

MEDICAL COLLEGE OF WISCONSIN SCHOOL OF PHARMACY STUDENT  
WRITING CLUB:

# INR At Home: Where Accuracy Meets Comfort

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**M**edications that require frequent monitoring can be challenging for patients and healthcare providers. The efficacy of warfarin (Coumadin®) efficacy, for example, is assessed with periodic international normalized ratio (INR) checks. INRs are often checked at least monthly through finger sticks or blood draws. Patients must come to a facility to get their blood assessed and providers must have time scheduled to review and interpret the results, ask clarifying questions, and provide a recommendation. The integration of INR self-testing, facilitated by machine-reading technology, enhances patient autonomy by providing patients the ability to complete this check independently and may foster a deeper understanding of their health. The transformative shift in anticoagulation monitoring not only empowers patients in managing their conditions effectively but also has a profound impact on the dynamics between patients and healthcare providers, enhancing a collaborative and informed approach to treatment.<sup>1</sup> This review article seeks to summarize the current state of at-home INR monitoring from a patient and provider perspective.

There are many chronic disease states in which maintaining INR within its

## Abstract

Warfarin safety and efficacy is assessed using weekly to monthly international normalized ratio (INR) checks. Many disease states necessitate that the INR remains within a specified therapeutic range to ensure warfarin is being dosed appropriately. This requires patients to go to a clinic or a lab to have their INR checked to ensure it is within range. The integration of INR self-testing devices provides a validated way for patients to measure their INR from home, providing patient autonomy and comfort. The purpose of this manuscript is to review INR self-testing, how it works, its effectiveness, and its implications for patient care.

**Keywords:** Warfarin Monitoring, INR, Self-Testing, Anticoagulation Management

therapeutic range is paramount towards positive clinical outcomes, including mechanical and prosthetic heart valves, atrial fibrillation, atrial flutter, and venous thromboembolism (VT) treatment and prophylaxis. INR is used as a marker to measure the therapeutic window of warfarin. INR goals vary based on the disease state but are usually between 2 and 3 or between 2.5 and 3.5. A subtherapeutic INR increases the risk for thromboembolic events such as the formation and release of clots in the vasculature, which could lead to a stroke, VT, or pulmonary embolism. A supratherapeutic INR, on the other

hand, increases the risk for significant bleeding events. Thus, it is important to monitor INR regularly and adjust therapy as appropriate to minimize these risks.

A traditional INR monitoring method involves getting blood drawn in a clinic, then sending the sample to a laboratory for the result. This can take significant time (driving, waiting for results, etc.), making this method cumbersome and time consuming for patients and providers alike. Point-of-care (POC) testing involves a fingerstick to obtain a drop of blood that is read by a POC INR device. This can be completed at a provider's office or

at home. The results are available within minutes, allowing for immediate therapy adjustments. Testing INR at home uses an identical POC device but is completed by the patient rather than a provider. In this scenario, the patient is responsible for knowing how to use the device correctly and informing their provider about the result accurately so the provider can make appropriate therapy adjustments. This method is also known as patient self-testing (PST).<sup>2,3</sup>

## Self-Testing for Patients

According to the Centers for Medicare and Medicaid Services (CMS), patients taking warfarin may monitor their INR at home under a certain set of criteria.<sup>4</sup> First, the patient must be anticoagulated on warfarin for at least three months. The patient must receive a prescription for the INR testing device and testing equipment from their provider. After the prescription is obtained, the patient must attend a face-to-face educational program on anticoagulation and proper INR testing. Upon completion of the program, the patient is eligible to test their INR at home using the prescribed device no more than once a week. Since most at-home INR monitors are reimbursable by insurance, patients should contact their insurance carrier for specific device coverage.<sup>5</sup>

Examples of devices that are approved by the U.S. Department of Food and Drug Administration (FDA) for home INR monitoring include, but are not limited to, the CoaguChek XS System<sup>®</sup>, CoagCare System<sup>®</sup>, the INRatio 2 Prothrombin Time Monitoring System<sup>®</sup>, and the Coag-Sense PT/INR Monitoring System<sup>®</sup>.<sup>6,7</sup> Due to differences in individual coverage, the cost of a home INR system is typically more expensive than other traditional at-home monitoring systems, such as a glucometer, with cash prices ranging from \$250 to \$1000. There are smart devices available, such as the Coag-Sense PT2 PT/INR System<sup>®</sup> that has Bluetooth and internet capabilities, which allow for direct upload of INR results to EHR systems.<sup>7</sup> Buying test strips in bulk should be discouraged, as some devices will not allow testing using an expired test strip.

While the total cost per patient over two years was slightly higher for PST compared to high-quality anticoagulation management

(HQACM) seen in a clinic setting, the financial implications were mitigated by the reduced number of outpatient visits, leading to overall cost savings.<sup>1</sup> Despite these higher costs in the self-testing group, the general expenses were not significantly different from clinic-based testing. Not only is there a reduction in healthcare utilization but also in time, reducing the patient's overall time burden by 1 hour and 19 minutes per INR test compared to traditional clinic-based care. This translated to an overall societal saving of \$66.83 per INR test, displaying the cost-effectiveness of home INR monitoring and supporting the findings from The Home INR Study (THINRS), which is further explored below.<sup>1,8</sup>

For most devices, a test strip is inserted inside the machine and a finger is pricked with a lancet, where a blood sample transfer tube is then used to draw approximately 10-12 microliters of blood from the site and then placed onto the strip. Some transfer tubes are included with the device, but additional tubes may be purchased separately.<sup>7</sup> Some devices allow connecting the strip to the device and then touching the strip directly to blood, similar to a traditional at-home glucometer.<sup>9</sup> The amount of blood needed for each test varies among products, but most require sample sizes of 6-12 microliters.<sup>6</sup> It is important to note that some devices only measure INR values within a range of 0.8-8.0, meaning that there may be difficulties monitoring extreme warfarin hyper- and hypo-responsiveness in at-home settings with these systems.<sup>7,9</sup>

## Patient Care Implications and Efficacy

There are many advantages to INR self-testing compared to in-office visits. Patients may have a sense of freedom due to not having to commit to routine appointments. Some studies found patients reporting more satisfaction in their quality of life and anticoagulation therapy, which highlights the patient perceived advantages of INR self-testing.<sup>2,3,10</sup> INR self-testing also allows for patients to check their INR levels more frequently compared to office visits. This allows for much closer monitoring, particularly if a new medication is started or stopped, a significant diet change is made, or if

there is a history of unstable INR values. Healthcare providers and pharmacists also benefit from home INR monitoring. PST contributes to more efficient and patient-centric anticoagulation management and allows for rapid adjustments to treatment plans. Customizing treatment based on individual patient needs becomes a feasible and practical approach within the anticoagulation clinic.<sup>11</sup>

Studies have also demonstrated that INR self-testing is clinically similar to laboratory or in-clinic testing.<sup>2</sup> Correlations between INR POC testing and INR laboratory values have been demonstrated with  $r^2$  values upwards of 0.95 in multiple studies.<sup>2,3,10</sup> There were also no significant differences between values obtained from the two sources.<sup>3,10</sup> One disease state of note where POC testing is unreliable is antiphospholipid syndrome (APS).<sup>12</sup> In patients with this condition, approximately 33% of patients saw INR readings that were falsely elevated or unreadable on their POC testing devices. This occurred on all available devices and thus patients with APS are recommended to perform frequent INR laboratory testing using blood draws rather than only utilize POC devices at home.<sup>12</sup>

## The Home INR Study

The Home INR Study (THINRS), a multisite trial comparing INR monitoring techniques, reports statistically significant improvements in time in therapeutic range (TTR) when comparing home testing to clinic-based testing.<sup>13</sup> The study compared anticoagulation management with frequent PST to traditional clinic-based testing. This two-part study involved 400 patients across 28 Veteran Affairs medical centers. The study underscored the significance of HQACM and laid the groundwork for subsequent advancements in home INR monitoring.<sup>13</sup> A comprehensive review article from 2016, subsequent to THINRS, explored the comfort and compliance improvements observed in patients and their families with home INR monitoring.<sup>8</sup> The article highlighted the role of self-management strategies, including self-testing equipment, and emphasized the importance of patient motivation and competency. The review encompassed 20 published randomized controlled trials, revealing and reinforcing findings of better



INR control in the self-testing or self-management group. However, statistically significant improvements such as improved quality of life and time in range were noted in only five trials.

Improvements in TTR from PST, as observed in THINRS, translate into the reduction of clot formations and bleeding events, resulting in both financial savings and enhanced patient well-being.<sup>1,8,11</sup> Home INR monitoring has been associated with reduced thromboembolic events, decreased all-cause mortality, and a lack of increased risk of significant bleeding.<sup>1,11</sup>

The current state of home INR monitoring is marked by evidence supporting its efficacy, with profound effects on patients' well-being and providers' ability to deliver high-quality care. The evolution from clinic-based monitoring to completing monitoring within the comfort of one's own home emphasizes the significance of home INR monitoring in reshaping anticoagulation management.

## Conclusion

Home INR monitoring enhances patient autonomy and maintains or improves clinical outcomes. This approach, underscored by THINRS and other studies, offers a reliable and convenient alternative to traditional clinic-based testing, leading to improved TTR.<sup>13</sup> While challenges, such as the need for patient education and device accuracy in specific conditions, persist, the overall benefits of PST, including cost-effectiveness, patient satisfaction, and improved quality of life, are evident. Home INR monitoring represents a transformative step in personalized and effective anticoagulation management, aligning

with the evolving landscape of healthcare technology and patient-centered care.

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