

**PATIENT SELF-TESTING FOR MONITORING OF PROTHROMBIN TIME
INTERNATIONAL NORMALIZED RATIO (INR) IN PATIENTS ON WARFARIN
ANTICOAGULATION THERAPY**

- 1. PURPOSE:** This Veterans Health Administration (VHA) directive provides guidance for establishment of a program for use of patient self-testing (PST) for prothrombin (PT) by international normalized ratio (INR) in monitoring of patients on anticoagulation therapy using warfarin.
- 2. SUMMARY OF CONTENT:** This VHA directive defines the requirements for the use of PST for monitoring of INR testing in patients on warfarin anticoagulation therapy within the VHA. The program provides requirements for patient clinical eligibility, criteria for PST device/supplies selection patient and provider education and training, establishes criteria for national surveillance, and outlines the requirements for instrument validation.
- 3. RESPONSIBLE OFFICE:** The National Director, Pathology and Laboratory Medicine Service (P&LMS), Diagnostic Services (10P11) is responsible for the content of this directive. Questions may be addressed to 319-338-0581 x5519.
- 4. RESCISSIONS:** None.
- 5. RECERTIFICATION:** This VHA directive is scheduled for recertification on or before the last working day of May 2022. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

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Acting Under Secretary for Health

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1. PURPOSE

This Veterans Health Administration (VHA) directive provides guidance for establishment of a program for use of patient self-testing (PST) for prothrombin (PT) by international normalized ratio (INR) in monitoring of patients on anticoagulation therapy using warfarin. **AUTHORITY:** Title 38 United States Code (U.S.C.) 7301(b).

2. BACKGROUND

a. The Home INR Study (THINRS) was a Department of Veterans Affairs (VA) funded cooperative study which randomized almost 3000 patients with atrial fibrillation or mechanical valves to PST or high-quality outpatient INR testing (anticoagulation clinics). The primary outcomes measured were time to stroke, major bleed, or death. After 8,730 patient-years of follow-up, there was no difference in the primary outcome between groups. Secondary outcomes measured included minor bleeds, time in INR therapeutic range, patient satisfaction, and quality of life.

b. THINRS found that compared with monthly high-quality clinic testing, weekly self-testing yielded similar results in reducing the risk of stroke, major bleeding episode, and death among patients taking warfarin therapy. It should be noted that the study was conducted by a skilled group of investigators, using a standardized instrument and reagents.

c. The study recommended that self-testing may be considered for patients whose access to high-quality anticoagulation care is limited by disability, geographic distance, or other factors, if the alternative would be to withhold a highly effective treatment.

d. VHA chartered a Patient Self-Testing Review Taskforce in the first quarter of fiscal year 2011 (FY11) to re-examine the long-standing VHA policy, VHA Directive 1106.01, Pathology and Laboratory Medicine Service Procedures. The primary conclusion of the taskforce was that VA policy should be revised to allow PST for INR testing. PST should only be supported in specific clinical circumstances and with consideration of key associated policy needs including appropriate patient selection and monitoring, patient and provider education and training, appropriate understanding of platform characteristics of the instruments to be used for self-testing, and associated VA national surveillance to ensure quality and safety of self-testing where implemented.

e. There are a wide variety of devices on the market for patient self-testing. The taskforce did not examine the many products available; however, it did recognize the need for VA to standardize on one or two products. Standardization will provide for improvements in patient care related to Veterans' ability to obtain supplies from any VA medical facility, staff competency in educating patients on the operation of a particular device, consistent interpretation of PST results, and PST instrument validation testing.

To the greatest extent possible, standardization of the instrument base will be a prime consideration in the instrument selection process.

3. DEFINITIONS

a. **Accuracy**. The accuracy of a system is determined by performing testing on specimens of known value or by comparing the results of the device with a method for which the known value has already been verified.

b. **Annual Re-Validation**. At a minimum of once per year, the patient must bring the self-testing device back to the VA medical facility that issued the device for comparison to a laboratory testing reference method.

c. **Anticoagulation Providers**. Pharmacists, physicians, physician assistants (PA), and/or advanced practice registered nurses (APRN) that manage warfarin, support staff nurses and others who assist in the management of anticoagulation therapy.

d. **Correlation**. Correlation is the relationship between test results obtained on the patient self-testing device and systems utilized in the clinical laboratory. Correlation studies must be performed between the patient self-testing device and each unique INR test method/system used to monitor anticoagulation therapy program patient testing within the VA clinical laboratory, including testing such as point-of-care (POC) testing performed at Community Based Outpatient Clinics (CBOCs).

e. **External Quality Control**. External quality control is a test performed on the instrument utilizing a material similar to a patient specimen with a known value that can be tested on the instrument to ensure the instrument is functioning accurately.

f. **Individual Patient Self-testing Device Validation**. Individual patient self-testing device validation is a study performed on each self-testing device before it is issued to a patient to ensure the device is working properly and to ensure the patient can obtain accurate results.

g. **Internal Quality Control**. Internal quality control is an electronic/procedural control process built into the instrument that can be utilized.

h. **International Normalized Ratio**. INR is the standardized measure of the prothrombin time (PT), which is used to determine the clotting tendency of the blood. The INR is the ratio of a patient's PT to a normal (control) sample, raised to the power of the International Sensitivity Index (ISI) value of the reagent system used.

i. **International Sensitivity Index**. ISI is a measure of thromboplastin sensitivity to an international standard. Each lot number of thromboplastin used in prothrombin or INR testing is assigned its own unique ISI value from the manufacturer.

j. **Independent Diagnostic Testing Facility**. Independent Diagnostic Testing Facilities (IDTFs) that provide PST are non-physician-owned, non-hospital-affiliated facilities whose operations are subject to the general supervision of a licensed physician

proficient in PST. The primary role of the contracted IDTF is to inventory, finance, and manage the logistics associated with the ancillary PST equipment and related supplies. Contracted IDTFs are also equipped to handle certain ancillary initial and ongoing services needed to support PST patients according to written instructions provided to the contracted IDTF by the patient's treating physician. These services include providing initial PST training, providing ongoing patient compliance reminders, and ensuring that the Anticoagulation Clinic receives test results requiring immediate medical attention in a timely manner. Only IDTFs that are contracted by VA can be utilized as part of this program.

k. **Patient Self-testing.** PST involves patients (or caregivers) performing INR testing using a device and related supplies that have been approved by the Food and Drug Administration (FDA) for home use. PST is considered an effective alternative treatment for patients who are suitably selected and trained. PST must be ordered in writing by the patient's treating physician who may also discontinue PST if the patient is no longer willing or able to perform testing according to instructions.

l. **Patient Self-testing Trainer.** A PST trainer is a healthcare professional (e.g. nurse, physician assistant, pharmacist, lab technician) with documented competencies in operation and patient education of INR PST devices.

m. **Precision.** Precision is the capability of the test method to consistently reproduce the same measured result when the same specimen is retested.

n. **Quality Control Testing.** There are two types of quality control, external and internal. External controls are liquid specimens with known values that are analyzed in the same manner as patient specimens. Internal controls are checks built into the test device to verify device is working as expected.

o. **System Method Validation.** System method validation is a comprehensive process used to determine that a method performs as claimed by the manufacturer. It is typically performed on one device or a subset of devices

p. **Therapeutic Anticoagulation Therapy.** Therapeutic anticoagulation therapy refers to achieving INR results within the prescribed goal range.

q. **User's Guide.** A user's guide is step-by-step instructions on the testing process following the manufacturer's guidelines and incorporating INR PST program information. Prior to the initiation of patient testing, the user guide must be developed to support patients in the INR PST Program. A user guide or Standard Operating Procedure (SOP) with complete instructions must also be developed for VA personnel providing step by step instructions on the activities required for the program operations. User guides and SOPs must be reviewed and approved by the Anticoagulant Therapy Program and Pathology and Laboratory Medicine Service (P&LMS).

r. **Validation.** Validation is the process used to confirm quality, reliability, and consistency of a testing device and to verify the test method is suitable for its intended use. Paragraph 11 outlines the validation requirements for VA INR PST programs.

4. POLICY

a. PST may be considered as an alternative method of PT/INR testing in accordance with VHA Directive 1033, Anticoagulation Therapy Management, for patients who have their warfarin therapy managed by a VA medical facility under the following circumstances:

b. When access to an accredited laboratory is limited (including limited access to a VA lab because of geographic distance, disability, or other factors);

c. In cases when more frequent INR monitoring may reduce the potential for harm;

d. When venipuncture access sites are limited; and

e. When otherwise determined to be clinically appropriate. See Patient Clinical Eligibility Criteria in paragraph 7 below.

5. RESPONSIBILITIES

a. **Veterans Integrated Service Network Director.** Each Veterans Integrated Service Network (VISN) Director is responsible for:

(1) Ensuring that monitoring of INR is available for all eligible Veterans requiring anticoagulation therapy with warfarin.

(2) Determining whether PST will be utilized within the VISN as a means of providing monitoring of INR.

(3) Ensuring that programs are operated in compliance with relevant VHA policy and procedures.

b. **Medical Facility Director.** Each medical facility Director is responsible for:

(1) Providing and maintaining anticoagulation therapy PST program oversight to ensure access, quality, and compliance with VHA Directive 1033, Anticoagulation Therapy Management, this directive and the facility Anticoagulant Program.

(2) Ensuring an Anticoagulant Program Manager is appointed.

(3) Ensuring the timely completion of all mandated reporting and monitoring.

(4) Establishing a comprehensive policy for INR patient self-testing as defined in this directive and with the same standards of care as mandated in VHA Directive 1033, Anticoagulation Therapy Management, and ensuring this policy is in accordance with this directive.

(5) Ensuring that all staff involved in anticoagulation management are educated and demonstrate understanding of national and local policy and requirements.

c. Facility Clinical Executives (the Facility Chief of Staff and Chief Nursing Officers). The facility Clinical Executives are responsible for:

(1) Ensuring that, if it is determined by a patient's anticoagulation provider that continuation with PST is not in the best interest of the patient, the patient shall be discharged from the PST program and an alternative monitoring method will be instituted.

(2) Ensuring a policy is defined for when a laboratory confirmation from an accredited laboratory is required for a PST result, including results from contracted IDTFs.

(3) Ensuring that the VA provider, based upon current clinical guidelines for specific diseases establishes a target therapeutic range for INR, the INR target ranges established by the and a threshold for the acceptable upper limit that would require laboratory confirmation.

(4) Ensuring method validation is performed in accordance with the protocol outlined in paragraph 11 of this directive prior to the implementation of a patient INR self-testing program.

(5) Ensuring that a validation study is performed between each PST instrument and VA medical facility laboratory at minimum on an annual basis.

(6) Ensuring that nursing and medical staff members serving as the direct educators of patients enrolled in INR self-testing programs must demonstrate on-going competency in the use of devices in order to validate that patients are using the devices correctly.

(7) Ensuring anticoagulation providers and support staff providing warfarin therapy management are following VA medical facility policy, VHA Directive 1033, Anticoagulation Therapy Management, and this directive for patient self-testing of INR.

(8) Partnering with rehabilitation professionals to ensure access and accuracy of self-testing for patients with impairments.

d. Facility Chief of Pharmacy Service. The facility Chief of Pharmacy Service is responsible for:

(1) Ensuring pharmacists providing warfarin therapy management are following VA medical facility policy, VHA Directive 1033, Anticoagulation Therapy Management, and this directive for patient self-testing of INR.

(2) Ensuring that pharmacy staff members serving as the direct educators of patients enrolled in INR self-testing programs demonstrate on-going competency in use of INR self-testing devices in order to validate that patients are using the devices correctly.

e. **Facility Chief of Prosthetic Services.** The facility Chief of Prosthetic Services is responsible for:

(1) Ensuring that instruments, if provided by VHA, are selected in accordance with criteria outlined in paragraph 8 and providing the device to the clinician who will train the patient in the use of the device.

(2) In the event of device malfunction, noted by the clinician, provide the patient with a replacement device.

f. **Facility Chief Pathology and Laboratory Medicine Service.**

(1) The facility Chief P&LMS is responsible for:

(a) Serving as a consultant to the service managing the patient self-testing program when a patient self-testing program is implemented.

(b) Participating in PST instrument selection and validation testing according to the protocol outlined in paragraph 8 and 11.

(c) Participating in staff education.

(d) Ensuring on-site laboratory requirements for PST devices are met (correlation of meters, ISI) in accordance with laboratory standards.

(2) It should be noted that as defined in the VHA Directive 1106.01 and title 42, Code of Federal Regulations (CFR) Part 493, PST is not subject to Clinical Laboratory Improvement Amendments of 1988 (CLIA) licensure, and does not require proficiency testing. The PST INR program falls under the scope of oversight of Facility Anticoagulant Program Manager as detailed below in paragraph 5.g. and, as outlined in the VHA Directive 1106.01, does not fall under the scope of the clinical laboratory.

(3) Since PST is not performed in a clinical laboratory according to the standards set forth in 42 CFR Part 493, accreditation standards prohibit laboratory test results from being co-mingled or recorded in the clinical laboratory results section of CPRS.

g. **Facility Anticoagulant Program Manager.** The Anticoagulant Program Manager is responsible for the daily operations and decision making that supports the PST INR program and as such is responsible for:

(1) The development, implementation, quality management, and ongoing operation of the PST INR program.

(2) Ensuring the PST INR policy defines when a laboratory confirmation from an accredited laboratory is required for a PST INR result.

(3) Ensuring there is a policy for a standardized and consistent process for documenting, in the patient's electronic medical record, reported PST INR results from

either the patient or contracted IDTF and ensuring staff receive training of how to readily retrieve this information.

(4) Ensuring PST devices are fully validated according to the validation requirements in paragraph 11 prior to issuance to a patient or, in the case of patient provided equipment, before the device is utilized for testing in the VA PST program.

(5) Including the PST INR program in the VA medical facility anticoagulant quality assurance plan.

(6) Reporting quality assurance information on the PST INR program to the appropriate facility committee for action.

(7) The development of a policy and process for disposition and/or disposal of returned equipment and ensuring adherence with proper methods of disposal.

h. **Anticoagulation Providers Managing Warfarin Therapy.** Anticoagulation providers managing warfarin therapy are responsible for:

(1) Following VA medical facility policies, VHA Directive 1033, Anticoagulation Therapy Management, and this directive for PST of INR.

(2) Ensuring INR target ranges are established for each patient based upon current clinical guidelines for specific diseases.

(3) Ensuring that an INR from an accredited laboratory is obtained at a minimum of once per year for patients that are monitored through PST.

(4) Ensuring that an INR is obtained from an accredited laboratory under the additional following circumstances:

(a) An INR using PST is above the acceptable range for the PST device as defined in the VA medical facility Anticoagulant Program Policy. The correlation study data/standards are available from the facility P&LMS.

(b) When deemed necessary by the provider based on the clinical situation (e.g., patient's INR is therapeutic but the patient or caregiver reports persistent signs and symptoms of bleeding, or patient's INR is subtherapeutic or fluctuating for no obvious reasons).

(5) Ensuring that when unexpected or unusual PST INR results are obtained, the patient's PST INR is confirmed by an INR performed at an accredited laboratory and the PST device function is validated.

6. USE OF PATIENT SELF-TESTING RESULTS

a. PST results may be used to:

(1) Confirm that INR levels conform to the targeted therapeutic range defined in the VA medical facility Anticoagulant Program Policy.

(2) Detect instances where INR levels are sub- or supra-therapeutic, so that subsequent instructions for warfarin adjustment may be provided by VA medical facility anticoagulation providers for the quick and safe return of the patient's INR to therapeutic range.

b. PST results **will not** be used exclusively to make substantive changes to the patient's anticoagulation therapy regime such as deciding to discontinue warfarin or changing the patient's target INR goal.

c. Patients or caregivers will be advised that PST should not be used to adjust the patient's warfarin doses without contacting the VA medical facility Anticoagulation Management Program Clinic.

d. An INR from an accredited laboratory will be required at a minimum of once per year.

e. Additionally, an INR performed at an accredited laboratory will be required under the following circumstances:

(1) An INR using PST is above the acceptable range for the PST device as determined by VA medical facility standards and the manufacturer. The correlation study data/standards are available upon request from the VA medical facility Pathology and Laboratory Medicine Service; or

(2) When deemed necessary by the provider managing warfarin therapy to improve patient care (e.g., patient's INR is therapeutic but the patient or caregiver reports persistent signs and symptoms of bleeding).

(3) If unexpected or unusual PST INR results are obtained, the patient PST INR should be confirmed by an INR performed at an accredited laboratory and the PST device function should be verified.

f. If it is determined by the provider managing warfarin therapy that continuation with PST is not in the best interest of the patient, an alternative INR monitoring method will be implemented.

7. PATIENT CLINICAL ELIGIBILITY CRITERIA

a. Each VA medical facility utilizing PST must develop a written policy defining the parameters and clinical eligibility criteria, along with specific procedures for the education and training of staff (i.e., Standard Operating Procedure), patients and/or their caregivers (i.e., Patient Use Directive) as defined in this directive and with the same standards of care as mandated in VHA Directive 1033, Anticoagulation Therapy Management, with documentation of patient encounters and follow-up in the Veteran's electronic medical record.

b. In addition to the criteria defined in paragraph 4 above, specific clinical Eligibility Criteria for PST for PT/INR monitoring should include the following:

(1) Patients require chronic warfarin; have been on warfarin therapy for a minimum of 3 months and they are stably anticoagulated with the same standards of care as mandated in VHA Directive 1033, Anticoagulation Therapy Management; and are committed to testing as directed and follow the policies and standards of care for INR patient self-testing of the VA medical facility. Patients/caregivers must receive education regarding warfarin therapy, and this education is to be documented in the patient's electronic medical record.

(2) Patients and or their caregivers have the necessary vision, hearing, dexterity, language, and cognitive skills to perform PST.

(3) Patients/caregivers undergo a face-to-face PST training program individually or in group setting by a PST trainer and demonstrate competency through both demonstration and knowledge based testing.

(4) Patients for PST must have regular access to a telephone and maintain good communication with their anticoagulation provider.

(5) PST for INR testing will be discontinued for patients who do not meet the eligibility criteria, or who fail to continue to meet the eligibility criteria.

(6) Patients with known or suspected lupus anticoagulant or antiphospholipid antibody syndrome will not be eligible to participate in PST.

(7) Self-testing with the device should not occur more frequently than once a week.

8. PATIENT SELF-TESTING DEVICE/SUPPLIES SELECTION CRITERIA

a. Several systems are currently approved by the FDA for INR patient self-testing. Each system uses a tissue thromboplastin reagent contained within a disposable test unit. The whole blood specimen is added and the time to clot formation is measured. Using a formula established by the manufacturer, the device software converts the observed time to an INR and/or plasma-equivalent PT. The method of endpoint detection differs from system to system and from that of a conventional laboratory plasma-based PT. This calibration is achieved by simultaneously testing blood specimens with the patient self-testing system and with the main clinical laboratory instrument/ thromboplastin combination. The conversion equation thus obtained is embedded in the device software. Results are customarily displayed on the instrument monitor.

b. Only those devices receiving FDA approval for patient self-testing are eligible for VHA purchase and issue to Veterans.

c. The following criteria must be considered when making a selection:

- (1) Reliability in multiple settings and under varying conditions of temperature, humidity, light, and physical handling.
- (2) Ease of use.
- (3) Test device quality control.
- (4) Result correlation with the clinical laboratory and other testing sites within VA.
- (5) Easily understood manufacturer instructions/package insert.
- (6) Evaluation of method (device) limitations.
- (7) Manufacturer support for troubleshooting.

NOTE: *Quality and comparability must be the primary drivers for the selection of the patient self-testing device. Cost should not be used as the sole determinant of the test device selection.*

d. The PST device and supplies should be selected in accordance with government acquisition regulations through national or VISN level contracts.

e. The PST device and corresponding supplies needed for PST INR testing may be supplied by a third party contractor (e.g., IDTF) under VA contract management.

f. At the request of the patient and in order to ensure uninterrupted care for patients transitioning to VA, medical facilities may but are not obligated to support testing performed on instruments that the patient obtained from non-VA sources, provided:

- (1) The instruments and reagents are FDA-approved for this purpose.
- (2) The VA medical facility provider staff are familiar with the performance characteristics of the instrumentation and deemed competent to assess patient competency and assess instrument function.
- (3) The patient meets the selection, training, and competency requirements.
- (4) The equipment is functioning properly and the device model and make has been validated according to the validation policy as outlined in paragraph 11.
- (5) The patient agrees to the other terms and requirements for participation in the PST program.
- (6) The patient should be transitioned to a VA-provided device as soon as possible.

9. PATIENT SELF-TESTING PROGRAM REQUIREMENTS

a. Patients who agree to perform INR testing by PST will notify the VA medical facility of the results generated as per their specific medical facility's policy.

b. The PST device will be tested before it is issued to the Veteran. Patients must, at a minimum of once per year, bring in their PST device to the VA medical facility and the results of the PST device be validated by the facility's accredited laboratory.

c. When the PST device is supplied by a contracted IDTF and the contracted IDTF is serving as the intermediate between the patient and VA provider for communication of test results, the INR target ranges established by the VA provider, based upon current clinical guidelines for specific diseases, must be conveyed to the contracted IDTF on the prescription form and documented in the electronic medical record.

d. The patient or contracted IDTF must convey PST INR test results to the anticoagulation provider on the same day as testing, within clinic hours, so the patients can be provided with instructions for warfarin dosage adjustments and/or retesting if needed. Patients/caregivers may not use the results of PST to adjust the patient's warfarin therapy.

e. A standardized and consistent process for documenting, in the patient's electronic medical record, reported PST INR results from either the patient or contracted IDTF must be in place and staff should be aware of how to readily retrieve this information as outlined in paragraph 5.g.(3).

f. Providers will need to contact patients and monitor the PST INR results with the same standards of care as mandated in VHA Directive 1033, Anticoagulation Therapy Management.

g. Each VA medical facility policy must establish clear guidelines for patient discharge from the PST program, with PST device and supplies returned to the supplier (i.e., when the supplier is VA or IDTF). Criteria that could be used for discharge include: need for repeated calls to review basic PST instructions, excessive use of testing supplies, refusal to test according to each facility policy, refusal to return phone calls or respond to letters by providers. Patients discharged from the PST program must be referred for anticoagulation therapy monitoring with laboratory performed INR testing.

h. Each VA medical facility will define a policy for when a laboratory confirmation from an accredited laboratory is required for a PST result as outlined in paragraph 5.g.(2).

i. The performance of PST by Veterans is not subject to the oversight of the Laboratory Ancillary testing coordinator. Responsibility of the facility P&LMS is limited to defining a method validation process, performance of instrument validation sample testing, and participation in staff education (and other responsibilities as designated in paragraph 5 of this directive).

10. PATIENT AND PROVIDER EDUCATION AND TRAINING

a. Patient and provider education is critical to establishing a safe and comprehensive INR-PST program. Results for INR testing may vary dependent upon the methods used (e.g., accredited lab, point of care testing device or patient self-testing device), the

competency of the person performing the test and the accuracy of the testing equipment or device. Prior to the implementation of a PST INR program the Anticoagulant Program Manager must ensure the following are developed:

(1) Comprehensive education and individually-tailored training for the Veteran enrolled in the program, defined training that includes return demonstration and on-going competencies for educating staff, and a comprehensive communication plan with a one-on-one plan between the patient and provider or health care team must be established to help ensure safety.

(2) Ongoing patient communication is critical for the success of the program. Except for initial training and on-going competencies with instrument validation which require face to face training, additional communication may be facilitated and enhanced through the use of clinical video telehealth (CVT) encounters.

(3) It is the responsibility of each medical facility Director to establish a comprehensive policy for INR patient self-testing as defined in this directive and with the same standards of care as mandated in VHA Directive 1033, Anticoagulation Therapy Management and ensure all staff involved in anticoagulation management are educated and demonstrate understanding of local policy and requirements.

(4) Staff members that serve as the direct educators of patients enrolled in INR self-testing programs must demonstrate on-going competency in use of the device in order to validate the patient is using the device correctly. Staff members must also know how to obtain support in the event of instrument malfunction or other problems.

(5) If patient training is provided from a third party contractor (i.e., IDTF), each time the patient is provided training or assessed for competency, the patient training and competency records must be obtained by the provider prior to managing the patient's anticoagulation therapy under the PST program, reviewed for accuracy, and documented in the medical record. **NOTE:** *This may be accomplished by scanning.* If patient records cannot be obtained, the anticoagulation therapy provider must independently verify the Veteran's competency in using the INR self-testing equipment through actual correct demonstration of use of the product and knowledge test (see appendices A and B).

(6) Before INR self-testing equipment is issued through VA to a Veteran, the Veteran and/or caregiver must be educated on use of the machine and able to demonstrate competency through actual correct demonstration of use of the product and knowledge test (see appendices A and B). In the case where the patient will use a device obtained from a non-VA source, the Veteran and/or caregiver must be able to demonstrate competency through actual correct demonstration of the use of the product and knowledge test before the device is utilized for testing in the VA PST program.

(7) Patients with mobility impairments may use prosthetic, and/or assistive devices prescribed for their impairment, to use the self-testing equipment. If Veterans with physical or visual impairments are not able to complete self-testing, patients can be

referred to rehabilitation professionals to adjust prosthetic and/or assistive devices, provide targeted training, or provide more effective devices for self-testing, if feasible.

(8) At minimum on an annual basis as defined in the facility PST INR policy, the Veteran and/or caregiver will bring the INR self-testing equipment to VA and the anticoagulation therapy provider will verify and document on-going competency in correct use. This includes equipment provided by a third party (i.e., IDTF or patient provided device).

(9) Veteran/caregiver education must also cover the following topics including, but is not limited to:

(a) Importance of not self-adjusting warfarin.

(b) Frequency of testing.

(c) Target range.

(d) How to communicate the results of self-testing to the provider and/or care team.

(e) Timely communication of test results to achieve optimal coagulation therapy management.

(f) Who and how to contact someone with questions regarding equipment and self-testing procedure.

(g) Situations when it will be necessary for the Veteran to comply with laboratory testing (e.g., signs and symptoms of adverse effects such as bleeding, confirmation of an out-of-range INR, or when deemed necessary by the provider to ensure the continued safe use of warfarin).

(h) Importance of reporting any signs and symptoms of bleeding immediately even if INR self-testing result is in therapeutic range.

(10) Veteran/caregiver education must also include comprehensive written material covering the above topics related to self-testing in addition to the education topics that are mandated in this directive. Written material must be Section 508 compliant (i.e., accessible for blind or visually impaired patients).

(11) VHA providers will also need to be familiar with performance characteristics of all the instruments used by their panel of patients including instruments provided by a third party contractor (i.e., IDTF or Veteran provided equipment).

(12) All patient education and competency assessments must be documented in the medical record.

11. INR SELF-TESTING DEVICE VALIDATION

a. Validation Requirements.

(1) Validation studies must be performed prior to placing devices into use for patient INR self-testing to confirm quality and reliability of a testing device. These studies are necessary to:

(a) Verify that the testing device works as the manufacturer described.

(b) Determine the suitability of the device for VHA patient self-testing.

(c) Assess how the patient self-testing device results compare to the clinical laboratory results (correlation).

(d) Assess the comparability of the testing when performed by a patient on the self-testing device to the VA laboratory method.

(e) Define the highest reportable value (cut-off value) at which the self-testing device is no longer accurate when compared to the value obtained by the laboratory method. Results beyond the cut-off value must be verified by a laboratory testing method performed at an accredited laboratory.

(2) Validation should be performed in a collaborative process between the patient self-testing INR Anticoagulant Therapy Program personnel, who will perform self-testing device testing, and P&LMS personnel, who will perform the corresponding laboratory instrument correlations. Validation is performed in three different phases as described in paragraph 10.b., 10.c., and 10.d., of this directive.

(3) When a healthcare system or VISN has selected identical (same manufacturer and method) self-testing devices for implementation within the system, the validation process may be coordinated for the entire healthcare system.

(a) When identical test methods are used in the clinical laboratory at multiple sites within a VA healthcare system or VISN, the VISN or healthcare group may collaborate on the system method validation. The system method validation process may be performed on only one device or a subset of devices at one site.

(b) When more than one test method/system is used for INR patient testing, a comparison study must be performed between the patient self-testing method/system and each unique test method/system in use for managing INR testing within the anticoagulation therapy program.

(4) This validation procedure is solely intended for self-testing devices purchased and distributed to Veterans by VA.

(5) Since the validation process will require validation testing in coordination with the P&LMS, the Chief, P&LMS must be consulted during the initial planning phases of the program.

b. **System Method Validation.** When introducing a new INR patient self-testing system for patient care, a system method validation must be performed on one or a small subset of the patient self-testing device(s) to ensure the test system performs as stated by the manufacturer and is appropriate for the VA patient self-testing INR program. After completion and approval of the device system validation, each patient self-testing device must be validated before it is issued to a patient to ensure the device is working properly and to ensure the patient can obtain accurate results.

c. **Chief or Director, P&LMS Consultation.** The Chief or Director, P&LMS, or designee, must collaborate and provide consultation to the service managing the patient self-testing program in the development of protocols for test method validation, criteria of acceptability, testing protocols and validation evaluation; P&LMS serves as a subject matter expert for the validation process.

(1) Correlation with clinical laboratory instrumentation (assessment of accuracy). Correlation must be performed with each unique instrument type/method used for INR testing within the clinical laboratory, VA medical facilities, or CBOCs where the patient receives anticoagulation management.

(2) Analysis and approval by the Chief or Director, P&LMS, or designee Pathology and Anticoagulant Program Manager.

d. **Operator Training and Competency Assessment.** It is recommended that Anticoagulant Management Program personnel responsible for the patient's care (who will train the patients on all aspects of the INR self-testing program) should participate in the primary method correlation process, so that in addition to performing the correlation testing, they will have the opportunity to obtain more experience with the testing device.

(1) Personnel must complete training on the patient self-testing device, must have satisfactorily demonstrated competency, and evidence of this competency must be documented prior to participation in the validation process.

(2) P&LMS will assist in establishing the initial training and competency program for all staff involved in teaching patients to perform INR self-testing.

(3) After personnel have documented competency, they may participate in patient testing for the purpose of correlation.

e. **Method Validation Plan and Acceptability Criteria.** The method validation plan and acceptability criteria must be defined prior to the validation process. The criteria should be based on the manufacturer's specifications and the precision and accuracy required for patient care. The data from the correlation study will be analyzed to evaluate differences in INR between instruments and its potential impact to clinicians

evaluating numerical values that are not equivalent between instruments. The P&LMS service should participate in the plan design.

f. **User Guide.** The manufacturer will provide step-by-step instructions on the testing process. Testing must be performed in accordance with manufacturer's product inserts and operational manuals. Prior to the initiation of correlation testing, the user guide must be reviewed and approved by the Anticoagulant Management Program and P&LMS. The user guide or SOP must be available to staff members performing validation testing.

g. **Other Preparations.** Validation testing should be accompanied by external and internal quality control testing. Quality control values must be within acceptable limits.

(1) Multiple operators should participate in the validation process to ensure that operator technique does not significantly affect test variability or reproducibility of results.

(2) The system method validation may be performed on one device or a subset of identical devices.

h. **Self-Testing Device Precision Studies.** *NOTE: Precision studies may be performed by P&LMS or other staff involved in the patient self-testing program. In order to evaluate the precision under typical testing situations, multiple testing personnel as well as testing personnel with different levels of testing experience should participate in testing to verify operator technique does not significantly affect test variability or reproducibility of results.*

(1) Liquid controls (2 levels) or other reference material must be analyzed in 10 replicates.

(2) Mean, standard deviation (SD) and coefficient of variation (CV) will be calculated for each control and compared against the manufacturer's data to determine acceptability.

i. **Correlation with Clinical Laboratory Instrumentation (Assessment of Accuracy).** Correlation studies are performed with whole blood samples on the patient self-testing device (on one device or a small subset of identical devices) in comparison with a specimen analyzed with the clinical laboratory methodology. Comparisons must be performed on a minimum of 20 patients.

(1) Patient whole blood samples will be analyzed simultaneously by both the patient self-testing device and the clinical laboratory method.

(2) The Anticoagulant Management Program must recruit patient volunteers to participate in the validation study. A variety of patients should be selected with different INR's so that the study will include therapeutic, low, and high values (representative of the range of values expected to be seen clinically).

(3) It is recommended that the personnel in the Anticoagulant Management Program who will ultimately be serving as the patient self-testing trainers should assist in the initial correlation testing on the device. **NOTE:** *Testing performed on the INR self-testing device as part of the validation process may not be utilized for patient care.*

(4) Concurrent with the testing on the self-testing device, the patient must have their blood drawn and submitted to the laboratory for testing in comparison with laboratory reference method. **NOTE:** *The INR laboratory test must be ordered in the Computerized Patient Record System (CPRS).* The blood specimen for INR testing submitted to the laboratory will be accessioned and the results will be available for patient care.

(5) The results should be analyzed using regression analysis. In addition, the bias should be calculated throughout the reportable range (e.g., at an INR of less than 2; and INR between 2 and 3; an INR between 3 and 4.5; and an INR greater than 4.5). The above correlation study must be performed with each unique instrument type/method used for INR testing within the clinical laboratory, VA medical facilities, or CBOCs where the self-testing patient will receive anticoagulation management.

j. **Define The Highest Reportable Value (Cut-Off Value).** Results exceeding an INR of 4.5 or higher may have reduced trueness, precision, and linearity, both in self-testing devices and laboratory-based POC testing. Appreciation of the general agreement between INR results obtained on self-testing devices and different laboratory-based systems is essential for optimal patient management.

Based on the correlation data, the organization must determine the cut-off value at which the patient is required to have INR testing repeated at an accredited laboratory.

k. **Interference Testing.** This will not be performed as it has been performed by manufacturer but must be reviewed from the manufacturer's product inserts. Information on interferences must be communicated to staff involved with patient training.

l. **Documentation of Primary Patient Self-Testing System Validation.** The results of the precision and accuracy studies will be evaluated according to criteria of acceptance defined by the Chief, P&LMS, or designee. If the validation process indicates the patient self-testing system meets the organization's requirements, the validation will be approved by the by the Chief, P&LMS and the Anticoagulant Program Manager.

The primary validation documentation should be retained by P&LMS until 2 years after the self-testing device is discontinued.

m. **Individual Patient Self-Testing Device Validation.** The performance of each device will be verified prior to issuance to the patient.

n. **Preparation.**

(1) Staff Competency. The healthcare professionals responsible for the patient's care in the Anticoagulant Therapy Program typically will be the designated trainers for the patient self-testing program.

(a) P&LMS must provide oversight for the training and competency program for trainers.

(b) Anticoagulant Management Program personnel must complete training on the patient self-testing device, must have satisfactorily demonstrated competency, and evidence of this competency must be documented.

(c) Competency assessment must be performed at a minimum of once per year as defined in the facility PST INR policies and procedures.

(d) Evaluation of the competency of the staff must include direct observation of testing.

(2) A user's guide, including the manufacturer's step-by-step instructions on the testing process reviewed and approved by the Anticoagulant Program Manager must be provided to each patient in the self-testing program. Information on the cut-off value, interferences, and a contact to call in case of device problems must be included.

(3) Criteria of acceptability must be defined for the individual device correlation.

o. Device Verification.

(1) External quality control must be performed on the INR self-testing INR device prior to issuance to the patient.

(a) The results must fall within the criteria of acceptability as defined in the method validation process.

(b) Devices failing quality control may not be issued for patient self-testing.

(2) The patient should be sent to the laboratory immediately prior to their training appointment to have a specimen drawn for an INR to be tested in the laboratory. It is recommended that the patient have laboratory INR collected before the patient reports for self-testing device training so the INR results will be available prior to completion of the self-testing training.

(3) Anticoagulant Management Program personnel responsible for the patient's care will provide patient's training on all aspects of the INR self-testing program.

(4) The patient will be observed performing INR self-testing and the result will be compared to the clinical laboratory result. The device will be considered acceptable if the value obtained by the patient falls within the criteria of acceptability defined by the validation study.

(5) If device validation is acceptable, the device may be issued to the patient. The trainer must document the serial number of the device, the date of issue, and results obtained by each method in the patient's medical record.

(6) The patient may begin the provisional home testing test period in accordance with the established program guidelines. **NOTE:** *The recommended provisional testing period is 2 weeks. During the provisional period, the patient will be assessed for program compliance and the provider may not approve warfarin adjustment until the patient returns to VA for the verification process outlined in the next step.*

(7) To document validation of the testing device operation in the patient's home environment, the patient should be scheduled for a return appointment with the VA Anticoagulant Management Program Clinic in 2 weeks. The patient must bring their device and testing documentation to their appointment.

(a) The provider should order an INR test in CPRS for the patient and the patient should be sent to the laboratory prior to their appointment to have a specimen drawn for an INR to be tested in the laboratory. It is recommended that the patient have laboratory INR collected before the patient reports for their appointment so the INR results will be available prior to completion of the self-testing assessment.

(b) The patient testing records will be reviewed by the Anticoagulant Management Program personnel responsible for the patient's care.

(c) The patient will again be observed performing INR self-testing.

(d) The result will be compared to the clinical lab result. If the value falls within the defined criteria of acceptability and the patient is deemed competent to perform self-testing, the patient can then be monitored according to the organization's patient self-testing guidelines.

(e) The successful completion of the individual patient meter validation and patient competency assessment must be documented in the patient's medical record.

p. **Annual Re-Validation.** The patient must bring the INR self-testing device to a scheduled appointment in Anticoagulant Management Program Clinic at least annually or when there is a problem or concern to compare the results obtained on the patient self-testing device to the INR value obtained on an accredited INR test method/system used to perform testing for patients. The patient's provider should order an INR test for the patient in CPRS.

(1) Immediately prior to the patient's Anticoagulant Management Program appointment, the patient must have their blood drawn and submitted to the laboratory for testing in comparison with laboratory reference method. **NOTE:** *The specimen for INR testing submitted to the laboratory will be accessioned so the results must be documented in the patient record.*

(2) The patient will be observed performing INR testing and the test result will be compared to the clinical laboratory result.

(3) The device will be considered acceptable if the value obtained by the patient falls within the defined range of acceptability as compared to the value obtained in the clinical lab.

(4) The successful completion of the patient annual meter validation and patient competency assessment must be documented in the patient's medical record.

q. **Patient-Provided Equipment.** Before a patient-provided device may be utilized for testing in the VA PST program, VA must ensure the device model has been validated according to the system method validation policy as outlined above in paragraph 11.a.(3) and that the individual device is validated according to the individual patient self-testing device validation policy as outlined in paragraphs 11.b. and 11.c. of this directive.

12. NATIONAL SURVEILLANCE

a. The implementation of this VHA policy for patient self-testing must be accompanied by a commitment from VHA to have in place a national process to monitor whether the results of the THINRS study remain valid with general utilization of PST. National surveillance assures standardized implementation and sustainability of this policy. Emphasis should be placed on effectiveness, patient safety, and device safety surveillance.

b. Two commonly used surveillance tools, process monitors, and outcome monitors, are applicable for this policy change. A process monitor assures implementation and surveillance data collection will be standardized at the VA medical facility, VISN, and national levels. The surveillance standards should be the same as used for laboratory-based patient data. The data collection is necessary to detect early warning indicators of systematic quality or safety issues. Documentation of process monitoring could be as simple as a VA medical facility checklist.

c. The second surveillance tool is outcome monitors. Outcome monitors evaluate the clinical outcome of patients in which the policy applies. These will identify enhanced clinical effectiveness or decreased clinical outcomes caused by unanticipated and unintended safety vulnerabilities. Veterans utilizing self-testing should have same level of surveillance of quality and outcomes as patients who have laboratory-based INR monitoring. Specifically, other than location of laboratory testing, there should be no differences in care processes or minimum standards of care. Outcome monitors should include:

(1) Appropriate monitoring and care from an anticoagulation provider or anticoagulation clinic for warfarin initiation, warfarin restarts or bridging, and long-term monitoring.

(2) Quality measures. Reports for tracking and trending of INR values at the national, VISN and VA medical facility levels.

(a) Calculation of INR test frequency.

(b) Calculation of time in therapeutic range (TTR).

(c) Calculation of the proportion of patients with pathologic bleeding events.

(d) Calculation of the proportion of patients with thromboembolic events.

(e) Anticoagulation adverse drug reaction.

(f) Emergency room visits and admissions.

(g) Other patient incidents, close calls, and near misses associated with INR patient self-testing.

13. REFERENCES

a. VHA Directive 1033, Anticoagulation Therapy Management.

b. VHA Directive 1106.01, Pathology and Laboratory Medicine Service Procedures.

c. VA, Veterans Health Administration – Patient Self-Testing Review Taskforce Report.

d. CLSI. One-Stage Prothrombin Time (PT) Test and Activated Partial Thromboplastin Time (aPTT) Test; Approved Guideline-Second Edition. CLSI Document H47-A2. (ISBN 1-56238-672-7). Wayne, PA; 2008.

e. CLSI. Procedures for validation of INR and local calibration of PT/INR systems; Approved Guideline. CLSI document H54-A. CLSI, Wayne, PA. 2008.

f. The Home INR Study (THINRS), CSP # - 481. Department of Veterans Affairs, 2012.

g. Matchar DB, Jacobson A, Dolor R, Edson R, Uyeda L, Phibbs CS, Vertrees JE, Shih MC, Holodniy M, Lavori P; THINRS Executive Committee and Site Investigators. Effect of home testing of international normalized ratio on clinical events. N Engl J Med. 2010.

SAMPLE PATIENT SKILLS CHECKLIST

Sample Patient Skills Checklist (adapt to type of machine)

Assembles Equipment

- Monitor **UP #:** _____
- Container of test strips
- Test strip code chip
- Lancet device and the single use disposable lancet
- Demonstrates removal and replacement of batteries

Reviews Procedure

- States when coding is needed
- Turns meter off before inserting or removing code chip
- Removes old code chip if one is installed
- Inserts new code chip and verifies the chip is properly positioned.
- Properly prepares lancet device
- Inserts test strip
- Presses M to match code

Reading & Reporting Results

- Obtains blood sample correctly.
- Applies blood to test strip correctly.
- Reads and records result performed during training.

INPUT TEST RESULT HERE:

1. _____ 2. _____ 3. _____

- Critical Value < 1.5 and > 5.0 **INTERVENTION:**

- Properly discards used test strip and blood drawing supplies.
- Correctly recalls results stored in memory.

- Understands provider's orders regarding:
- Test Frequency: _____ times per week / month
- Target INR Range _____ to _____
- Test Reporting Instructions
- During the training session, report results according to instructions provided by provider **TIME CALLED IN:** _____

Problem Solving

- Understands to reference Error Messages in the user manual when a problem occurs.
- Understands to call at xxx-xxx-xxxx or the 24 hour Technical Service number at x-xxx-xxx-xxxx for assistance if more than one strip is needed to obtain a result or for other testing related problems.
- Is aware to call the technical service number if product problems arise.

Cleaning

- States cleaning frequency.
- Demonstrates exterior and test strip guide cleaning procedure as stated in the updated user instructions.

Knowledge Test

- Completed Knowledge Test in Appendix B) and understands areas of confusion.

Next Appointment

- Phone appointment scheduled to assist patient with their first solo test.

DATE & TIME: _____

Supplies Provided to Patient:

- _____ meter
- _____ boxes of strips
- _____ lancing device
- _____ single use lancets

TRAINER & PATIENT ACKNOWLEDGEMENT

TRAINER: I acknowledge that this patient (or their care provider) has demonstrated his/her ability to perform Home INR Testing according to their provider's instructions.

PRINT TRAINER NAME

DOB

TRAINER SIGNATURE

TRAINING LOCATION

DATE

PROVIDER PRESCRIBING PST INR TESTING

ID Number

PATIENT: I acknowledge receipt of training and understand my provider's instructions for reporting test results.

PRINT PATIENT NAME

DOB

PATIENT SIGNATURE

TRAINING LOCATION

DATE

EXAMPLE: PATIENT KNOWLEDGE ASSESSMENT (adapt to type of machine)

Mark “T” if the statement is true and “F” if the statement is false.

1. It is important to correctly set the date, time, and result format to make sure results are reported accurately.
2. A target range may be set on your own, without your healthcare professional.
3. After turning on the monitor, you may test at any time.
4. Every time you test, you must match the code on the monitor display to the code on the test strip pouch.
5. When applying the sample to the test strip, you can press your finger on the test strip.
6. During testing, it is important to hold the finger with the blood to the test strip sample well until the meter beeps.
7. Every time a blood test is performed, the monitor also performs automatic quality control tests.
8. If you receive an error, you may test again using the same test strip.
9. The most recent INR result appears first when reviewing the memory.
10. The monitor must be cleaned after each test.

Please answer the following questions:

1. If the code on your monitor display reads “AD7GF”, and the code on your test strip reads “WY1UA”, what would you do?

2. What is the first step after receiving an error message?

3. Why is it important to wait for the green light before applying the blood to the test strip?

4. What would you do if you got an INR result of 7.5?

5. Why is it important to apply blood to the test strip within 15 seconds of sticking the finger?

Patient and Trainer Acknowledgement

Trainer **Date**

Trainee **Date**