Original Article

Implementation of an Order Set to Adhere to National Patient Safety Goals for Warfarin Therapy

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Abstract

Background: In 2009, The Joint Commission mandated full compliance with National Patient Safety Goal (NPSG) 03.05.01 to reduce the likelihood of patient harm associated with anticoagulant therapy.

Methods: We conducted a retrospective chart review of inpatients receiving warfarin at Methodist Hospital pre and post implementation of a warfarin order set between January 2008 and July 2011. The primary endpoint of this study was overall adherence to laboratory monitoring. Secondary endpoints included compliance with individual laboratory parameters, percentage of patient educational sessions completed prior to discharge, and percentage of appropriate follow-up arrangements documented on discharge.

Results: A total of 707 patients were assessed. Overall adherence to laboratory monitoring parameters significantly improved from 71.8% to 87.5% (odds ratio [OR], 2.76; 95% CI, 1.87–4.07; $P < .001$). Additional improvements were seen in patient education prior to discharge, and appropriate follow-up arrangements were documented at discharge.

Conclusions: This analysis demonstrates that implementation of an order set assists in adherence to policies and procedures designed to address the NPSG 03.05.01. Additionally, pharmacy involvement in monitoring, educating, and arranging for follow-up may lead to successful completion of these parameters.

Key Words—education, follow-up, laboratory monitoring, National Patient Safety Goal, warfarin

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In 2008, The Joint Commission published a National Patient Safety Goal (NPSG) about safe use of anticoagulant therapy in hospitalized patients. Full compliance with these standards was expected by January 2009.¹ The intent of this goal was to “reduce the likelihood of patient harm associated with the use of anticoagulant therapy.” To assist institutions in complying with this standard, The Joint Commission set several elements of performance. Four of these elements focus specifically on warfarin management (Table 1).

Methodist Hospital (MH) is an 800-bed community-teaching hospital in downtown Indian-

apolis and is part of the larger academic health care organization called Indiana University Health. To standardize practice at MH and throughout the health care system, a workgroup was formed to design policies and procedures addressing NPSG 03.05.01. The workgroup had representation from pharmacy, nursing, drug information, and administration across campuses. Additionally, the workgroup reported to a larger, multisite, anticoagulation quality committee. This committee had representation from a variety of disciplines including nursing, patient education, pharmacy, administration, and quality improvement.

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Table 1. National Patient Safety Goal (NPSG) 03.05.01 procedures

NPSG 03.05.01 element	Institution procedure
Use only oral unit-dose products when these types of products are available.	Only pre-packed unit-dose products are stocked in the automated dispensing cabinets for nursing use.
Use approved protocols for the initiation and maintenance of anticoagulant therapy.	An order set and policy were developed.
Before starting a patient on warfarin, assess the patient's baseline coagulation status; for all patients receiving warfarin therapy, use a current INR to adjust this therapy. The baseline status and current INR are documented in the medical record.	An INR within the last 72 hours ^a is required for all patients with an order for warfarin. A daily INR is required until the patient is within target range for a minimum of 4 consecutive days; then the INR may be ordered every 3 days.
Use authoritative resources to manage potential food and drug interactions for patients receiving warfarin.	Each patient is reviewed daily by a pharmacist to manage potential food and drug interactions.
A written policy addresses baseline and ongoing laboratory tests that are required for anticoagulants.	INR within 72 hours ^a prior to warfarin initiation. INR daily until the target range is achieved for a minimum of 4 consecutive days; then INR every 3 days. Hgb within 72 hours ^a prior to warfarin initiation. Hgb every 7 days while on warfarin.
Provide education regarding anticoagulant therapy to prescribers, staff, patients, and families. Patient/family education includes the following: <ol style="list-style-type: none"> 1. Importance of follow-up monitoring 2. Compliance 3. Drug-food interactions 4. The potential for adverse drug reactions and interactions 	Verbal education is to be done by a pharmacist prior to discharge. Written materials and a warfarin video are made available to patients for use.
Evaluate anticoagulation safety practices, take action to improve practices, and measure the effectiveness of those actions in a time frame determined by the organization.	Quality improvement metrics are performed and reported annually to the Anticoagulation Quality Committee.

Note: Hgb = hemoglobin; INR = international normalized ratio.

^aIf the patient was admitted for an elective procedure, laboratory testing done within the previous 30 days was accepted.

An anticoagulation policy to address each of the NPSG elements of performance was completed in 2008. In addition to addressing all injectable therapeutic anticoagulation, the anticoagulation policy included all patients receiving warfarin. To enhance policy adherence, several measures were employed. These measures included use of a mandatory order set, pharmacist review prior to order entry, and development of electronic alerts. Required elements within the order set included documenting the indication for warfarin and goal international normalized ratio (INR) range for therapy (Figure 1). Automatic orders embedded in the order set included routine INR and hemoglobin (Hgb) monitoring, warfarin education by a pharmacist, and default warfarin adjustment and monitoring by a pharmacist.

Providers had the option to opt out of pharmacist management and select prescriber management, if desired. Those opting out of the pharmacist service were still required to comply with all institutional policies and procedures throughout warfarin therapy. Prior to a warfarin order being processed, a baseline INR and Hgb or hematocrit (Hct) must be available for review by the entering pharmacist. Patients without the essential baseline laboratory values do not have their warfarin order processed until the initial policy requirements are met. Electronic alerts were designed to identify patients not adhering to baseline or routine laboratory monitoring parameters. These alerts fired in response to inappropriate laboratory orders and were reviewed by pharmacists prior to order entry and daily. As part of the current policy,

Indiana University Health

Indiana University Health Warfarin Order Set		
The person initiating entry should write <u>legibly</u> , date the form (using Mo / Day / Yr), enter time, <u>sign</u> , and indicate their title.		
Until signed, these are for general information and reference only. They should not be relied on as advice for a particular patient or situation or as a substitute for the independent professional judgment of the physician.		
Date	Time	Documentation Section
		☐ New medication start ☐ Continuation of out-patient therapy Last dose given: _____ (date/time)
		Warfarin Indication: (REQUIRED for National Patient Safety Goal 3E) Physician to Document(✓) <div style="display: flex; justify-content: space-between;"> <div> ☐ Venous Thromboembolism (VTE) ☐ Atrial Fibrillation ☐ Mechanical Mitral Valve ☐ Mechanical Aortic Valve ☐ Bioprosthetic Mitral Valve ☐ Bioprosthetic Aortic Valve ☐ Acute Spinal Cord Injury-rehabilitation phase ☐ Genetic hypercoagulable state ☐ Other(specify): _____ </div> <div> ☐ Pulmonary Embolus (PE) ☐ Valvular Heart Disease ☐ Fontan Surgery ☐ Venous Thromboembolism (VTE) Prophylaxis ☐ Ventricular Assist Device (VAD) ☐ Pulmonary hypertension </div> </div>
		Target INR: (REQUIRED for National Patient Safety Goal 3E) Physician to Document(✓) ☐ 2 – 3 ☐ 2.5 – 3.5 ☐ other _____
		Physician Orders
		Warfarin Dose: (REQUIRED) Physician to Order First Dose ☐ _____mg PO at 1800 daily ☐ See Initial Warfarin Dose Order Per Medication Reconciliation Form ☒ Pharmacist to adjust and monitor warfarin dose and subsequent doses per P&T policy ☐ Physician will manage warfarin dosing (Do not initiate pharmacist warfarin dosing service)
		(REQUIRED) Physician to Order (✓) Baseline if NO result within past 72 hours: ☐ INR now ☐ Hemoglobin now Labs ☒ INR daily _____ ☒ Hemoglobin every week starting tomorrow at 6AM
		Patient education ☒ Warfarin counseling by Pharmacist
		Discharge planning ☐ Care Coordinator to evaluate for discharge planning for warfarin follow up, including laboratory Draws **At IU and Riley, physician must notify case manager via pager

Practitioner Signature _____ Printed Name _____ Dictation# _____
Entered by: _____ Order Entry Verified _____
Sent to Pharmacy by: _____ (Scan, Tube / Fax / Copy) Date _____ Time _____

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Warfarin Order Set

Medical Record - Original
Pharmacy - Copy

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Figure 1. Warfarin order set.

pharmacists are able to order necessary labs to ensure adherence. Table 1 identifies all the NPSG 03.05.01 items pertaining to warfarin and the procedures in place at our institution to address each one.

In addition to the elements listed within NPSG 03.05.01, additional efforts have been focused on arranging warfarin follow-up after discharge from the hospital. This area is of particular focus due to the high risk for complications with use of oral anticoagulation. Education was provided to discharge coordinators and pharmacists to increase success in appropriate follow-up arrangements on discharge. Appointments for an INR check within 1 week of discharge were encouraged, and clear discharge patient instructions for follow-up arrangements were expected.

Despite the implementation of these procedures, questions remained about the efficacy of this system. We sought to compare our adherence to the NPSG 03.05.01 pre and post implementation of our current policies and procedures.

METHODS

Two data queries were compiled, one for preimplementation and one for postimplementation of the warfarin order set, for all admitted patients with warfarin orders at MH. Preimplementation warfarin orders were from January 1, 2008, to December 31, 2008 (12 months). Postimplementation warfarin orders were from January 1, 2010, to July 31, 2011 (18 months). There were a total of 3,439 preimplementation and 5,125 postimplementation warfarin orders eligible for review. Three hundred forty-seven preimplementation and 360 postimplementation warfarin orders were randomly selected for review based on sample size calculations. Orders selected for review were chosen at random utilizing an online randomizer (www.random.org).

Data points of interest were collected by retrospective chart review. Data collected included adherence to laboratory monitoring, baseline values and routine monitoring, education of patient or caregiver prior to discharge, and outpatient follow-up arrangements documented on the patient's discharge instructions.

Adherence to initial laboratory monitoring was defined as baseline INR and Hgb or Hct. Baseline was defined as any of the aforementioned laboratory values within the previous 72 hours of the order being written or within the previous 30 days if the patient was undergoing an elective procedure. Routine laboratory monitoring was defined as Hgb or Hct every 7 days and daily INR. If the INR was within range for 4 consecutive days, then INR measurements could de-

crease to every 3 days. Overall adherence was assessed by compliance with all 4 of the laboratory tests stated above; if one or more tests were not completed, overall adherence was not achieved.

Education of the patient or caregiver was determined by the presence of a pharmacy progress note within the electronic medical record documenting the educational points discussed. Each patient was assessed for the preferred teaching style, any barriers to learning, and understanding of the material provided. Specific warfarin education points are listed in Table 2. Each educational session utilized supplementary warfarin booklets and an informational video, as desired by the patient.

Outpatient follow-up appointments were assessed through a review of the discharge instructions provided to each patient. The date of follow-up and the name of the responsible provider for warfarin monitoring and adjustment must have been present on the discharge instructions to achieve compliance with this data point.

The primary endpoint of this study was overall adherence to laboratory monitoring. Secondary endpoints included compliance with individual laboratory parameters, percentage of patient educational sessions completed prior to discharge, and percentage of appropriate follow-up arrangements documented on discharge instructions.

Table 2. Warfarin educational points

Required teaching points:

- Compliance issues
- Monitoring and follow-up
- Dietary issues
- Adverse drug reactions or interactions

Additional teaching points:

- Indication
- Warfarin = *Coumadin* = *Jantoven*
- INR monitoring and goal range
- Importance of notifying provider or pharmacist prior to start or stop of any medications
- Signs/symptoms of thrombus/embolus and course of action
- Importance of informing other providers of warfarin therapy
- Contraindications in pregnancy
- Use of a wallet card or medic-alert bracelet
- Suggest using one pharmacy to receive all medications

Note: INR = international normalized ratio.

All measures were summarized using descriptive statistics (mean and standard deviation for continuous variables; count and percent for categorical variables). Categorical measures were compared between pre- and postprotocol implementation time periods using Pearson chi-square tests. Additionally, odds ratios with 95% confidence intervals were calculated. All statistical analysis was performed using SPSS software (IBM SPSS, Inc., Armonk, NY).

RESULTS

A total of 707 patients were assessed in this chart review. The population sizes were comparable, with 347 patients in the preimplementation group and 360 patients in the postimplementation group. The baseline demographics of age and gender were similar between the pre- and postimplementation groups (67 years [57% male] and 64 years [50% male], respectively). After initiation of the order set, overall adherence to laboratory monitoring parameters improved from 71.8% to 87.5% (odds ratio [OR], 2.76; 95% CI, 1.87-4.07; $P < .001$). No significant improvements were seen in either baseline or routine Hgb or Hct monitoring. Baseline INR monitoring improved by nearly 15% ($P < .001$), but no statistically significant improvement was seen in routine INR monitoring. The number of patients discharged with outpatient arrangements increased from 27.7% to 52.8% (OR, 2.92; 95% CI, 2.14-4.00; $P < .001$).

Prior to order set implementation, only 27.4% of patients initiated on warfarin therapy received education prior to discharge. Implementation of the order set increased the number of patients educated; however, approximately 25% of patients were still discharged without education. Table 3 provides a summary of the outcomes.

DISCUSSION

The implementation of policies and procedures addressing the safe use of anticoagulant therapy at MH was successful in its effort to improve anticoagulant therapy monitoring. The primary outcome of overall adherence to MH laboratory policies significantly improved as a result of the warfarin order set. All aspects of baseline and routine warfarin monitoring also improved, though only baseline INR monitoring was significant. Outpatient arrangements and education for patients discharged on warfarin therapy improved dramatically.

This retrospective chart review is the largest study to date evaluating the efficacy of a mandatory order set on adherence with warfarin inpatient policies and procedures. A review of the literature revealed one publication that addressed development of warfarin protocols by a task force in the Memphis, Tennessee, area, but no outcome measures were established.² Eight health systems from the Memphis area met regularly to establish important components for protocols to help achieve compliance with The Joint Commission's standards. Each institution was then able to develop a unique warfarin protocol that was best suited for its patient care group(s). Components addressed included dietary services, staff education, monitoring policies, and patient and family education. Although the details of each monitoring policy varied, all hospitals required a baseline INR and complete blood count (CBC) prior to warfarin initiation. Several policies included a daily INR until stable as well as CBC or Hgb and Hct monitoring daily to every 3 days. Pharmacy was elected to be the discipline responsible for warfarin education at each health system. All but one institution chose to notify pharmacy of a required patient educational session via computerized task list. Most policies developed by

Table 3. Policy adherence pre and post order set implementation

	2008 (%)	2010-2011 (%)	Odds ratio [95% CI]	P value
Hgb at least every 7 days	96	97.8	1.85 [0.77 – 4.47]	.17
INR daily or every 3 days	93.1	94.4	1.26 [0.69 – 2.33]	.46
Baseline INR	79.5	94.2	4.15 [2.49 – 6.93]	<.001*
Baseline Hgb or Hct	91.9	94.2	1.42 [0.79 – 2.55]	.24
Adherence to MH laboratory policy	71.8	87.5	2.76 [1.87 – 4.07]	<.001*
Education sessions	27.4	77.8	9.28 [6.59 – 13.1]	<.001*
Outpatient arrangements	27.7	52.8	2.92 [2.14 – 4.00]	<.001*

Note: Hct = hematocrit; Hgb = hemoglobin; INR = international normalized ratio; MH = Methodist Hospital.

* $P < .05$, demonstrating statistical significance; chi-square test.

participating institutions also required written and oral materials to be provided to the patient during the educational session. Components of the MH anticoagulation order set are comparable to those established by this task force.

Additionally, one randomized study evaluating the clinical and safety impact of a pharmacist-directed anticoagulation service (PDAS), inpatient communication to an outpatient physician, or anticoagulation clinic was significantly improved for those patients who were managed by the PDAS.³ Only 12.4% of patients managed by usual hospitalist care had documented communications to an outpatient physician for follow-up, whereas 99.6% of PDAS patients had communication (relative risk [RR], 8.03; 95% CI, 5.78-11.2; $P < .001$). Although our findings also demonstrate improvement in discharge arrangement, continued improvement is warranted.

Our study is not without limitations. As a retrospective chart review, we were reliant on chart documentation for discharge instructions and education sessions. This may have lead to an underestimation of actual efforts to arrange appropriate follow-up appointments and educate patients or families about warfarin. Another potential limitation is the use of electronic alerts to notify pharmacists of missing laboratory values and the need for warfarin education. These alerts were designed to increase awareness about the policies and procedures, leading to an expected increase in adherence.

Despite improvement in many data points after the implementation of our current policies and proce-

dures, we identified 2 areas for continued improvement. First, approximately 25% of patients receiving warfarin while hospitalized were not educated prior to discharge. Second, only half of patients discharged on warfarin had follow-up arrangements documented on their discharge instructions. Continued pharmacist and care management education efforts are underway to ensure appropriate warfarin education and discharge instructions for every patient receiving warfarin.

CONCLUSION

Anticoagulants are an integral component in the treatment of several disease states, but they can cause serious adverse events. Our analysis demonstrates that implementation of an order set assists in adherence to policies and procedures designed to address the safety concerns outlined in NPSG 03.05.01.

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