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Development of Computerized Adverse Drug Event Surveillance System in Korea: Retrospective and Prospective Patient Medical Record Reviews

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Abstract and objective

A computerized adverse drug events surveillance system (CADESS) was implemented in Seoul National University Bundang Hospital (SNUBH), Korea with advanced electronic medical record systems. For the purpose of system evaluation at the beginning stage of implementation, two months were randomly selected and patient medical records screened with ADE signals were reviewed in retrospective and prospective respectively. The knowledge base of CADESS was developed by clinical experts and the ADE identifications were reviewed by 6 clinical pharmacists. The incidences of ADEs were 4% and 3.4% in retrospective and prospective respectively. Rates of preventability and severity were different; however, most differences of our results were due to the system errors and the natural characteristics of the prospective information flow.

Keywords:

Clinical Decision Support Systems, Adverse Drug Events, ADEs, Computerized Medical Record Systems

Introduction

Adverse drug events are common, costly and often preventable. Monitoring ADEs is the most important part of ADE prevention. Computerized ADE surveillance systems using signals to detect potential ADEs have been reported more cost-effective than other types of ADE monitoring system. To identify and prevent ADEs, the Computerized Adverse Drug Event Surveillance System (CADESS) was developed in the hospital information system, SNUBH.

Methods

SNUBH is an educational hospital with 909 beds in Bundang, Korea and has been operated an computerized medical record system, BESTCare, since 2003. CADESS was implemented in the pharmacy information system in early 2006. Signals detecting ADEs were adopted from the previous studies and reviewed by clinical experts in SNUBH. Patient medical records screened with ADE signals were reviewed to identify ADEs by 6 clinical pharmacists for selected months. After the training of medical record reviewers, the reliability among reviewers was measured. The medical record of inpatient during April 2005 was reviewed retrospectively; from Jul. 18, 2006 to Aug. 17, 2006, prospectively. Severity, preventability, suspicious drugs, ADE mechanism, and so on were recorded in a structured format by trained reviewers.

Results

The total numbers of hospitalized patients were 3,608 for a month of April 2005 and 3,510 from August to July in 2006. The percentage of patient generated ADE alerts was 12.7% and 13.6%; the incidence of ADE, 4% and 3.4% of inpatient in retrospective and prospective reviews respectively. The preventability was 29% vs. 10%; the severity of significant, serious and life-threatening was 75.2%, 22.8% and 2.1% vs. 80.3%, 13.3% and 1.7%.

Conclusions

The difference between retrospective and prospective reviews was mostly due to simple computational errors. 4 signals were missing in the retrospective review and it caused the differences in the total number of ADE alerts, incidence and others. Preventability still significantly differs although the availability of information sources and the data completeness were considered. Lastly, sample size was too small to compare the predictive positive values of each signal. But the comparison between retrospective and prospective reviews was a meaningful at the beginning stage of system development process.

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