Myth Buster

Busting the myths around 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 (know as the International Normalised Ratio or INR). In this document, we attempt to dispel some of the 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 having an adverse event, such as a stroke or a 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 for it to be safe to self monitor your INR levels; please use the following as a guide:

- ✓ You must be on long-term warfarin
- ✓ Be manually dexterous (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%. Together these provide a robust case for self-monitoring to deliver a model of care that is customised to the individual and is in line with the drive for self and supported care. There is also evidence outlining improvements in patient-reported outcomes measures (PROMs) and quality of life indicators through the freedom gained from not visiting hospital clinics on a regular basis. By self-monitoring, patients can:

1) Improve time in therapeutic range and reduced risk of bleeding or clots
2) Enjoy greater independence and quality of life
3) Reduction in travel and associated costs and time savings
4) Have an improved feeling of wellbeing

3) Every patient who is on long-term warfarin is well aware that he or she has the possibility to self-monitor their condition.

False: In a 2011 survey from AntiCoagulation Europe (ACE) and AF Association (AFA - formerly the Atrial Fibrillation Association), it was revealed that:

- More than half of those taking warfarin did not know that self-monitoring existed, despite the medical and quality of life benefits it offers.

Myth Buster

Busting the myths around INR self-monitoring

- More than nine out of ten people wanted to be more involved and consulted in care decisions. However, the majority of people were not aware of the current NHS actions to involve patients in care decisions.

The National Institute for Health and Care Excellence (NICE) estimates that 46% of patients who are indicated for warfarin or newer oral anticoagulation drugs (NOACs) are not currently taking any anticoagulation treatment[1].

The reasons are multiple; variations in the quality of primary care, reluctance by GPs to recommend warfarin, capacity issues within anticoagulation clinics and the reluctance of patients to take warfarin due to concerns with the drug and the inconvenience it can bring.

4) Patients have no choice in how they manage their treatment of their long-term condition.

False: 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.

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 superior to that attained 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-testing and so discourage their patients from self-testing. It is important that patients talk to their Doctor or nurse about their wish to self-test. Patients will need their support for some initial training and will need to arrange with them how to contact them if an INR result is outside of the ideal target (therapeutic) range.

6) Self-testing does not provide results as accurate as clinically supervised testing.

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 care[2]. In 2006, NICE recommended the use of self-monitoring devices as an option for specific patients[3]. One such self-monitoring device that

[1] *Atrial fibrillation. The management of atrial fibrillation*, NICE, June 2006, http://www.nice.org.uk/nicemedia/live/10982/30054/30054.pdf accessed 29th May 2013

[2] *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

[3] *Atrial fibrillation. The management of atrial fibrillation*, NICE, June 2006, http://www.nice.org.uk/nicemedia/live/10982/30054/30054.pdf accessed 29th May 2013

could be used is the CoaguChek® XS, which has a number of inbuilt technologies to ensure the accuracy of results. Built-in controls on both the meter and the test strip confirm the blood is correctly applied and the test was successful. The CoaguChek® XS has been independently evaluated and approved by the Centre for Evidence-based Purchasing. It has an International Sensitivity Index (ISI) of 1.0 as recommended by the World Health Organisation (WHO) and the British Society of Haematology, for results that closely correlate with clinic methods, and a coefficient of variation (CV) of <4.5% making it both accurate and precise.

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

False: According to a recent survey, 70% of patients find regular visits to their GP or clinic inconvenient, and find it restricts their quality of life. 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: Many patients are able to obtain their test strips on NHS prescription. However, it is dependent on whether a GP supports their patient in self-monitoring. The GP has to issue the prescription so this is where some patients are finding they are not allowed to obtain test strips. NICE has approved in principle the issuing of test strips on prescription but has left it to individual Clinical Commissioning Groups (CCGs) to give local direction. Some CCGs do not allow GPs to issue test strips on prescription because of the perceived cost, so there still remains variability within the NHS.

9) Only older people take warfarin.

False: There is a vast age range of people who are on warfarin and it is not solely for older people. Many people who suffer from Atrial Fibrillation (AF) are generally older; however AF can develop in the early 40s or 50s; therefore these people would be good candidates for self-monitoring. Dr. Carl Heneghan commented that "while there will obviously be many older patients who are not suitable for self-monitoring such as those with dexterity or memory problems, most younger patients on warfarin would be good candidates, and they would receive all the medical benefits we found, as well as the enormous lifestyle benefits, such as independence and freedom of travel. Many children and young people are on warfarin now for life, having received artificial heart valves, and these would be the first obvious candidates"[4].

10) INR self-monitoring devices machines aren't validated to hospital standards.

False: All INR devices will have to carry a CE Mark of Conformity, which means the manufacturer guarantees that the product meets all the appropriate provisions of the relevant

[4] Comments made by Dr Carl Heneghan to heart*wire*, heart*wire* website, 2nd February 2006, http://www.theheart.org/article/640375.do accessed 30th May 2013.

Myth Buster

Busting the myths around INR self-monitoring

Essential Requirements of the European Medical Devices Directive[5]. These provisions include safety, quality control, and ensure the device is fit for intended purpose[6]. Conformity assessment procedures become more demanding as the perceived level of risk associated with the device increases. As anticoagulation self-monitoring devices come under Class IIa[7] (medium risk[8]) due to their invasive use, there must be the involvement of independent third party certification bodies called Notified Bodies[9], which in the UK, is the Medicines and Healthcare products Regulatory Agency (MHRA). The MHRA has certified all self-monitoring anticoagulation in the UK with the CE marking, with POC devices for testing INR having been available and used in a clinical setting since the late 1980s[10]. Studies have shown that anticoagulation devices, such as the widely used CoaguChek monitors, not only provide a safer alternative to routine hospital testing[11] but also are adequate for clinical use if used by patients to determine their INR value by themselves[12].

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

False: Studies show that if just 1 in 4 warfarin patients were able to self-monitor their INR 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"[13].

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

NOACs are anticoagulants (blood-thinning medicines) used to reduce the risk of blood clot formation in patients with AF (an abnormal heart beat) and additional stroke risk factors. However, not all warfarin users will be suitable for these medicines.

---

[5] 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.

[6] *Frequently Asked Questions*, MHRA website, http://www.mhra.gov.uk/Publications/Regulatoryguidance/Devices/Otherdevicesregulatoryguidance/Frequentlyaskedquestions/ accessed online 30th May 2013

[7] Devices covered by the Directive are grouped into four classes: Class I (low risk), Class IIa (medium risk), Class IIb (medium risk with added assessment checks), Class III (high risk)

[8] The Classification Rules, MHRA bulletin No.10, June 2011, http://www.mhra.gov.uk/home/groups/es-era/documents/publication/con007495.pdf accessed 30th May 2013

[9] A Notified Body is an independent certification body designated by a Competent Authority to conduct conformity assessment procedures specified in the various Directives. A manufacturer may choose any Notified Body provided it has been designated to perform the particular conformity assessment procedure it wishes to use. A complete list of Notified Bodies is available on the EU Commission's website.

[10] *Warfarin therapy: Tips and tools for better control*, The Journal of Family Practice, February 2011, http://www.jfponline.com/Pages.asp?AID=9332 accessed 30th May 2013

[11] *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=AoetUfmxGY3l0AXmoHgDg&usg=AFQjCNHdy8L6PoM21joXwHGVb6ZSSJZbdQ&sig2=Sff1SlBxF6Kx9-j8M_FJYA accessed 30th May 2013

[12] *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 accessed 30th May 2013

[13] *PM 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 accessed 30th May 2013.