



## Self-monitoring for people on vitamin K antagonist anticoagulant therapy

A meta-analysis found that for people receiving long-term vitamin K antagonist therapy, self-monitoring of anticoagulation status with point-of-care devices was at least as safe as monitoring by healthcare professionals.

### Overview:

- Compared with standard monitoring, self-monitoring of anticoagulation status did not affect the risk of bleeding or death in people receiving long-term vitamin K antagonist therapy, and was associated with a lower risk of thromboembolic events.
- In this meta-analysis, the effects of self-monitoring were largely driven by the beneficial effects of self-management (where people adjust their medication dose themselves after testing).
- Care must be taken in generalising these results to the UK, where standard care is generally very good and may be cheaper than the cost of self-monitoring.

**Background:** Many people with atrial fibrillation, heart valve disease or other conditions associated with a high risk of blood clots (thrombosis) are prescribed long-term anticoagulation treatment with vitamin K antagonists, such as warfarin.

People receiving long-term vitamin K antagonists need regular tests (using the international normalised ratio [INR]) to measure the clotting tendency of their blood ([NHS Choices 2014](#)). Their medication dose is then adjusted accordingly to ensure blood clots are prevented without increasing the risk of bleeding. This repeated monitoring may be carried out in specialist anticoagulation clinics, or by primary or secondary care staff.

An alternative is for people to carry out these tests at home with point-of-care coagulometers (self-monitoring; [NICE 2014](#)). People may then alter their medication dose themselves (self-management) or contact a healthcare professional for advice on any change to dosage (self-testing). The use of these coagulometers may improve health outcomes by enabling anticoagulation dose to be adjusted more accurately ([Heneghan et al. 2006](#)).



**Current advice:** NICE has diagnostics guidance on [atrial fibrillation and heart valve disease: self-monitoring coagulation status using point-of-care coagulometers](#).

The CoaguChek XS system and the INRatio2 PT/INR monitor are recommended for self-monitoring of coagulation status in adults and children on long-term vitamin K antagonist therapy who have atrial fibrillation or heart valve disease if:

- the person prefers this form of testing and
- the person, or their carer, is both physically and cognitively able to self-monitor effectively.

Patients and carers should be trained in the effective use of the CoaguChek XS system or the INRatio2 PT/INR monitor, and clinicians involved in their care should regularly review their ability to self-monitor.

The NICE pathways on [atrial fibrillation](#) and [structural heart defects](#) bring together all related NICE guidance and associated products on these conditions in sets of interactive topic-based diagrams.

**New evidence:** A meta-analysis by [Sharma et al. \(2015\)](#) assessed the effectiveness of self-monitoring of anticoagulation status in people receiving long-term vitamin K antagonist therapy.

The authors searched for randomised controlled trials that compared self-testing or self-management of anticoagulation control using point-of-care coagulometers (self-monitoring) with monitoring by healthcare professionals (standard care). The review included studies of both adults and children with heart valve disease, atrial fibrillation or other clinical conditions who required long-term vitamin K antagonist therapy.

A total of 26 trials from Europe and North America were identified. Of these trials, 22 were included in the analysis (n=8394).

In a pooled analysis of all 22 trials, self-monitoring was associated with a significant reduction in the risk of thromboembolic events compared with standard care (relative risk [RR]=0.58, 95% confidence interval [CI] 0.40 to 0.84, p=0.004). When the two different types of self-monitoring were considered separately, self-management was associated with a significantly lower risk of thromboembolic events than standard care (RR=0.51, 95% CI 0.37 to 0.69, p<0.0001; 15 trials, n=4640). No significant risk reduction was seen among trials of self-testing (RR=0.99, 95% CI 0.75 to 1.31, p=0.56; 7 trials, n=3754).

The risk of any bleeding event with self-monitoring did not differ significantly from that with standard care (RR=0.95, 95% CI 0.74 to 1.21, p=0.66; 22 trials, n=8394). However, self-testing was associated with a slightly higher risk of bleeding than standard care (RR=1.15, 95% CI 1.03 to 1.28, p=0.02; 7 trials, n=3754).

There was no significant difference in all-cause mortality between self-monitoring and standard care (RR=0.83, 95% CI 0.63 to 1.10, p=0.20; 13 trials, n=6537). Self-management appeared to be associated with a reduction in mortality that was close to statistical significance (RR=0.68, 95% CI 0.46 to 1.01, p=0.06; 10 trials, n=3293). Self-testing had no effect on mortality (RR=0.97 95% CI 0.78 to 1.19, p=0.74; 3 trials, n=3244).

The authors concluded that self-monitoring of anticoagulation status was at least as safe and effective as monitoring by healthcare professionals for people receiving long-term vitamin K antagonist therapy. Limitations of this analysis include the variation among trials; for example, in clinical indications for anticoagulation and training in self-monitoring provided to participants. In addition, most of the included trials were considered to be at high or unclear risk of bias.

**Commentary by Professor DA Fitzmaurice, Professor of Primary Care, Primary Care Clinical Sciences, Institute of Applied Healthcare Research, University of Birmingham:**

“These data are not particularly novel, do not really add much to current evidence and unfortunately repeat the faults of previous reviews in this area. The studies that drive the seeming improvement in outcomes with self-monitoring are those with high patient selection bias in areas where routine care was relatively poor.

“Conversely, where routine care is good, for example the UK, no improvement in clinical outcomes is seen. Indeed, the one UK-based trial found no improvement in outcome among people using self-management, and self-management was five times as expensive as routine clinic-based care ([Jowett et al. 2006](#)). Many of the studies included in the evidence review for the NICE diagnostics guidance did not include UK costs.

“There are additional patient benefits self-monitoring in terms of convenience and not having to attend anticoagulation clinics. In my opinion, the ability to test without having to access a clinic is the most positive aspect of self-monitoring.

“It is often noted that self-management seems to confer benefit whereas self-testing, where dose is adjusted by a healthcare professional, is not. This effect is most likely due to patient selection, in that only the most highly motivated and educated patients are deemed to be able to self-manage and adjust their own dose. It may however reflect real improvement driven by increased patient autonomy.

“There is no doubt that self-testing and self-management are good options for some patients. Unfortunately, these approaches may come at a cost to service providers, in this case the NHS. This new meta-analysis makes it difficult to have a sensible debate about the role of self-monitoring by overstating the clinical effectiveness and understating the costs.”

**Study sponsorship:** National Institute for Health Research.

**About this article:** This article appeared in the May 2016 issue of [Eyes on Evidence](#).

Eyes on Evidence is a monthly email service that summarises and provides expert commentary on important new evidence in health, public health and social care, to help busy professionals stay up to date. The service outlines how the new evidence fits in with current guidance and provides expert views on how the evidence might influence practice. It does not constitute formal NICE guidance. The commentaries included are the opinions of contributors and do not necessarily reflect the views of NICE.

Subscribe on the [NICE website](#) to receive Eyes on Evidence each month.

[Visit NICE Evidence search](#)

Copyright © 2016 National Institute for Health and Care Excellence. All Rights Reserved.