

Codman Awards

Reduction in Anticoagulation-Related Adverse Drug Events Using a Trigger-Based Methodology

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Novant Health System, with seven hospitals, three nursing home and senior residential facilities, physician practices, outpatient surgery centers, rehabilitation and community health outreach programs, serves 3.4 million residents in western North Carolina.

In 2001 the system participated in a VHA Research Series multicenter (13 health care systems) collaborative on adverse drug events (ADEs). Data for the collaborative revealed 763 ADEs for the 3,078 records reviewed from the 13 systems; an ADE occurred in one of every four admissions. On the basis of these data, the system's executive team made reduction of patient harm from medication-associated events a long-term corporate goal. The first phase of an overall program to reduce ADEs from high-use medications that are associated with the greatest potential for harm focused on warfarin-associated events, one of the most common types of ADEs across the collaborative and at Novant Health. This initiative is reported in this article.

The ADE Reduction Team, established at Novant Health in early 2002, consisted of three vice presidents of medical affairs, four pharmacists and two pharmacy directors, three nursing leaders, two outpatient medical directors, a senior vice president of clinical improvement [D.B.], a medical director of clinical improvement [J.L.], and clinical improvement department support personnel. The ADE Reduction Team began trial data collection in April 2002 to ensure valid sample identification, chart extraction, and inter-observer reliability. Baseline ADE data were established starting July 2002, when the team also began developing process improvements and medication management

Article-at-a-Glance

Background: An initiative was undertaken by Novant Health System to address warfarin-related adverse drug events (ADEs) using lab-based patient-specific International Normalized Ratio (INR) triggers and pharmacy-based patient-specific Vitamin K triggers. The goal was to reduce ADEs related to the use of warfarin in both the inpatient and outpatient settings. Process improvements and medication management protocols were developed for patients managed with warfarin anticoagulation.

Methods: During each month's seven-day sampling period, the hospital information system generated the lab and pharmacy triggers, and the clinical pharmacists used these patient-specific triggers to identify the patient charts for review. All triggered charts were reviewed. Preliminary harm classification based on the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) index was assigned by the clinical pharmacists and recorded for each patient.

Results: The system achieved reductions in ADEs related to warfarin administration on an inpatient management (45%) and outpatient management (52%) basis.

Discussion: Although based on inpatient facility-generated triggers, the initiative also served as a reasonable outpatient model, with improvements seen in the outpatient physician intervention groups.

protocols for the patients being managed with warfarin anticoagulation throughout the system. During the rest of 2002 and all of 2003, the team monitored the data and continually improved the warfarin management and alert processes to achieve better performance. Inpatient and outpatient nursing staff were key to the implementation of the management protocols and alerts systems.

Inpatient Program

The inpatient program was based on the medical literature that showed that automated triggers from laboratory and pharmacy systems could better identify harmful ADEs. Interventions were as follows:

- Utilization of automated Vitamin K (a reversal agent for excessive anticoagulation) triggers from the pharmacy system and of automated reporting of all International Normalized Ratio (INR) values > 3.0 from the laboratory system
- A nursing policy and supporting standing orders that require nursing staff to hold all medication administration of warfarin with an INR > 3.0, to contact the responsible physician to alert him or her as to the elevated level, and then to await orders to continue with current dosing or await new dosing orders. Furthermore, nursing was to order an INR level at any time the previous level reported was noted to be greater than 3 days prior.

All patients assigned harm categories underwent secondary review by a physician for agreement. The data were aggregated and normalized to inpatient days (events per 10,000 patient days based on the corresponding inpatient census to ensure that the ebb and flow of patient volume would not be mistaken for higher or lower events as recorded by the clinical review of all the triggers).

Outpatient Program

The outpatient program was based on the baseline data that showed that automated triggers from laboratory and pharmacy systems could better identify harmful outpatient derived ADEs if specifically targeting emergency department (ED) elevated INR values or Vitamin K use or if those abnormal triggers were also noted within the first 24 hours of admission to the hospitals.

The system's physician practices educated all physicians as to the problems and potential pitfalls of anticoagulation management. Warfarin-dosing nomograms

were reviewed from the literature, and a common nomogram was developed for use on the basis of the best practices as identified by the outpatient medical directors. In addition, each physician practice developed a patient tracking system to identify all patients currently monitored on warfarin therapy to ensure timely INR monitoring. In addition, some of the practices implemented the use of INR point-of-care testing devices to provide immediate patient feedback and medication regimen adjustments to the patients within their practices.

Specific patients who were evaluated in the ED or who were admitted to the hospital with elevated INR level (with or without harm associated) were reported to the outpatient medical directors for outpatient chart review and for further improvement cycle action and re-education, as appropriate.

Methods

Patients

The patients involved in the initiative were identified within the facilities by either one of two trigger methodologies:

- The laboratory systems will identify all patients with an INR of > 3.0
- The pharmacy system will identify all patients who receive Vitamin K as an anticoagulation reversal agent

Patients whose triggering event (in rare cases, patients were identified through both triggering events) occurred wholly within an inpatient stay were classified as inpatients. Patients whose triggering event occurred in the ED before admission or after admission but attributable to the outpatient setting were classified as outpatients.

Data Collection

The physician consultant conducted initial individual training with the clinical pharmacists to ensure accuracy of chart data extraction and ADE harm scoring. All pharmacists were evaluated against each other to ensure minimum interobserver variation. The medical director of clinical improvement overread all chart extracts and initial-harm determinations and provided ongoing feedback to the clinical pharmacists. Senior nursing leadership conducted education for the nursing staff on the alert systems and on the medical staff-approved anticoagulation management protocols. This education was repeated at intervals to ensure that all new employees were instructed and

to provide reinforcement of the policies and protocols involved to all nursing staff. Education and updates were provided to the medical staff and organizational staff on the whole through memos, posters, and leadership presentations with emphasis on the data and progress of the overall initiative.

Bias Issues in Performance Measures

Several issues were addressed that might have led to bias in the measurement of outcomes, as now described.

Sample Randomization. To account for differences in admission rates during different hours of the day, the lab and pharmacy triggers encompassed a 24-hour period for each day of the trigger-sampling period. A 25% sample size was felt to be adequate to assess the ADE rates; it was achieved by sampling patient charts as identified by the triggers from the first seven working days of each month. Although this seven-day sampling period does not take into account weekend days, the main difference between weekend days and weekdays is a marked reduction in elective and office referral admissions from the office practices, resulting in fewer patients being identified, in absolute numbers, with ADEs, as compared with practices on weekend days. In our opinion, this was not significant to the overall ADE identification process and may have allowed for more ADE identification to occur than would have occurred had weekend days been included.

Hospital Bed Census Differences. To account for census differences between the facilities involved, the ADE rates were standardized to 10,000 patient days. This allowed for large-to-small facility comparisons on a standardized event-per-patient days basis rather than raw number comparisons.

Chart Extraction Inter-Observer Differences. Chart extractions were conducted by as few clinical pharmacists as possible, given work flow and resource needs. All pharmacists received the same training by the physician consultant. The medical director of clinical improvement reviewed all the data extract forms and initial-harm classifications determined by the pharmacists. This physician clarified all clinical data questions before the final harm categories were assigned. The physician reviewer provided instructional feedback to the pharmacists on all cases in which he determined a different

harm category for any given patient and educated them as to the reason for the corrected harm category given.

Intervention Start Dates. Although the protocols and improvements were the same for all facilities in the health system, the time it took to implement them was dependant on many factors within each facility, resulting in different pre- and postintervention periods. Because all the data from the facilities was standardized for reporting purposes to the executive team, the facilities' percentage improvements were averaged, with each facility's percentage calculated from the its own pre- and postintervention period.

Performance Measures

During each month's seven-day sampling period, the hospital information system generated the lab and pharmacy triggers, and the clinical pharmacists used these patient-specific triggers to identify the patient charts for review. All triggered charts were reviewed and the following data was collected and recorded within the data collection database: trigger type (INR or Vitamin K), INR value, date, facility, location (inpatient or outpatient), patient name, medical record number, attending physician, and a brief clinical course to describe the factors involved with the trigger, with special emphasis on the appropriate use of and dosing of warfarin. Attention was also given to concurrent medications and diet, physical state of the patient, and adequacy of lab monitoring and medication adjustments based on lab reports.

Preliminary harm classification based on the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP)¹ index was assigned by the clinical pharmacists and recorded for each patient. It was these data from which the ADE rates were calculated after the physician reviewer completed all data review and harm-class assignment. We modified the NCC MERP index for our use as follow:

- In A events, the trigger was related to drug therapy but the therapy was appropriate
- In C and D events, the trigger was related to drug therapy, and the therapy was judged to vary from best practice by a minor (C events) or a significant (D events) degree, but no harm was associated
- All category E through I events represent anticoagulation therapy deviations from the norm, and harm (including major loss of function and death) was associated

Inpatient Anticoagulation Events

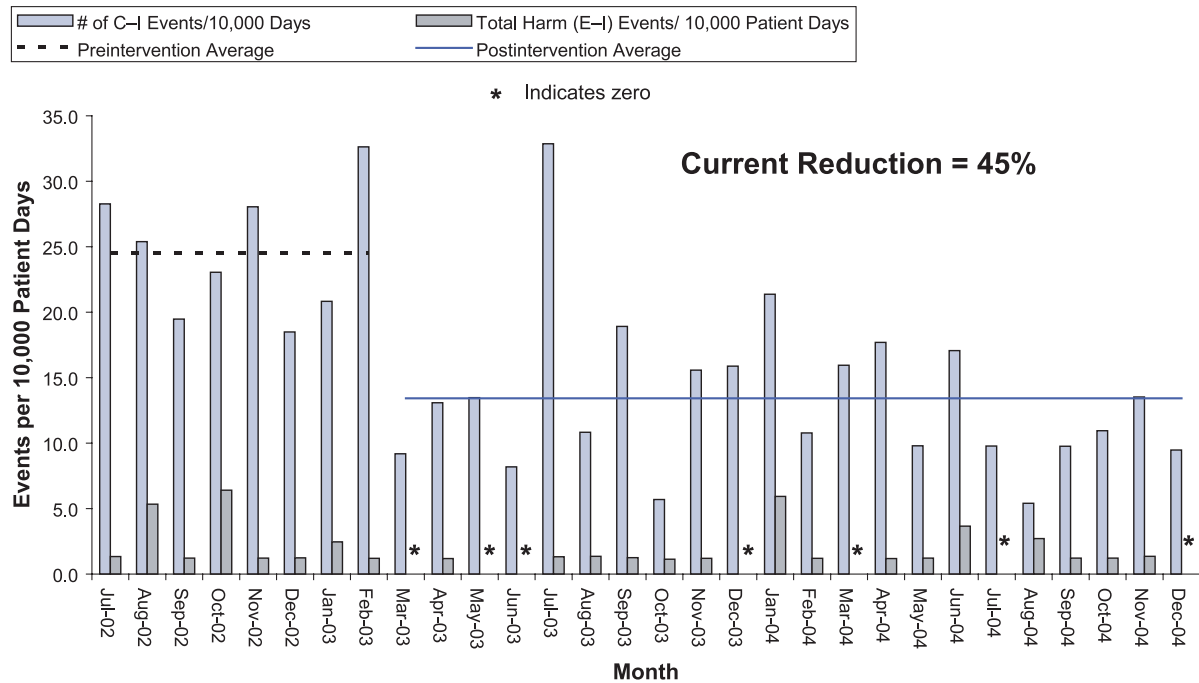


Figure 1. The inpatient data showed a 45% reduction in anticoagulation events scored C-I.

The hospital information system also provided the facility-specific census reports for each month's sampling period.

Novant Health required that all compensation-based goals undergo internal audit review of methods, chart extraction validation, and data analysis. A clinical improvement department statistician confirmed the spreadsheet equations and calculations for accuracy and confirmed a sample of the ADE rates obtained.

Data Analysis

The Novant Health System consists of two main regions, each with multiple facilities. The Executive Team required a single roll-up value of the percent improvement of all the interventions undertaken. However, to continue to fine-tune the interventions, the data were reported to each region separately and by inpatient and outpatient areas. Data were displayed using bar charts, with baseline and post-intervention means added. The data was expressed by month as events per 10,000 patient days. The data were further stratified by NCC MERP class C-I events,

which represent true harm and potential harm events, and by NCC MERP Class E-I events, which represent only true harm to patients up to and including death.

Results

The inpatient data showed a 45% reduction in C-I anticoagulation events when the two regions were considered together (Figure 1, above). The outpatient data showed a 53% reduction in C-I anticoagulation events (Figure 2, page 317). Inpatient E-I (true harm) events were very infrequent, and the data suggested a trend towards fewer events in the postintervention period.

The ADE Reduction Team members needed monthly data feeds to fine-tune the interventions. The administrative leadership teams received quarterly reports to be able to track success and support the overall initiative. The organization on the whole received updates on a 4- to 6-month frequency. When individual nurses or physicians who may have been involved in significant harm events or when triggered patients were found who were not addressed by the policies and protocols in place, these events were addressed as they occurred.

Outpatient Anticoagulation Events

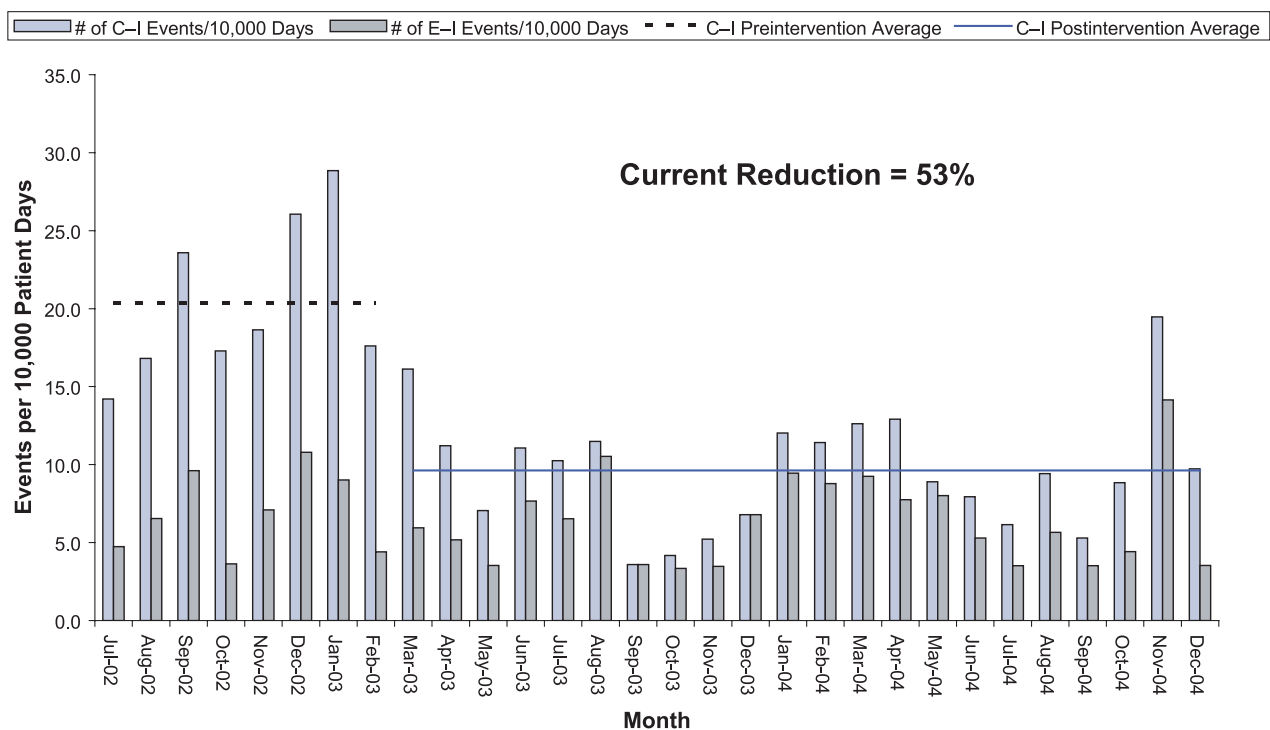


Figure 2. The outpatient data showed a 53% reduction in anticoagulation events scored C-I.

Discussion

This initiative demonstrates that literature-based best practice can be easily implemented on a large or small scale, with results achievable in any organization. Although based on inpatient facility-generated triggers, the initiative also serves as a reasonable outpatient model, with improvements seen in the outpatient physician intervention groups.

The initiative laid the groundwork for our developing real-time alert-based interventions. The effectiveness of the nonautomated outpatient processes has spurred development of an automated, computer-based ADE prevention system. For the physician practice which is already significantly computerized or automated, this anticoagulation management system can be even more easily implemented and save personnel resources.

The ADE Reduction Team has continually refined both the inpatient and outpatient aspects of this initiatives on the basis of monthly data reports and specific patient clinical analysis to further reduce harm-based ADEs. A pharmacy order entry computer-generated

rules engine model is under development (testing is now ongoing by the pharmacists in one facility) to automate the three-day INR nursing derived standing order to ensure that all patients receive an INR level at least every three days while receiving warfarin. In addition, a second rule has been developed to alert the pharmacists when the INR level is > 3.0 or has had an increase of > 0.8 from the previous level. These two computerized enhancements will serve to take this initiative from a retrospective review of ADEs for validation of the improvement process to a real-time trigger-based intervention system. Finally, an inpatient warfarin loading dose nomogram was developed from the literature to use on an inpatient basis. It is anticipated that the initiative's continued success will set the stage for a rules-based physician order entry program under development.

This project had the good fortune of being developed and endorsed at the senior leadership level, which was responsible for the initiative's widespread diffusion. We present what we consider to critical success factors for implementation (Table 1, page 318). ■

Table 1. Critical Success Factors

1. Leadership ownership, direction, and support are critical not only to development and implementation but also to an initiative's organizationwide diffusion.
2. Physician leadership is also critical to success insofar as the interventions directly affect practicing physicians. Cardiology support is particularly needed because cardiologists may be affected to a greater extent because of the International Normalized Ratio (INR) levels desired for artificial-valve patients.
3. Nursing input and advice during the policy development phase is important; many good ideas were met with resistance when they did not take into account current practice, culture, or existing barriers.
4. When possible, develop automated systems to trigger and alert using existing information technology solutions already in place.
5. Only develop what can be supported. Specifically, for outpatients do not try to affect all physicians at once but work with a pilot group willing to implement the changes or new systems.
6. To decrease variation in chart extraction, try to use a dedicated pharmacist or team with a single physician backup as reviewer validation.
7. Encourage the expectation that harm categories can be reduced by retrospective review and feedback but that real-time automated order entry alerts and interventions may have the potential to reduce both harm and nonharm events.

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Reference

1. National Coordinating Council for Medication Error Reporting and Prevention: *Index for Categorizing Medication Errors*. Adopted July 16, 1996, revised Feb 20, 2001. <http://www.nccmerp.org/medErrorCatIndex.html> (last accessed Mar. 23, 2005).