

Myth Buster

Busting the myths about INR self-monitoring

At ACSMA, we regularly hear stories about people on long-term warfarin being given incorrect or misleading advice about the options for self-monitoring blood clotting levels (known as the International Normalised Ratio or INR). Here we attempt to dispel some of the common myths and misconceptions.

1) It isn't safe for a person to self-monitor their own levels.

False: Patients on long-term warfarin who self-monitor their own INR levels can achieve a higher level of time in therapeutic range, which means their INR levels are within the range as specified by their doctor or nurse for more of the time. When the INR is in the specified range the chances of developing a blood clot, or having a stroke or an excessive bleed are reduced. It is advisable that you speak with your doctor or nurse before changing any aspect of your care, as they will be able to offer you advice. There are certain criteria that must be met in order to self monitor your INR level safely:

- ✓ You must be able to use your hands to hold smaller objects
- ✓ Have sufficient eyesight for normal daily tasks
- ✓ Have a good mental capacity
- ✓ Be motivated to get involved with your own care
- ✓ Have consent from your doctor/Nurse

2) Self-monitoring does not provide patients with any additional health benefits or improve their quality of life.

False: There are many published studies that demonstrate the significant benefits that self-monitoring can bring. Self-monitoring reduces the risk of stroke by 50% and lowers mortality rate by nearly 40%. By self-monitoring their own blood clotting level, patients can:

- 1) Improve the amount of time spent in therapeutic range
- 2) Have a reduced risk of bleeding or developing a clot
- 3) Enjoy greater independence and quality of life, with freedom to go on holiday
- 4) Reduce time spent travelling to and from clinic appointment, time taken off work or school, and the associated travel and parking costs
- 5) Have an improved feeling of wellbeing

Anticoagulation self-monitoring is also aligned with Government and NHS priorities to increase patient choice, to put the patient at the centre of the health service, and to encourage people with long-term conditions to self-manage their condition wherever possible or appropriate.

3) Patients have no choice in how they manage their treatment of their long-term condition. It is for the doctor or nurse to decide what is best.

False: NHS England and Department of Health policy sets out the importance of having the patient at the heart of care. Patients should be offered choices into their preferred therapy and model of care that must include discussion of the relative benefits and risks. Patients should be able to have an informative discussion with their health professional about their options for treatment and care.

Myth Buster

Busting the myths about INR self-monitoring

4) Self-monitoring is not allowed by the NHS.

False: The National Institute for Health and Care Excellence (NICE) supports self-monitoring in a number of ways:

- NICE diagnostics guidance DG14¹ recommends two different coagulometers for use by people taking long-term anti-blood clotting therapy who have atrial fibrillation (AF) or heart valve disease, if they prefer and are able to effectively use this type of monitoring. NICE concluded that self-monitoring is both clinically-effective and a cost-effective use of NHS resources.
- The NICE Quality Standard 93 for atrial fibrillation (AF) treatment and management² includes a developmental standard, which says that adult patients with AF who are taking warfarin on a long-term basis are supported to self-manage their blood levels with a coagulometer.

5) Self-monitoring with INR devices is complicated and can only be done by a trained clinician or anticoagulant nurse.

False: Self-monitoring is just as accurate as being tested with a GP or at an anticoagulation clinic. Most people on long-term warfarin with reasonable eyesight and manual dexterity, or their carer, may be suitable for self-monitoring. There is no age limit. Those who self-monitor achieve a quality of anticoagulant control, which may be better than that in routine specialist anticoagulation clinics.

Some healthcare professionals can be initially cautious; this might be because they are not familiar with the concept of self-monitoring and so might discourage their patients from doing so. It is important to talk to your doctor or nurse about your wish to self-monitor. You will need their support for some initial training and will need to agree how to contact the healthcare professional if an INR result is outside of the ideal target (therapeutic) range, as this might indicate that your warfarin dose should be changed.

6) Self-testing does not provide results as accurate as testing supervised by a clinic.

False: Self-monitoring is just as accurate as being tested with a GP or at an anticoagulation clinic. Studies have shown that the accuracy of Point of Care (POC) devices are comparable to laboratory measures, with patients showing improvement in anticoagulant control and reduced risk of thrombosis compared to clinic-based care³. In 2014, NICE recommended the use of two self-monitoring devices (known as coagulometers) as an option for specific patients¹. The devices and the test strips have a number of inbuilt controls to ensure the blood is correctly applied to the strip and the test was successful.

¹ NICE diagnostics guidance DG14. 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). <http://www.nice.org.uk/guidance/dg14>. Published September 2014.

² NICE Quality Standard on Atrial Fibrillation management. No. 93. <https://www.nice.org.uk/guidance/qs93>. Published July 2015.

³ Point-of-care INR coagulometers for self-management of oral anticoagulation: primary care diagnostic technology update, British Journal of General Practice, October 2012, <http://pubmedcentralcanada.ca/pmcc/articles/PMC3481522/> accessed 29th May 2013

Myth Buster

Busting the myths about INR self-monitoring

7) Self-monitoring isn't necessary because GP and hospital clinics provide satisfactory monitoring and testing services.

False: Many patients find regular visits to their GP or clinic inconvenient, and find it restricts their quality of life or interferes with work or school. Self-monitoring enables people to not be restricted by clinic appointments and helps them regain a sense of independence in their daily and professional lives. People would be able to liaise with their Doctor/nurse from the comfort of their own home, saving both the person and their healthcare professional valuable time.

8) The test strips for the INR testing machines are expensive and are not available on NHS prescription.

False: Test strips have been available on NHS prescription since 2002 and many patients are able to have their strips on prescription in this way. However, it is a local decision for the GP and/or his or her NHS Clinical Commissioning Group (CCG) to decide what the prescribing policy should be in any given part of the country. Some CCGs are starting to restrict the number of strips they will allow to be prescribed, or are refusing to pay for the strips altogether. Some CCGs do not allow GPs to issue test strips on prescription because of the perceived cost. Unless you can persuade your GP to support you, you will need to purchase the test strips yourself.

10) INR self-monitoring devices machines are not validated to hospital standards.

False: All INR devices have to carry a CE Mark of Conformity, which means the manufacturer guarantees that the product meets all the appropriate provisions of the relevant European Medical Devices Directive⁴. These provisions include safety, quality control, and ensure the device is fit for intended purpose. The Medicines and Healthcare products Regulatory Agency has certified all self-monitoring anticoagulation devices in the UK with the CE marking.

Studies have shown that anticoagulation devices, such as the widely used CoaguChek monitors, not only provide a safer alternative to routine hospital testing⁵ but also are adequate for clinical use if used by patients to determine their INR value by themselves⁶. Furthermore, NICE has approved the use of the CoaguChek XS system and the INRatio2 PT/INR monitors within the NHS in England, believing them to be clinically-effective for certain types of patients¹. CoaguChek XS machines are used by healthcare professionals for near-patient testing in both Primary and Secondary Care.

11) There are no cost benefits to the NHS from patients self-monitoring.

False: Studies show that if just 1 in 4 warfarin patients were able to self-monitor their INR

⁴ Most medical devices now placed on the UK market have to comply with device specific legislation. There are three European Directives concerning medical devices. Active Implantable Medical Devices Directive (90/385/EEC), Medical Devices Directive (93/42/EEC), and In Vitro Diagnostic Medical Devices Directive (98/79/EC). Each Directive contains a wide-ranging and comprehensive list of Essential Requirements covering items such as electrical safety, chemical and mechanical safety, biocompatibility, and labelling requirements.

⁵ Precision and accuracy of CoaguChek S and XS monitors: The need for external quality assessment, Leon Poller, European Action on Anticoagulation, March 2009

http://www.google.co.uk/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&cad=rja&ved=0CDEQFJAA&url=http%3A%2F%2Fwww.ncbi.nlm.nih.gov%2Fpubmed%2F19277400&ei=AoetUfmXGY3I0AXrnoHgDg&usq=AFQjCNHdy8L6PoM21joXwHGVb6ZSSJZbdQ&sig2=Sff1SIBx6Kx9-j8M_FJYA accessed 30th May 2013

⁶ Accuracy of the point-of-care coagulometer CoaguChek XS in the hands of patients, Journal of Thrombosis and Haemostasis, January 2013, <http://onlinelibrary.wiley.com/doi/10.1111/jth.12050/full>

Myth Buster

Busting the myths about INR self-monitoring

levels, the NHS could save up to £62 million a year. Even the Prime Minister, the Rt. Hon. David Cameron MP, said in December 2011 that self-monitoring technology is “effective, convenient, and in the end, cheaper for the NHS”⁷.

12) No-one needs to take warfarin anymore now that novel oral anticoagulants (NOACs) are available.

False: NOACs are anticoagulants (blood-thinning medicines) used to reduce the risk of blood clot formation in patients with non-valvular AF (an abnormal heart beat) and additional AF-related stroke risk factors. However, not everyone who needs anticoagulation treatment is suitable for these medicines. For example, children under 18 and people fitted with a mechanical heart valve usually need to take warfarin.

⁷ Prime Minister’s speech on life sciences and opening up the NHS, FT Global Pharmaceutical and Biotechnology Conference, 6th December 2011 <https://www.gov.uk/government/speeches/pm-speech-on-life-sciences-and-opening-up-the-nhs>