

Point-of-Care INR Monitoring for Managing Warfarin Therapy

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The vitamin K antagonists have many difficulties associated with their use resulting in a high rate of serious adverse events and a high risk-to-benefit profile. They have a narrow therapeutic window of efficacy and safety; many factors influence their response; and maintaining patients within the therapeutic window requires considerable effort. Furthermore, the assay used to assess anticoagulant response, the prothrombin time (PT), is plagued with its own problems of standardization. Maintaining patients within the therapeutic range is difficult and requires expert dose adjustment and a coordinated approach to care as is practiced in specialized programs known as anticoagulation clinics. “Usual care” provided by individual physicians within the context of their practice may result in a high incidence of major hemorrhage and thrombosis that approximates 15% per year. Most events occur when the INR is out of therapeutic range. This rate can be significantly reduced to 2 – 5% by providing care through an anticoagulation clinic. Anticoagulation clinics achieve these better outcomes by maintaining patients in therapeutic range a greater percentage of time compared to usual care.

Point-of-care (POC) prothrombin time monitoring is now possible using portable instruments that measure an INR from a fingerstick sample of capillary whole blood. Exhaustive correlation studies have been done to assess the accuracy and precision of POC instruments with plasma-based PTs using international standards. These have consistently confirmed the adequacy of the POC method to monitor oral anticoagulation, especially with INR results in or near the therapeutic range. Given their size, portability, and ease of use, these devices allow patients to measure their own INR at home (patient self-testing or PST), and with proper education, manage their own anticoagulation dosing (patient self-management or PSM). A number of clinical trials have demonstrated improved outcomes as measured by time in therapeutic range, or in some instances, reduced major hemorrhage or thrombosis when compared to a usual care model. Recent meta-analyses have strengthened these findings.

The major barrier to greater use in the United States and elsewhere has been reimbursement limitations by the major insurers (Medicare in the US). Medicare established a reimbursement guideline for home monitoring in patients with mechanical heart valves several years ago. Medicare has recently announced their intention to extend this coverage to patients with atrial fibrillation and venous thromboembolism. However, the mechanism established for reimbursement is complex and is a further barrier to encourage use. In order to expand this modality of anticoagulation management, reimbursement needs to be expanded and simplified, and physicians need to be educated about its availability, utility, and value.

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