Application of Information Technology \blacksquare

Costs Associated with Developing and Implementing a Computerized Clinical Decision Support System for Medication Dosing for Patients with Renal Insufficiency in the Long-term Care Setting

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Abstract A team of physicians, pharmacists, and informatics professionals developed a CDSS added to a commercial electronic medical record system to provide prescribers with patient-specific maximum dosing recommendations based on renal function. We tracked the time spent by team members and used US national averages of relevant hourly wages to estimate costs. The team required 924.5 hours and \$48,668.57 in estimated costs to develop 94 alerts for 62 drugs. The most time intensive phase of the project was preparing the contents of the CDSS (482.25 hours, \$27,455.61). Physicians were the team members with the highest time commitment (414.25 hours, \$25,902.04). Estimates under alternative scenarios found lower total cost estimates with the existence of a valid renal dosing database (\$34,200.71) or an existing decision support add-on for renal dosing (\$23,694.51). Development of a CDSS for a commercial computerized prescriber order entry system requires extensive commitment of personnel, particularly among clinical staff.

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Introduction

Renal insufficiency has an impact on the elimination of renally excreted drugs, leading to drug accumulation and the potential for serious adverse events. For patients with renal insufficiency, maximum dosing recommendations for many drugs should be based on assessment of the current level of renal function. This problem is particularly prevalent in nursing homes, where nearly half of residents have been found to have substantial levels of renal impairment.¹ In a previous study we found that nursing home residents are taking, on average, 9 regularly scheduled medications per day.² This combination of high prevalence of renal impairment and exposure to multiple medications places nursing home residents at high risk for medication-related problems.

Patient-specific dosing required for adults with renal impairment has been found to be a challenging aspect of medication prescribing in many settings. Several hospital-

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based studies have succeeded in improving prescribing for these patients through the use of computerized clinical decision support systems (CDSS) incorporated in computerized prescriber order entry systems (CPOE).^{3,4}

Many of the assessments of successful CDSS are based on locally developed systems designed to support CDSS.^{3,5} The success of these experiments in improving the safety of medication use has inspired many healthcare systems to consider adding this tool to their commercially purchased CPOE systems.⁶ However, the impact on staff time and the potential costs of developing CDSS in this situation have not been clear.⁷

We developed and implemented a CDSS to provide prescribers with recommended maximum doses of 62 drugs for patients with renal insufficiency in the long-term care setting. The CDSS was built on a commercially purchased CPOE system. As we developed the CDSS we tracked the process and the time involvement of all participants, as well as any external costs.

Methods

This study was conducted in the long-stay units of a large, academically-affiliated long-term care facility in Canada with four years of experience using CPOE that incorporated a basic level CDSS. The system was a Meditech electronic medical record based on the MAGIC platform with CPOE using Provider Order Management (POM 4.9). To increase the likelihood that physicians personally entered medication orders using the CPOE system, the facility had added wireless capabilities and the option for physicians to access the system from their off-site offices and homes.^{8,9} Within a randomized trial of the potential impact of advanced CDSS

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on the quality of prescribing and monitoring medications for long-term care residents, we developed a renal dosing CDSS that is representative of computerized programs for support of patient-specific dosing, including multiple types of alerts based on calculation of combinations of patient characteristics. As we developed and implemented this CDSS, we performed a sub-study estimating the time and costs involved. The study was approved by the institutional review boards of the University of Massachusetts Medical School and the participating facility.

CDSS and the Underlying Software

Not all commercially available CPOE systems are designed to support the elements required to deliver advanced decision support.^{10,11,12} A guide developed by the early developers of successful CDSS described the components recommended for an advanced CDSS to support medication prescribing: quick system responsiveness, the capacity to provide information to clinicians when they need it, integration of suggestions with actual practice, avoidance of requests to users that they obtain and enter additional information, making it easy to do the right thing, provision of alternative actions, and a focus on aspects of the care process that clinicians are most willing to change.¹³ In the case of medication dosing based on renal function, including these components requires that the underlying system and the CPOE software be prompt in responding to clinician requests, able to interact with locally written programming code to allow assessment of medication orders in real time, allow calculation of total daily dose of medication ordered, include linkages to electronic sources of lab test results and patients' weights in real time for programmed calculations, include the capacity to show specifically designed alerts to prescribers during the medication ordering process based on results of these calculations, support insertion of information from lab results into alerts, and be capable of identifying and acting on missing information. There also appear to be substantial advantages for CDSS in which alerts include revised medication orders that prescribers can generate simply by clicking on the alert.

The electronic medical record and CPOE software for which we developed the CDSS included most of these recommended capabilities, but was not able to present alerts from which prescribers could directly submit medication orders and did not calculate total daily doses automatically.

Process of Developing and Implementing the Renal Dosing Alerts

The CDSS was developed by a team that included physicians, pharmacists, informatics professionals, project coordinators, and a health services researcher. The physicians and pharmacists selected drugs for inclusion by reviewing published guidelines^{14,15} and lists from previous hospital-based renal dosing alert systems³ with updates for newer medications and/or recent evidence. The focus was on drugs primarily eliminated by the kidney with known potential nephrotoxic effects. We limited the review to oral drugs commonly prescribed in the long-term care setting. The resulting list was then compared to frequency of use of these therapies within the facility and the potential severity of the adverse effects. Final selection was based on team consensus and included 62 medications (Table 1). Decisions on dosing recommendations were based on specific recom-

Table 1 • Medications Included in the Renal Dosing CDSS

Acyclovir	Allopurinol
Amoxicillin	Amoxicillin/clavulanate
Cefaclor	Cefprozil
Cephalexim	Cetirizine
Chlorpropamide	Ciprofloxacin
Clodronate	Colchicine
Diclofenac	Digoxin
Famciclovir	Famotidine
Fluconazole	Gabapentin
Glyburide	Ibuprofen
Ketoprofen	Levofloxacin
Loratidine	Meloxicam
Metformin	Methenamine
Methyldopa	Metoclopramide
Naproxen	Nitrofurantoin
Norfloxacin	Oxaprozin
Penicillin VK	Pentoxifylline
Pramipexole	Primidone
Rifampin	Sulfinpyrazone
Tetracycline	Topiramate
Venlafaxine	-
	Acyclovir Amoxicillin Cefaclor Cephalexim Chlorpropamide Clodronate Diclofenac Famciclovir Fluconazole Glyburide Ketoprofen Loratidine Metformin Methyldopa Naproxen Norfloxacin Penicillin VK Pramipexole Rifampin Tetracycline Venlafaxine

mendations for dose adjustment in geriatric and psychotropic drug dosing handbooks^{14,15} and the MicroMedex[®] online knowledge base. We also took into consideration the availability on formulary of specific dosages and potential problems in splitting some drug dose forms. Where recommended frequency was 18 to 24 hours, we rounded to 24 hours.

Type and wording of alerts was determined by the team with subsequent review by the facility's Pharmacy and Therapeutics Committee. Four types of alerts were developed for various levels of creatinine clearance for residents with impaired renal function: 1) alerts recommending maximum total daily dose; 2) alerts recommending maximum frequency of administration; 3) alerts recommending that the medication be avoided; and 4) alerts notifying prescribers that no creatinine clearance could be calculated for this resident (due to missing creatinine test results or weight.) Examples of wording are provided in figures 1 and 2. Ultimately, 94 alerts were developed within these categories.

Based on these decisions, the project coordinators prepared a "blueprint" for each alert that included scenario, alert message, mnemonics for all drugs and range of creatinine clearance that would trigger that alert. To identify mnemonics for all strengths of each included drug, pharmacists reviewed the facility's formulary and medication usage history. The facility's pharmacists had previously developed an underlying calculation of creatinine clearance using the Cockcroft-Gault equation based on age, weight, sex and serum creatinine¹⁶ and this calculation had already been programmed within the CPOE system. Pre-testing proceeded with the selection of four prototypical drugs which were programmed and fully tested off-line with a cycle of test and revision of programming until all problems were eliminated. The remaining alerts were then programmed and tested off-line. A message was sent to prescribers to inform them of the new CDSS messages before the alerts were transferred to the live system. The facility had a history of including alerts within their CPOE system so training

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Figure 1. Screen shot of an alert that will display if the physician orders allopurinol for a resident with severe renal impairment.

requirements were minimal and few user problems were encountered. The CDSS also included programming that outputs audit trails of all alerts. This component enables on-going tracking of the usage and impact of the system.

Tracking Costs and Personnel Time

Because the alerts were added to an existing CPOE system within an electronic medical record that included laboratory test results and nursing notes, no additional hardware or software were required. Costs for developing and implementing the system resulted entirely from personnel time. Six categories of personnel were required: physician, pharmacist, informatics project manager, project coordinator, health services researcher, and specialized computer programmer. The programmer was external to the facility and was paid hourly as a consultant; estimates of the time and costs of programming are based on tracking of submitted bills. Time

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Figure 2. Screen shot of an alert that will display if the physician orders any of the 62 included drugs when creatinine clearance is not available. This occurs if data for either a serum creatinine lab test or weight for a resident are missing from the electronic medical record.

Table 2 Project Activities

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Project Management
Identifying staff and introducing them to the project
Scheduling and managing related conference calls, meetings
Travel time
Meetings and conference calls with management and
department heads
Designing process and procedures for developing CDSS components
Preparation of the contents of the CDSS
Thinking about and drafting preliminary descriptions of
potential drug issues for inclusion
Reviewing proposed drug issues for feasibility
Constructing and reviewing rules for inclusion in the CDSS
Meetings and conference calls related to rule development and
wording of alerts
Informatics Project Management (this collapsed category also
included all activities of the informatics project manager)
Reviewing the current CPOE system and making decisions
about up-grades and other changes
Preparation of blueprints and instructions for the programmer
Meetings and conference calls related to work on programming
and CPOE system issues
Designing computer programming for CDSS implementation
Designing the audit trail for tracking usage of the CDSS and
developing programming specifications
Extracting information from the CPOE system for developing
programming (e.g., drug utilization, drug mnemonics)
Programming
Programming the CDSS
Testing and implementing
Testing the CDSS
Reviewing the CDSS with groups of users
Training users

tracking for the remaining personnel is based on weekly reports that required participants to specifically categorize the time spent on the project. Optional categories are provided in Table 2. For analyses, we collapsed categories into: project management, preparation of the contents of the CDSS, preparation of blueprints and instructions for the programmer, programming, and testing and implementing. For this report, we include data collection through 2 weeks following the go live date and do not include personnel time for on-going maintenance and upgrades.

Cost Analysis

Our goal was to produce cost estimates that would be of use to clinicians considering development of CDSS within their own facilities. Therefore, we did not collect facility-specific costs for this project, such as actual wages of the participants, fringe benefits or overhead costs. Rather, we based estimates on the reported hours for each individual combined with US national average hourly wages for their personnel category, obtained from the Bureau of Labor Statistics, National Compensation Survey (Table 3).¹⁷ Costs for the specialized computer programmer were the exception to this approach; they are based on the actual billed hours converted from Canadian to US currency. We produced summary tables by personnel categories as well as activity categories.

Several aspects of the project were likely to produce large costs, including the need to develop the contents of the CDSS and the use of a specialized and expensive computer programmer. To support estimates of the reduction in costs that might be attained with variations in these factors, we developed a series of alternative scenarios:

- 1. Availability of a pre-existing and updated database with recommended dosing for drugs according to level of renal impairment assessed by creatinine clearance and appropriate for frail elderly patients^{18,19,20}
- 2. Availability of an off-the-shelf renal dosing program compatible with the CPOE system
- 3. Use of a CPOE system that is programmable by a less specialized programmer

The physicians and project coordinators estimated the reductions in hours for each category of personnel that would result from each of these scenarios and we estimated alternative total and activity category costs using these reduced estimates.

Results

The total estimate of costs for personnel involved in the production of the renal dosing CDSS is \$48,178.11. The total time spent on the project across all personnel types (presented in Table 4) was 924.5 hours with physicians providing nearly half of that time. The three participating physicians spent the majority of their project time (390 hours) preparing the content of the CDSS. The two pharmacists contributed 179.75 hours. Seventy-nine percent of their time was split between participating in the preparation of the content of the CDSS and performing extensive testing of each alert. The informatics project manager contributed nearly 122 hours. Her activities included managing interactions between the project and the Information Management department, selecting and overseeing the activities of the specialized computer programmer, and coordinating and supporting the process of testing and implementing the alerts. She also participated in all project meetings throughout the development process. Over the course of the project, several project

Table 3 🗖	Hourly	Wages	Used	for	Cost	Estimates
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Hourly Wage	Comments
\$62.52	
\$44.23	
\$30.36	Based on average of pharmacist (\$44.23) and technician (\$16.49)
\$40.98	Based on wages for managers and administrators, not elsewhere classified
\$28.60	Based on wages for biological or life scientist/medical scientist
\$16.49	Based on wages for health technologists and technicians
\$30.89	
\$79.76	Actual cost
	Hourly Wage \$62.52 \$44.23 \$30.36 \$40.98 \$28.60 \$16.49 \$30.89 \$79.76

Table 4
Personnel Time and Estimated Costs

Personnel Category	Hours	Cost (\$)	% of Total Time
Master's level Pharmacist	120	5 <i>,</i> 307.60	13
Baccalaureate level Pharmacist	59.75	1,814.01	6
Physician	414.25	25,902.04	45
Project Coordinator	79.75	1,315.08	9
Health Services Researcher	18.5	529.10	2
Informatics Project Manager	121.75	4,987.27	13
Specialized Computer Programmer	110.5	8,813.48	12
Total	924.5	48,668.57	

coordinators participated. They attended all project meetings, maintained and distributed agendas and meeting minutes and handled communication flow among the various participants. They also prepared the alert blueprints under the direction of the health services researcher who also designed the audit trail system to allow on-going evaluation of the impact of the alerts. The project required a computer programmer with extensive expertise in programming within the Meditech electronic medical record system. The total programming time was 110.5 hours.

Table 5 presents the estimated costs for personnel time across the collapsed categories of project activities. Fifty-six percent of the costs were associated with preparation of the contents of the CDSS. This reflects the extensive time required from physicians and pharmacists. Because the alerts were designed to guide dosing decisions, the process of selecting the drugs and deciding on the combinations of renal impairment and dose recommendations was painstakingly thorough, including reviews of geriatric dosing guidelines and the dosing recommendations used in hospital-based CDSS. The personnel time for physicians also includes meetings with the facility's Pharmacy and Therapeutics and Medical Advisory Committees. Eighteen percent of the project's costs were for programming. The other project activities accounted for the remaining 26% of project costs.

The first alternative scenario was constructed to estimate the reduction in costs that would be attained if a standard database existed with recommended drug dosing for frail elderly patients with renal impairment based on the best evidence. We estimate a substantial reduction in the costs for developing the content of the CDSS of 50% and an accompanying 33% reduction in project management time (Table 6). Estimated reductions are limited by the need for a facility's physicians to carefully review and weigh a database's recommendations before enacting them within the CDSS.^{18,19,21} Nevertheless, the total estimated cost is lowered by approximately 30% to \$34,200.71 (Table 6).

The second alternative (Table 6) scenario further reduces costs to \$23,694.51 by positing the existence of a CDSS renal dosing product compatible with the CPOE system. We estimate the same reductions in costs for developing the content of the system and managing the project as for the first scenario. Additional reductions include half of informatics project management time, and three-quarters of the time required for programming and preparing instructions for the programmer. If the CDSS product was truly "plug and play", there could be further reductions in programming and informatics management time.

The third scenario produced a more modest reduction to \$43,268.44 by assuming a CPOE system that did not require specialized programming skills. Estimates for this scenario do not reduce the hours involved in any of the activities but reduce the hourly cost for programming by using the average hourly wage for computer programmers in the United States in 2005 of \$30.89.

Discussion

During development of a computerized clinical decision support system for renal dosing, we tracked 924.5 hours of personnel time at an estimated total cost of \$48,668.57. We developed the CDSS for application in a long-term care setting and included 62 drugs and 94 different alerts. Other healthcare settings may involve a larger number of drugs and patient conditions of special concern. For example, in the hospital setting the CDSS would include intravenous drugs requiring extensive additional design time. In the ambulatory setting, the CDSS would need to be expanded to take into account additional patient-specific factors. We intend our experience to provide a baseline for considering the personnel time and costs that may be involved in developing CDSS. For facilities considering such a development, a particularly noteworthy finding was the many hours of physician and pharmacist time required. In most clinical settings, extensive involvement of these clinicians would place a heavy burden on the on-going functions of the facility. It is also clear that such a project would be difficult to undertake without many hours of time from an in-house informatics specialist with knowledge of the facility's electronic medical record and CPOE systems as well as an understanding of specific elements of their local implementation.

The goal of implementing a CDSS is to lower the rate of adverse events among patients and this will reduce the costs associated with treating adverse events. That cost reduction will offset a portion of the initial costs of implementing the system. Costs for treating adverse drug events have been estimated in the hospita^{22–26} and ambulatory settings²⁷ but we have found no comparable evidence from long-term care. In all of these settings the savings only partly accrue to the providers who pay for the development and implementation of the CDSS. This is a particular issue in the ambulatory and long-term care setting where the most serious and costly adverse events involve hospitalizations, which are usually the responsibility of other payers. Thus,

Table 5 Costs of Activities

			% of
Activity Category	Hours	Cost (\$)	Total Cost
Project management	80.25	2,220.17	5
Preparing contents of the CDSS	482.25	27,455.61	56
Informatics project management	121.7	4,987.27	10
Preparing blueprints and instructions for programmer	50.8	1,869.95	4
Programming	110.5	8,813.48	18
Testing and implementing	79.0	3,322.09	7
Total	924.5	48,668.57	

	Scenario 1 Renal Dosing Database Exists		Scenario 2 CDSS Product Exists		Scenario 3 CPOE System Does Not Require Special Programmer	
Activity	Hours	Cost (\$)	Hours	Cost (\$)	Hours	Cost (\$)
Project management	53.5	1,480	53.5	1,480	80.25	2,220
Preparing contents of the CDSS	241.2	13,728	241.2	13,728	482.25	27,456
Informatics project management	121.7	4,987	60.9	2,494	121.7	4,987
Preparing blueprints and instructions for progammer	50.8	1,870	12.7	467	50.8	1,870
Programming	110.5	8,813	27.63	2,203	110.5	3,413
Testing and implementing	79.0	3,322	79.0	3,322	79.0	3,322
Total	656.7	34,201	474.93	23,695	924.5	43,268

Table 6 Costs for Alternative Scenarios

prediction of the extent to which savings downstream will offset the initial costs is a complex undertaking.

Several of the alternative scenarios that we posited led to substantially lower cost and time estimates. Because over half of the time and costs were devoted to preparing the contents of the CDSS, the existence of an off-the-shelf CDSS product appropriate to the patient population had the largest impact on the costs, leading to an estimated total of \$23,694.51. However, even in this scenario our team estimated 241 hours of preparation time that would be spent reviewing and validating the CDSS rules, assessing the appropriateness of the alerts, and evaluating the system's acceptability to affiliated physicians and pharmacists. Commercial entities developing CDSS assume some legal responsibility for the use of their products so they often include an excessive number of alerts.^{18,19} The display of excess alerts and those perceived by prescribers as unnecessary or irrelevant have been found to lower the response of prescribers²⁸ so successful implementations usually include review by local clinicians and decisions to de-activate some alerts. Commercial CDSS products are also likely to be directed at broad patient populations so their rules and alerts will require careful local review and editing. Protection of the safety of patients requires complete testing of the alerts, with substantial time needed from pharmacists and possibly physicians. Thus, this scenario would reduce costs but the time required of clinicians would continue to burden the facility.

These estimates are based wholly on tracked personnel time combined with average U.S. hourly wages for categories of personnel. To allow these estimates to be of maximum use for sites considering parallel development, we did not include any costs specific to the facility or its personnel. Inclusion of overhead costs would add considerable expense. Cost estimates for personnel would differ by the level and experience of the staff members involved in the project. We also began the project within a fully implemented electronic medical record and CPOE system and a facility with a previous history of developing and using prescribing alerts. Thus, very little time was required for training and supporting users. Even for sites with an existing CPOE system in place, instituting a CDSS application for users with no previous experience would require substantial training.

Our time tracking process included only the development and initial implementation of the renal dosing CDSS. There

are likely to be substantial additional costs for maintaining the system over time. For example, six months after implementation there was a major upgrade to the underlying CPOE software that replaced components that the CDSS used. The alerts ceased appearing. Extensive time was required to trouble-shoot the problem, communicate with the vendor, and re-program the CDSS rules to function within the revised software. In addition, we project future changes to both the facility's formulary and the evidence that underlies our decisions about the CDSS content, both of which will require edits to the system. New clinicians will be added to the facility who will require training and support. As we continue to track utilization and its impact on prescribing behavior, we expect to find areas requiring revision. We also hope that future upgrades to the software will allow us to develop further enhancements to the CDSS. Each of these are important aspects of long-term maintenance that will add to the overall costs of developing and using CDSS, with cost and time implications that may surpass the initial outlay.

As the implementation of CPOE systems spreads through hospital, out-patient and long-term care settings, the opportunity to add clinical decision support to the prescribing process is considered one of the major advantages.¹² Currently, implementation of a CDSS that is truly responsive to the needs of a facility's patients and the practice style of its clinical staff appears to require individual site-specific adaptation. The estimates of time and cost found in our study should provide some guidance to plans for such development. The significantly lower estimated costs for implementation of a pre-constructed CDSS suggests one advantage for this option, although we project extensive time involvement from clinicians even for this alternative. The widespread use of CDSS may depend on the development of CDSS products that are based on the best evidence for specific patient populations and are compatible with a variety of popular CPOE software.

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