Health care quality management by means of an incident report system and an electronic patient record system

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Abstract

Background: Quality management in health care services has not been as successful as in other industries. Objective: To assess the potential contribution of an on-line incident reporting system (OIRS) and of an electronic patient record (EPR) system to quality management in hospitals. Methods: The two approaches are being implemented in Osaka University Hospital. Results: Analysis of the early use of the on-line reporting system indicates that this qualitative approach has been effective to avoid adverse medical events. The quantitative methodology with the EPR is still in the phase of developing. Conclusion: Direct data entry by medical staff and an EPR based on dynamic templates and a dynamic problem oriented approach could be useful for building clinical data repositories that can support clinical quality management.

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1. Introduction

Health care has always tried to utilize the capabilities of emerging technologies as to improve the quality of the delivered care. Hospital information system, intranet and other information and communication technology (ICT) increasingly robust communications in the health care environment. In the early days, ICT contributed mainly to the timely and efficient communication of care data. Now its focus is shifting to improve quality and efficiency in health care by using on-line clinical data acquisition and processing.

Although healthcare delivery inherently has a risk of adverse events, preventable injuries occur more frequently than in other complex industries. In spite of some pioneering works [1], quality control or management has not
been a major concern in health care service until the Institute of Medicine reported their estimate that medical errors kill 44 000–98 000 hospital patients each year [2]. Worldwide, the health care community was pressed to give prevention of medical errors a high priority. Since then, various actions have been made by the global health care services. Only a continuous management of the quality of health care can maintain such a reduction.

The mechanism of health care is so complex that medical quality management should be system-oriented and based on evidence and/or statistical data. This paper will elucidate the authors’ experience with a qualitative and quantitative approach to quality management using ICT in routine health care.

2. Qualitative approach for medical risk management

2.1. Objective

A transparent, honest, and blame-free culture is the critical element of continuous quality improvement including clinical risk management. The incident report should be collected efficiently and appropriately analyzed to determine latent and active failures. Preventive actions should be prioritized according to the frequency and the severity of risks [3], well planned, and implemented in a timely manner to prevent recurring events. However, if those documents are paper-based, it will take time and consume health care resources to communicate, archive, and feed back the relevant information. The primary objective of the qualitative approach to patient safety and quality issues is to develop a system for the electronic collection of incidents for effectively evaluating the possible causes of the incidents.

2.2. Design and methods

We have developed and utilized an on-line incident reporting system (OIRS) to streamline the incident reporting process and to achieve an immediate and effective Plan–Do–Check–Act (PDCA) cycle. It collects incident reports through the intranet in the Osaka University Hospital. The design principles of the OIRS were anonymity of the reporters and their immunity for punitive actions by the institution, the timely input through easier access and report, and multidisciplinary reviewing of reported incidents. The reporting processes were simplified by using templates and checkboxes, while some data elements such as facts, suggested causes, and preventive methods should be described in the free-text (see Fig. 1).

The OIRS is not only the report form itself but also links to the clinical risk management committee, which is responsible for reviewing incidents and making improvement plans on a daily basis. A committee member on duty should monitor summaries of the reports on that day and immediately introduce them to the other members in the on-line committee within the closed mailing list system via the internet for the discussions. The organizational structure relating to the OIRS is illustrated in Fig. 2.

2.3. Results

The OIRS was first introduced and available to all disciplines of the hospital on 1 July 2000. The data from 1 July 2001 to 31 March 2002 were analyzed in this study. The number of reports per month varied between 140 and 180. Before the introduction of this system, only the nursing division filled in the paper-based incident reports. They reported about 50 incidents per month. Of the reporters using
the new system, 84.0% were nurses, 10.2% physicians including trainees, and 3.1% pharmacists during the analyzed period. Medication (44.3%), lines and tubes (22.0%), and falls and slips (13.9%) were the most frequent incidents in our hospital (Table 1).

Fig. 1. An example view of structured data entry in the OIRS in the Osaka University Hospital.

Fig. 2. The organization and the process from data gathering to feedback in the risk management process in Osaka University Hospital.
Major factors that the reporters considered as root causes of the incidents are fundamental in the process of care, and related to how supervising and communication among the team members takes place. The average input time for the OIRS, which is automatically calculated, was approximately 9 min. Considering that it took generally 30 min in the previous paper-based reports by nurses, at least 30 h a month were saved in data entry time using the new system. Although, obvious shifts in the type and the number of incidents reported have not been observed during the reporting period, some specific incidents have been eliminated or reduced by the system-oriented intervention including error proof and error absorption through the immediate monitoring, decision making and the following actions for the improvement. Examples included the purchase of irradiated platelets from the blood center instead of the irradiation by physicians after business hour and development of a new tubes and syringe for the parenteral nutrition, with which one is unable to connect these nutrition lines erroneously with vessel lines.

3. Quantitative approach for medical quality management

3.1. Objectives

To assess the medical quality of the care process, quantitative data concerning process and outcome of each care intervention should be accumulated, aggregated, and combined with other data of hospital management. As an EPR is a combination of the contents of a (paper-based) medical record, physicians’ direct order entry (POE) and professional audits such as pharmacist order review, the EPR as a whole is a quantitative tool to manage the quality of health care.

3.2. Design and methods

The POE system, implemented in Osaka University Hospital [4] has been successfully integrated in the care process. It contributes to a saving of manpower and an increase in efficiency of the hospital functions. All orders and reports except for the pathological examination order are electronically exchanged and stored in the database. Due to the successful operation of the ordering and reporting system, an electronic patient record (EPR) system of the Osaka University Hospital (EPROU) [5] was introduced in January 2001.

The EPROU features (1) physicians’ direct structured data entry, (2) multi-modal output of registered clinical data and (3) dynamic problem oriented approach. One of the requirements of this EPR system was to enable faster input of necessary clinical data as to enhance the usability and the utility of the EPR. We developed a system for the structured entry of data items by means of dynamic navigation of templates [6]: the dynamic template driven data entry system (DTDES). The EPROU viewer provides an integrated

| Table 1: Contents of reported incidents in the OIRS (period, June 2001 – March 2001; N = 1550) |
|-----------------------------------------------|---------------|
| Drugs (order dispensing administration)       | 43.2          |
| Lines and tubes and equipment                 | 19.2          |
| Falls/slips                                   | 10.1          |
| Therapeutics and procedures                   | 3.2           |
| Blood transfusion                             | 3.0           |
| Surgery and anesthesia                        | 2.6           |
| Diet                                          | 1.8           |
| Clinical lab-related                          | 1.7           |
| Patient/family complaints                     | 1.0           |
| Radiology/endoscopy-related                   | 1.0           |
| Patient/family behavior                       | 0.8           |
| Exposure control                              | 0.5           |
| Rehabilitation                                | 0.4           |
| Others                                        | 8.1           |
| Total                                         | 100.0         |
view of information of one patient [7]. The conceptual design of the EPROM is shown in Fig. 3.

The EPROM database stores the medical event data for more than 5 years. ‘Medical event’ is an abstract concept which includes the records of healthcare providers, ordering and processing data, examination reports, image header data, and so on. One medical event corresponds to the set of data entered at one time. The records by healthcare providers, e.g. the progress notes by medical doctors, are entered with dynamic template tools and saved into the EPROM database. The ordering data and the processing data are entered through the order entry system and transferred from the order database to the EPROM database. The examination reports are made by the reporting system and stored in the report database, which is then transferred to the EPROM database. The medical images are stored in the DICOM database. When the DICOM database receives images, it sends the header information to the EPROM database [8].

The structure of the EPROM database is so simple that there is only one database file. One record corresponds to one medical event with medical event ID, patient ID, medical event type, department name, transaction time, validation time, user ID, and several content fields. The values of the contents vary according to the medical event type and they encapsulate the data structure. Neither deletion nor editing is allowed in this database. Records that require modification or deletion are marked as such and the modified record is added.

We have been attempting to extract quantitative data from the EPROM database for the medical quality management. A preliminary study has been conducted with length of stay (LOS) data for in-patients using the Japanese edition of the diagnosis related group (DRG), called as the diagnosis procedure combination (DPC).
3.3. Results

Patient data concerning LOS, diagnosis and major procedure were extracted from the clinical information database that is closely linked to EProu. A total number of 10 687 discharged patients from April 2000 to March 2001 was sampled and analyzed. The overall average of LOS in the fiscal year of 2000 was 31.7 days (including the department of psychiatry, with its LOS 78.8 days). At first, a comparison with Japanese DPC version 1.0 was made. Only 51.2% of the patients was classified into 80 DPC categories. The low covering rate is due to immaturity of the DPC. The DPC-specific LOS distributions were obtained and values of the mean, median and standard deviation (S.D.) in each DPC were calculated. The results showed that most DPC-specific distributions were not normal and rather similar to logarithmic-normal. Some distributions had more than two phases. In general, mean values and S.D.s were larger than found in data obtained from other national hospitals. The results indicate that either the medical quality has not been managed well or the hospital dealt with more complicated and more difficult cases than other national hospitals.

4. Discussion

To minimize preventable adverse events [9], we have reengineered the paper-based incident report into a computerized reporting, notification, and tracking system. The use of information technology in the hospital-wide approach to patient safety seems to facilitate the continuing process of health care quality management. The OIRS seems to have successfully increased the number of incident reports, decreased the time needed to complete the report, and enabled the hospital staff with different disciplines to participate. The rather high proportion of reporting by physicians may also reconfirm the effectiveness and acceptance of this system. However, the OIRS alone does not work sufficiently. It is noted that the persons in charge of the on-line view and immediate actions, such as the clinical risk manager, the risk management committee and the department of clinical quality management, are required to make the OIRS truly function. In addition, root cause analysis focusing on the process of care and the hospital systems should be undertaken for the appropriate actions. The capability to automatically extract root causes using structured data set is under development.

Incident-reporting systems may produce much potentially valuable information, but seriously underestimate the true level of reportable incidents [10]. Occurrence rate of a certain health care error will not be estimated by the qualitative approach to quality management. We have to use another methodology; the quantitative approach. An EPR system is a potent tool for directly identifying sources of health care incidents, error and accidents.

An EPR is used primarily on the site of health care for a quick and easy safety check. For example, by scanning the identification bracelet on the patient’s wrist by a health care provider, causing that patient’s EPR to appear on the computer screen. Then the bar code on the drug, ordered by the patient’s doctor to be given at that time is scanned. If all is fine, the computer gives no alert and instantly changes the medical record to show that the treatment was given.

Moreover, it is important to recognize that the EPR database such as EProu provides a quantitative basis for risk and quality management, since the medical record should represent whole process and outcome of the health care provided. Risk managers should
have access to the EPR to be able to extract incidents and errors as a routine procedure of medical record audit or peer review. If such a methodology is established, the quality management in health care will reach the same level of quality as in the production of goods. W. Deming [11] suggested 14 principles for transformation of quality management in medical service. Among them, he mentioned that “Require statistical evidence of quality of incoming materials, such as pharmaceuticals, serums and equipment. Inspection is not the answer. Inspection is too late and unreliable. Inspection does not produce quality. The quality is already built in and paid for.” In applying advanced ICT, the resource, process and outcome data will be integrated and statistical evidence will be extracted and analyzed.

Our preliminary study of a quantitative approach showed that the DRG or DPC specific distribution of length of hospital stay, extracted from an EPR can be one of the elements of the statistical evidence of medical quality. As the principle of quality control clearly indicates, the larger S.D. should be made smaller and the long mean LOS should be shorten by another interventions of quality management such as application of evidence based medicine guidelines and critical paths. The concept is illustrated in Fig. 4.

There has been a great deal of discussion in the media about ways to implement an EPR, including computerized physician order entry systems. Because of the improvement of the man–machine interface of the order entry system, most Japanese physicians and nurses are now in favor of direct order entry. However, data input and output for an EPR that covers the same contents as a paper-based medical record, might be another major problem for physicians. It turns out that the dynamic problem-oriented approach, based on a dynamic template system for structured data entry and with multiple display modes has been well accepted by Japanese physicians in this hospital [12].

The database of the EPR system is composed of a single database file. The data in the structured contents fields are tagged according to the type of medical event. The merit of the structured data is to retrieve and extract necessary data easily, and the DTDES will be one of the important tool if the data will be utilized for quantitative approach of the medical quality management.

Protection of data against unauthorized modification is essential for an EPR. EPROU has a mechanism for making a message digest for each record. Thus illegal changes of the record can be detected. When the data is transferred from the server to the client, the data is encoded to avoid theft or change during transmission. The files stored in PCs are also encoded to protect the data. Although ownership is a well-established principle concerning the paper-based medical record, there still exist difficulties in the context of an EPR. Accessibility would be enhanced if a quality manager were able to link EPR data within a institution. Such data for quantitative quality management should be obtainable via institutional or patient permission and a key consideration should be paid to follow security policy guideline.

Two approaches toward the medical quality management are studied in the paper. Qualitative approach by using a comprehensive system that includes on-line incident reporting method has been well received and considered very effective. Although another approach by means of EPR is still under development, the quantitative methodology will be the final goal for medical informatics community to support global health care services.
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