Where does patient self-management of oral anticoagulation fit within the current models of service provision?

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> 'Self-management may provide an alternative model for those patients who do not achieve satisfactory International Normalized Ratio control within larger-scale clinics.'

Therapeutic management of oral anticoagulation is not straightforward. The British Committee for Standards in Haematology produced updated evidence-based guidelines in 1998 for therapeutic management, which encourage clinicians to aim for a target International Normalized Ratio (INR), with specific targets and ranges stated for individual conditions [1]. However, there remain concerns over where and how warfarin monitoring should be undertaken [2,3]. Historically, oral anticoagulation has been underutilized as a thromboprophylactic agent for patients with atrial fibrillation, whilst without screening programs, it is possible that approximately 60% of patients with atrial fibrillation remain unidentified [3,4]. It is clear, therefore, that the number of patients receiving warfarin therapy will continue to rise above the currently estimated 1 million [5,6].

Traditionally, patients receiving oral anticoagulant therapy attended a hospital out-patient clinic where INR estimation was undertaken using either capillary or venous citrated blood samples, with the result being available either immediately or at a later stage. Whilst the clinic has traditionally been led by a consultant hematologist, alternative arrangements have utilized cardiologists, surgeons, specialist nurses [7], laboratory staff and pharmacists [8]. Based on UK data, patients should expect to be within their own therapeutic range at least 65% of the time. This is the standard to which any alternative models have to compare [6].

Where INR results are available with the patient present, dosing recommendations are made and the patient given a date for the next appointment (up to 12 weeks in a stable patient [1]). When there is a delay in the INR estimation, patients receive dosing and recall advice through the post via patient-held records, or alternatively via the telephone. This model has been widely used throughout the UK, with patients carrying personal yellow national record booklets, but has come under increasing strain due to the increase in the number of patients requiring warfarin therapy.

Whilst this model has been standard practice for much of the UK, the performance of these clinics has not always been ideal, either in terms of INR control, adverse events or patient satisfaction [6]. Figures for clinics using manual dosing systems showed a point prevalence of patients achieving therapeutic INR levels of between 43 and 55% [6], improving to 65% in other clinic models [7]. This compares with general practice clinics using similar methods, which achieved 54% based on the same criteria and treating a similar population [9]. These data for routine performance within UK anticoagulant clinics compare very favorably with routine data from other countries, particularly the USA [10] and Germany [11], where rates of 40% are found. This has important consequences for the implementation of alternative models of care.

The Birmingham model of primary care anticoagulation management has become an acceptable alternative to hospital outpatient management [12], although at present it is only utilized by a relatively small number of patients. This model utilizes computerized decision support and near-patient testing within a practice nurse-led clinic, supervised by a general practitioner.

However, the most widespread primary care model entails venous blood samples being taken in primary care and transported to the hospital laboratory for INR estimation and interpretation [13]. Patients usually receive dosing information through the post, or by telephone [14]. In addition, general practices with limited access to hospital clinics are more likely to undertake dosing [9].

The use of near-patient testing for INR estimation affords the possibility of selected patients undertaking self-management [15,16]. Reliable, portable machines are available that have been subject to rigorous laboratory evaluation [17–19]. Previous data demonstrated reliable performance

characteristics of commercially available INR monitors in terms of accuracy, reproducibility and long-term reliability when used by selected patients [20].

Two publications appear to give contradictory messages regarding the clinical- and cost-effectiveness of patient self-management of oral anticoagulation within a UK setting.

Heneghan *et al.* undertook a meta-analysis of trials of self-testing or management compared with routine care and concluded that self-management "improves the quality of oral anticoagulation. Patients capable of self-monitoring and self-adjusting therapy have fewer thromboembolic events and lower mortality than those who self-monitor alone" [21].

In a systematic review investigating clinical and cost-effectiveness of different models of oral anticoagulation management, whilst agreeing that self-monitoring is safe, Connock *et al.* concluded that it is not as cost–effective as specialized clinics within the UK [22]. However, in healthcare environments where routine care is poor, cost–effectiveness can be achieved.

Where does this leave us with regards to implementing self-management of oral anticoagulation within the National Health Service? The central UK study to both these secondary analyses was undertaken through primary care [23]. The SMART study included over 600 patients, of whom 337 undertook self-management. Results demonstrated good control for both self-managed patients and those seen in routine care, with approximately 70% time in range in both groups, with equal complication rates. However, within the self-managed population, those patients who had poor INR control prior to study entry showed statistically significant improvement with self-management. This is the group that are most costly when managed through routine clinics, due to increased frequency of attendance, and who are also most likely to run into problems with adverse events such as bleeding or thrombosis. It is clear from the data that self-management is not suitable for everyone, and that the costs of providing it are prohibitive for it to be introduced as a routine alternative to clinic management, be it in primary or secondary care.

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Therefore, the current move for cost–efficiency, whilst also providing increased self-care for those with chronic illness, seems to be incompatible in this clinical scenario. The general trend within anticoagulation service provision seems to be moving backwards towards merely providing an INR monitoring service, despite the evidence of poor clinical outcomes. Given this trend, self-management may provide an alternative model for those patients who do not achieve satisfactory INR control within these larger-scale clinics? In this way, the cost–effectiveness argument is overcome, particularly if costs of adverse events are factored in. One additional benefit for patients undertaking self-management is the level of education provided regarding oral anticoagulation treatment. This increased level of knowledge, combined with increased autonomy to manage their clinical condition, could make self-management a potential treatment option for patients achieving therapeutic INRs for less than 60% of the time, for example. This would also free up valuable clinic time to hopefully enable the current services to provide a little more than just INR monitoring. Given the increasing numbers of patients, and the fact that warfarin alternatives remain some way off, the inclusion of self-management within the treatment options is imperative and needs to be included within clinical guidelines, and perhaps more importantly within funding arrangements such as nationally or locally enhanced services.

Financial & competing interests disclosure

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