Implementation and Evaluation of Practice Guidelines

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ABSTRACT

Practice guidelines for the management of deep vein thrombosis were implemented in a Problem-Oriented Patient Management System on the HELP Hospital Information System at the LDS Hospital. A hierarchical knowledge representation was used. The Problem-Oriented Patient Management System was designed to generate patient-specific guideline suggestions according to the clinical situation at the time of generation. A retrospective evaluation was used to compare the appropriateness of the generated guideline suggestions to the appropriateness of the attending physician's management decisions. A significantly higher proportion of guideline suggestions was evaluated to be appropriate, compared to the proportion of attending physician's management decisions found to be appropriate.

INTRODUCTION

Practice guidelines are statements that recommend appropriate practice of patient care for specific clinical circumstances. The development of practice guidelines has gathered momentum in the 1990s, due to such factors as the increased health care spending, the rapid introduction of new technology, and concern about the quality of health care [1-4]. Many institutions, public and private, are involved in developing guidelines [1,3,5-12]. The expectation is that practice guidelines, by helping health care providers make more appropriate decisions, will result in less practice variation, in turn improving the quality of care and the benefit to cost ratio [1,4,5,13]. However, guidelines are not self-implementing [1]. Awareness of the existence of guidelines does not guarantee their use or even acceptance. Guidelines need to be used - their recommendations considered, then followed or rejected - to influence practice. Kosecoff et al. found that guidelines disseminated by the NIH Consensus Development Program did not influence physician practice, despite reaching the target audience [14]. Lomas et al. reported that obstetricians who received guidelines on Cesarean-section indications felt that their practice changed as a result of the guidelines. However, objective findings revealed no change in Cesarean-section rates. The authors concluded that although guidelines might predispose physicians to consider changing their behavior, other incentives or active efforts are needed to promote compliance [15,16]. Lomas conducted a later study that found significantly improved compliance when the same guidelines were actively promoted by influential opinion leaders among the obstetricians [17]. The study also showed that non-individualized audit and feedback did not improve compliance, in contrast to the good compliance reported in other studies when individualized monitoring and feedback were used [18-20].

Therefore, to be effective, guidelines must be integrated into the physician's decision-making process in daily practice. With the increasing presence of hospital information systems (HISs) in patient care, an HIS may be an effective mechanism to provide practice guidelines for use. This is suggested by the LDS Hospital's experience with the ventilator management protocols for patients with adult respiratory distress syndrome (ARDS). The ARDS protocols were initially developed to assure comparability of care in a randomized clinical trial comparing traditional positive pressure treatment of ARDS with extra corporeal carbon dioxide removal. The protocols started as 25 pages of paper flow diagrams which were later computerized, taking advantage of the patient database in the HELP HIS at the LDS Hospital. Certain information needed for protocol execution, such as the blood gas data, was available from the database, so that manual data entry was reduced. Based on the patient data, ventilator management instructions were automatically generated and available at bedside computer terminals round the clock. Care provider compliance with the paper protocol was found to be 84%, and the compliance with the computerized protocol was 64% in the start-up period (first 8 patients) and 92% subsequently. The survival rate of the ARDS patients in both periods of protocol use was 41%, more than four times that expected from historical data [21-23].

Since the ARDS protocols were developed for a specific project (a clinical trial), the computer module in the HELP system containing the computerized protocols was essentially "stand-alone" - that is, its knowledge could not be used for other patient care purposes. If this approach is used in other settings, a separate module will have to be developed for each set of guidelines. Yet it is likely that different modules may make use of some of the same patient data and medical knowledge. Keeping in mind the many

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guidelines that have been developed, and the potential numbers of guidelines to be developed, a Problem-Oriented Patient Management approach to implement practice guidelines is proposed. Such an approach is modeled after the problem-oriented concept introduced by Weed [24,25]. A Problem-Oriented Patient Management System is designed to contain multiple guidelines for a variety of clinical problems. By simply indicating the clinical problem to be managed, the physician can activate guidelines relevant to the problem. The Problem-Oriented Patient Management System is based upon a hierarchical, or layered, structure of knowledge representation. To illustrate the Problem-Oriented Patient Management System and its underlying knowledge representation scheme, practice guidelines for the management of Deep Vein Thrombosis (DVT) have been implemented on the HELP system.

METHODS AND PROCEDURES

The HELP (Health Evaluation through Logic Processing) Hospital Information System at the LDS Hospital served as the development platform for the Problem-Oriented Patient Management System. Clinical information on patients is routinely captured by the HELP system [26]. The clinical data can be used by the Problem-Oriented Patient Management System to generate patient- and situation-specific guidelines. In addition, implementing practice guidelines in a standardized computer subsystem on the HELP system allows the guidelines to be available on-line for routine clinical use.

The HELP system supports the Arden Homestead Medical Logic Module, an emerging standard for knowledge sharing [27]. The Arden syntax is based on the representation of medical knowledge in the form of structured frames called Medical Logic Modules (MLMs). Each MLM contains all the information required to define a single medical decision. Furthermore, the Arden syntax attempts to maximize readability so that the medical decision logic in each module may be examined and critiqued by medical experts with little experience with computers. Therefore, the MLMs are the logical choice as building blocks for the knowledge base in the Problem-Oriented Patient Management System.

A layered, hierarchical structure of knowledge representation with the MLMs is used for the Problem-Oriented Patient Management System. This representation allows a clear view of how different items of knowledge and data are used to arrive at a final guideline suggestion. Instead of one large, complex MLM containing multiple sublayers of rules, the semantic and logical connections between items of medical knowledge are represented by links within a layer of MLMs as well as links between layers of MLMs. MLMs are grouped into layers that represent disease problems, clinical events, goals, and actions. The "bottom-most" layer of MLMs each contains a single action, such as "change the IV heparin dosage". These action MLMs thus generate guideline recommendations. The action MLMs are the only MLMs that contain calls to hardware- or institution-specific routines, for example, to obtain patient data. The next layer of MLMs is the goal layer. Each MLM in the goal layer defines a goal, such as "adjustment of anticoagulant therapy", and calls upon the action MLMs required for the goal to be reached. The layer above the goal MLMs is the clinical event layer. The management of a clinical problem is triggered by a series of events, the first of which is the realization of the problem. Each subsequent management decision can be viewed as the result of a specific clinical event. The decision may be data-driven, in which case a change in management is determined by a specific piece of clinical data, or time-driven, in which case a management decision is made when a particular time is reached. Each event MLM calls and thus links together various goal MLMs pertinent to that clinical event. The "top-most" layer in the representation scheme is the problem layer. For a particular clinical problem, the associated problem MLM links together several event MLMs representing the possible events that may occur in the management of the problem.

This knowledge representation approach has been used to implement DVT management guidelines. As an example, figure 1 shows the representation of the following subset of DVT guidelines:

1. Anticoagulant therapy should be initiated with:
   a. a bolus dose of IV 5000 U heparin.
   b. IV heparin drip at 1680 U/hour.
   c. oral coumadin 10 mg.
2. Adjustment in IV heparin drip rate (dose) should be determined by PTT (Partial Thromboplastin Time) value.
3. A repeat PTT should be done 6 hours after a change in IV heparin drip rate.
4. Do a PTT at 6 am daily if none was done in the previous 6 hours.

When a physician interacts with the Problem-Oriented Patient Management System to manage a patient with DVT, the System determines the possible clinical events by looking at the DVT problem MLM in the problem layer and tracing the links to the event layer. If DVT is a new problem for this patient, the event MLM "new problem" is triggered, calling on the goal MLM "initiation of anticoagulant therapy", which

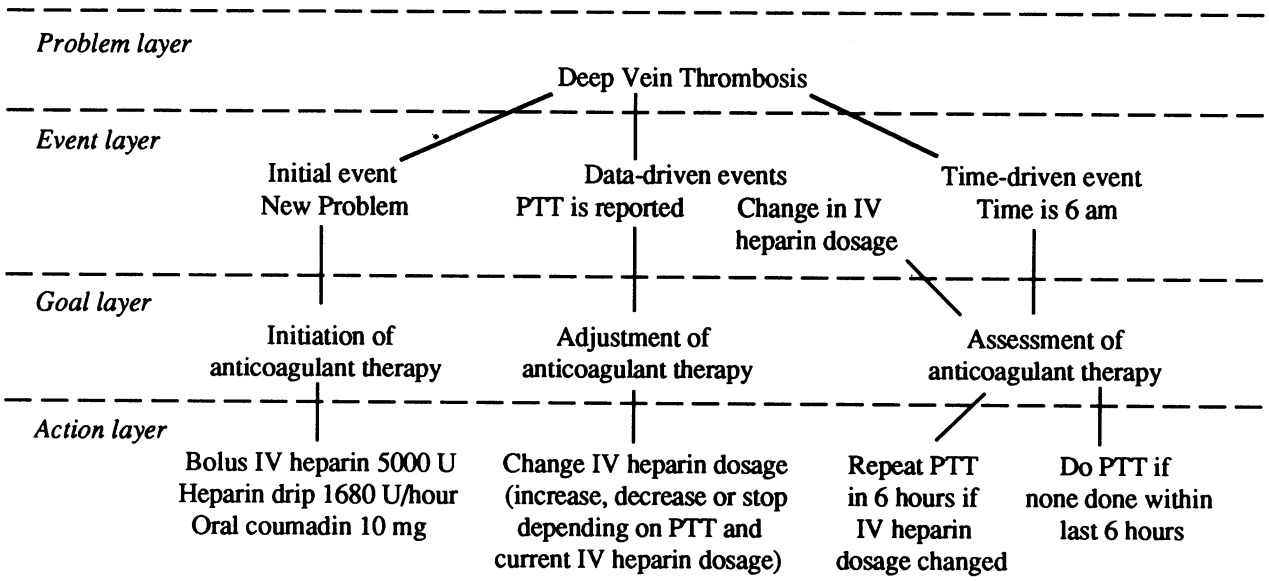
in turn calls the linked action MLMs (see figure 1) to generate the appropriate suggestions. In a similar fashion, at 6 am in the morning, the time-driven event MLM "the time is 6 am" is triggered. The event MLM calls the goal MLM "assessment of anti-coagulant therapy" which in turn calls the associated action MLM to assess if a PTT test were done within the last 6 hours, and if not, generate a suggestion to order one. When a PTT result is reported, the data-driven event MLM "PTT reported" is triggered, in turn triggering the goal MLM "adjustment of anticoagulant therapy" , which triggers the action MLMs for changing of heparin dosage (increasing, decreasing or stopping the heparin depending on the current heparin dosage and the value of the PTT). The action MLMs may call institution specific routines to gather relevant patient data, in this case the last heparin dosage. Suppose that the action MLM determined that the heparin dose should be increased. When a change in heparin dose is recorded, the "assessment of antic-oagulant therapy" goal is then triggered, resulting in the recommendation of a repeat PTT to be done in six hours time.

In clinical use, the Problem-Oriented Patient Management System is the interface for physicians to access relevant management guidelines and clinical data. The physician would begin interaction with the system by indicating the clinical problem to be managed for a particular patient. Based on the guidelines for that problem, stored in the Problem-Oriented Patient Management System, and the patient's clinical data, stored in the HELP database, the System will generate applicable guideline suggestions in the form of a treatment plan. The guideline suggestions may be the appropriate drug therapies and the laboratory investigations necessary to monitor the patient's progress, or other relevant recommendations such as nursing orders, dietary plans and therapeutic actions. The guideline suggestions are selected for their applicability to the patient's clinical situation at that time, and presented in a patient-specific form. For instance, if an applicable guideline is "give IV heparin 18 U/Kg body weight ", the Problem-Oriented Patient Management System will obtain the patient's body weight from the clinical database and generate the suggestion "give IV heparin 1350 U". Those guideline suggestions deemed not applicable to the patient's clinical situation will not be displayed.

To test the appropriateness of the guidelines generated by the Problem-Oriented Patient Management System, a retrospective evaluation technique using real patient cases was designed. Retrospective testing does not involve risk to human subjects and allows a systematic determination of the impact of practice guidelines. This is an important preamble to prospective studies or clinical use.

The retrospective evaluation was carried out for the DVT guidelines implemented in the Problem-Oriented Patient Management System. Clinical data and physician management decisions were obtained from the charts of ddischarged patients. Next, every clinical event in each case, defined as each point in time when the attending physician made a management decision, was identified, and the Problem-Oriented Patient Management System was used to generate the relevant guidelines for each of these critical times. The guideline suggestions

Figure 1. Hierarchical Representation of Knowledge



generated in this manner thus simulate those that would be received by the attending physician in a prospective study or actual clinical care. These retrospectively-generated guideline suggestions were then evaluated for their appropriateness. The appropriateness of the attending physician's management decisions in each of the events in the case were also evaluated and compared to the the computer-generated guideline suggestions for each event. If the guideline suggestions were judged to be appropriate when the attending physician made inappropriate decisions, then providing guideline suggestions to the physician could have prompted more appropriate care for the patient. Therefore, this evaluation also provided an indication of the potential usefulness of the Problem-Oriented Patient Management System.

For each case, the relevant patient data and the attending physician's management decisions were extracted from the patient chart and given with the computer-generated guideline suggestions to a "gold standard" physician for evaluation. The phrasing of both the guideline suggestions and the attending physician's decisions as "orders" are made as similar as possible, and the "gold standard" physician is blinded as to which "set" of "orders" are computer-generated and which came from the attending physician. Thus, for each point in the case when an event occurred, there would be two "orders" which may be identical or different, for example, "IV heparin 900 U/hr" versus "IV heparin 1000 U/hr". The two orders could be both evaluated by the "gold standard" physician to be appropriate or inappropriate, or one appropriate and the other inappropriate.

RESULTS

As a pilot study, the "gold standard" evaluation of five DVT cases was completed, thus providing some preliminary results.

The "gold standard" appropriateness evaluation results of the computer-generated guideline suggestions versus that of the attending physician's management decisions are summarized in table 1. Pooling the data from all five cases, there was a total of 247 "pairs" of "orders" (the computer-generated guideline suggestions versus the attending physician's management decisions). For 162 of these "pairs" of "orders", both the computer-generated guideline suggestions and the attending physician's management decisions were found by the "gold standard" evaluation to be appropriate. For 3 of these "pairs" of "orders", both the guideline suggestions and the attending physician's decisions were found to be inappropriate. For 72 of these "pairs" of "orders", the guideline suggestions were found to be appropriate while the attending physician's decisions were found to be inappropriate. For 10 of these "pairs" of "orders", the attending physician's decisions were found to be appropriate while the guideline suggestions were found to be inappropriate. The McNemar's chi-square test found a significantly higher proportion of computer-generated guideline suggestions to be appropriate, compared to the attending physician's management decisions ($p < 0.001$). Each individual case also showed a significantly higher proportion of appropriate computer-generated guideline suggestions ($p < 0.001$, $p < 0.01$, $p < 0.05$, $p < 0.01$, $p < 0.01$ respectively).

To summarize, 95% of all the computer-generated guideline suggestions (pooling the five cases) were evaluated to be appropriate (see table 2), while 70% of all the attending physician's management decisions were evaluated to be appropriate (see table 3). The paired t-test also found the difference between the two proportions to be significant ($p<0.001$).

A possible source of bias must be addressed. Because this was a pilot study, only one "gold standard" physician evaluated the guideline suggestions made by the Problem-Oriented Patient Management System. This physician did not participate in the development of the DVT guidelines, and care was taken to blind him to the origins of the "orders" he was asked to evaluate. However, it might still be possible for him to guess the source of the "orders". With this problem in mind, future evaluation is designed to be independently performed by two "gold standard" physicians, and inter-rater reliability will be calculated.

Nevertheless, it is felt that these initial results are encouraging. They indicate that the DVT guidelines generated by the Problem-Oriented Patient Management System are sufficiently appropriate to be potentially useful to clinicians in their DVT problem management. Additional cases will be evaluated to obtain more conclusive results. In addition, practice guidelines for other problems are planned for the Problem-Oriented Patient Management System and will also be evaluated upon completion. The Problem-Oriented Patient Management System thus shows

Table 1. "Gold Standard" Evaluation Results (Pooling all 5 Cases)

	Attending Physician's Decisions: Appropriate	Inappropriate
Computer Suggestions:		
Appropriate	162	72
Inappropriate	10	3

Table 2. "Gold Standard" Evaluation of the Computer-Generated Guideline Suggestions

Case	Appropriate	Inappropriate	Total
1	60 (95%)	3	63
2	50 (93%)	4	54
3	41 (89%)	5	46
4	45 (100%)	0	45
5	38 (97%)	1	39
pooled	234(95%)	13	247

Table 3. "Gold Standard" Evaluation of the Attending Physician's Management Decisions

Case	Appropriate	Inappropriate	Total
1	43 (68%)	20	63
2	38 (70%)	16	54
3	29 (63%)	17	46
4	34 (76%)	11	45
5	28 (72%)	11	39
pooled	172 (70%)	75	247

promise as an effective mechanism to provide practice guidelines for use by physicians. The retrospective evaluation method may also be useful as a safe and efficient preamble to a prospective evaluation of the impact of guidelines on physician practice.

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