INR Monitoring for Anticoagulation Treatment

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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.
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

- Self –monitoring – personal control
- Gain more comprehensive knowledge and understanding of what can affect INR
- Reduction in morbidity and mortality
- Time in Therapeutic Range average 80 +
- Peace of mind for patient and family
- Flexibility of when and where to test
- No restrictions on travel for work or pleasure
- 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.
- 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
4 Data on file Atrial Fibrillation Association, AntiCoagulation Europe 2011
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
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)

NICE diagnostcs guidance [DG14] Published date: September 2014

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.
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.
MEDIAN 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 to find out more about self-testing from their health services.
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 patient's life, from missing 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.

New patients can join the County Durham and Darlington Foundation Trust's home 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 as an automated phone call. Software automatically matches 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 300 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 the therapeutic range around 60% of the time; in other words, 40% 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, the INR in the therapeutic range had increased to around 75%, that is a significant benefit for the trust.

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<th>Patients across both cohorts saw significant improvements in their INR compared with pre-study INR</th>
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| INR | Before study | 1.00±0.11 | 1.19±0.10
| After study | 1.17±0.13 | 1.10±0.10 |
| Difference | 0.17±0.13 | 0.09±0.10 |

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

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