



## Briefing for the Public Petitions Committee

**Petition Number:** [PE01566](#)

**Main Petitioner:** Mary Hempill and Ian Reid

**Subject:** A National Service Delivery Model for Warfarin Patients

Calls on the Parliament to urge the Scottish Government to implement a National Service Delivery Model to ensure that all NHS boards have the resources to assess warfarin patients who request (i.e. self-present) for self-testing and/or self-management of their condition.

### Warfarin

Warfarin is an anticoagulant which is a medicine that stops blood from clotting. In Scotland, around 74,000 individuals were prescribed warfarin in 2011–2012 and latest figures show this number increasing to around 80,000 in 2013-2014<sup>1</sup>. Anticoagulants are used for the treatment of cardiovascular diseases by reducing the formation of blood clots, which is important in the prevention of heart attacks, strokes and blockages of major veins and arteries.

### Monitoring

The [effect of warfarin](#) is monitored by regular blood tests that measure how long blood takes to clot. This measure is called the International Normalised Ratio or INR<sup>2</sup>. Warfarin increases the time taken for blood to clot and thus the INR. The higher the INR, the longer blood clotting takes, and there is an increased risk of bleeding. A low INR may not provide enough protection against excess clotting. The dose of warfarin is adjusted to maintain the INR at a predetermined target level and requires careful monitoring.

If the INR is stable, a test might only be needed every eight weeks. If it is unstable or if warfarin therapy has just started, weekly visits may be required. On average, patients have their INR checked every four to five weeks. Many factors can affect the action of warfarin in the body, for example, illness and

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<sup>1</sup> Figures from personal communication on 12th June 2015 from Lewis Jack, ISD Prescribing Team.

<sup>2</sup> INR is a standardised measurement of the time that it takes blood to clot.

alcohol intake. If warfarin levels are not well controlled, then serious complications can arise, such as [major bleeding](#)<sup>3</sup>.

## Self-monitoring

The latest National Institute for Health and Care Excellence (NICE) diagnostic guidance [DG14 for atrial fibrillation and heart valve disease](#) in 2014 states that INR monitoring can be managed by local GP practices or anticoagulant clinics in primary care<sup>4</sup>, but sometimes clinics are based in secondary care<sup>5</sup>, involving travel to hospital. It discussed monitoring by two other methods of care: self-testing and self-managing.

Self-testing refers to the user performing the INR blood sampling test and analysis at home and then contacting their healthcare professional with the reading for advice on any dosage change. Self-managing refers to the user performing the INR test themselves using [test strips](#) and then self-adjusting the dosage of their anticoagulant medication by following an agreed care protocol. Together, these methods of care are referred to as self-monitoring. In Scotland, from July-December 2014, around 1%.of warfarin patients were prescribed test strips<sup>6</sup>. This provides an indication of self-monitoring.

## Clinical guidelines, recommendations and costing

In 2002, the Scottish Executive published guidance from the Chief Medical Officer and the Chief Pharmaceutical Officer on the [Self-management of Warfarin Therapy](#). This set out the criteria under which the self-management of warfarin therapy should be considered. There were a number of conditions which must be met before self-management could be recommended. Patients must be able and willing to perform self-management, their competence to do so must be assessed, they must have given their informed consent in writing and they must have gone through rigorous training.

The Scottish Intercollegiate Guidelines Network (SIGN) is the department of Healthcare Improvement Scotland (HIS) that develops clinical practice guidelines for NHS Scotland. [SIGN Guideline 129](#), updated in June 2013, provides recommendations based on best practice in the management of adult patients on antithrombotic therapy. The recommendations for models of care for long term anticoagulation were:

- Self-monitoring and self-dosing is safe and effective and can be considered for some patients.

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<sup>3</sup> This can occur but is not common. The risk of a bleed as a result of taking warfarin is approximately two per cent of patients per year.

<sup>4</sup> Primary care is the local healthcare that we receive from GPs, NHS-walk-in centres, dentists, pharmacists and optometrists

<sup>5</sup> Secondary care is the healthcare that people receive in hospital.

<sup>6</sup> Approximately 2/3 of these are 65 years old or over. Personal communication from James Smith, Information Analyst at ISD on 21<sup>st</sup> May 2015.

- For patients who are self-monitoring, appropriate education and training should be provided, clinical advice should be available on request, and provision should be made for quality assurance.
- Healthcare professionals providing dosing advice on INR should be appropriately trained and able to provide documented evidence of competence and those undertaking point of care (POC) testing<sup>7</sup> should be trained in its operation and maintenance prior to use.

An analysis of the clinical and cost effectiveness of different models of long term oral anticoagulation therapy management suggests that “self-monitoring is unlikely to be more cost effective than current usual care in the UK”.

In June 2013, Healthcare Improvement Scotland published an Evidence note<sup>8</sup>, [‘Is patient self-monitoring \(including self-testing and management of oral anticoagulation therapy, safe, efficacious and cost effective?’](#).

The note considers the clinical and cost-effectiveness of patient self-testing. Its key points include:

- The evidence base varies considerably for patient self-monitoring in terms of: eligibility criteria for therapy; patient selection; the intensity of education and support provided; the frequency of testing and comparisons of care provision.
- Self-monitoring reduces the rate of blood vessel blockages from blood clots, compared with usual care, without affecting the rate of serious bleeding events or mortality. Self-management was more effective than self-testing.
- Three economic analyses (from 2005-2007) suggest that in the UK healthcare setting, INR self-monitoring is unlikely to be cost effective when compared with usual care. Self-monitoring has been reported to be cost effective in Canadian, German and Belgian healthcare settings.

An Advice Statement published in July 2013 from [HIS and Scottish Health Technologies group](#) stated that POC devices have acceptable accuracy and precision when compared to laboratory measures of INR.

POC devices cost from £275 to £399 (2013 prices excluding VAT) and are not provided to patients by the NHS. The test strips and lancets<sup>9</sup> used are available on prescription (£2.60–£2.81 per test strip) and national spend on test strips dispensed in the community in 2011/2012 was £127,221. The number of self-testing strips dispensed per 100,000 population was highest in NHS Western Isles, NHS Orkney and NHS Shetland.

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<sup>7</sup> Point of care testing normally involves performing blood sampling and analysis at home using a portable, battery operated INR testing machine. This uses a drop of blood from a finger prick and produces the INR result within a few minutes.

<sup>8</sup> Evidence note 50 is scheduled to be updated in June 2015.

<sup>9</sup> Lancets are used to make small punctures, e.g. a finger prick, to obtain blood for POC testing.

In September 2014, [NICE diagnostics guidance DG14](#), 'Atrial fibrillation and heart valve disease: self-monitoring coagulation status using point-of-care coagulometers' included a [costing statement](#) on self-monitoring coagulation status using POCs for atrial fibrillation and heart valve disease. It concluded that:

- Self-monitoring through use of POCs had the potential to save costs as the increased frequency of INR monitoring may improve health outcomes by enabling the dose to be adjusted more accurately.
- Self-monitoring could result in a decreased demand for INR monitoring at anticoagulation clinics which may lead to savings.

The guidance also suggested that carers should be considered as a source of support and help with self-monitoring for people who are unable to perform or have difficulty with self-monitoring, such as children, or those with disabilities.

[The Royal College of Physicians of Edinburgh](#) UK Consensus Conference on "Approaching the comprehensive management of Atrial Fibrillation: Evolution or revolution?" in March 2012 supported the view that anticoagulant control may be improved by POC testing and engaging patients in their own care and that patient education should be supported at every stage.

In March 2014, the York Health Economics Consortium at York University published a paper on [Warfarin monitoring economic evaluation of point of care self-monitoring compared to clinic settings](#). It found that over 10 years, self-monitoring saved £1187 per person compared to usual care. Patients who self-monitored had notably fewer strokes and deaths.

The Cochrane collaboration published a systematic review of [Self-monitoring and self-management of oral anticoagulation therapy](#) in 2010. It highlighted that in some countries, like Germany where 20% (160 000) of patients on anticoagulation undertook self-management, self-monitoring with portable monitors is an established therapeutic method.

## **Scottish Government Policy**

The Scottish Government's [2020 Vision](#) is that by 2020 everyone is able to live longer healthier lives at home, or in a homely setting and, that there will be a healthcare system where there is a focus on prevention, anticipation and supported self-management and, whatever the setting, care will be provided to the highest standards of quality and safety, with the person at the centre of all decisions.

[The Healthcare Quality Strategy for NHS Scotland](#) is central to the 2020 vision and was designed to build on the progress made in improving healthcare, particularly in terms of care and support for people with long term conditions and better outcomes for people with Cancer, Stroke, heart disease and diabetes.

[The Self-Management Strategy for Long Term Conditions in Scotland](#), 'Gauin Yersel', was written by people with long-term conditions and published in August 2008. It highlights that partnership with the individual is central to the Scottish Government's self-management agenda.

## **Scottish Parliament Action**

In 2013, Nanette Milne MSP sponsored a round table meeting in the Scottish Parliament on anti-coagulation therapy. The meeting involved MPs, patient groups, and senior clinicians who supported patients on anti-coagulation therapy.

[Recommendations](#) made from this session<sup>10</sup> included that there should be: support for SIGN guideline 129; a comparative review of the uptake of appropriate technology in Scotland with England and Europe; a learning needs-assessment for medical and healthcare professionals and a national service delivery model for anticoagulation.

There have been a number of parliamentary questions<sup>11</sup> and a debate [S4M-09430](#) on Warfarin self-monitoring and management. These have centred on issues such as:

- The support provided for self-monitoring and management and the changing nature of expert advice.
- That warfarin therapy remained the treatment of choice for many patients although there were newer anti-coagulants available.
- The maintenance of INR levels without the need for frequent or inconvenient hospital or GP visits.
- Government action in the implementation of SIGN guideline recommendations and barriers to its implementation by GPs.
- Whether the Scottish Government planned to introduce a national service delivery model for INR testing.

The Scottish Government responded by stating that:

- The decision on which drug to take, and how best to manage INR testing, should be taken on a case by case basis jointly by people, with their clinicians, in line with current evidence in the [SIGN 129 guidelines](#) and [Evidence note 50](#). This should be safe, effective and appropriate for each individual patient. Boards use the guidelines but adapt the approach to their local circumstances. They may or may not opt for self-testing. [S4W-20108](#)

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<sup>10</sup> Discussed by Nanette Milne at 17.03 during motion [S4M-09430](#)

<sup>11</sup> Other questions include: [S4W-20103](#); [S4W-20110](#); [S4W-20176](#); and [S4W-18169](#)

- Self-monitoring may be considered for some patients, specifically for remote and rural residents or for frequent travellers. [S4W-20111](#)
- For patients who are self-monitoring, appropriate education and training should be provided, clinical advice should be available on request, and provision should be made for quality assurance. [S4W-18167](#)
- It was not considered that a national delivery service was required as boards already had a responsibility to have local protocols in place. [S4W-20102](#)
- There were also no plans to review and analyse the uptake INR self-testing/self-management in comparison with rates in England and other European countries. [S4W-20104](#)

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