BUSTING THE MYTHS AROUND INR SELF-MONITORING

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

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). In this document, we attempt to dispel some of the myths and misconceptions.

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:

- Improve time in therapeutic range and reduced risk of bleeding or clots
- Enjoy greater independence and quality of life
- Reduction in travel and associated costs and time savings
- 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.
- 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.

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 involving 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 CLINICIANS 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 as compared to clinic-based care.

In 2006, NICE recommended the use of self-monitoring devices as an option for specific patients. One such self-monitoring device that could be used is the CoaguChek® XS, which has a number of built-in 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 recommended by the World Health Organisation (WHO) and the British Society for Clinical Haematology, based on the International Sensitivity Index (ISI) of 1.0 as recommended by the International Sensitivity Index (ISI) of 1.0.

4 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 Essential Requirements of the European Medical Devices Directive. These provisions include safety, quality control, and ensure the device is fit for intended purpose. 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 Ilb (medium risk) due to their invasive use, there must be the involvement of independent third party certification bodies called Notified Bodies, 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. Studies have shown that anticoagulation devices, such as the widely used CoaguChek monitors, not only provide a safer alternative to routine hospital testing but also are adequate for clinical use if used by patients to determine their INR value by themselves.

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. Carol 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.”

10 NO-ONE NEEDS TO TAKE WARFARIN ANYMORE NOW THAT NEWER ORAL ANTICOAGULANTS (NOACs) ARE AVAILABLE

FALSE: 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.