Pharmacy-Based Model Enabling Patient Self-Monitoring of Warfarin: Development and Evaluation

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EXECUTIVE SUMMARY

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Executive Summary (max. 3 pages):

Introduction

Previous studies suggest that patient self-monitoring (PSM) of the international normalised ratio (INR) may improve the outcomes of oral anticoagulation therapy through increasing the time spent within the target range (TTR), and improving both consumer satisfaction and participation in healthcare. There is clear evidence that better strategies are required to optimise warfarin therapy in Australia. New strategies have been implemented elsewhere in the world and have been demonstrated to improve clinical outcomes, and consumer satisfaction and quality of life. The implementation of PSM in Australian healthcare is an example of an intervention that would address a number of principles to improve the management of warfarin therapy through improved access to monitoring, improved consumer awareness of monitoring requirements, and empowering consumers and enhancing their understanding of their chronic disease and warfarin therapy.

The primary objective of this project was to develop, implement and evaluate a pharmacy-centred pathway to enable Australians who take warfarin to monitor their own therapy. Additional objectives included:

- Development of a train-the-trainer package to enable pharmacists to train consumers to perform PSM;
- Development of a credentialing process to enable pharmacists to deliver training for PSM;
- Development of a train-the-consumer package for pharmacists to use to train consumers; and
- Performance of a preliminary evaluation of the model to allow for its refinement for national roll-out.

Methods used

A clinical pathway to enable self-monitoring of warfarin therapy was developed in consultation with input from a wide range of stakeholders. The pathway included a structured training program, which was developed to facilitate the transition of consumers from usual care to PSM using the existing Home Medicines Review (HMR) model (Figure 1). Educational packages and web-based anticoagulation resources were developed in consultation with stakeholder representatives to support the trial of the pathway.

A preliminary evaluation was performed to implement the clinical process in Hobart, Tasmania and Wagga Wagga, NSW. Consumers were recruited through their participating community pharmacies and, in collaboration with their general practitioners (GPs), received intensive one-on-one warfarin education and training in using the CoaguChek®XS point of care INR monitor by a trained HMR accredited pharmacist. Once trained, a 'run-in' phase was completed where consumers compared results to pathology results to ensure effective use of the monitor. PSM was undertaken for six months. Outcome measures included factors relating to INR control (including TTR), warfarin knowledge, quality of life, and satisfaction with the pathway.
Key findings

Twenty-eight consumers were recruited through 13 community pharmacies in Tasmania and NSW, and successfully trained to participate. The majority of patients (60.7%; 17/28) were male and the median age was 66.5 years. AF was the most common indication for warfarin therapy and a target INR range of 2.0-3.0 was the most common.

Results from the present study indicate, albeit in a small number of patients willing to self-monitor, that there is scope for improvement in control. Literature suggests that the TTR is closely correlated with outcomes. The mean TTR in this study rose from 57.8% to 72.5% with PSM, an improvement that has been suggested to impart a clinically significant improvement in outcomes. The proportion of tests in range in the study population also significantly improved from 55.2% tests in range prior to PSM to 71.7% during PSM.

The literature supports the notion that increased frequency of INR testing leads to an increased TTR, and improved outcomes. Participants in this study recorded a significant increase in frequency of testing during the intervention period, increasing from a median of 1.2 to 2.7 INR tests per month. Even in the absence of any improvements in INR control, the improvement in frequency would suggest improved outcomes for study participants.

Many studies have demonstrated a link between improved warfarin knowledge and outcomes. Participants’ warfarin knowledge improved significantly from baseline following the education session delivered as part of the training program. This improvement was sustained over the course of the intervention with no significant change in warfarin knowledge between the post education period and the conclusion of the PSM phase.

No improvement in quality of life was recorded using the EQ5D instrument; however participants expressed a self-reported improvement in quality of life during the evaluation process.

Feedback from GPs, consumers and pharmacists has indicated a high level of satisfaction with both the training program and PSM. Feedback from the qualitative analysis was also generally positive and supportive of the model for the implementation of PSM that was proposed and trialled in this study.

The qualitative researchers drew a number of conclusions from the interviews with participants. These included the following:

- Self-monitoring of INR is a viable option for some consumers able to cope with the self-testing procedure;
- Consumers adapt to the testing procedure quickly and without clinical problems given appropriate selection, training and support;
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- Once adapted to PSM, consumers are very positive towards the experience and eager to continue;
- PSM has no detrimental effect on the GP/consumer relationship;
- The training and support provided in this study was well accepted; and
- A national program for PSM could be implemented using this project’s educational materials and support model.

This study was successful at demonstrating the feasibility of the proposed clinical pathway to enable PSM of warfarin therapy. Measures of INR control and consumer outcomes improved during the PSM phase. The level of satisfaction expressed by all groups of participants in regard to both the study materials and the method of management was very high, supporting the implementation of a national program to enable INR self-monitoring in Australia.

Recommendations

PSM is a rapidly evolving area and Australian consumers have access to monitoring devices with no access to training, support, or appropriate follow-up. Implementation of a program such as the pathway piloted in this study is critical to improve the safety of consumers who take warfarin.

A number of recommendations have arisen from this study to inform implementation of the piloted clinical pathway as part of a national program to enable PSM:

- Implementation of PSM needs to be supported by health promotional activities to raise the awareness of the availability of point-of-care INR devices, of their place in therapy, and the usefulness of PSM as a warfarin management model. Awareness should be raised among all stakeholder groups, especially among consumers, GPs and pharmacists.
- Raised awareness should be supported by information and education to enable implementation of PSM. The web-based resource developed in this study may be an appropriate platform to raise awareness and provide access to educational materials.
- The training materials refined for use in this study have been reviewed by stakeholder organisations and piloted in the study population. It would now be appropriate for stakeholder organisations to formally endorse these materials for use in a national program.
- The screening tool used in this project should be refined and converted to a checklist to enable the selection of appropriate consumers for PSM.
- A funding model should be developed to support the proposed pathway. Recommendations include:
  - The training program developed in this study should be funded and implemented on a national level. Funded training programs should cover the training program to credential pharmacists and the training program to train consumers.
  - An incentive scheme could be implemented to complement the rollout of accredited pharmacist training to ensure a critical mass of pharmacists is available to deliver the training service. This could be done in a manner similar to the incentive schemes that have been used in the Diabetes Medication Assistance Service and Pharmacy Asthma Management Service.
  - It may be appropriate to consider government subsidies for portable INR monitoring devices and/or consumables to consumers. It may be appropriate for conditions regarding training and ongoing QA to be attached to theses subsidies.
- Training and credentialing of pharmacists to provide the PSM training service needs to be coordinated by a professional pharmacy organisation.
- Any national program to enable PSM should be accompanied by appropriate quality assurance measures, including initial and ongoing comparison pathology tests and an annual HMR. A partnership with the Royal College of Pathologists of Australasia may be appropriate to ensure ongoing QA is completed.