

# **INR Monitoring for Anticoagulation Treatment**

**Eve Knight**

**Chief Executive**

**AntiCoagulation Europe**

# Introducing ACE



- Founded in 2000, AntiCoagulation Europe (UK) is a charity dedicated to supporting patients who take anticoagulant and antiplatelet therapy.
- ACE provides information, education and support via a dedicated helpline, contact network and has a membership base.
- The primary aim of the Charity is to heighten awareness of prevention of thrombosis and for those already on medication, to help access a first class anticoagulation service which supports patient needs whilst encouraging people to take an active role in their own healthcare
- Collaborates with medical professionals, other charities, government and industry for continuous improvements in anticoagulation services across UK.
- ACE has a panel of medical experts who are able to provide advice and clinical updates on all aspects of anticoagulation therapy



ACE@AntiCoagEurope



ACSMA@ACSMAUK



All-Party Parliamentary  
Thrombosis Group

# What is Self-monitoring



Self-monitoring is when a patient on warfarin does their INR test themselves. Self-monitoring is a part of self-care. Self-care is a key NHS initiative. It has been identified that there is sub-optimal support for self-care which if addressed may add value improvements. For example, self-monitoring could help improve the current under emphasis of a person's role in managing their illness.

# The Advantages of Self-monitoring



- ➊ Self –monitoring – personal control
- ➋ Gain more comprehensive knowledge and understanding of what can affect INR
- ➌ Reduction in morbidity and mortality
- ➍ Time in Therapeutic Range average 80 +
- ➎ Peace of mind for patient and family
- ➏ Flexibility of when and where to test
- ➐ No restrictions on travel for work or pleasure
- ➑ Not having to factor in time for blood tests and being reminded that you have a health problem every time you visit a clinic setting.
- ➒ Well being – physical and mental. Just get on with life

# Clinical Benefits of Self-monitoring



INR is more stable through spending more time in the INR therapeutic range

Less risk as self-monitoring reduces the risk of thromboembolic events by 49%

Self-monitoring offers particular benefits in those younger than 55 years, in whom the likelihood of developing thromboembolic events is reduced by two-thirds, and patients with a mechanical heart valve, where risk is halved

Self-monitoring lowers mortality and does not increase complications in people aged 85 and older, who are at high risk of major bleeding, which suggests that age should **not be a factor in determining eligibility for self-management**

1 Gardiner C et al, [Patient self-testing is a reliable and acceptable alternative to laboratory INR monitoring](#), British Journal of Haematology, 2004

2 [Self-care strategy: Self-care – a real choice](#). Department of Health, 2005

3 Heneghan C et al, [Self-monitoring of oral anticoagulation: systematic review and meta-analysis of individual patient data](#), The Lancet, Volume 379, Issue 9813, 28 January–3 February 2012, Pages 322–334

4 Data on file Atrial Fibrillation Association , AntiCoagulation Europe 2011

# Professor Heneghan Cochrane Collaboration



## Papers

### Articles

#### Self-monitoring of oral anticoagulation: systematic review and meta-analysis of individual patient data

Cof Heneghan, Alan Ward, Edith Evans, Chaitanya Reddy, Alvaro Gómez, Richard Evans, Karen Bradford, Sally Tordoff, Pablo Alonso-Coello, José Areal, Rubén González, Ángel Benito, Thomas Dohle, Christopher, Michael Greenhalge, Robert G. Evans, David Fitzmaurice, Alan P.A. Galbraith, Josep M. Garcia-Alvarez, Chris Gardiner, Michael Heineken, Alvaro Júarez, Scott Keay, Farhad Kamali, Tayebeh Kiani, Iman Khan, Fawaz Knight, Heinrich Küller, Michael Laine, David Livermore, Michael Mandes-DeLoach, Ian McLean, Christian Schaefer, Andrea Salmerón, Juan Carlos Sánchez, Rubén Sardina, Kenneth Gay, Karen Shukla, Peter Völker, Otto Wagner, Áronas Zádorovics, and the Self-monitoring Trialists Collaboration

#### Summary

**Background:** Uptake of self-testing and self-management of oral anticoagulation has remained inconsistent, despite good evidence of their effectiveness. To clarify the value of self-monitoring of oral anticoagulation, we did a meta-analysis of individual patient data addressing several important gaps in the evidence, including an estimate of the effect on time to death, first major haemorrhage, and thromboembolic events.

**Methods:** We used the Cochrane Collaboration ([TRoB](#)—2009) and [Medline](#) (1966–2009), limiting searches to randomised trials with a minimum of 12 months of follow-up. We approached all authors of included trials and requested individual patient data; primary outcomes were time to death, first major haemorrhage, and first thromboembolic event. We did pre-specified subgroup analyses according to age, type of control-group care (anticoagulation-clinic care vs primary care), self-testing alone versus self-management, and sex. We analysed patients with mechanical heart valves or atrial fibrillation separately. We used a random-effects model method to calculate pooled hazard ratios and did tests for interaction and heterogeneity, and calculated a time-specific number needed to treat.

**Findings:** Of 1157 abstracts, we included 11 trials with data for 6417 participants and 12 000 person-years of follow-up. We reported a significant reduction in thromboembolic events in the self-monitoring group (hazard ratio 0.51; 95% CI 0.31–0.71) but not for major haemorrhage events (0.38; 95% CI 0.24–0.52) or death (0.82; 95% CI 0.42–1.09). Participants younger than 55 years showed a striking reduction in thromboembolic events (0.23; 95% CI 0.13–0.33), whereas those aged 65–77, as did those with mechanical heart valves (0.52; 95% CI 0.35–0.77). Analysis of major outcome in the very elderly (age ≥85 years, n=99) showed no significant adverse effects of the intervention for all outcomes.

**Interpretation:** Our analysis showed that self-monitoring and self-management of oral anticoagulation is a safe option for suitable patients of all ages. Patients should also be offered the option to self-manage their disease with suitable healthcare support at home.

**Funding:** UK National Institute for Health Research (NIHR) Technology Assessment Programme, UK NIHR National School for Primary Care Research.

#### Introduction

Oral anticoagulation with vitamin K antagonists substantially reduces the incidence of thromboembolic events,<sup>1–4</sup> although the number of patients requiring oral anticoagulation has increased in recent years due to increased life expectancy and the introduction of the international normalised ratio (INR) within a narrow target range, which includes frequent testing and appropriate dose adjustments. Benefits shown in clinical trials might not generalise well to other settings. However, previous conclusions were limited by methodological problems and inadequate reporting of important outcome data over time.<sup>5–8</sup> Also important subgroup analyses, stratified by age, sex, and indication for anticoagulation therapy, have not been possible.

Uptake of self-testing and self-management has remained inconsistent in and between countries, despite good evidence of their effectiveness and guidance from the World Health Organization and the European Society of Clinical Cardiology.<sup>9–11</sup> Patients can self-test their INR if managed by their health-care provider (self-testing) or they can interpret their INR result, and adjust their own dose of anticoagulant accordingly (self-management).

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*www.thelancet.com* Vol 379 January 18, 2012

#### Self-monitoring and self-management of oral anticoagulation (Review)

García-Alamino JM, Ward AM, Alonso-Coello P, Perera R, Rankin C, Fitzmaurice D, Heneghan CJ



This is a reprint of a Cochrane review prepared and maintained by The Cochrane Collaboration and published in *The Cochrane Library*, 2010, Issue 4. <http://www.thecochranelibrary.com>



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### Articles

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# Progressing anticoagulation self -monitoring in the NHS



- 3 year campaign to make the testing strips available on prescription.  
Achieved in 2002
- In 2012, ACE along with other charities formed the AntiCoagulation Self- monitoring Alliance (ACSMA) with the aims of:
- Achieving greater access to self–monitoring technology for people on long term warfarin
- The devices to be made available on prescription for those who to self-monitor and are eligible
- The campaign continues and to date, ACSMA has more than 1500 individual patient and carer supporters



# Campaign milestones

- More than 275 Westminster MPs elect to receive ACSMA updates
- Participation in Medical Technology Week, an opportunity to discuss how technology can improve patient outcomes and be cost saving to NHS
- 1.1 Meetings with MPs and policy makers, NHS England, NHS Wales and most recently, National Clinical Director for Stroke
- Supported patient petition in the Scottish Parliament
- Freedom of Information requests to CCGS to establish position with regard to protocols around self monitoring within their anticoagulation service provision
- Engaging support from senior clinicians for inclusion of devices on NHS tariff – application to the NHS pending

# Freedom of Information outcomes



- Only 34% of CCGs allow patients to self-test their INR level with the same % of GPs being able to prescribe the testing strips on NHS
- Only 28% of all CCGs allow self-management (patient dosing)
- Only 7% have any formal or local published guidelines in place
- 75% of CCGs do not offer information on self-monitoring or have any information available

# Freedom of Information outcomes



- 67% had not taken steps to assess patient experience
- 41% have not assessed the quality of their services
- 43% have not assessed the number of people using services
- Only 34% have assessed the total cost of services
- 71% are not planning to reconfigure services



# Overcoming barriers



# Challenges...



- Funding
- Governance and safety
- Medico-legal concerns
- Lack of awareness and education on the part of the healthcare professionals
- Lack of patient awareness of technology
- Redesign of services nationally but undertaken by 211 CCGs – trying to decide on best fit for their populations

# NICE Guidelines September 2014

Atrial fibrillation and heart ... [www.nice.org.uk/guidance/dg14](http://www.nice.org.uk/guidance/dg14)

NICE National Institute for Health and Care Excellence

NICE Pathways Guidance Standards and indicators Evidence services Sign in

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Conditions and diseases

Cardiovascular conditions

Structural heart defects

Overview

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2 The technologies

3 Clinical need and practice

4 The diagnostic tests

5 Outcomes

6 Considerations

7 Implementation

8 Related NICE guidance

9 Review

10 Diagnostics Advisory Committee members and NICE project team

11 Sources of evidence considered by the Committee

About this guidance

## 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)

 Guidance  Tools and resources  Information for the public  Download  Share  Print

NICE diagnostics guidance [DG14] Published date: September 2014

 2 Pathways 

NICE has assessed 2 point-of-care coagulometers to help the NHS decide whether to use these products. They are called CoaguChek XS and InRatio2 PT/INR.

Coagulometers monitor blood clotting in people taking long-term anti-blood clotting drugs (such as warfarin) to reduce their risk of blood clots. These tests allow people taking anti-blood clotting drugs to monitor blood clotting themselves. They can then change their dose in agreement with their health professional.

Both coagulometers are recommended for use by people taking long-term anti-blood clotting therapy who have atrial fibrillation or heart valve disease, if they prefer and are able to effectively use this type of monitoring.

People (and their carers) who will be using 1 of these devices should be given training, and their doctor should regularly assess self-monitoring.



 NICE accredited  
[www.nice.org.uk/accreditation](http://www.nice.org.uk/accreditation)

06:55 15/05/2015

# Atrial fibrillation: treatment and management

NICE quality standard [QS93] Published date: July 2015

## Atrial fibrillation: treatment and management

The quality standard for atrial fibrillation is made up of 6 statements that describe high-quality care for adults with atrial fibrillation. These statements set out the quality of care you should receive.

1. Adults with a type of atrial fibrillation called 'non-valvular' who are identified by their doctor as being at higher risk of having a stroke are offered treatment with a medicine called an anticoagulant, to lower their risk of having a blood clot that could cause a stroke.
2. Adults with atrial fibrillation are not prescribed aspirin on its own for preventing stroke.
3. Adults with atrial fibrillation who are prescribed an anticoagulant have the chance to talk with their doctor at least once a year about the types of anticoagulant they could have and the advantages and disadvantages of each.
4. Adults with atrial fibrillation who are taking a type of anticoagulant called a vitamin K antagonist (such as warfarin) have their anticoagulation treatment reassessed if regular tests show that it isn't working well.
5. Adults with atrial fibrillation who still have symptoms after treatment are referred within 4 weeks for specialised care that aims to ease their symptoms and reduce their risk of having a stroke or heart failure.
6. Adults with atrial fibrillation who are taking a vitamin K antagonist over a long time are (if appropriate) offered a monitor they can use to help check how well the treatment is working, if they want to use the monitor and can do so. They are also given support by healthcare professionals to use the monitor.

# Progress



Basildon and Thurrock University Hospitals NHS Foundation Trust

## MEDIA INFORMATION

3 February 2015

### Basildon Hospital helping patients take control of their care



*Patient Roy Johnson (left) with Russell Lee, lead anticoagulation nurse*

Nurses at Basildon University Hospital are helping patients at risk of blood clots avoid visits to blood-testing clinics and take more control of their lives.

It is essential for people who take Warfarin, a 'blood-thinning' anticoagulant medication to have frequent blood tests, but this can be time-consuming and inconvenient. Now by using a pocket-sized monitor, some patients, depending on their circumstances, can test their blood at home.

Basildon Hospital runs one the biggest self-testing programmes in the country, with six per cent of 4,500 Warfarin patients taking part. The national average for self-testing is two per cent.

Roy Johnson, 65, a patient at Basildon Hospital, says his life has been improved by self-testing and has appeared in a short YouTube film to explain the benefits of self-testing to other Warfarin patients. He also praises the support he has received from the anticoagulation nurses at Basildon Hospital, and encourages others find out more about self-testing from their health services.

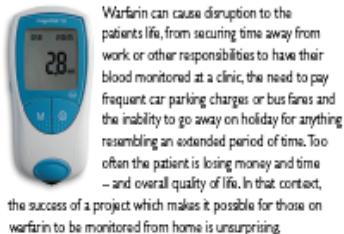
*more ...*

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Website: [www.basildonandthurrock.nhs.uk](http://www.basildonandthurrock.nhs.uk)

Durham & Darlington Foundation Trust

# LEAD THE WAY IN INR HOME MONITORING

THERE ARE APPROXIMATELY ONE AND A QUARTER MILLION PEOPLE IN THE UK WHO TAKE THE ANTICOAGULANT WARFARIN TO REDUCE THEIR RISK OF THE SERIOUS CONDITIONS SUCH AS DEEP VEIN THROMBOSIS, PULMONARY EMBOLISM, AND STROKE.



Warfarin can cause disruption to the patients life, from securing time away from work or other responsibilities to have their blood monitored at a clinic, the need to pay frequent car parking charges or bus fares and the inability to go away on holiday for anything resembling an extended period of time. Too often the patient is losing money and time – and overall quality of life. In that context, the success of a project which makes it possible for those on warfarin to be monitored from home is unsurprising.

Now patients cared for by County Durham and Darlington Foundation Trust have the option to use a digital self-monitoring service. They are trained to take a finger prick blood sample, put it onto a test strip, and then place the test strip in the monitor that is provided for them.

The monitor gives a reading of the person's INR (International Normalised Ratio), which is a measure of how quickly blood clots. They then give the result via an automated phone call. Software automatically shares the figure with clinical staff, who check it, and the patient receives an automated call back letting them know whether they need to change their dose of warfarin.

That is all there is to it. No need to attend a clinic, and the patient can even choose the time of day at which they submit

their reading and at which they receive the call back with their dose. For the 200 people who have been on the service during its initial trial, the system has changed their lives.

It has also helped improve the patients' outcomes. Before the project began, these people were only in therapeutic range around 60 per cent of the time. In other words, 40 per cent of the time their blood was either clotting too quickly, putting them at risk of thrombosis, or too slowly putting them at risk of bleeding complications. By the end of the trial, time in therapeutic range had increased to around 75 percent, that is a significant benefit for the trust.

Patients across both cohorts saw significant improvements in their TTR compared with pre-study TTR.

	INR Self Testing Cohort 1	INR Self Testing Cohort 2
Number of patients	300	130
Recruitment Selection Criteria	Hospital Admissions forced to self	Most unmet medical needs
TTR - 6 months before study	60.4%	59.0%
TTR - 6 months before study	58.8%	58.0%
TTR - 3 months after study	72.8%	71.0%
TTR - 6 months after study	74.4%	75.0%

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## ISLE OF WIGHT CCG IS FIRST TO LAUNCH NEW DIGITAL SELF-MONITORING SERVICE IN THE UK



An automated phone call system is used to collect the INR reading from the patient ...

Please enter both digits of the INR result using the digits on your keypad, including decimal. When finished, press the star key. For example, if your INR result is 2.3, please press 2 then 3, followed by star.

Thank you. The INR reading you entered is 1.0. If this is correct, please press 1. If this is not correct, please press 5.

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... and in the evening, after the clinic has completed their assessment, the patient is called with their new warfarin dose

I will now provide you with your warfarin dosage instructions and details about your next INR test. Please listen carefully to the instructions I am giving you. It is important that you listen to all the instructions and do not hang up the telephone until the end of the call. Press any key when you are ready.

Your new warfarin dosage regime is the same dose every day. Your new dose is 2.0mg a day. I will now ask you to confirm by entering your new dose on the keypad, using the digits on your keypad, including decimal. When finished, press star.

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# Here and now



- CCGs redesigned anticoagulation services including appointing AQPs
  - self monitoring options not being factored into provision or contracts
- NICE Guidance (DG14) not being integrated into national policy and local implementation, discussions continue with NHS England
- Strips scripts being refused, withdrawn or limited by GPs
- Disparity between GP practices in a CCG leading to inequalities to patients in being able to access strips
- Issues around patient safety – who's responsible?
- Patients who have successfully been self-monitoring for several years being told they will need to come back to clinic setting and in some cases, venous blood tests!

# Examples of ACE involvement the bigger picture



- Support to the All Party Parliamentary Thrombosis Group
- Ready for Change report for CCGs – published
- Patient experts invited to NICE Appraisal technologies for new anticoagulants, review of VTE and AF guidelines
- ACE member of PIN (Patients involved in NICE) and NIC (NICE Implementation Collaborative) a partnership which involves organisations and individuals from across the healthcare system working to improve patient outcomes for all
- Invitation to participate in studies for self-monitoring, diagnostic DVT devices and software programmes to capture patient INR results



# Further examples...

- Direct approaches from CCGs requesting input when assessing or re-designing services
- Direct approaches from AQP (any qualified provider) considering the tendering process for future services
- NHS England developing 'Participation Academy' and inviting input from patients, service users, public voice representatives and healthcare staff

# Patient expectations



- Accurate and current information relating to self–testing options
- Signposting to information sources relating to their conditions and treatment options
- Opportunity to network and engage with other patients to share knowledge and experience
- Access to treatment options – not restricted by local directives
- Pathway to challenge decisions constructively



Thank you

**AntiCoagulation Europe (ACE)**

[www.anticoagulationeurope.org](http://www.anticoagulationeurope.org)