# Anticoagulation Outcomes in a Pharmacy Clinic and in Other Settings

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Abstract

**Background**: Disease management programs, such as programs for managing anticoagulated patients, are receiving more attention as promising methods for improving outcomes in certain groups of patients. Carefully monitored anticoagulation therapy is important in preventing adverse events and outcomes in patients at risk for development of thrombi.

**Research questions**: Do patients who are followed in UMC's anticoagulation clinic (AC) have fewer subsequent hospitalizations and emergency department (ED) visits than patients who are not followed in the AC? Are AC patients more likely to maintain therapeutic INR levels than non-AC patients? What referral patterns exist at UMC for anticoagulation patients? Can data maintained electronically in laboratory and administrative files be used to monitor the effectiveness of a disease management program such as that administered by the AC?

**Results**: Sixty-nine percent of the sampled patients from the AC had no subsequent hospitalizations or ED visits compared to sixty percent of the patients followed in other clinics. There was no definitive difference in anticoagulation control as measured by the percentage of patients maintaining a therapeutic INR in the AC as compared to other clinics. The majority of patients (61 percent) requiring anticoagulation monitoring in this UMC sample were followed by the AC. Data maintained electronically can provide useful, but not comprehensive information that is helpful in gauging the effectiveness of a disease management program.

**Application to Health Information Management (HIM) education**: Emerging HIM roles are enhanced by knowledge of developments in reimbursement for disease management programs as well as the potential for monitoring outcomes and program effectiveness through routinely maintained clinical data.

## Background

Pharmacy-managed anticoagulation clinics have increased in number across North America as evidence has grown that such clinics are both clinically and economically effective. The University of Mississippi Medical Center began providing pharmacist-managed anticoagulation services in 1994. Following a physician-approved protocol, pharmacists monitor and adjust warfarin (Coumadin) therapy in order to maintain patients at appropriate therapeutic levels to prevent thromboembolic events.

An anticoagulation clinic, such as that offered by the University of Mississippi, is an example of a disease management program. Disease management is aimed at identifying diseases and patients who could require costly interventions and developing programs to maintain such patients at an optimum state of health. One approach to disease management is to analyze factors related to improved outcomes and cost-savings for many diseases using data mining techniques. Improved clinical guidelines can be developed when potential areas for improvement are identified.[1] Another approach would be to target a specific disease or treatment known to have definite risk factors that

without "perfect" management could lead to an increase in costly hospital admissions or emergency department visits.[2] The anticoagulation clinic at the University of Mississippi Medical Center (UMC) is an example of the latter approach.

UMC's anticoagulation clinic is also an example of a trend in reimbursement for pharmacists' cognitive services. UMC's Pharmaceutical Care Clinic at the Jackson Medical Mall became eligible to receive Medicaid reimbursement for patient visits when Mississippi became the first state to receive approval from the Centers for Medicare and Medicaid Services (CMS) to provide reimbursement from Medicaid for pharmacists' cognitive services.[3, 4] Such a reimbursement program is an example of an administrative program designed to save money that also has health benefits obtained by increasing the effectiveness of the patient's drug regimen through monitoring and counseling services provided by pharmacists. Medicaid previously had used a disease management approach in other states, although they had never before paid directly for pharmacists' evaluation and management of patients.

The Mississippi Medicaid Pharmacy Manual provides the requirements for reimbursement to pharmacists for Medicaid's disease management programs.[5] In order to be reimbursed, the pharmacist must pass a certifying examination to obtain special credentials to manage a particular disease. In 1999, the diseases eligible for this program were diabetes, asthma, hyperlipidemia, and coagulation disorders. The Medicaid program will pay for up to twelve disease-management encounters per year, which does not count against the limit of twelve physician office visits per beneficiary per year. The intent is to provide better access to health services for patients with the targeted diseases.

Why is anticoagulation therapy necessary? Prevention of the development of thrombi is important in high-risk patients because thrombosis can lead to embolism when a portion of the thrombus breaks off and travels through the circulatory system. Embolization can result in serious injury when an embolus lodges in a vital organ, such as the brain, heart, or lungs. Anticoagulation therapy reduces the risk of such injuries. For example, warfarin reduces the risk of ischemic stroke in patients with atrial fibrillation.[6] Trauma, bed rest, cancer, obesity, pregnancy, and prolonged sitting or standing may lead to deep vein thrombosis (DVT). A patient with a disorder such as DVT would be at risk for thromboembolic injury.[7] Patients at risk for DVT need anticoagulation therapy to prevent thrombosis and the concomitant risks of embolization.

Warfarin given orally is the most common form of outpatient anticoagulant therapy. Its effects are monitored by the International Normalized Ratio (INR).[8] The INR was introduced by the World Health Organization (WHO) as a mechanism to allow comparability of results from different labs. Prothrombin time (PT) results can vary from laboratory to laboratory, depending on the thromboplastin the laboratory uses. The formula for calculating the INR adjusts for these differences.[9]

Warfarin's antithrombotic effect is seen within four to five days of starting therapy. The effects of warfarin persist after the drug has been discontinued. The major complication of warfarin therapy is bleeding. Bleeding can result from excess warfarin, which is treated by administration of vitamin K. Because foods containing vitamin K inhibit the action of warfarin, patients must be educated about which foods contain this vitamin and must maintain a consistent intake of such foods. Also there are numerous drug interactions of which warfarin patients and clinicians must be aware.[10] All of these factors require monitoring and education to assure that the patient receives the maximum

benefit from the warfarin therapy with the minimum possible risk. Pharmacist-managed programs have been used to provide cost-effective treatment for these types of patients.[11]

## Literature Review

Previous studies of pharmacy-driven anticoagulation monitoring have shed light on the effectiveness of pharmacy involvement in the management of anticoagulation patients.

One of the first outcomes studies on this topic was from the early 1990s. A new pharmacy-managed anticoagulation service had been established to perform the following functions: chart review, lab interpretation, dosage recommendation, physician and patient education, and coordination of follow-up. They compared 52 patients in the new program with 97 previous patients and found that patients in the new program were more likely to have therapeutic prothrombin times at the initial follow-up appointment.[12]

More recent studies have also shown improved outcomes. In one retrospective study, outcomes for anticoagulation monitoring service patients were compared with outcomes for family practice residency patients (control). Patients in the control group were 20 times more likely to experience either a thromboembolic or bleeding event. Since costs for these adverse events totaled $119,075 ($5040 per person, per year), this study indicated that a pharmacist-managed anticoagulation service could result in cost savings in addition to improved clinical outcomes.[13]

Another study showed a decrease in warfarin-related readmissions for a new anticoagulation clinic that received patients referred after hospitalization. This study paired clinic patients with controls who were on warfarin while in the hospital, but were not referred to the clinic after discharge. Patients from the anticoagulation clinic were found to have had fewer warfarin-related readmissions within 90 days post-discharge.[14]

A 1998 study examined anticoagulation control, outcomes, and costs for patients in an anticoagulation clinic (AC) as compared to those receiving usual medical care. It was found that the AC patients had more INR values in the therapeutic range, fewer bleeding events and fewer thromboembolic events than the patients receiving usual medical care. The study also estimated cost savings of over $168,000 per 100 patients annually in reduced hospitalizations and emergency department visits.[15]

## Objective

The objective of this study is to compare the effectiveness of the University of Mississippi Medical Center (UMC) Anticoagulation Clinic (AC) with other UMC settings for anticoagulation control and to examine differences in outcomes as measured by subsequent hospitalizations and emergency department visits.

## Research Questions

1. Do patients who are followed in the AC have fewer subsequent hospitalizations and emergency department visits than patients who are not followed in the AC?
2. Are AC patients more likely to maintain therapeutic INR levels than non-AC patients?
3. What referral patterns exist at UMC for anticoagulation patients?

4. Can data maintained electronically in laboratory and administrative files be used to monitor the effectiveness of a disease management program such as that administered by the AC?

**Methods**

Patients selected for inclusion were those who had INR test results in the UMC laboratory database between July 1, 1998 and June 30, 1999, and who also had one of the following diagnoses or procedures:

- deep vein thrombosis
- aortic valve replacement
- mitral valve replacement
- transient ischemic attack
- “stroke” or cerebrovascular accident
- atrial fibrillation.

**Data for Analysis**

Hospitalization and emergency department visits would be identified by INR test results sent to inpatient units or the emergency department.

Anticoagulation control would be measured by INR values within therapeutic range (4.0 >= 1.7).

Referral patterns would be identified by identifying the outpatient clinics to which INR results were sent.

**Sources of Data**

Two computer-generated files provided the data used for this study:

(1) a laboratory file containing INR results and locations (clinics and other patient care units) where the results were sent and

(2) a file from the SMS system containing diagnoses and locations of service.

After removing duplicate dates of service from the laboratory file, the lab file was merged with the SMS file. The resulting merged file was then purged to eliminate:

(1) patients who had INR results but none of the diagnoses or procedures included in the study and

(2) patients who had a diagnosis or procedure included in the study but no INR results.

Three-hundred-ninety-eight patients were identified who had both INR results and one of the diagnoses or procedures included in the study.

**Data Analysis Techniques**

Data files were analyzed using both SPSS and Excel. Using SPSS, the names of inpatient units and clinics were re-coded and categorized to provide more meaningful groupings of data. Likewise, INR test results were re-coded in order to group them into three categories—"low," "acceptable," and "high." SPSS was also used to cross-tabulate categories of INR results by clinic groupings.

In Excel, INR results were sorted by patient number and by date. This resulted in a spreadsheet of 3,374 rows that could be used to identify apparent patterns in referrals and inpatient (IP) and emergency department (ED) admissions. For example, a patient whose initial INR results were sent to an inpatient unit, but whose subsequent results were sent to the anticoagulation clinic would be interpreted as an inpatient subsequently referred to the anticoagulation clinic. When INR results were sent to a clinic, then later to an inpatient unit, this pattern would be interpreted as a clinic patient with a subsequent IP admission. Identifying these patterns was a manual process, so 1,691 rows of data (more than 50 percent) were selected as a sample. This sample included 183 patient episodes for analysis.

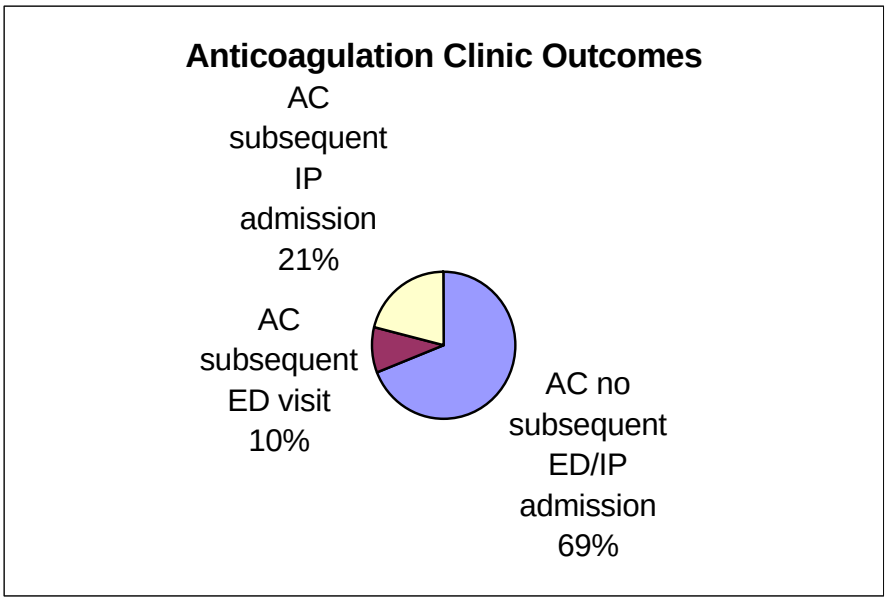
**Results and Discussion**

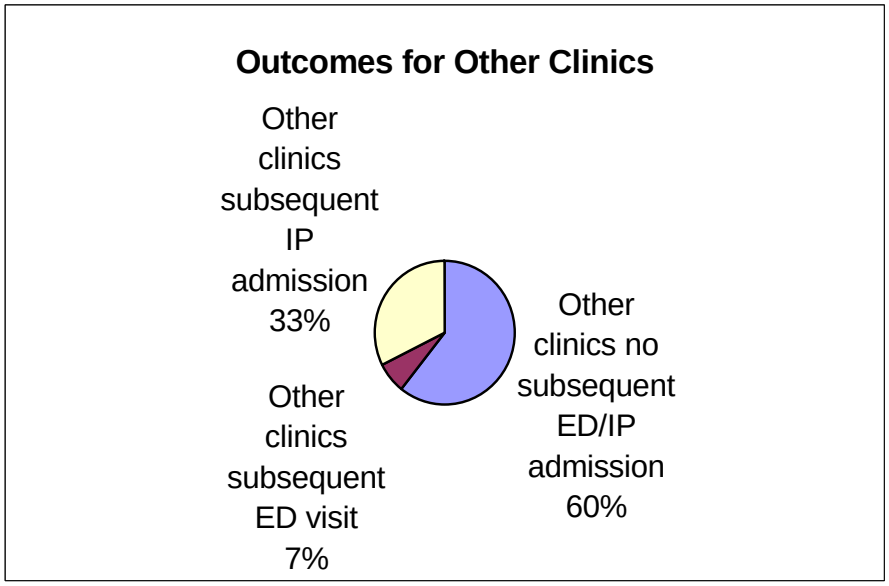
Subsequent Hospitalizations and Emergency Department Visits

As Table one and the accompanying charts indicate, the outcomes for the anticoagulation clinic (AC) appear to be better with regard to subsequent emergency department (ED) and inpatient (IP) admissions. Sixty-nine percent of AC patient episodes avoided subsequent ED and IP admissions, compared to sixty percent of the episodes of other clinics. Although other clinics' ED admission rate was slightly lower (seven percent compared to 10 percent for the AC), inpatient admissions for other clinics were substantially higher (33 percent compared to 21 percent for the AC). Since an inpatient admission is ordinarily a more serious outcome than an emergency department visit, the higher rate of inpatient admissions for other clinics appears significant.

**Table 1**

| Clinic and Outcome | Outcome Frequency | As a Percent of Clinic Outcomes | Subtotal Category | Sub-total |
|---|---|---|---|---|
| AC no subsequent ED/IP admission | 75 | 68.8% | | |
| AC subsequent ED visit | 11 | 10.1% | | |
| AC subsequent IP admission | 23 | 21.1% | Subtotal AC | 109 |
| Other clinics no subsequent ED/IP admission | 26 | 60.5% | | |
| Other clinics subsequent ED visit | 3 | 7.0% | | |
| Other clinics subsequent IP admission | 14 | 32.6% | Subtotal other clinics | 43 |
| No clinic follow-up (ED or IP admission only) | 31 | n/a | Subtotal non clinic | 31 |
| TOTAL all patient episodes in sample | 183 | | | 183 |



**Therapeutic INR Levels**

Table two shows that only one clinic, the hypertension clinic (HTN), maintained a better ratio of therapeutic INR levels than the anticoagulation clinic (AC). At 63.0 percent acceptable, the AC INR levels are only slightly better than average (61.5 percent) with the HTN clinic included in the analysis.

Table Two
Therapeutic INR Levels by Clinic

| | | Location of Clinics by Category | | | | | | | Total |
|---|---|---|---|---|---|---|---|---|---|
| | | Adult ER | AC | CARD | CHST | HTN | MED | Other | |
| Low | Count | 46 | 327 | 9 | 38 | 50 | 36 | 102 | 608 |
| | Percentage within clinic location | 36.2% | 31.3% | 40.9% | 32.5% | 18.4% | 40.4% | 42.5% | 31.8% |
| Acceptable | Count | 68 | 659 | 9 | 69 | 199 | 47 | 125 | 1176 |
| | Percentage within clinic location | 53.5% | 63.0% | 40.9% | 59.0% | 73.2% | 52.8% | 52.1% | 61.5% |
| High | Count | 13 | 60 | 4 | 10 | 23 | 6 | 13 | 129 |
| | Percentage within clinic location | 10.2% | 5.7% | 18.2% | 8.5% | 8.5% | 6.7% | 5.4% | 6.7% |
| Total | Count | 127 | 1046 | 22 | 117 | 272 | 89 | 240 | 1913 |
| | Percentage within clinic location | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |

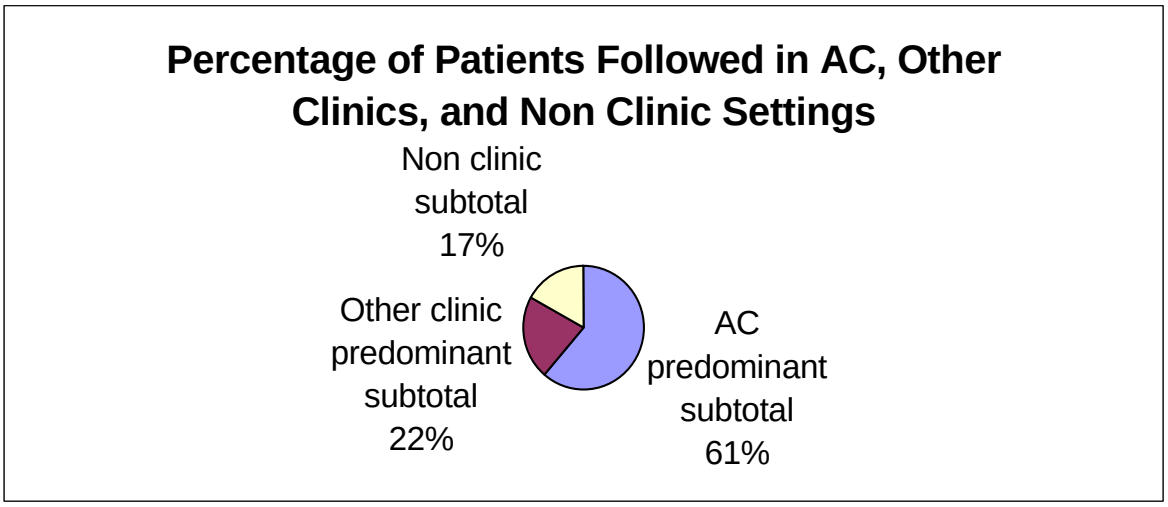
No inpatient data is included in Table two.

**Referral Patterns**

Table three shows that the majority (61 percent of patients in need of anticoagulation monitoring are followed in the anticoagulation clinic. However, in conducting this analysis, it was noted that patients are often followed in more than one clinic simultaneously, possibly indicating multiple problems or diagnoses. This could have implications for outcomes analyses, since patients with more problems may be expected to be at higher risk for ED or IP admission.

**Table 3**

| Visit and Referral Patterns by Episode | Frequency | Percent | Predominant Clinic | Frequency | Percent |
|---|---|---|---|---|---|
| AC only | 38 | 20.8% | | | |
| Inpatient or ED to AC | 29 | 15.8% | | | |
| Inpatient to other clinic to AC | 5 | 2.7% | | | |
| Multiple clinics, AC more frequent | 36 | 19.7% | | | |
| Other clinics to AC | 4 | 2.2% | AC predominant subtotal | 112 | 61.2% |
| Inpatient to other clinic | 10 | 5.5% | | | |
| Multiple clinics, other clinic more frequent | 7 | 3.8% | | | |
| Other clinics only | 23 | 12.6% | Other clinic predominant subtotal | 40 | 21.9% |
| Inpatient or ED only (no clinic visits) | 31 | 16.9% | Non clinic subtotal | 31 | 16.9% |
| Total number of patient episodes in sample | 183 | 100.0% | | 183 | 100.0% |



**Use of Electronic Data in Monitoring the Effectiveness of a Disease-Management Program**

There are limitations in using electronic data for monitoring the effectiveness of a disease-management program. Because the researcher does not have complete records for each patient available, the meaning of patterns discovered is uncertain. For example, a subsequent inpatient admission after being followed in the AC is viewed as a negative outcome for the AC. However, the subsequent inpatient admission could be the result of an accident or injury totally unrelated to the patient's treatment in the AC. Data files that deal with limited subsets of information, such as those used in this study, cannot provide the level of detail needed for conclusive results. However, such files can provide a "ballpark" idea of whether a disease management program is achieving its objectives.

An advantage of using a "big picture" data set is that patterns can be discovered that were not necessarily the focus of investigation. For example, one pattern noted in this data set indicates that one factor in successful anticoagulation outcomes is the pattern of follow up. Three patterns were noted in the data:

(1) patient was followed consistently for three months or more,
(2) patient's follow-up was inconsistent (possibly because of noncompliance and missed appointments), and
(3) patient was followed for less than three months.

Table four shows that in this study, 81.9 percent of the patients who were followed according to the first pattern avoided subsequent IP admissions and ED visits. On the other hand 60.9 percent of the patients with inconsistent follow up were admitted to the ED or IP status during the time frame of this study. The results for those who have been in follow-up for only a short time (less than three months) are not so dramatic, possibly because some patients achieve good compliance early in the monitoring period.

Table Four
Outcomes by Follow-Up Pattern

| | | Frequency | Percentage |
|---|---|---|---|
| **Pattern No. 1** | **Followed consistently for three months or more** | | |
| | no subsequent admission or ED visit Total | 59 | 81.9% |
| | subsequent ED visit Total | 8 | 11.1% |
| | subsequent IP admission Total | 5 | 6.9% |
| **Pattern No. 2** | **Inconsistent follow-up** | | |
| | no subsequent admission or ED visit Total | 9 | 39.1% |
| | subsequent ED visit Total | 4 | 17.4% |
| | subsequent IP admission Total | 10 | 43.5% |
| **Pattern No. 3** | **Less than three months of follow-up** | | |
| | no subsequent admission or ED visit Total | 33 | 57.9% |
| | subsequent ED visit Total | 2 | 3.5% |
| | subsequent IP admission Total | 22 | 38.6% |

With regard to achieving success as a disease management program, Table five indicates that AC patients fall into pattern one (the most successful pattern) more frequently than do the other clinics. Pattern two (the least successful pattern) is the least frequent pattern found in the AC. Pattern three also is found less frequently in the AC than in other clinics.

Table Five
Follow-Up Patterns by Clinic

| **Clinic** | **Pattern No.** | **Subtotal by Clinic/ Pattern** | **Percent of Pattern for Clinic** |
|---|---|---|---|
| AC | 1 | 58 | 53.2% |
| AC | 2 | 13 | 11.9% |
| AC | 3 | 38 | 34.9% |
| Total AC | | 109 | 100.0% |
| Other | 1 | 14 | 32.6% |
| Other | 2 | 10 | 23.3% |
| Other | 3 | 19 | 44.2% |
| Total Other | | 43 | 100.0% |

The data in Table five may also be related to some of the administrative issues presented earlier. Perhaps the fact that Medicaid does not count these clinic visits against regular physician visits provides incentive for this portion of the population to visit the AC on a more regular basis.

**Conclusions and Recommendations**

Do patients who are followed in the AC have fewer subsequent hospitalizations

and emergency department visits than patients who are not followed in the AC? Are AC patients more likely to maintain therapeutic INR levels than non-AC patients? What referral patterns exist at UMC for anticoagulation patients? Can data maintained electronically in laboratory and administrative files be used to monitor the effectiveness of a disease management program such as that administered by the AC?

The data used in this study indicate that AC patients do have fewer subsequent hospitalizations and ED visits than other clinic patients. However, there was no clear evidence that AC patients were more likely to maintain therapeutic INR levels than non-AC patients. Referral patterns overall indicated that the majority of patients (61 percent) were being followed predominantly by the AC. The electronic data used in this study provided opportunities to discover patterns in the data set that may have otherwise been missed. However, the electronic data available was limited in scope and could not be relied upon to provide definitive answers because of the many unknown factors not included in the data set.

Recommendations for future study center on providing more conclusive answers to the research questions raised. Two approaches are possible that should yield more reliable data. One approach is the traditional medical record review, in which relevant data is abstracted from patient clinical records. A newer approach would be to use a more complete data set obtained in electronic form from UMC's "Lifetime Clinical Record" (LCR). At the time this research was undertaken, very little data was available in the LCR. However, this institutional data repository has been growing over the past year, and much more detailed data is now available. Difficulties that arose in trying to merge the two data sets used for this study would be avoided with the LCR since all data items could be obtained from a single source.

**Application to Health Information Management Education**

HIM students can benefit from exposure to studies of this type as they consider emerging professional roles. This project has implications for at least two HIM roles identified by the American Health Information Management Association's Vision 2006 project – clinical data specialist and data resource administrator.[16] The role of the clinical data specialist requires expertise in outcomes management. Evaluating methods for monitoring the outcomes of disease management programs, such as a pharmacist-managed anticoagulation clinic, can provide HIM students with valuable insights into this role. In another HIM role, data resource administrators make use of data repositories and data warehouses to meet the information needs of their organizations. Projects such as this can provide a starting point for students to examine how to improve the structure of data resources so that outcomes of disease management programs can be routinely monitored with a minimum of effort. A final point to consider is that HIM students should be aware of trends in reimbursement. Directly reimbursing pharmacists for encounters with patients is a relatively new concept and can be used to demonstrate how policy makers attempt to use reimbursement systems to improve access to care while at the same time decreasing costs through improved outcomes.

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References


1. Marietti, Charlene. “Seize the Disease.” *Healthcare Informatics* 16, no. 3 (1999): 44-50.
2. Cottrell, Carlton. “Measuring, Managing, Making a Difference.” *Journal of the American Health Information Management Association* 70, no. 4 (1999): 28-33.
3. University of Mississippi Medical Center, “Pharmaceutical Care Clinic leads nation with Medicaid OK,” *This Week at UMC,* May 3-8, 1999, p. 1-2
4. St. Anthony Publishing, “Mississippi's Medicaid Pharmaceutical Care Program Receives HCFA Approval,” *Payment Strategies for Pharmaceutical Care* 3, no. 7 (1998): 5-6
5. State of Mississippi, Division of Medicaid, “Chapter 7: Disease Management Services,” in *Pharmacy Manual* (Jackson, MS: State of Mississippi, 1998) 1-4.
6. Hansen, Margie, “Disorders of Hemostasis,” *Pathophysiology: Foundations of Disease and Clinical Intervention.* (Philadelphia, PA: W. B. Saunders Company, 1998), 315-319.
7. O’Reilly, Robert A., “Drugs Used in Disorders of Coagulation,” in *Basic and Clinical Pharmacology*, ed. Bertram G. Katzung (Stamford, Connecticut: Appleton & Lange, 1998), 547-562.
8. Lehne, Richard A. *Pharmacology for Nursing Care,* 3rd ed. (Philadelphia, PA: W. B. Saunders Company, 1998), 533-551.
9. Go, A. S. et al., “Warfarin Use Among Ambulatory Patients with Nonvalvular Atrial Fibrillation: The Anticoagulation and Risk Factors in Atrial Fibrillation (ATRIA) Study,” *Annals of Internal Medicine* 131, no. 12 (1999): 927-934.
10. Yanchick, Jillmarie K., “Implementation of a Drug Therapy Monitoring Clinic in a Primary-care Setting” *American Journal of Health-System Pharmacy* 57, no. 24, Supplement 4 (2000): S30-S37.
11. Beers, Mark H. and Robert Berkow, eds. *The Merck Manual of Diagnosis and Therapy*, 17th ed. (Rahway, N.J.: Merck Research Laboratories, 1999), 910-911.
12. Ellis, R. F., M. A. Stephens, and G. B. Sharp. “Evaluation of a Pharmacy-Managed Warfarin-Monitoring Service to Coordinate Inpatient and Outpatient Therapy.” *American Journal of Hospital Pharmacy* 49, no. 2 (1992): 387-394.
13. Wilt, V. M., J. G. Gums, O. I. Ahmed, and L. M. Moore. “Outcome Analysis of a Pharmacist-Managed Anticoagulation Service.” *Pharmacotherapy* 15, no. 6 (1995): 732-739.
14. Lee, Yu-Ping, and Jon C. Schommer. “Effect of a Pharmacist-Managed Anticoagulation Clinic on Warfarin-Related Hospital Readmissions.” *American Journal of Health-System Pharmacists* 53, no. 13 (1996): 1580-1583.
15. Chiquette, Elaine, Mary G. Amato, and Henry I. Bussey. “Comparison of an Anticoagulation Clinic with Usual Medical Care.” *Archives of Internal Medicine* 158, no. Aug 10/24 (1998): 1641-1647.
16. American Health Information Management Association. *Evolving HIM Careers: Seven Roles for the Future.* (Chicago: American Health Information Management Association, 1999).