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Computerized Surveillance for Adverse Drug Events in a Pediatric Hospital

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Abstract There are limited data on adverse drug event rates in pediatrics. The authors describe the implementation and evaluation of an automated surveillance system modified to detect adverse drug events (ADEs) in pediatric patients. The authors constructed an automated surveillance system to screen admissions to a large pediatric hospital. Potential ADEs identified by the system were reviewed by medication safety pharmacists and a physician and scored for causality and severity. Over the 6 month study period, 6,889 study children were admitted to the hospital for a total of 40,250 patient-days. The ADE surveillance system generated 1226 alerts, which yielded 160 true ADEs. This represents a rate of 2.3 ADEs per 100 admissions or 4 per 1,000 patient-days. Medications most frequently implicated were diuretics, antibiotics, immunosuppressants, narcotics, and anticonvulsants. The composite positive predictive value of the ADE surveillance system was 13%. Automated surveillance can be an effective method for detecting ADEs in hospitalized children.

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Introduction and Background

Adverse drug events (ADEs) comprise the largest single category of adverse events in large populations studies of patient safety.[1,2] Estimates of the incidence of ADEs vary widely,[3–6] depending upon definitions, measurement methodologies, and populations studied. Methods used for ADE detection have included implicit chart review,[1,7,8] explicit chart review,[9,10] and computerized signal detection with manual validation of alerts.[3,4,11] While chart review has traditionally been considered a gold standard, there is evidence that computerized surveillance detects many events that are not easily detected during chart review.[4] Automated surveillance has advantages over chart review, including the ability to survey a patient population (e.g., all inpatients) comprehensively and continuously, and a significantly lower resource requirement than chart review.[4] It is generally agreed that voluntary reporting of ADEs is low-yield and anecdotal in nature, and not valuable for ADE quantification.[3,4,12,13]

Despite the extensive literature on ADEs in adult populations, relatively little is known about the frequency and nature of these events in children. In a study based on concurrent order and chart review and error reporting by providers, Kaushal et al. examined ADEs in pediatric inpatients at two institutions and described an ADE rate of 2.3 per 100 admissions, or 6.6 per 1,000 patient-days.[14] Using a system that the current author (PMK) implemented at another institution,[11] another group has examined ADEs on the pediatric inpatient service of a general hospital; using triggers designed primarily for ADE detection in adults, they described an ADE rate of 1.6 per 100 admissions or 1.8 per 1,000 patient-days.[15]

Given the significant differences in the types and frequencies with which various categories of medication are used in pediatrics, we hypothesized that automated ADE detection for pediatrics might be enhanced by consideration of a wider range of rules than those that have been previously employed for computerized surveillance in adults. Our hypothesis was reinforced by preliminary data suggesting greater importance of medications that affect electrolyte balance in pediatric compared with adult populations.[16] This paper describes our implementation of an automated ADE detection system at a large pediatric hospital, and data from the operation of the system over a six month period. We describe our findings regarding the utility of different rule categories for event detection, and our overall findings of ADE rates in our pediatric population.

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Methods

St Louis Children's Hospital (SLCH) is a 250-bed hospital specializing in the care of acutely ill pediatric patients. The SLCH is a member of BJC HealthCare, a 13 hospital integrated delivery system headquartered in St Louis. The hospital has approximately 14,500 admissions annually, with an average length of stay of 3.4 days. The SLCH is the principal pediatric teaching hospital for the Washington University School of Medicine (WUSM), and is located with Barnes-Jewish Hospital on the WUSM-BJC academic medical center campus in St Louis. Our study population included all patients admitted between Feb 1 and Jul 31, 2008, with the exception of oncology patients, for reasons described below. The study was approved by Washington University School of Medicine's Human Research Protection Office.

Building upon our previous work with expert systems,[17–19] we modified a rules-based computer program to perform real-time surveillance of patient data from SLCH clinical systems, searching for combinations of demographic, encounter, laboratory and pharmacy data that suggest that an ADE may have occurred.

Data from SLCH systems is sent in near-real time by HL7 interfaces to a relational database. Triggers for rule evaluations are identified as data are stored in the database, which prompts our Automated Guideline Monitor (AGM) to evaluate these data against rules. The AGM manages the rule base and database queries in the following manner.[20] An application called event handler queries the database and constructs a Virtual Medical Record (VMR) for any patient on whom one or more rules have been triggered. The VMR is translated into an eXtensible Markup Language (XML) message and sent via HTTP to an open source Active BPEL (Business Process Execution Language) engine that employs Web services Business Process Execution Language (BPEL). The BPEL engine executes the given rule and returns a list of one or more clinical decision support actions (e.g., alert, no action, etc). Rules use XPath expression language, a W3C standard for extracting and evaluating XML data. This architecture is shown in Figure 1.

Alerts generated by AGM are displayed on a Web-based user interface for evaluation by pharmacists. For the purposes of this study, the interface was modified to allow for two independent assessments and a final assessment interface for a third reviewer (PMK) that showed all alert details and the two independent assessments. See Figure 2.

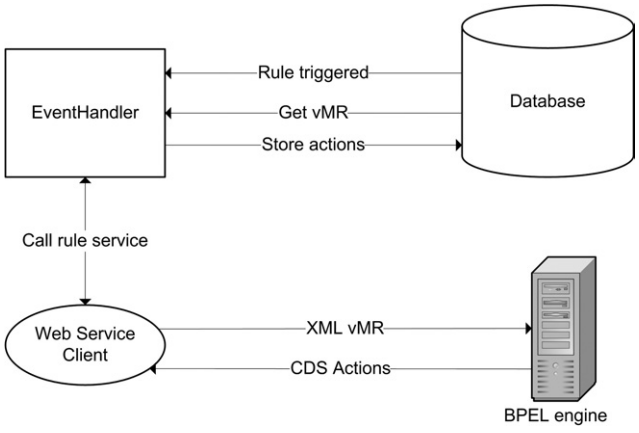

Figure 1. Automated guidelines monitor: architecture.

Our rule set was constructed based on our previous work in adult hospitals,[11] but expanded for the pediatric environment. Additional rules were included in an effort to detect certain ADEs that we suspect to be more common in the pediatric environment than in general hospitals, based on previous experience,[16] event reports, and the frequency and use of different medication classes in our hospital. For example, we hypothesized that a rule for detecting seizures secondary to medications might be useful. Also, we suspected that medication-induced electrolyte abnormalities requiring intervention represent a common and potentially under-appreciated type of pediatric ADE. We altered our previous rule for insulin-induced hypoglycemia, requiring a glucose level of 40 mg/dL or less, in response to the large number of clinically insignificant values between 40 and 50 that we detected in our previous work.[13] We also tested a number of rules targeting medication-induced GI dysfunction. The rule set employed during the study period is shown in Table 1.

The ADE Surveillance Rules

Using this "broad spectrum" rule set we anticipated a high level of false-positive alerts in our oncology population, due to the high incidence of well-recognized and currently unavoidable adverse events from antineoplastic medications. Therefore, for purposes of this specific investigation, we excluded all oncology patients from our data collection and subtracted their numbers from our admission and hospital-day data.

Each of the two study pharmacists (CS, MN) independently reviewed all the resulting alerts using training and evaluation methodologies described previously.[11,13] To review current alerts, they accessed the system's Web site approximately three times per week. The Web site displays all alerts fired by the system that have not yet been reviewed. Selecting an alert from the list displays the information screen containing information about the alert plus critical patient data, including current medication lists, relevant laboratory values, patient weight, and demographic data. The pharmacists had access to other online systems including the hospital pharmacy system and the enterprise clinical data repository to assist them in their evaluation of alerts. They examined every alert independently, reviewing the patient's record to determine whether an ADE had occurred. Each alert was scored for causality using the Naranjo algorithm for determining probability of causality;[21] events with causality scores 5 or higher (probable or definite ADEs) were then scored for severity using the NCC-MERP scoring system (http://www.nccmerp.org). They also recorded the responsible medications, and a narrative of the event. All pharmacist findings were then reviewed and adjudicated by a physician expert (PMK), whose evaluation served as the gold standard. Events scoring 5 or higher on the Naranjo scale (probable or definite causation), and with NCC-MERP scores of E or higher (indicating harm to the patient) were considered ADEs in this study.

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