



A New Approach to Anticoagulation Therapy: the Fiscal and Quality Impact of Computerized Decision Support and Point of Care Testing

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Background:

In the United States, most chronic anticoagulation treatment is provided by personal physicians.¹ Anticoagulation therapy with this traditional approach has been associated with significant risk of adverse outcomes.ⁱⁱ According to studies sponsored by the Agency for Health Care Policy and Research, inappropriate or insufficient use of anticoagulation results in 40,000 strokes and 600 million dollars in health care costs annually. Sub-specialty anticoagulation clinics have been shown to improve clinical outcomes compared to traditional care.ⁱⁱⁱ However, use of this approach has been limited by insufficient number and capacity of existing clinics, due largely to expense and difficulty of clinic implementation and administration.

The problem, in essence, is how to provide a means of monitoring and administering anticoagulation therapy in a primary care setting that is cost effective, reproducible, and therapeutically efficacious.

Purpose:

To evaluate the use of Point of Service (POS) testing in combination with computerized decision support (CDS) as a means of managing anticoagulation therapy.

Methods:

As a component of a study sponsored by the National Institutes of Health, two primary care clinic systems were compared with respect to approaches used for anticoagulation and clinical results achieved. One system (test group, n=139) utilized an experimental approach combining POS testing and CDS for anticoagulation management. The other system (control group, n=51) used a traditional approach to anticoagulation, consisting of centralized laboratory testing, paper based record keeping and telephone contact. The population characteristics for both groups are outlined in Table 1. Endpoints in this study included:

1. Frequency of test results within therapeutic range;
2. Documentation of treatment indication, INR goal, therapy duration, and testing intervals;
3. Complications related to anticoagulation therapy;
4. Treatment related complications and costs;
5. Fiscal impact on participating systems.

The decision support software used in this study is CoagClinic™, by Standing Stone, Inc. The software is designed to reduce potential sources of medical error, facilitate decision support through automated guideline enforcement, and assist with documentation requirements. The software is currently in use in 96 health care systems throughout the United States. As of January 2004, approximately 30,000 patients were being monitored with CoagClinic™, with approximately 270,000 patient encounters recorded in 2002. The POS testing device used in this study is the CoaguChek™, by Roche Diagnostics. This CLIA-waived device allows reliable INR testing onsite with a laboratory turnaround time measured in minutes. Previous evaluation of this instrument has shown good reliability and reproducibility of results.

Results:

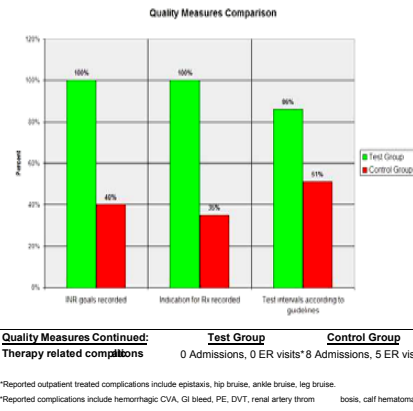
Population characteristics for each patient group were similar, with a slightly higher percentage of valvular heart disease noted in the test group (see Table 1). Over a 3-month evaluation period, the test and control groups were compared with respect to INR compliance, as defined by the frequency of INR results found to be within therapeutic range. For the test group (see Figure 2), INR compliance was significantly better at 62%, compared to 38% for the control group (p<0.01). The test and control groups were examined with respect to several quality measures, including chart documentation of INR goal and indication for therapy, as well as the degree of compliance with recommended testing intervals. As shown in Figure 1, documentation of INR goal and indication for therapy were 100% for the test group, as opposed to 40% and 35% for the control group, respectively. Compliance with testing intervals was 86% for the test group, and 51% for the controls (p<0.01).

The INR compliance rate for the test group exceeded those reported for sub-specialty anticoagulation clinics previously.^{iv}

Table 1. PATIENT POPULATION CHARACTERISTICS

| Population Characteristics | Test Group | % | Control Group | % |
|----------------------------|------------|-----|---------------|-----|
| Total # patients | 139 | | 51 | |
| Mean Age | 67.1 years | | 68.5 years | |
| Male gender | 63 | 45% | 26 | 51% |
| Female gender | 77 | 55% | 25 | 49% |
| INR goal = 2.5 | 97 | 70% | 45 | 88% |
| INR goal = 3.0 | 39 | 28% | 5 | 10% |
| INR goal = other | 3 | 2% | 1 | 2% |
| Afib | 38 | 28% | 17 | 33% |
| DVT | 35 | 25% | 18 | 35% |
| Valve disease | 36 | 26% | 5 | 10% |
| PE | 9 | 6% | 2 | 4% |
| CVA/TIA | 11 | 8% | 2 | 4% |
| Other | 10 | 7% | 7 | 14% |

Figure 1. COMPARISON OF APPROACHES



Quality Impact:

The test and control groups were evaluated over a one year period with respect to treatment related complications. Chart data were reviewed, and all instances of hospital admissions and emergency room visits examined. A treatment related complication was defined as an episode of significant bleeding or thrombosis temporally associated with an INR outside the therapeutic range. In the control group, 13 complications occurred that required hospitalization and/or ER treatment. The test group experienced four minor complications treated in clinic, none of which required ER treatment or hospitalization. For the test group, this represented a relative risk reduction of 89%, odds ratio = 0.11 (95% CI = 0.0352, 0.3622). These results are summarized in Figure 3.

Financial Impact

The thirteen complications that occurred in the control group resulted in hospitalization and emergency room charges totaling \$336,347.44. The four complications noted in the test group resulted in outpatient treatment charges of \$225.00. A comparison of the two methodologies showed potentially avoidable costs of \$6614.00 per patient treated per year.

The test group site generated additional revenue charges of \$320.56 per patient per year, based on Medicare minimum allowable charges. Based on proformas developed previously, labor related overhead costs related to anticoagulation treatment were found to be reduced by approximately 75% in the test group.

Figure 2. COMPARISON OF APPROACHES FOR INR COMPLIANCE RATES

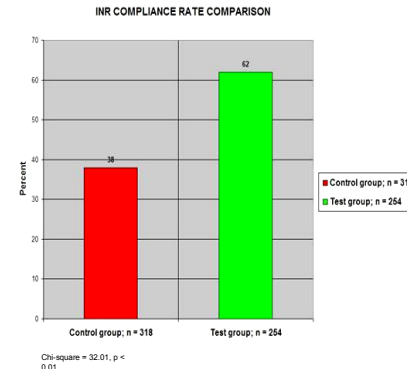
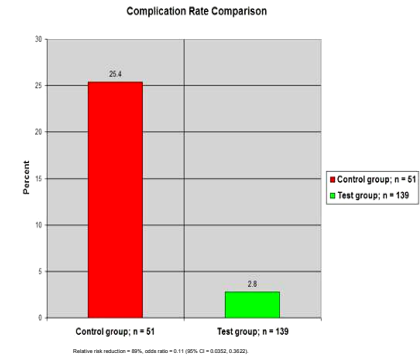


Figure 3. COMPARISON OF APPROACHES FOR COMPLICATIONS



Conclusion:

An approach combining computerized decision support and point of service testing can significantly improve the quality of care for patients undergoing chronic anticoagulation therapy, while also providing improvements in financial efficiency for participating groups. The approach is efficient enough in terms of implementation costs and labor support to allow its use in a variety of situations, including primary care sites, rural locales and underserved populations. The economic viability as well as positive effects on quality of care of this approach have been confirmed in widespread commercial use.^{vi} Studies to evaluate the potential of this approach to improve quality of care for anticoagulation on a larger scale are under consideration by the National Institutes of Health.

References:

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- ^{iv}Chiquette E, Amato M, Bussey H. Comparison of an anticoagulation clinic with usual medical care. Arch Intern Med 1998; 158; 1641-1647.
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