

Is self-monitoring a cost-effective option for people receiving long-term vitamin K antagonist (Warfarin) therapy?

Key Findings

- Based on meta-analyses of available randomised data, self-management (self-testing using a point of care device at home and subsequent dose adjustment) was found to significantly reduce the risk of thromboembolic events in patients with atrial fibrillation or an artificial heart valve.
- Self-testing (self-testing and communication with a health care professional for advice on dose adjustment) was found to result in a modest increase in time in therapeutic range compared with standard care, but did not significantly impact on thromboembolic or bleeding events.
- On the whole, self-monitoring of coagulation status using a point-of-care testing device appears to be a safe and cost-effective option for individuals receiving long-term vitamin K antagonist therapy who have atrial fibrillation or an artificial heart valve.

What problem was this research addressing?

Individuals with atrial fibrillation, heart valve disease, or other cardiac conditions are at heightened risk of blood clots forming in the chambers of their heart. These clots can break away and travel in the blood stream and ultimately block vessels (thromboembolism) in the brain causing a stroke. Many individuals with these conditions therefore require long-term oral anticoagulation therapy (OAT) to reduce the risk of clots forming. This is often achieved using warfarin, where the goal is to establish a balance between the bleeding and clotting risk. Under-anticoagulation does not effectively reduce the increased risk of thromboembolism, while over-anticoagulation results in an increased risk of haemorrhage which can also have devastating consequences. Hence, treatment with warfarin requires frequent monitoring of the individual's international normalised ratio (INR) - a standardised unit for measuring the time it takes for blood to clot.

As standard practice, warfarin monitoring is managed by healthcare professionals in anticoagulant clinics based in hospitals using laboratory testing or in primary care using a laboratory testing service or point-of-care testing device

(coagulometer) situated in the practice. The other option for warfarin monitoring is the use of a personal coagulometer at home, which allows people to perform self-testing (when people carry out the test themselves and the results of the test are managed by healthcare professionals) or self-management (when people carry out the test and alter the dose of anticoagulation therapy themselves according to a personalised protocol). Self-testing and self-management are together referred to as self-monitoring.

What this research adds

This study, commissioned by the National Institute for Health and Care Excellence (NICE) through the National Institute for Health Research (NIHR) Health Technology Assessment (HTA) programme, involved a systematic review of randomised controlled trials assessing the clinical effectiveness of self-monitoring strategies compared with primary or secondary care based INR monitoring. The pooled effects of self-monitoring on thromboembolic and major and minor bleeding events were applied in a new economic model designed to assess the cost-effectiveness of self-monitoring strategies versus standard care.^{1,2}

Methods

Randomised controlled trials (RCTs) comparing self-monitoring with standard clinical care in people with atrial fibrillation or heart valve disease were systematically identified and appraised for inclusion in the review. Meta-analyses assessed the effects of self-management, self-testing and self-monitoring as a whole on the risk of thromboembolic events, major and minor bleeding events, all-cause mortality, and time in target therapeutic INR range.

An economic model was developed to simulate the incidence of stroke and bleeding events in a cohort of individuals on long-term warfarin therapy under standard primary/secondary care monitoring. The effects of self-testing and self-management were derived from the meta-analysis of existing randomised controlled trials, and incorporated in the model to assess the projected impact of these strategies on the 10 year incidence of stroke and bleeding events. Health service and personal social care costs associated with the alternative monitoring strategies and the modelled clinical events were incorporated in the model, allowing cumulative costs to be estimated over the ten-year time horizon.

Health state utility weights were also applied to events and post-event health states. These utility weights were derived, where possible, from studies reporting EQ-5D scores for cohorts experiencing the different types of event. EQ-5D scores reflect the desirability of generic health states on a scale where zero represents death and one represents full health. By using these weights to adjust the time (in years) spent by the modelled cohort in the different health states of the model, quality adjusted life years (QALYs) were estimated for the alternative monitoring strategies. The analysis then focused on estimating the difference in modelled events, cumulative costs and QALYs between the self-monitoring strategies and standard practice.

Research Highlights

- Self-monitoring of coagulation status using a point-of-care testing device appears to be a safe and cost-effective option for people receiving long term vitamin K antagonist therapy who have atrial fibrillation or an artificial heart valve.
- Self-management in particular was found to be associated with a significant reduction in thromboembolic events and could be cost saving compared to standard care from a health and social care perspective.

Policy relevance of research findings

Based on evidence from 26 RCTs (8763 participants), both self-management and self-testing were found to be as safe as standard care in terms of major bleeding events. Self-management was associated with fewer thromboembolic events, with a pooled relative risk (RR) of 0.51 (95% CI 0.37 to 0.69), and a borderline significant reduction in all-cause mortality (RR 0.68, 95% CI 0.46 to 1.01) compared with standard care. Self-testing resulted in a modest increase in the time spent by individuals with their INR in therapeutic range compared with standard care (weighted mean difference, 4.4%, 95% CI 1.71 to 7.18), but was not found to have a significant effect on thromboembolic events (RR 0.99, 95% CI 0.75 to 1.31).

Incorporating these findings in the economic model, and assuming 50% of self-monitoring patients self-manage and 50% self-test, mean health and social care costs (per individual) amounted to £7,324 with standard care and £7,326 with self-monitoring. Self-monitoring was associated with an absolute reduction of 2.5% in the proportion of people suffering a thromboembolic event, and generated an average QALY gain of 0.028 compared with standard care. Based on probabilistic analysis, self-monitoring was found to have ~80% probability of being cost-effective compared with standard care at a ceiling willingness-to-pay ratio of £20,000 per QALY gained.

References

1. Sharma P, Scotland G, Cruickshank M, Tassie E, Fraser C, Burton C, Croal B, Ramsay CR, Brazzelli M. The clinical effectiveness and cost-effectiveness of point-of-care tests (CoaguChek system, INRatio2 PT/INR monitor and ProTime Microcoagulation system) for the self-monitoring of the coagulation status of people receiving long-term vitamin K antagonist therapy, compared with standard UK practice: systematic review and economic evaluation. *Health Technology Assessment*. 2015; 19(48):1-172
2. Sharma P, Scotland G, Cruickshank M, Tassie E, Fraser C, Burton C, Croal B, Ramsay CR, Brazzelli M. Is self-monitoring an effective option for people receiving long-term vitamin K antagonist therapy? A systematic review and economic evaluation. *BMJ Open*. 2015 Jun 25; 5(6): e007758.

Acknowledgements

The work carried out for this project was commissioned by NICE and funded by the National Institute for Health Research (NIHR) Health Technology Assessment (HTA) Programme. The views and opinions expressed herein are those of the authors and do not necessarily reflect those of NICE, the NIHR HTA Programme, NIHR, NHS or Department of Health.

Investigators and researchers on this project were Pawana Sharma, Graham Scotland, Moira Cruickshank, Emma Tassie, Cynthia Fraser, Christopher Burton, Bernard Croal, Craig R Ramsay, and Miriam Brazzelli.

For further information see the full paper: Sharma P, Scotland G, Cruickshank M, Tassie E, Fraser C, Burton C, Croal B, Ramsay CR, Brazzelli M. Is self-monitoring an effective option for people receiving long-term vitamin K antagonist therapy? A systematic review and economic evaluation. *BMJ Open*. 2015 Jun 25; 5(6): e007758.



http://twitter.com/HERU_Abdn

CONTACT US

HEALTH ECONOMICS RESEARCH UNIT

Institute of Applied Health Sciences, Polwarth Building, Foresterhill, Aberdeen AB25 2ZD

Tel: +44 (0)1224 437197/437196 Fax: +44 (0)1224 437195 Email: heru@abdn.ac.uk www.abdn.ac.uk/heru