The Role of Community Pharmacy in Post Hospital Management of Patients Initiated on Warfarin

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EXECUTIVE SUMMARY

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Executive Summary:

Introduction

Warfarin has been in widespread use since the 1950s and is currently the most commonly prescribed vitamin K antagonist worldwide. Warfarin prescribing continues to increase, because of its proven benefits in a number of clinical situations. It is, however, recognised as a high-risk drug for adverse drug events (ADEs), especially bleeding. In 1992, warfarin-related ADEs in Australia were estimated to cost over $100 million per annum in direct hospital costs alone. Bleeding risk is highest early in the course of therapy and hospitalisation has been demonstrated to be an independent cause of reduced anticoagulant control. Anticoagulant control can be problematic in the post-discharge period due to various factors, including insufficient communication across the continuum of care and an inadequate frequency of monitoring of the International Normalised Ratio (INR, the blood test used to monitor the anticoagulant effect of warfarin), which may be compounded by patients’ transportation difficulties and physical limitations.

Project Overview

This prospective controlled cohort study trialled a flexible post-discharge warfarin management service based on the existing home medicines review (HMR) process. Patients received two or three home visits by a trained accredited pharmacist in their first 8 to 10 days after discharge from hospital. The service provided point-of-care (POC) INR monitoring using a finger prick blood test, warfarin education and a HMR, in collaboration with a patient’s GP and community pharmacist.

Logistical problems in the early phases of the study and difficulties with patient recruitment resulted in smaller than anticipated patient groups, limiting the statistical power of the study. The outcomes of 129 patients receiving the service were compared with those of 139 patients receiving usual care (defined as traditional GP or pathology-based INR testing). A non-statistically significant reduction in the primary outcome measure, the rate of major bleeding events in the 90 days after hospital discharge, was demonstrated. There were also no statistically significant decreases in the rates of the secondary outcomes of major bleeding or thrombotic events (although a positive trend was observed), unplanned hospital readmissions or death. The service was associated with an improvement in the secondary outcome of persistence with warfarin therapy (83.6% in the group receiving usual care vs 95.2% in the group receiving the service), as well as significantly decreased rates of total bleeding events at both Day 8 (7.4% vs 0.9%) and Day 90 (14.7% vs 5.3%) after hospital discharge, and combined bleeding and thrombotic events at Day 8 and Day 90 (8.3% vs 0.9%, and 19.0% vs 6.4%, respectively) (p<0.05 in all cases). Benefits were especially significant in patients newly initiated on warfarin. These must be considered conservative estimates of the benefits of the service as ethical requirements resulted in a number of GPs being contacted about non-therapeutic INR results in the patients receiving usual care, potentially reducing the risk of ADEs in these patients.

Stakeholder satisfaction with the post-discharge service was very good, with the convenience of the home visits and the improved opportunities for comprehensive warfarin education perceived as especially beneficial. The service was seen as best targeted to newly initiated patients, those with complex medical conditions and medication regimens, those living alone, and the elderly, immobile or otherwise disabled.

A cost-effectiveness analysis of the service revealed that it was associated with significant savings in warfarin-related healthcare costs in the 90 day post-discharge period, especially in the costs of bleeding and thrombosis-related hospital readmissions. Extrapolation of these figures to a population level suggested that the service has the potential to produce annual savings to the Australian healthcare system of over $6.4 million.

Sixteen appropriate patients were then transitioned on to patient self-monitoring (PSM) of their INRs, receiving supplemental training during an additional home visit and the opportunity to communicate their INR results to their healthcare providers via www.anticoagulation.com.au. Previous studies have demonstrated that PSM is associated with better, or at least equivalent, INR control to usual care, as well as improved patient empowerment, convenience, adherence and awareness of their health status by the patient, and reduced dependence on the healthcare system. Patients require appropriate training to safely undertake PSM and while formalised training programs are widespread in countries such as Germany, they are virtually non-existent at present in Australia. In this study, PSM was subsequently associated with improvements over usual care in all measures of INR control. Patient satisfaction was high and both patients and GPs expressed satisfaction with the ability to communicate patient-obtained INR results over the internet.

Limitations

The outcomes of the post-discharge service cannot necessarily be generalised to the entire population of patients taking warfarin after discharge from hospital. Some minor differences were detected between the groups’ bleeding and clotting-related risk factors which may have affected the patients’ eventual outcomes. Patients were recruited from only eight hospitals in Tasmania, South Australia and New South Wales, with the majority recruited from three major metropolitan sites. Patients living in regional and remote areas and non-English speaking patients participated.
only to a limited degree, and certain patient groups were excluded for ethical reasons. In addition, the service was not trialled in any of the states where warfarin therapy for community-based patients is primarily managed by pathology providers rather than GPs. Recruitment was limited by the existence of pre-existing post-discharge services in some sites. Although this demonstrated significant geographical variability, it may limit the broader utility of the service in some areas. The extent of such services Australia-wide is unknown, and further research regarding their capacity to service patients discharged from hospital on warfarin across the country would prove useful in clearly elucidating the feasibility of national implementation of the pharmacist-provided service. Patient outcome and healthcare service utilisation data relied heavily on patient and GP reports and thus the accuracy of this information potentially suffered as a result of recall bias and a lack of recorded information. This was complicated by a slight lower follow up rate in the group receiving the service. It was ameliorated somewhat, however, by accessing patients’ medical records for information on their hospital readmissions, which enabled data on the majority of significant adverse events to be captured.

Despite these limitations, the results of this study provide solid evidence to suggest that the optimal implementation of pharmacy-based anticoagulation management services has the potential to improve the health outcomes of eligible patients discharged from hospital taking warfarin and reduce healthcare costs, especially those associated with warfarin-related hospital readmissions.

Benefits for Patients

- Although the post-discharge service failed to significantly reduce the rate of major bleeding events, it resulted in a decreased rate of total bleeding events at both Day 8 and Day 90 post-discharge. Patients were spared the discomfort, distress, inconvenience and cost associated with minor bleeding episodes, as well as the potential morbidity and mortality associated with more serious events.
- There was also a decrease in combined bleeding and thrombotic adverse events at Day 8 and Day 90, which equated to an additional reduction in the number of transient ischaemic attacks, myocardial infarctions and deep vein thrombosis-related complications.
- Patients found the convenience of home INR monitoring in the post-discharge period reassuring. This was especially true for those unable to drive who found travelling to their GP and pathology laboratory difficult. The educational component of the post-discharge service was perceived as highly valuable by patients, GPs and pharmacists alike. It resulted in a significant short-term improvement in warfarin knowledge levels, with previous studies indicating that improved patient knowledge reduces the risk of adverse outcomes from warfarin therapy.19 It was especially appreciated that this education was provided in the patients’ homes, where the more relaxed, familiar environment made them more receptive to absorbing the information provided than they had been while in hospital.
- As well as improved convenience and self-reported quality of life, patients trained to undertake PSM demonstrated an improvement in their time in therapeutic INR range (TTR) of 13.8% over usual care. Improvements in TTR of as little as 10% have been shown to convey a 29% improvement in all-cause mortality.20-24

Benefits for the Healthcare System

- The post-discharge service resulted in an additional 5.5% of patients continuing warfarin 90 days after discharge from hospital due to reduced warfarin-related adverse events or difficulties with their warfarin management. By maintaining these patients more successfully on a potentially life-saving therapy, there is the potential to reduce thrombotic events (such as strokes and pulmonary emboli) and the associated hospitalisation and other healthcare costs.
- The post-discharge service was also associated with a decreased requirement for GP visits and pathology or GP-based INR tests in the post-discharge period, freeing up GP appointments and thus reducing the burden on already overstretched community-based healthcare services.
- The post-discharge service has the potential to produce significant overall reductions in warfarin-related costs in the post-discharge period. This is especially true in relation to the costs of hospital readmissions for warfarin-related bleeding and thrombotic events, thus reducing the financial burden of iatrogenic disease on society.

Benefits for Community Pharmacy

- A business case for the involvement of community pharmacy in these services indicated a likely financial benefit for those pharmacies making the commitment to expanding the range of innovative professional services available to one of our most high-risk patient groups. Conservative estimates indicate a small surplus on investment would be expected in the first year, with ongoing profit opportunities from consumables and potentially increased customer loyalty in the following years.
- The services could be even more profitable were an incentive scheme (similar to that offered for the Diabetes Medication Assistance Service and Pharmacy Asthma Management Service) or government subsidies for portable INR monitors and/or consumables provided, especially in rural and remote areas.
- The service benefitted the personal relationships between patients and their community pharmacies, while accredited pharmacists reported greater professional satisfaction from providing the post-discharge warfarin service...
than from completing ‘standard’ HMRs. Community pharmacy engagement with the service could be improved by direct HMR referral from the hospital to the community pharmacy, information technology solutions to aid communication, and change management programs to facilitate increased involvement with post-discharge patients.

**Recommendations**

- **Wider implementation of a pharmacy-based post-discharge warfarin management service, incorporating POC INR monitoring, warfarin education and an HMR, should be undertaken.** The exact components of the service (INR monitoring ± warfarin education), as well as the frequency of the visits and the duration of follow up, should be dictated by individual patients’ needs, although good acceptance of the two vs three visit model was demonstrated. Patients who are identified in hospital as being at high risk of medication misadventure should be considered as candidates for a post-discharge HMR to address their warfarin education needs, regardless of their need for home POC INR monitoring. *(Final Report Recommendations 1 and 2)*

- **This service should be implemented as an extension of the existing HMR program and remunerated via a similar mechanism.** Payments of $180 for the first visit, and $75 for subsequent visits proved acceptable to the accredited pharmacists involved in the project. Community pharmacists could continue to receive a portion of this payment, according to the current HMR system. GPs were satisfied with payment in line with the current MBS Item 900 payment. *(3)*

- **The post-discharge service should be offered as an alternative to existing post-discharge services, especially in geographical areas where limited or no services exist.** It could be offered to all patients as appropriate, but specifically target patients newly initiated on warfarin; for whom timely community-based follow up is problematic due to the limited availability of urgent post-discharge GP appointments; lacking access to GP surgery-based POC monitoring or other formalised systems of INR monitoring; who are frail, immobile or disabled, unable to attend GP surgeries or pathology clinics post-discharge, and in situations where a home phlebotomy service is difficult to access. *(4)*

- **If implemented, the availability of the service should be widely promoted to both hospital-based and community-based stakeholders (e.g. discharge coordinators, clinical pharmacists, GPs, community pharmacists, accredited pharmacists, consumer groups).** This will ensure its recognition as an alternative home-based service and its integration into existing discharge planning procedures. A promotional campaign such as that supporting the existing HMR program should be developed and funded by the Department of Health and Ageing. *(5)*

- **To facilitate implementation of the post-discharge service, alterations should be made to the existing HMR Business Rules to allow hospital doctors to authorise referrals for patients for post-discharge HMRs directly to a community pharmacy or accredited pharmacist.** *(6)*

- **Information technology solutions to aid communication (such as e-Health) and change management programs should be investigated to assist with multidisciplinary collaboration models such as the post-discharge service and to facilitate community pharmacist engagement.** *(6, 7)*

- **Consideration must be made of who bears responsibility for the cost of the POC INR monitor and annual quality assurance (QA) costs.** An incentive scheme or government subsidies for POC INR monitors and/or consumables to community pharmacies (especially in rural and remote areas) and patients, linked to conditions regarding training and ongoing QA, may be appropriate. *(8)*

- **Health promotional activities aimed at all stakeholder groups to raise the awareness of the availability of POC INR monitors, their place in therapy, and the usefulness of PSM should be undertaken.** PSM has the potential to improve TTR and quality of life for patients on long-term warfarin therapy and a HMR-based training and education program to facilitate PSM complements the post-discharge service. *(9)*

- **The web-based resource developed in this study should be supported as an appropriate platform to raise awareness and provide access to educational materials.** It is also a useful tool for patients to record their INR results and communicate with their healthcare providers regarding their INR monitoring and warfarin dosing. *(10)*

- **The number of trained accredited pharmacists should be maximised to ensure optimal delivery of both services.** This would also alleviate the difficulties that some accredited pharmacists reported in accommodating provision of the service within their existing workloads. Training and credentialing should also be optimised, with these two programs offered as a single amalgamated training course. The Anticoagulation Education Program should be made available to all accredited pharmacists via an organisation such as PSA or AACP. Standard credentialing and regular (possibly three yearly) re-credentialing processes should then be implemented and managed by this organisation. *(11, 12)*

- **Any national program of pharmacy-based anticoagulation monitoring services should be accompanied by appropriate QA measures.** These should include enrolment in a formal QA program for pharmacy-based monitors and initial and ongoing comparison pathology tests and an annual HMR for patients undertaking PSM. A partnership with the RCPA may be appropriate to ensure ongoing QA is completed. *(13)*
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References