MEDINFO 2007
HISA Ltd Australia
© 2007 The authors. All rights reserved.

Pharmaceutical Safety Reporting System on UMIN

Daisuke Koide[a], Hisako Matsuba[b], Hiroyuki Furukawa[c], Kiyoshi Kubota[a], Takahiro Kiuchi[d]

[a] *Graduate School of Medicine, the University of Tokyo, Japan*
[b] *Translational Research Center, Kyoto University Hospital, Japan*
[c] *Clinical Trial Management Center, Kanazawa University Hospital, Japan*
[d] *University hospital Medical Information Network (UMIN) Center, the University of Tokyo Hospital, Japan*

Abstract and objective

The number of pharmaceutical safety reports from medical institutions to the government is about 5,000 annually and only one fifth comparing to industry in Japan. In order to facilitate such reporting, and enhance early detection or prevention of adverse drug reactions (ADRs), we have developed a pharmaceutical safety reporting system on University hospital Medical Information Network (UMIN). UMIN is the largest and most versatile academic network information center for biomedical sciences in the world, and considered as indispensable information infrastructure for the Japanese medical community.

The major benefits of this system are as follows; user-friendly interface to make reports, easy management of reports, and immediate sharing information on suspect ADRs among medical institutions. In the future, it will be more beneficial for reporters if the government accepts pharmaceutical safety reports directly through UMIN.

Keywords:

adverse drug reaction reporting systems, internet, safety management

Introduction

Based upon national or international agreements, rules, and regulations, individual case safety reports (ICSR) of ADRs need to be transmitted. The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) is a project that brings together the regulatory authorities of Europe, Japan and the United States and experts from the pharmaceutical industry in the three regions to discuss scientific and technical aspects of medicinal products. E2b is one of the expert working groups (EWG) in ICH for harmonization of Data Elements for Transmission of ICSRs. This group published E2b guideline in 1997. Due to the advantage of information technology, the Specification for the electronic message of ICSR was released in 2001 by ICH M2. M2 is a Multi-disciplinary Group 2 EWG in ICH and discusses Electronic Standards for the Transfer of Regulatory Information (ESTRI) that will meet the requirements of the pharmaceutical companies and regulatory authorities. After this development of specification, each region implemented electronic ICSR system. Since October 2003, electronic ICSRs have been accepted for industry by the Ministry of Health, Labor and Welfare (MHLW). However, most medical institutions need to report ICSRs to the government as paper form. The number of ICSRs from medical institutions to the government is currently about 5,000 annually and only one fifth comparing to industry in Japan.

In order to facilitate such reporting from medical institutions to the government, and enhance early detection or prevention of ADRs, we have developed a pharmaceutical safety reporting system on University hospital Medical Information Network (UMIN). UMIN is the largest and most versatile academic network information center for biomedical sciences in the world, and considered as indispensable information infrastructure for the Japanese medical community.

Methods

The system was designed as web-based in Japanese. Although the form is based upon paper which is currently used for safety reporting from medical institutions to the government, each element reflects the global standard which ICH E2b/M2 produced. There are two steps to create a report. The form 1 is designed as the first step for capturing minimum data which should include at least one identifiable patient, one identifiable reporter, one reaction/event, and one suspect drug. If any of such data is missing or wrong, a reporter can't register it. The form 2 is the second step appearing as the next page to the form 1 and designed for entering other detailed information as optional. These optional data are for example, relevant medical history and concurrent conditions, and results of laboratory tests, etc. Our system also provides the function to search a drug by product name or substance name.

There are three classes for users; administrator, responsible user, and reporter. An administrator is usually a representative of a medical institution. This administrator assigns a responsible user in the same institution who has right to approve reports to be open to outside or not. A reporter is a person creating a report and usually a health professional.

There are three repository statuses of reporting, "temporary saving", "waiting for approval", and "approved reports". The reports which are temporary saving or waiting for approval, are reviewable only within the same institution. The approved reports are open to outside the institution, but privacy information such as reporter's name or patient's name is anonymous. A reporter can receive a question via e-mail from an identifiable reviewer, and this reporter can answer anonymously.

Results

The system has been developed successfully. The first page of ICSR system has two parts; the upper section is for reporting, the lower section is for the administrative function. A reporter is likely to belong to two or more institutions. Therefore a reporter should define at which institution an ADR occurred.

The reporting function has three sections mainly; the first is for creating or amending reports, the second is for reviewing reports, and the third is for setting up reporter's information. For the first time to use this system, a report needs to fill out reporter's information. Once a reporter has completed this section, it is not required to fill out any more.

In order to create a new ICSR, a reporter is required to enter patient's age and select gender. After that, identification number is assigned to each case automatically. Then the form 1 appears. The top section is to enter an adverse event. A reporter can enter several events. Then, the next column is for a suspect drug. There are two ways; one is to enter a substance name, and the other is to enter a product name. If you enter some characters for either of them, applicable drug names appear. Then a reporter can select intended drug name. There is also descriptive section about details of adverse reactions or events. After clicking the button "next" and no missing data on the form 1, the page can move to the form2. If there is any missing data, this system indicates which information is missing.

In the top section of the form 2, patient's gender and age are placed automatically. A reporter can enter more information regarding a patient such as height, weight, pregnancy, if needed. As the next section, a reporter can enter relevant medical history and concurrent conditions. Also, there are some sections to capture some information, such as smoking, alcohol consumption, allergy, etc. The next section is for adverse reactions/events, and the major adverse reaction/event which was entered in the form 1 is placed in the top. And if necessary, a reporter can add more reactions/events. Also a reporter can enter the outcomes about ADRs, such as recovered, not recovered, fatal, etc. Also a reporter can enter the information about severity and concomitant drugs. And the next to them, a reporter can put results of laboratory tests. Also a reporter can enter descriptive information regarding ADRs. A reporter can stop the process any time and the entered data can be stored temporary and restart anytime.

Discussion

The two-step data entering prioritizes the information according to its importance, and contributes user-friendly interface. Archiving reports by three statuses helps to count how many ADRs occurred inside/outside the institution. Therefore, the system brings us easy management of reports. If lots of reports are stored, we can apply data mining to detect a signal of a real ADR. Furthermore, the numbers of suspect ADRs inside one institution is limited. Our system has the function to know the similar suspect ADRs outside and contact the reporter by e-mail to get the detail information immediately. This is helpful to evaluate ADRs and prevent more cases.

Since the government hasn't approved our system yet, reporters need to print out and send ICSRs by surface mail or fax to the government. If the government accepts reports directly through UMIN, it is actually more beneficial for them. Created report can be exported as a Microsoft Word format, this format is acceptable through e-government portal gateway. Therefore our system is useful to adapt a report to this e-government. However, in order to send a report through this e-government portal gateway, a reporter should get an electronic certification from any certificate authority. This process of obtaining an electronic certification is difficult and complicated. If UMIN can take a role of a certificate authority; a reporter would not need to obtain an electronic certification from any other certificate authority.

The Pharmaceuticals and Medical Devices Agency (PMDA) was established in 2004 based on the law for the incorporated administrative agency. This agency started to open ICSRs which were submitted from pharmaceutical companies to the government. But there is about one-year time lag from reporting to disclosure because of evaluation process. Our system on UMIN has no such time lag. In addition, our system has a detail searching function which PMDA doesn't provide.

Another benefit of our system is that it can be useful for data mining. FDA and WHO have already started to use data mining methods to detect suspect ADRs. These methods are probably applied to our system.

The strong proof of feasibility is necessary to get permission from the government. There is a plan to carry out a feasibility test of it in the near future.

Conclusion

In order to facilitate pharmaceutical safety reporting from medical institutions, and enhance early detection or prevention of ADRs, we have developed a system on UMIN successfully. The major benefits of this system are user-friendly interface, easy management of reports, and immediate sharing information on suspect ADRs among medical institutions. The feasibility test of it is necessary in the near future.