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Realizing pharmacists' potential: Pharmacist-led anticoagulation management services

This issue of the Translator highlights pharmacists taking on advanced roles by leading and managing anticoagulation services.

- Pharmacist-led anticoagulation clinic improves patient care
- Significant cost savings result from pharmacist-managed anticoagulation service
- Pharmacist-managed anticoagulation may be superior to standard care
- Pharmacists and physicians provide equally safe and effective warfarin management

Warfarin, used for well over 60 years, has historically been the only oral anticoagulant for the treatment and/or prevention of thrombosis (blood clots). While novel anticoagulants, such as dabigatran and riva-

roxaban, appear likely to offer alternatives for certain patient populations in the future, warfarin therapy will continue to be used for many years to come. Research involving pharmacists in the management of

drugs with a narrow safety margin, such as warfarin, suggests that this is an important role that pharmacists can play in optimizing pharmacotherapy in their patients.

Pharmacist-led anticoagulation clinic improves patient care

Bungard TJ, Gardner L, Archer SL, Hamilton P, Ritchie B, Tymchak W, Tsuyuki RT. Evaluation of a pharmacist-managed anticoagulation clinic: improving patient care. *Open Med.* 2009;3(1):16-21.

Issue: Warfarin therapy is used in the prevention and treatment of blood clots. Warfarin treatment is very complex because warfarin has a very narrow safety range that is maintained through blood tests measuring the international normalized ratio (INR).¹ Anticoagulation, or "blood thinning," is a fine balance – too little anticoagulation forecasts clotting events such as stroke or pulmonary embolism, whereas too much anticoagulation puts the patient at high risk of bleeding.² Due to the complexities surrounding the use of warfarin, it is often underused and poorly managed.^{3,4}

Cost savings were over \$122,000.

A solution: Anticoagulation management service (AMS), a systematic approach to warfarin therapy, may improve the management of warfarin and reduce consumption of health care resources. This paper examined the impact of pharmacist-led AMS on anticoagulant control, anticoagulation-related hospitalizations and costs to the health care system.

Anticoagulant control was significantly

improved in AMS care, with patients in their target INR range 66.5% of the time, compared to only 48.8% of the time before referral to the AMS. Throughout the AMS care, patients experienced significantly fewer clotting events, as well as a non-significant trend toward fewer bleeding events.

AMS care also significantly reduced the utilization of health care resources. The cost savings for 125 patients over a 10.7 months follow-up period for clotting and bleeding events were 573 emergency department hours and \$122,144.95 due to referral to AMS care.



Pharmacist-led anticoagulation clinic improves patient care

Implications: Pharmacist-led anticoagulation services are valuable, safe and superior to standard care. This study demonstrated that AMS led to an improvement in the

quality of anticoagulation care, increased anticoagulant control and allowed fewer adverse events. Although limited by a small sample size, the improvement in

anticoagulant control and cost savings to the health care system warrant the establishment of other pharmacist-led AMSs.

¹ Ansell J, Hirsh J, Poller L, Bussey H, Jacobson A, Hylek E. The pharmacology and management of the vitamin K antagonists: the seventh ACCP conference on antithrombotic and thrombolytic therapy. *Chest*. 2004;126(3 Suppl):S204-S233.

² Hylek EM, Singer DR. Risk factors for intracranial hemorrhage in outpatients taking warfarin. *Ann Intern Med*. 1994;120(11):897-902.

³ Bungard TJ, Ghali WA, Teo KK, McAlister FA, Tsuyuki RT. Why do patients with atrial fibrillation not receive warfarin? *Arch Intern Med*. 2000;160:41-46.

⁴ Bungard TJ, Ackman ML, Ho G, Tsuyuki RT. Adequacy of anticoagulation in patients with atrial fibrillation coming to a hospital. *Pharmacotherapy*. 2000;20(9):1060-1065.

Background or research methods:

Between April 2001 and December 2003, patients referred to the AMS at the University of Alberta Hospital were screened for eligibility for this study. Those taking warfarin for at least four months prior to and during AMS care were considered eligible. AMS care consisted of a thorough one-on-one educational session on anticoagulation therapy, including: information on the role of AMS; factors

that could affect warfarin therapy, such as interaction with other medications; and warning signs of bleeding and clotting. The pharmacist also assessed each INR and followed up with patients by phone to provide them with new warfarin dosing instructions, if needed. The primary outcome was adequate control of anticoagulation within the target INR range. The secondary outcome was a measurement of the occurrence of anticoagulant-

related adverse events requiring health care resources. The utilization of health care resources was determined by the number of hours spent in an emergency department and resources consumed during a hospital stay, based on resource intensity weight (RIW).

Financial support: The AMS program was funded by Alberta Health and Wellness through the Health Innovation Fund.

Significant cost savings result from pharmacist-managed anticoagulation service

Mamdani MM, Racine E, McCreddie S, Zimmerman C, O'Sullivan TL, Jenson G, Ragatzki P, Stevenson JG. Clinical and economic effectiveness of an inpatient anticoagulation service. *Pharmacotherapy*. 1999;19(9):1064-1074.

Issue: Deep vein thrombosis (DVT) and pulmonary embolism (PE) are life-threatening conditions causing roughly 300,000 hospitalizations and millions of dollars in direct medical costs each year in the United States.¹⁻² Drug therapy with warfarin is very complex, and requires close monitoring to avoid potential adverse events, drug interactions and inappropriate usage, which may itself lead to hospitalization.

A solution: Research led by the Detroit Medical Center and Wayne State University evaluated the clinical and financial impacts of an in-hospital, pharmacist-managed anticoagulation service.

Cost savings of 17% were realized by the pharmacist-managed group.

The group receiving the inpatient pharmacist-managed care had a significantly greater proportion of anticoagulation control and significantly fewer patients below the therapeutic levels.

Length of hospital stay and cost of hospitalization were linked to when both medications were first administered. A significantly larger proportion of patients in the pharmacist-managed group (82%) were started on warfarin within 2 days of starting heparin therapy than in the usual

care group (63%). The pharmacist-managed group had a shorter average length of hospital stay: five days compared to the usual care group's seven days. The cost savings were estimated to be \$340 per patient (in 1997 terms), resulting in a benefit:cost ratio of 5:1.

Implications: These results indicate that the implementation of a pharmacist-managed anticoagulation service may offer significant clinical and financial benefits. These results are promising for patients and the health care system. A larger randomized controlled study should be commenced to confirm the broader applicability of the findings.

¹ Goldhaber S. Thrombolysis for pulmonary embolism. *Prog Cardiovasc Dis*. 1991;34:113-134.

² Anderson FA Jr, Wheeler HB, Goldberg RJ, Hosmer DW, Patwardhan NA, Jovanovic B, et al. A population-based perspective of the hospital incidence and the case-fatality rates of deep vein thrombosis and pulmonary embolism. The Worcester DVT Study. *Arch Intern Med*. 1991;151:933-938.

Background or research methods: In this prospective cohort study, patients were selected after reviewing their medical charts at two teaching hospitals at the Detroit Medical Centre between June 1996 and April 1997. Eligible patients (50/group) had a diagnosis of DVT or PE and were receiving intravenous heparin therapy. The pharmacist-managed anticoagulation service used dosing protocols to dose and monitor heparin and

warfarin treatments when requested by a physician. The primary therapeutic outcome was time between starting heparin therapy and reaching the therapeutic target, while secondary endpoints were time to reach the target levels for heparin and warfarin therapy, compliance with dosing protocols and assessment of adverse events. The primary economic endpoint was the cost of hospitalization, while secondary endpoints were the length of

hospital stay and the cost of pharmacists' time in providing this enhanced care. Economic information was independently determined by the department of finance. The pharmacists' time and workload were evaluated by a questionnaire.

Financial support: This project was undertaken as part of a Fellowship through the Detroit Medical Centre and was supported by Bristol-Myers Squibb.

Pharmacist-managed anticoagulation may be superior to standard care

Donovan JL, Drake JA, Whittaker P, Tran MT. Pharmacy-managed anticoagulation: assessment of in-hospital efficacy and evaluation of financial impact and community acceptance. *J Thromb Thrombolysis*. 2006;22:23-30.

Issue: Though blood clots are very dangerous and effective drug therapies for anticoagulation are available, these drugs are often underused.¹ Prescribers often underuse warfarin for anticoagulation due to its association with its high risk for drug interactions and adverse events; thus necessitating very precise dosing and monitoring. Several methods of managing this requirement include: the use of dosing protocols called nomograms, patient self-monitoring and the use of an anticoagulation monitoring service by pharmacists or physicians. However, the utility of pharmacist-managed anticoagulation in the hospital setting has not yet been thoroughly evaluated.

A solution: The purpose of this study was to perform a literature search around in-hospital pharmacy-managed anticoagulation to determine its efficacy, potential economic benefits and general acceptance. Evidence suggests that pharmacy-managed anticoagulation service is an effective means of monitoring warfarin

A multidisciplinary approach may be the ideal means of anticoagulation management.

use, however, it is not yet known whether this is due to adherence to dosing protocols.²⁻³ When directly compared to physician-managed anticoagulation, pharmacist-managed anticoagulation appeared to be at least equivalent, or in some cases superior, resulting in shorter hospital stays, better dosing control and fewer adverse events.

Although few studies examined in-hospital care, it was suggested that a significant economic advantage may result from pharmacist-managed anticoagulation. The studies examined in this literature search demonstrated that a large number of patients receiving anticoagulation care can result in small per-patient savings adding up to substantial cost savings to the health care system. However, most studies were small and contained several

flaws, so the broader applicability of the data presented here is not recommended. Overall, patients were highly satisfied with the pharmacy-managed care, as were physicians, with only one exception. Pharmacist-led anticoagulation services may be an ideal opportunity to free up physicians' time and bridge gaps in physician availability in overextended health care systems.

Implications: The studies reviewed in this paper suggest that pharmacy-managed anticoagulation is effective and at least equal or in some cases better than standard care. Pharmacist-led anticoagulation services may also offer substantial cost savings to the health care system. The superiority of pharmacist-managed care may be attributed to closer adherence to dosing protocols. Large and well-designed studies are required in order to confirm these findings, as large-scale randomized studies have yet to be conducted.

¹Tapson VF, Hyers TM, Waldo AL, Ballard DJ, Becker RC, Caprini JA, et al. Antithrombotic therapy practices in US hospitals in an era of practice guidelines. *Arch Intern Med*. 2005;165:1458-1464.

²Shalansky KF, Sunderji RA. A simple warfarin dosing nomogram for orthopedic prophylaxis. *Can J Hosp Pharm*. 2000;53:40-43.

³To EK, Pearson GJ. Implementation and evaluation of a pharmacist-assisted warfarin dosing program. *Can J Hosp Pharm*. 1997; 50: 169-175.

Background or research methods: The PubMed database was searched to identify relevant articles dated from 1966 to March 2006. Specific search terms included "pharmacist" or "pharmacy"

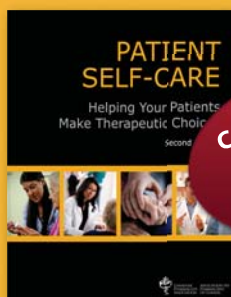
with "anticoagulation," "warfarin" and "heparin." The Science Citation Index was then used to search for additional papers that had referenced the relevant articles found in the initial search, but

which were not found using the initial search protocol.

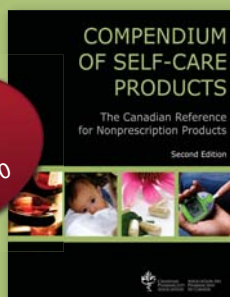
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Pharmacists and physicians provide equally safe and effective warfarin management

Tschol N, Lai DKS, Tilley JA, Wong H, Brown GR. Comparison of physician- and pharmacist-managed warfarin sodium treatment in open heart surgery patients. *Can J Cardiol.* 2003;19(12):1413-1417.

Issue: Controlled anticoagulation, measured by the international normalized ratio (INR), is critical for patients who have undergone cardiac valve treatment.¹ Warfarin use has a narrow margin of safety, and its treatment is complicated by a multitude of factors, including individual responses to warfarin and interacting medications. Warfarin treatment requires very close monitoring to obtain an appropriate level of blood thinning, without putting the patient at risk for bleeding.

A solution: This study explored the opportunity for pharmacists to manage warfarin dosing by comparing the effectiveness of pharmacist- and physician-managed warfarin treatment in obtaining controlled anticoagulation, with an INR between the therapeutic range of two to three (2.5 to 3.5 for mechanical valve patients). Both groups had similar levels of warfarin control.

There was no difference between the pharmacist- and physician-managed

Pharmacists and physicians provided similar warfarin control.

groups in the percentage of days within the therapeutic range, the percentage of days with INR less than two, the percentage of patients being discharged before having a stable INR or the percentage of patients experiencing a major bleed. However, the pharmacist-managed group did experience 5.9% fewer days with an INR above four than the physician-managed group.

Patients in the pharmacist-managed group seemed to be anticoagulated more gradually, whereas physicians tended to anticoagulate patients more aggressively. However, this did not change the time to reach a stable INR or the length of hospitalization. The pharmacist-managed group tended to have a lower average INR at discharge than the physician-managed group, but the average INRs for both groups fell within the therapeutic range.

Implications: Trained pharmacists and physicians can provide equally safe and effective management of warfarin therapy in patients who have undergone cardiac valve surgery. The rigour of this study is compromised by two major limitations. First, the before-and-after design was not randomized or blinded, and did not take place over the same study period. This presents a major challenge for eliminating bias and appropriately evaluating the two study groups. The second major limitation was that physicians independently dosed warfarin based on personal strategy, whereas the pharmacists followed a structured protocol. As such, the study did not specifically compare structured physician- and pharmacist-managed anticoagulation practices. The implications on health human resources of this study are significant, as pharmacists and physicians are equally effective in anticoagulation management.

¹Dalen JE, Hirsh J. Introduction: antithrombotic therapy – the evolving consensus. *Chest.* 1998;114(Suppl 5):439-440.

Background or research methods: This before-and-after comparison included 227 patients, and was conducted at an academic cardiac surgery hospital. Medical charts were reviewed retrospectively to identify patients who were prescribed warfarin sodium following cardiac valve surgery. The physician group comprised patients from February 1999 to July 1999,

while the pharmacist-managed group was studied between October 1999 and March 2000. The physician group prescribed warfarin sodium independently, whereas the pharmacist-managed group followed a structured protocol to determine dosing. The primary objective was to compare the effectiveness of pharmacist and physician initiation and management

of warfarin treatment following cardiac valve surgery. The secondary outcomes evaluated several objectives surrounding the monitoring of warfarin therapy.

Financial support: Financial support for this study was provided by St. Paul's Hospital pharmacy department.

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