Outcomes Research Using the Electronic Patient Record: Beth Israel Hospital's Experience with Anticoagulation

Jonathan S. Einbinder MD, Charles Rury BA, Charles Safran MD
Beth Israel Hospital, Harvard Medical School, Boston, Massachusetts

Using data captured as part of the routine care of outpatients taking the oral anticoagulant warfarin, we described variation in recording reasons for anticoagulation, selecting target International Normalized Ratio (INR) ranges, and performing coagulation blood tests. Laboratory results were directly captured by or entered into an Anticoagulation Flowsheet, a computer program which is fully integrated with our Online Medical Record (OMR). We studied the 177 patients with flowsheets between October 1993 and January 1995. 90% had a reason for anticoagulation entered; 29 different target INR ranges were entered. For patients with a target INR of 2.0-3.0, the mean number of weeks between blood tests, after a test which was in range, was three weeks (standard deviation 1.7 weeks, range one to twelve weeks). We conclude that routinely collected data contained in an electronic patient record (EPR) can be a rich resource for describing and evaluating clinical practice. We also address several limitations to using EPR data: validity of EPR information, lack of coded information, and imperfect capture of clinician thought processes.

INTRODUCTION

Increasing use of electronic patient records (EPR) has raised expectations of easy access to clinical outcomes data. However, the EPR does not, by itself, represent the solution to extracting, for clinical research, information contained in patient records.

We reviewed data contained in our EPR in order to study the care of outpatients who take the oral anticoagulant warfarin. In this paper, we present our results to demonstrate the promise of using the EPR for describing patient care and to illustrate issues which must be confronted to realize the potential of the EPR for outcomes research.

BACKGROUND

Study Site

The Beth Israel Hospital clinical computing system, developed by the Center for Clinical Computing, is a heavily used hospital information system.[1,2] Each week, clinicians use the system more than 50,000 times to look up laboratory results, review diagnostic reports, obtain medication and discharge information on hospitalized patients, and perform literature searches from any of 2000 terminals located throughout the hospital and outpatient facilities.

Online Medical Record

Healthcare Associates, an outpatient teaching practice affiliated with Beth Israel Hospital that had more than 39,000 visits by 12,500 patients in 1994, uses the Online Medical Record (OMR). Clinicians interact directly with OMR to enter and review many aspects of patient care, including progress notes, problem lists, medication lists, prescriptions, laboratory tests, and referrals.[3] OMR is fully integrated with the Beth Israel Hospital clinical computing system.

Anticoagulation Flowsheet

OMR contains several screening and flowsheets intended to facilitate patient care, e.g. for diabetes, prenatal care, and routine screening tests. The flowsheets gather and present, in one place, information from various parts of the patient record. Flowsheet information is automatically extracted from other parts of OMR or directly entered by the clinician.

In October 1993, an Anticoagulation Flowsheet option was introduced. (Figure 1) Prior to the introduction of this flowsheet, each nurse maintained a paper notebook, manually recording laboratory results and follow-up for patients taking warfarin. The anticoagulation flowsheet was intended to support the nurses' clinical workflow and to replace their notebooks.

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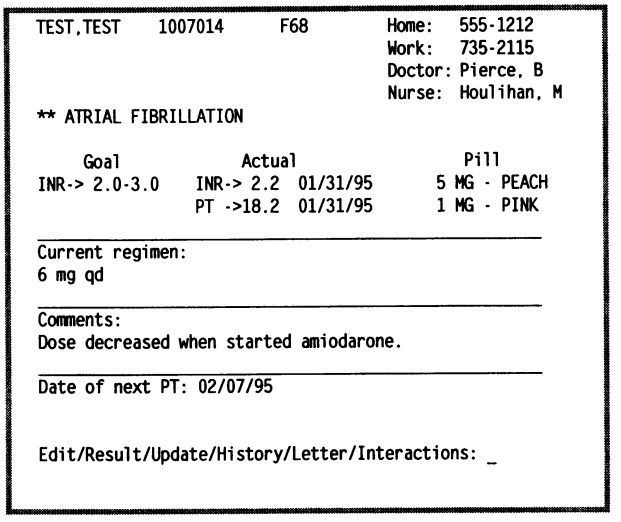

```
TEST,TEST    1007014      F68        Home:   555-1212
                                     Work:   735-2115
                                     Doctor: Pierce, B
                                     Nurse:  Houlihan, M
** ATRIAL FIBRILLATION

     Goal            Actual                  Pill
INR-> 2.0-3.0    INR-> 2.2  01/31/95      5 MG - PEACH
                 PT ->18.2  01/31/95      1 MG - PINK
_____________________________________________________
Current regimen:
6 mg qd
_____________________________________________________
Comments:
Dose decreased when started amiodarone.
_____________________________________________________
Date of next PT: 02/07/95

Edit/Result/Update/History/Letter/Interactions: _
```

Figure 1: Beth Israel Hospital Anticoagulation Flow Sheet.

This program permits any clinician to maintain a list of patients who are anticoagulated and to:

- document their warfarin dose
- record the reason for anticoagulation as well as the target International Normalized Ratio (INR) range
- review possible drug interactions
- record the telephone numbers of contact persons or outside laboratories
- enter test results from outside laboratories
- add free-text comments
- write a letter to a patient, incorporating blood test results
- indicate when the next blood test is expected to be performed.

Each night, a program searches for new results in the laboratory system and inserts these results into the appropriate flowsheets. If an unexpected result is found, an electronic message is sent to the nurse following the patient.

METHODS

We performed a retrospective analysis using data contained in OMR, Beth Israel Hospital's outpatient electronic record:

- *to describe, in Healthcare Associates, the management of outpatients taking warfarin.*
- *to assess and improve the use of the anticoagulation flowsheet.*

Patient Selection and Data Extraction

We wrote computer programs to identify patients who had an anticoagulation flowsheet used at least once between 10/28/93 (when the flowsheet option was first introduced) and 1/12/95 (when the study was performed). Additional programs were written to download selected information into a Microsoft Access™ database for further analysis. Information retrieved included:

- Patient demographic information
- Primary doctor, nurse
- Dates of warfarin prescriptions
- Reason for anticoagulation
- Target INR range
- Dates and values for all coagulation results entered into flowsheets
- Dates and locations of all visits-- outpatient, Beth Israel inpatient, emergency room (ER), and ambulatory surgery
- Diagnoses for inpatient and ER visits.

Online Chart Review

Online chart review of each patient's electronic record was performed to determine the start and end dates of anticoagulation therapy.

Focus Groups

Two meetings were held with the nurses and nurse practitioners who are responsible for following the majority of the anticoagulation patients. These meetings addressed three areas:

- Reviewing selection of target INR ranges, warfarin doses, and follow-up intervals
- Learning how the nurses actually use the flowsheet
- Obtaining feedback on the flowsheet and suggestions for improvement.

RESULTS

Identification of flowsheet patients

We found 177 patients who have had anticoagulation flowsheets used at least once between 10/28/93 and 1/12/95. This number corresponds with the practice's estimate of the number of anticoagulation patients followed in Healthcare Associates.

Reason for anticoagulation

Clinicians are prompted to enter a reason for anticoagulation into the flowsheet. They can choose from four coded choices (atrial fibrillation, deep venous thrombosis, cardiac

valve replacement, acute myocardial infarction) or can select "other" and enter a free-text reason. 159 (90%) out of 177 patients had a reason for anticoagulation entered into the flowsheet. For 64 of these 159 patients (40%), a reason other than one of the four coded choices was entered. (Table 1)

Reason for Anticoagulation	#Patients
Atrial Fibrillation	58
Cardiac Valve Replacement	25
Deep Venous Thrombosis	12
Acute Myocardial Infarction	0
No reason entered	18
Other	64
TOTAL	177

Table 1: Reasons for Anticoagulation

Target INR ranges

The flowsheet provides two default target INR ranges. A target range of 2.0-3.0 is suggested except in cases of mechanical valve replacements for which 2.5-3.5 is advised. We found that clinicians specified 29 different INR ranges. Eleven patients did not have a target INR range entered.

Follow-up after coagulation blood tests

There were 3,780 coagulation test results entered between 10/28/93 and 1/12/95. Of these, 3,750 included the INR, in addition to the prothrombin time. We focused on the 3,323 outpatient INR results for which the next blood test was also performed as an outpatient. Using this data, we have been able to look at routine follow-up for selected target INR ranges. An example is found in Figure 2.

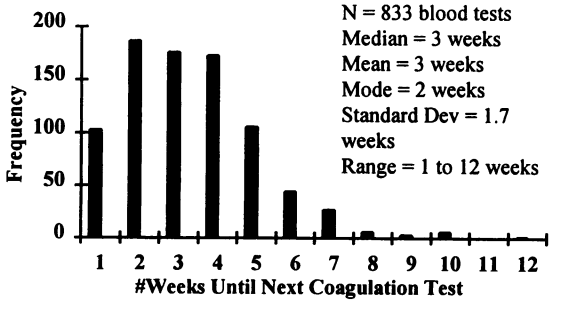

Figure 2: Frequency Distribution for # Weeks Until Next Coagulation Blood Test for Flowsheet Patients with Target INR 2-3 and Result INR 2-3.

DISCUSSION

Using routinely collected clinical data, we were able to describe selected aspects of the care of anticoagulation patients at Beth Israel Hospital and to demonstrate that there is variation in their treatment-- for instance, in selection of target INR ranges and in how often blood tests are performed.

Impact on patients

Identifying and decreasing clinical practice variation in anticoagulation has implications for cost, utilization of services, and patient satisfaction. It is unclear how often the INR should be measured to ensure stable control-- some authorities state that stable patients can be tested as infrequently as every eight weeks.[4] Our data suggests that many patients are monitored every two to five weeks, which is consistent with previous studies.[5] The difference in convenience and cost for a patient in having a blood test every two or three weeks versus every eight weeks is potentially significant.

Previous work has demonstrated that routinely collected clinical data stored in clinical information systems can be a rich resource for clinical research.[6] Our experience supports that premise, but also raises questions about the promise of the EPR for providing "easy" access to outcomes data.

Validity of EPR information

Warfarin was prescribed for 707 patients between 10/93 and 1/95; however, only 177 patients have flowsheets. Our analysis, to date, has focused on the 177 flowsheet patients. We are studying the 530 patients with warfarin prescriptions since 10/93 who do not have anticoagulation flowsheets-- we think that the majority of them are followed at outside physicians' offices (e.g. cardiology, orthopedics). The existence of a large number of anticoagulation patients who are largely unknown to the practice has obvious implications with regard to clinical quality and risk management and also to our efforts to build computerized tools for identifying and managing selected groups of patients.

The difficulty answering "simple" questions is only partly due to database design issues-- more significant is the imperfect entry and capture of

information such as when a medication has been discontinued or when a patient is no longer being followed for a problem.

Lack of coded information

The anticoagulation flowsheet contains both coded and uncoded data. (Table 2) In general, a clinician can reject coded choices and make free-text entries.

Coded Data Fields	Uncoded Data Fields
Reason for Anticoag.	Current Regimen
Target INR Range	Comment
Pill Type	Outside Lab Phone

Table 2: Examples of coded and uncoded flowsheet fields

Forty percent of the time, clinicians entered uncoded reasons for anticoagulation. There are several explanations for the entry of free-text reasons. Some were conditions we did not support as coded choices-- uncommon conditions, e.g. *lupus microthromboses,* and common conditions, e.g. *cardiomyopathy*. Free-text entries were also used to include modifiers such as *s/p*, *h/o*, *massive*, or *recurrent*. There were also variations on problems which conveyed more specific information than available coded choices, e.g. *PAF with cerebral embolus*. However, some free-text entries were exact or near duplicates of coded reasons.

Coded information is generally easier to extract from the record-- it can be readily downloaded, sorted, etc. However, as our experience demonstrates, even coded data are "dirty"-- one can not assume that appropriate data is always entered. To some extent this problem can be countered with strict input checking and by not allowing free-text entries; however, restrictions on input may also result in clinician frustration and loss of specificity.

EPR imperfectly captures how clinicians think

Current recommendations support only two target INR ranges[4]; we found 29 different ranges entered. However, 71% of the entered ranges are either 2.0-3.0 or 2.5-3.5. This suggests that clinicians are aware of current recommendations for intensity of anticoagulation, a supposition supported by our discussions with the nurses. Most of other entered ranges significantly overlap these limits, e.g. 1.7-2.7.

In our discussions with the nurses, it became clear that the target INR range was seen as a way to translate a *philosophy* of therapy into numerical limits. For example, a target INR range of 1.7-2.7 might mean, "Keep the patient between two and three, but preferably on the lower side." The imprecision of translating what clinicians mean into coded data should be taken into consideration when attempting to use the EPR to describe the patient care process.

Retrospective exploratory data analysis is difficult with a complex EPR

Several institutions have published their experiences with computer-based systems for monitoring patients taking warfarin.[7,8,9] Du Pont, the manufacturer of Coumadin™, even supplies upon request a PC-based program for this purpose.[10] These systems support entry of coagulation blood test results, and some also provide recommendations for warfarin dosage and blood test intervals. Their effects on intervals between visits and on the proportion of time coagulation tests are in the desired range have been studied in specialized clinics dedicated to monitoring anticoagulation patients.

Management of anticoagulation patients at Healthcare Associates is distributed throughout the practice, involving many physicians, nurses, and support staff. The Anticoagulation Flowsheet supports the care of the anticoagulation patients, but is only one piece of a heavily used, fully functional EPR. As our efforts have demonstrated, data extraction and analysis are difficult when anticoagulation data are integrated into a comprehensive EPR, such as the one at Beth Israel Hospital.

CONCLUSIONS

Our experience with anticoagulation illustrates that routinely collected data contained in an electronic patient record (EPR) can be a rich resource for describing and evaluating clinical practice. However, implementation of an EPR should not be expected to result in an immediate windfall of outcomes data. Achieving a successful EPR involves an ongoing cycle of design and redesign. In particular, careful attention must be paid to how clinicians use the EPR and to how well the EPR captures how they practice.

Future efforts

Our experience points to several limitations to using EPR data: validity of EPR information, lack of coded information, and imperfect capture of clinician thought processes. We plan several interventions to address these limitations.

To improve the validity of information on who is actually taking warfarin, we will identify patients who have not had a lab result entered for eight weeks-- if the clinician indicates that the patient is no longer taking warfarin, the medication list and flowsheet will be updated accordingly.

To improve the capture of coded reasons for anticoagulation, we will support the use of modifiers and will add coded options for commonly used free-text entries such as *cardiomyopathy*.

To explore more fully how clincians actually use and interact with the anticoagulation flowsheet, we will prompt them for a brief explanation when a non-standard INR range is entered.

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