language We chose JAVA (JDK1.1.6, JDK stands for Java Developmental Kit) because we wanted to create an application executable that could run on a variety of operating systems without having to recompile for each platform.

2-3. Basic System Specifications Our system was designed to meet the requirements of the Pharmaceutical and Medical Device Safety Information program. The Electronic ADR reporting system features the following: (Fig. 1)

1) The ability to launch the ADR system at any time from HIS. For example, when a doctor orders a prescription, the ADR reporting form is displayed at the click of a button. (Fig. 2, Fig. 3)

2) The information contained in the HIS database, such as a patient’s medical history and previous prescriptions, is automatically transferred to the ADR system.

3) The HIS information is displayed in the relevant fields, which include the drug names or the dose and usage of it, on the ADR form.

4) A user can enter, update, or modify all fields displayed on the ADR form.

5) The user information is converted to an XML-based text file. The text file format conforms very closely to the ICH guideline.

6) The ADR report is sent to the text database at the University of Tokyo Hospital using Simple Mail Transfer Protocol (SMTP). If required, the administrator can specify a different destination for the report.

2-4. Test Operations The reporting system has been functioning smoothly on Windows NT4.0 and Solaris 2.6 systems.

DISCUSSION

Our pilot survey indicated that Japanese doctors
were unaware of the World Health Organization’s International Drug Monitoring Program. To increase awareness of the program, and subsequently the number of reports, we designed and integrated an Adverse Drug Reaction (ADR) reporting system with the existing Hospital Information System (HIS) system that was already in use at many hospitals.

We tried to implement the SGML-based ICH M2 Expert Working Group (EWG) case report format, but since the recommended 1998 format had problems processing Japanese characters, we adopted the XML-format. As well, XML had some useful features that SGML didn’t offer.

JDK 1.1.6 was premature in some features, which made our developing process difficult. The current JAVA2 version is supposed to be more stable, and it’s likely that many difficulties we experienced will be resolved soon.

In the future, we’ll add encryption technologies to our system and conduct a wide-range pilot operation. We’ll also conduct a study to compare the workload of reporting between a paper-based system and our electronic system.

Conclusion

The WHO Drug Monitoring Program proved that ADR reporting is an effective way of collecting information about adverse drug reactions. However, since many adverse reactions have gone unreported in Japan, it was essential that medical professionals get easy access to a reporting system. Our research indicated that an interactive and comprehensive information system that’s shared between the regulatory body (MHW) and the medical institutions would offer the
best possible solution. Consequently, we designed an online Electronic ADR reporting system that was integrated with the existing HIS system that’s prevalent in many hospitals in Japan today.

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References