Computable Decision Modules for Patient Safety in Child Health Care

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Abstract

**Objective:** To identify controlled evidence from the child health literature on patient conditions and clinical procedures that resulted in unacceptable adverse outcomes.

**Methods:** Systematic searches of MEDLINE (1966 to 2001), and Cochrane Database of Systematic Reviews (2001) were done. Studies that met the eligibility criteria, were verified for quality of methodology and lack of conflicting studies. A knowledge base of Child Health Safety Modules was then developed. The knowledge base could be used to transfer controlled evidence on potentially harmful interventions into clinical decision support systems conforming with Arden Syntax, a widely applied computer standard.

**Results:** The searches identified knowledge to create 41 Child Health Safety Modules for medications and procedures in child health care, from 29 randomized controlled trials and 12 non-randomized controlled studies. The modules are focused on 28 medication interventions and 13 other clinical procedures. Eighty five percent of the studies were published between 1997-2001.

**Conclusion:** An increasing amount of controlled evidence on risks of adverse outcomes in child health is available to alert clinicians when potential planning errors are about to be overlooked.

INTRODUCTION

In 1999, an Institute of Medicine report increased public awareness of medical errors. The report indicates that deaths resulting from medical errors exceed the number of lost lives due to diabetes, motor vehicle accidents, or breast cancer annually. Data on compromises of patient safety are compelling, but the retrospective nature of studies and application of expert opinion to establish cause-effect relationship, matching responsible clinical actions to adverse outcomes, raise concerns.

Medical error is the failure to complete a planned action as intended or the use of a wrong plan to achieve an aim. While errors of execution are simple to define based on unapproved deviations from the clinician-patient decision, errors of planning are harder to pinpoint and instinct can be grossly misleading.

Studies show that medication error is most common in child health. A major pediatric study reviewing 10,778 medication errors from two urban teaching hospitals found that potential adverse drug events are significantly more frequent among pediatric patients than among adult patients (p=0.001). Another study found that the most common medication error in pediatric patients was an incorrect dose of medication (37%) or incorrect medication given (36%).

Shortage of computable knowledge is a major barrier in providing pertinent information technologies for clinicians to reduce planning errors. Randomized clinical trials have substantiated the beneficial impact of reminder messages in prompting preventive care. Computable knowledge support adds significant value when integrated with reminder systems by providing feedback to the physician at the point of order planning. Standards for computable knowledge representation exist but the transfer of clinical evidence to practice shows decades of delay. Most of the guidelines lack the adequate specificity required to be translated in clinical decision support systems. There is a need for clinical decision support, but there is a lack of necessity and priority in implementing the systems in clinical practice.

The evidence from previously published studies forms the basis of dealing with adverse outcomes among pediatric patients. The goals of this study were to (i) utilize adverse outcomes from clinical studies evidence as a means of responding to child health safety concerns; and (ii) create a comprehensive set of Child Health Safety Modules for the management of child health care.

METHODS

Child health serves as the clinical focus area of the development of evidence-based patient safety modules. This study used the National Institute of Health definition of child (individual under the age of 21). The following sources of original research data were
explored when searching for controlled clinical evidence: (i) randomized controlled trials and meta-analyses; and (ii) retrospective cohort or before-after studies of clinical interventions.

Eligibility Criteria The eligibility criteria for selection of studies were: (1) study focusing on conditions and procedures for child health care; (2) at least 10 children in sample groups; (3) controlled observation (e.g., randomized controlled trials, meta-analysis, or controlled retrospective study); (4) clinical intervention where harm exceeds benefits; and (5) statistical data that demonstrate significant harm such as higher odds ratio or risk ratio of an adverse event.

Literature Search Eligible studies were identified by searching electronic databases such as MEDLINE (1966 to August, 2001) and Cochrane Database of Systematic Reviews (issue 2, 2001). The following words were used without restriction to language: child$S$, medic$S$, error, diagnostic, procedure, therapeutic, intervention, therapy, odds ratio and risk ratio. Hand searches of reference lists of retrieved articles; major textbooks and Internet sources like adverse event databases complemented the gathering of the initial pool of eligible studies. For major drugs, searches were conducted for “drug” AND “drug interaction” MeSH term. To identify the most non-controversial items, initially eligible studies were further analyzed to exclude ineligible studies.

Table 1. Classes of Clinical Evidence (Modified Zynx Scale)

<table>
<thead>
<tr>
<th>Type of Evidence</th>
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<tr>
<td>(M) Meta-analysis of randomized controlled trials</td>
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<tr>
<td>(A) Prospective randomized controlled trials</td>
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<tr>
<td>(B) Nonrandomized, contemporaneously controlled or before-after clinical study</td>
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<tr>
<td>(C) Retrospective analysis of clinical data</td>
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<td>(S) Systematic reviews that synthesize pooled data without formal meta-analysis</td>
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<td>(E) Based on indirect evidence, personal experience or expert opinion</td>
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<td>(P) Public ruling by professional association, health insurer, or government</td>
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Typical research scenarios that led to evidence of errors are:
- A study analyzes the combination of two or more useful drugs which provide bad outcomes, for example: analgesic and sedative therapy with remifentanil AND midazolam in children undergoing a brief painful procedure. 11
- A study analyzes a drug that does not provide any benefit for a specific diagnosis but harm does were recorded. For example: the use of pseudoephedrine in air-travel associated ear pain. 12

Quality Check Eligible studies were classified according to the modified ZYNX scale of classes of evidence (Table 1). 13 The category of professional consensus was added as a separate class to understand the social interpretation of original research data on adverse outcomes.

Development of Child Health Safety Modules

From eligible studies, information about patient condition, clinical intervention disparity, desired benefit and major harm, corroborating evidence, and warning message, were abstracted to develop a knowledge base of Child Health Safety Modules (CHSMs). Each CHSM comprises a short message summarizing the essential of the contradiction between patient condition and intervention. The message emphasizes the odds of adverse outcome and follows the international standard of Short Message Service (SMS), a store and forward application that enables text messages to be sent from and received by mobile phones. Each message should be less than 160 characters, including spaces.

Medical logic modules consistent with Arden syntax include maintenance slots (title, file name, version, originating institution, author, date, specialist, and module, keywords for searching), and knowledge slots (IF condition and THEN action of the Boolean rule). The CHSMs from this study are completely transferable into clinical decision support systems with Arden syntax. The name of the module can be placed into the maintenance slot; the harm/benefit and controlled evidence into the library slots; patient condition with the conflicting clinical intervention (IF condition) and short message (THEN action) into the knowledge slots.

Analysis Clinical interventions and adverse outcomes were categorized to summarize and evaluate the distribution of collected patient safety concerns. Two reviewers awarded outcome scores for each CHSM. The outcome score was modified based on the harm score developed by the Armed Forces Institute of Pathology. 14 The CHSMs were classified into four outcome score categories: catastrophic, major, moderate, and minor.
RESULTS

Based on the eligibility criteria, 41 studies were identified including 29 randomized clinical trials and 12 non-randomized controlled studies. Eligible studies focused on 28 medication interventions and 13 other clinical procedures. Over half of the retrieved eligible studies (85.3%) were published between 1997-2001.

Forty-one modules were developed and categorized (table 2). Fifteen modules comprise diagnoses of asthma, ear nose throat, cerebral palsy, and hydrocephalus (37%); and 20 modules are surgical procedures pre-medications, and immunization (48.8%). An example of a child health safety module on the topic of asthma is provided in table 3.

Table 2. Number of Modules Based on Diagnoses and Procedures

<table>
<thead>
<tr>
<th>Categories</th>
<th>Number of Modules</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asthma</td>
<td>7</td>
</tr>
<tr>
<td>Ear Nose Throat (ENT)</td>
<td>4</td>
</tr>
<tr>
<td>Cerebral Palsy</td>
<td>2</td>
</tr>
<tr>
<td>Hydrocephalus</td>
<td>2</td>
</tr>
<tr>
<td>Surgical Procedures</td>
<td>18</td>
</tr>
<tr>
<td>Immunization</td>
<td>2</td>
</tr>
<tr>
<td>Muscular dystrophy</td>
<td>1</td>
</tr>
<tr>
<td>Obsessive compulsive disorder</td>
<td>1</td>
</tr>
<tr>
<td>Chemotherapy</td>
<td>1</td>
</tr>
<tr>
<td>Nephrotic syndrome</td>
<td>1</td>
</tr>
<tr>
<td>Postnatal</td>
<td>1</td>
</tr>
<tr>
<td>intraventricular hemorrhage</td>
<td>1</td>
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<tr>
<td>Tympanic ear thermometer</td>
<td>1</td>
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</table>

Table 3. Child Health Safety Module

Patient Condition: Acute Asthma
Intervention: Prednisone Vs. Dexamethasone
Benefit vs.Harm: Treatment of asthma Vs. vomiting, noncompliance, and missed school days
Evidence: Children with acute asthma who received Prednisone treatment are more likely to experience adverse events such as vomiting (p=.008), noncompliance (p=.004), and missed 2 days of school (p=.05) compared to Dexamethasone.
Reference: Qureshi 15
Short Message: In children with acute asthma, Prednisone increases the risk of vomiting, noncompliance and missed school days.

Outcome scores are provided in table 4. Based on the outcome score, 41.5% of the modules describe an intervention that resulted in minor harm, 51.2% in moderate and major harm, and 7.3% in catastrophic harm.

Table 4. Outcome Score

<table>
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<tr>
<th>Outcome Category</th>
<th>Definition</th>
<th>Number of Modules</th>
</tr>
</thead>
<tbody>
<tr>
<td>Catastrophic</td>
<td>Life or death</td>
<td>3</td>
</tr>
<tr>
<td>Major</td>
<td>Permanent bodily change (improvement or impairment)</td>
<td>9</td>
</tr>
<tr>
<td>Moderate</td>
<td>Significant change in level of health care services</td>
<td>12</td>
</tr>
<tr>
<td>Minor</td>
<td>Health status change without significant change in level of health care services</td>
<td>17</td>
</tr>
</tbody>
</table>

DISCUSSION

Equal proportions of diagnoses and procedure modules are represented in this study. Based on the outcome scores, over half of the CHSMS present controlled evidence of interventions that resulted in a significant change in level health care services or permanent bodily change. Less than ten percent of CHSMS provide information on interventions that caused death. Outcome scores in this study show that the harm associated with half of the child health safety modules could result in permanent bodily change and significant change in level of care. A Harvard Medical Practice study shows that 71% of adverse events recorded in the study resulted in a disability that lasted less than 6 months, 3% in permanent disabling injuries, and 14% led to death. 10

Since the pediatric population has a high exposure to drugs, medication errors are common in children. Children pose unique challenges to the system for ordering, dispensing, administering, and monitoring medication since needed dosing is weight-based for practically all drugs in pediatrics. 6 Incorrect recording of patient weights leading to an incorrect medication dose and failure to note drug allergy are common causes for medication errors in pediatric patients. 4

The results of this study document the increased number of controlled-evidence studies addressing the concerns of adverse outcomes in child health care. Connection of clinical interventions and significant adverse outcomes represent a convincing reason to
notify clinicians about the possibility of a planning error.

The next step of this study is to transfer the CHSMs into Arden Syntax. A Clinical Decision Support System linking the computable knowledge database and a physician order entry system will facilitate clinicians practicing evidence-based therapeutic decision-making and eliminate prescribing and dosing errors. In clinical setting, Arden Syntax based clinical decision support system can provide clinical alerts and reminder systems that have proven to be effective in improving the quality of care and reducing the cost of care. One study showed clinical decision support decreased the number of adverse drug events by 55 percent. A hospital study showed clinical decision support system implementation led to significant reductions in excess drug dosages (P<0.01) and adverse events caused by anti-infective agents (4 vs. 28, P<0.02).

Further research in computable decision modules for clinical decision support system will facilitate availability and use of high-quality guidelines in clinical practice, and clinical settings and clinicians can incorporate knowledge that was developed and refined elsewhere into their systems, without the need to re-invent the wheel.

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References


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Study I. New England Journal of Medicine
