### Advice Statement 003/2015

#### December 2015

<table>
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<tr>
<th>Is patient self-monitoring (including self-testing and self-management) of oral anticoagulation with vitamin K antagonist therapy safe, efficacious and cost-effective?</th>
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<td>This advice has been produced following completion of evidence note 57 by Healthcare Improvement Scotland (update of evidence note 50)</td>
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#### Background

In Scotland, in 2014–2015 around 80,000 individuals were prescribed the vitamin K antagonist warfarin. Approximately 1.4% (1,100) of people prescribed warfarin also receive reagent strips on prescription.

#### Variants of self-monitoring

Patient self-testing involves patients performing blood sampling and analysis at home using a portable, battery operated international normalised ratio (INR) testing machine. Results are communicated to a healthcare professional who then decides on dose adjustment.

In patient self-management the patient not only performs the blood sampling and analysis but also makes any vitamin K antagonist dose adjustment required.

#### Clinical effectiveness and safety of anticoagulation monitoring

- Meta-analyses of data from mainly low quality randomised controlled trials in patients receiving long-term oral anticoagulation therapy with vitamin K antagonists consistently report that self-monitoring of INR reduces the incidence of thromboembolic events, compared with usual care, without increasing major bleeding events. In subgroup analyses the benefit is associated with self-management but not with self-testing. Where it is reported, the majority of studies record benefits of self-monitoring on patient satisfaction or quality of life. There is clinical heterogeneity in the evidence base particularly around study duration and extent of patient education and support. There is also heterogeneity in the specification of the usual care intervention, and, since the analyses incorporated few United Kingdom (UK) based trials, the applicability of findings to the pathway of care in NHSScotland may be limited.

#### Device safety

- Portable coagulometers have acceptable accuracy and precision when compared with laboratory measures of INR. In the largest randomised controlled trial (4,495 patient years of weekly self-testing) no adverse events related to operation of the blood testing device were reported.

#### Cost effectiveness

- A recent UK economic evaluation provided good quality evidence to suggest that patient self-monitoring is cost effective when compared with usual care.
- However, the results of the analysis are driven by the assumption that self-monitoring of INR reduces the incidence of thromboembolic events compared with usual care. As such, subgroup analysis demonstrated that whilst self-management is a cost-effective strategy,
patient self-testing was not.

- The findings support the view that the cost effectiveness of self-monitoring is strongly contingent on the willingness and ability of the patient to manage their own oral anticoagulation therapy. By doing so, this helps to ensure that successful patient outcomes are maintained, and that an increase in consumable costs is offset by resource savings (non-cash releasing).
- Devices cost from £286 to £299. The test strips and lancets are available on prescription (£2.49 to £2.80 per test strip).

**Context**

- Recent National Institute for Health and Care Excellence diagnostics guidance [DG14,2015] recommends self-monitoring of coagulation status in adults and children on long-term vitamin K antagonist therapy who have atrial fibrillation or heart valve disease if: the person prefers this form of testing and the person or their carer is both physically and cognitively able to self-monitor effectively. This is in agreement with SIGN guideline 129. Antithrombotics: indications and management.
- A public petition (PE01566) was lodged with the Scottish Parliament in May 2015 calling for the Scottish Government to implement a national service delivery model to ensure that all NHS boards have the resources to assess patients who request self-testing or self-management of their warfarin therapy.

**Conclusion**

- Although there are uncertainties due to clinical heterogeneity in the evidence base, self-monitoring of INR, and particularly self-management, where patients carry out both testing and dose adjustment, is likely to be a safe, effective and cost-effective monitoring option for motivated and competent patients receiving long-term vitamin K antagonist oral anticoagulation therapy. Where existing care pathways result in good control of INR the potential for additional clinical and economic benefit may be limited.
- Self-monitoring of oral anticoagulation therapy should not be facilitated without provision of appropriate education, training and medical and technical support, and quality control. The motivation and physical and cognitive competence of patients/carers performing self-monitoring should be regularly assessed.

**Advice context:**

*The status of SHTG Advice Statements is ‘required to consider’.*

No part of this advice may be used without the whole of the advice being quoted in full. This advice represents the view of the SHTG at the date noted.

It is provided to inform NHS boards in Scotland when determining the place of health technologies for local use. The content of this Advice Statement was based upon the evidence and factors available at the time of publication. An international evidence base is reviewed and thus its generalisability to NHSScotland should be considered by those using this advice to plan services. It is acknowledged that the evidence constitutes only one of the sources needed for decision making and planning in NHSScotland. Readers are asked to consider that new trials and technologies may have emerged since first publication and the evidence presented may no longer be current. SHTG Advice Statements are considered for review on a 2-yearly basis. The evidence will be updated if requested by the clinical community, dependent on new published reports. This advice does not override the individual responsibility of health professionals to make decisions in the exercise of their clinical judgment in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

**Chair**

Scottish Health Technologies Group

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