

SUPPLEMENT TO

M A N A G E D

Care

Oral Anticoagulation Patient Self-Testing: Consensus Guidelines For Practical Implementation

HIGHLIGHTS

- Rationale for Wider Implementation of Patient Self-Testing

- Patient Self-Testing Costs and Related Reimbursement

- Practical Guidelines for Implementation of Patient Self-Testing

- Summary of Consensus Panel Recommendations

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Oral Anticoagulation Patient Self-Testing: Consensus Guidelines for Practical Implementation

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Introduction

Challenges of managing patients on warfarin therapy

Oral anticoagulation therapy with warfarin is effective in reducing the risk of thromboembolism in patients with hereditary or acquired thrombophilia, heart valve replacement, atrial fibrillation (AF), and other conditions (Heneghan 2006) ($P=.001$). The goals of oral anticoagulant therapy are to prevent thromboembolism and to minimize the risk of bleeding complications by achieving and maintaining the international normalized ratio (INR) within an appropriate target range. However, warfarin's narrow therapeutic range, variable biological effects, and potential for drug and food interactions, including fluctuations in patient dietary intake of vitamin K-containing foods, present challenges to reaching these goals (Ansell 2004). Because of these factors, regular INR monitoring is required to determine dose adjustments that may be necessary to maintain the INR in the target range. The mean plasma half-life of warfarin is approximately 40 hours, and the mean terminal half-life of a single dose is approximately 1 week (warfarin PI 2007). U.S. Food and Drug Administration-approved labeling of warfarin now includes a black box warning regarding the risks of major or fatal bleeding. Risk factors for bleeding include high intensity of anticoagulation (INR>4.0), age 65 or older, highly variable INRs, history of gastrointestinal (GI) bleeding, hypertension, cerebrovascular disease, serious heart disease, anemia, malignancy, trauma, renal insufficiency, concomitant drugs, and a prolonged duration of warfarin therapy. Those at high risk of bleeding may benefit from more frequent INR monitoring, careful dose adjustment to the desired INR, and a shorter duration of therapy (warfarin PI 2007).

In the United States, approximately 75 percent of patients taking warfarin are managed individually by a physician or other practitioner (CMS 2008), with periodic office visits that include INR testing performed either by centralized laboratory methods or with point-of-care (POC) INR devices in the office. In this setting, referred to as usual care, patients are typically evaluated by the practitioner once every 4–6 weeks, any INR-based dose adjustments are then prescribed, and patients remain on that dose until the next office visit. Alternatively, monitoring by anticoagulation clinics provides a standardized system of patient management, and this type of care has been associated with improved outcomes relative to the usual care model (Ansell 2005).

Patient self-testing

Patient self-testing (PST) may consist of weekly, as indicated, INR testing with a home

INR device in addition to regular office visits with the health care practitioner. Each week, the patient communicates the INR to the practitioner, who then instructs the patient about any dose adjustments that may be needed. PST is not a stand-alone management method; ideally, it should be combined with periodic visits to an anticoagulation clinic or a health care practitioner's office on a predetermined schedule for clinical assessment, patient education, and periodic parallel testing of the patient's INR device. Patient self-management (PSM) occurs in addition to all the components of a weekly self-testing program, and includes teaching the patient to follow a practitioner-prescribed, dose-adjustment algorithm based on weekly INR values.

In addition to the extensive body of evidence supporting the efficacy, safety, and improved quality of life associated with PST (Ansell 2005, Sawicki 1989, Heneghan 2006), additional factors (discussed later in this monograph) support its incorporation into the U.S. care model for patients who require oral anticoagulation. As the general patient population has become better informed about health care, patients desire a more active role in the management of their health. PST, like home blood-glucose monitoring by patients with diabetes, is a simple and practical method that enables more frequent testing, and has been demonstrated to improve INR control and significantly reduce the risk of bleeding and thrombotic complications.

Need for oral anticoagulation therapy expected to increase

The incidence of venous thromboembolism (VTE) rises exponentially with age and increases sharply in pa-

TABLE 1
Selected studies of patient self-testing (PST) and patient self-management (PSM)

Study	N	Patient population	% patients within INR target range ^a	
			Usual care	PST/PSM
White 1989	46	Mixed	75	93
Ansell 1995	40	Mixed	68	89
Beyth 2000	325	Mixed	33	56
Sawicki 1989 ^b	179	Mixed	43	53
Horstkotte 1998	150	MHV	59	92
Körtke 2001	1200	MHV	62	80
Voller 2005	202	AF	59	68

AF=atrial fibrillation, MHV=mechanical heart valve, mixed=patient population with regard to indication for therapy.

^aRounded to nearest whole digit.

^bResults indicate percentage of patients in the therapeutic range at 6 months.

tients older than age 60 (White 2003), approximating the current age of the oldest of the baby boom generation. In the United States, the aging of this large segment of the population is expected to result in a significant increase in the incidence of VTE and the need for oral anticoagulation in the coming years. Likewise, the incidence of AF increases after age 40 and more so after age 65 (Albers 2001).

The wider implementation of PST may be a critical component of the U.S. health care system's response to ensure high-quality care for the growing population of patients who will require oral anticoagulant therapy. If Medicare office visit reimbursements become more limited for practitioners treating patients who receive oral anticoagulant therapy, PST would provide a feasible way to maintain high-quality patient management as the reimbursement schedule evolves. In February 2008, a consensus panel consisting of a multidisciplinary group of U.S. health care practitioners with expertise in anticoagulation management was convened to determine the best practices for implementing PST in clinical practice. Their recommendations are presented herein.

Rationale for wider implementation of PST ***Comparative studies of PST and PSM*** ***as an adjuvant to usual care***

Patient INR self-testing by those who receive oral anticoagulant therapy with warfarin is an effective tool for monitoring therapy and managing dose adjustments. Many clinical studies have demonstrated significant reductions in the risk of bleeding and thrombotic complications when PST is added to a comprehensive care plan, and these management tools are commonly used in several European countries. As an adjuvant to standard medical management by health care practitioners or anticoagulation clinics, weekly INR testing with PST, in addition to the office-based medical evaluation and management provided by primary care practitioners, has been shown to result in better INR control, lower rates of bleeding and thrombotic complications, and superior patient satisfaction. The Centers for Medicare and Medicaid Services (CMS) evaluators noted that within the large body of data collected from randomized controlled trials demonstrating consistently favorable results for PST, no trials have shown a decrease in time in therapeutic range with self-testing (CMS 2008). A summary of selected studies of PST/PSM supporting this claim is presented in Table 1.

PST costs and related reimbursement

Recent changes in the reimbursement system in the United States have made implementation of PST feasible for a wider range of patients receiving oral anticoagulant therapy and for their health care practitioners. In 2002, CMS approved reimbursement for home INR

monitoring for patients with mechanical heart valves. In March 2008, CMS expanded coverage to patients with AF and VTE, including deep vein thrombosis (DVT) and pulmonary embolism (PE) (CMS 2008). This decision is supported by the American Heart Association, the American Stroke Association, the American College of Cardiology, and the American College of Clinical Pharmacy.

The CMS decision states several conditions for reimbursement eligibility, including the patient's need for chronic oral anticoagulation with warfarin, at least 3 months of therapy prior to beginning PST, successful completion of a face-to-face training program and correct demonstration of device operation, continued proper use of the device in the context of a comprehensive management plan, and a testing frequency of no more than once weekly. The CMS decision was based on 10 clinical studies demonstrating that home testing is associated with consistently higher rates of time in therapeutic range and improved patient outcomes, regardless of the clinical indication or type of INR device used. Among the advantages related to the immediate availability of weekly results with PST, CMS lists:

- The ability of the health care practitioner to make dose adjustments quickly
- The ability of the patient to correlate lifestyle factors to INR stability
- Increased confidence on the part of the practitioner to prescribe sufficient doses of warfarin to achieve the therapeutic range (CMS 2008)

Reimbursement is approved for PST-related services in addition to the standard fees for management of patients. Currently, the payment for review of each set of 4 PST results is \$9.08; for providing one-time initial device training (described in more detail on page 7), \$191.20; and for leasing an INR device and providing testing supplies to the patient, \$140.54 per month (Table 2, page 4).

Practitioner options

Practitioners who implement PST as part of a patient's overall management plan may choose only to review and evaluate the additional INR results provided by PST, and ask patients to purchase their own devices and supplies and receive device training through a licensed, third-party vendor. Alternatively, they may choose to review results and provide patients with initial device training, but require that they obtain their device and supplies through the third-party vendor. A third option is for the practitioner to review results, purchase the INR devices and then lease them to patients, and make test strips and other supplies available to patients. Table 2 (page 4) shows the PST reimbursement for three different levels of practitioner involvement.

TABLE 2**Patient self-testing (PST) reimbursement***

CPT code	Description	Option A	Option B	Option C
		<ul style="list-style-type: none"> • Practitioner reviews INR results only • Third party provides device training • Third party provides INR device and testing supplies 	<ul style="list-style-type: none"> • Practitioner reviews INR results • Practitioner provides one-time device training • Third party provides device and testing supplies 	<ul style="list-style-type: none"> • Practitioner reviews INR results • Practitioner provides one-time device training • Practitioner leases device to patient • Practitioner provides testing supplies
G-0250	Practitioner review of each set of 4 PST results	\$9.08	\$9.08	\$9.08
G-0248	One-time training on device operation		\$191.20	\$191.20
G-0249	Leasing of device and provision of testing supplies			\$140.54/month
Total yearly^a per patient + one-time initial training		\$118.04	\$118.04 + \$191.20	\$1,804.52 + \$191.20
Total yearly^a per patient, first year of PST		\$118.04	\$309.24	\$1,995.72

*In addition to comprehensive management, according to practitioner options for device ownership, patient training, provision of devices, and distribution of testing supplies.

^a1 year includes 13 sets of four (once-weekly) patient self-testing results.

INR=international normalized ratio.

Source: CMS 2008

Cost-effectiveness

The benefits that have been demonstrated by the addition of PST to the usual care model include greater time in therapeutic range, fewer dose changes, reduced risk of bleeding and thrombotic complications, improved survival, and improved quality of life for patients (Ansell 1995, Ansell 2005, Sawicki 1989, Koertke 2007). In addition, several studies have determined that there are significant cost savings for the health care system associated with the decreased incidence of adverse events related to warfarin therapy. Lafata (2000) calculated a cost-effectiveness ratio of \$24,818 per avoided adverse event with PST, compared with anticoagulation clinic management alone. This figure, which reflects costs for the year 1997, includes all direct medical costs and patient and caregiver costs related to PST and utilization of care that would be required for treatment of a hemorrhagic or thrombotic event. In a long-term follow-up of the effects of PST, Ansell (1995) determined that patients who self-tested required 50 percent fewer dose adjustments compared with patients in the control group. Both the increased time in therapeutic range and the decrease in required dose adjustments were statistically significant (both $P < .001$). In addition to the efficacy and safety implications of PST, there may be an advantage for practition-

ers in terms of less time and effort required to manage patients who achieve tighter INR control through PST.

Practical guidelines for implementation of PST

The CMS criteria and the panel's recommendations provide general guidance for implementing PST. The panel recognizes there is no one correct way to incorporate PST into a medical practice. Similar to recommendations for management of other diseases, there are many acceptable ways for guidelines to be implemented in the day-to-day delivery of primary care, allowing practitioners the flexibility to develop individualized protocols and procedures that function best in their particular settings.

Patient selection

Selection of appropriate candidates is an important part of successful implementation of PST in a medical practice. A wide range of patients may be appropriate candidates for PST, including those with risk factors for major or fatal bleeding, such as high intensity of anticoagulation; age 65 or older; highly variable INRs; or a history of GI bleeding, hypertension, cerebrovascular disease, serious heart disease, anemia, malignancy, trauma, renal insufficiency, concomitant drugs, and the need for long-

term anticoagulant therapy (warfarin PI 2007). Other patients who stand to benefit from PST include those with conditions or circumstances that make accessing usual care difficult; physical disabilities and financial constraints may limit a patient's transportation options, for instance, or the patient may live far from the practitioner or clinic, preventing the patient from receiving INR monitoring at the frequency needed for optimal warfarin management. Patients who spend significant periods of time traveling from home or who have demanding work schedules also may benefit from the availability of PST programs. Likewise, caregivers who may have to make special work or child care arrangements to accompany the patient to office visits may welcome the flexibility that PST offers.

Implementing PST as part of a comprehensive management plan offers patients and their caregivers an option to achieve or maintain high-quality care and may be more practical for some patients than the traditional model. The panel did not recommend an upper age limit for patient selection, but advised that practitioners evaluate each patient individually for clinical appropriateness to perform weekly self-testing. The panel recommends that physicians and other practitioners offer PST to any patient who meets the following criteria:

- Willingness to participate in training on the proper use of PST in the context of a comprehensive management plan
- Ability to attend face-to-face training and follow all procedures for testing, communicating results, complying with dose adjustments, and attending follow-up office visits
- Reliability with regard to the practitioner's assessment of the patient's trustworthiness to adhere to all instructions
- Access to a telephone or other devices to communicate with the practitioner
- The presence of a caregiver or proxy who meets the above criteria if the patient does not

Practitioners might consider a contract-based arrangement with patients who begin PST so that expectations are clear, and the patient understands that PST is based on medical necessity. All patients and/or caregivers should understand that participating in PST can continue only if adherence is consistently high, and that termination of PST will be implemented if adherence is inadequate. Such a contract might include specific elements that define compliance, including frequency of testing, timeliness of reporting results, and following all prescribed instructions regarding care. Panel members reported that some patients with chronic conditions become even more motivated to improve their health when offered the opportunity to take on more responsibility for their own care.

"[Practitioners] should not underestimate the ability of patients to take care of their own problems as long as we give them the tools and guidelines."

— DAVID GREEN, MD, PHD

Communication between practitioners and patients

Effective, clear, consistent communication between practitioners and patients is a critical component of any high-quality oral anticoagulant management system. With the implementation of PST, there must be an easily accessible system for patients to report their weekly INR results and for practitioners to communicate dose adjustments or other instructions to the patient.

There are several ways to set up a reliable system for patients to report their weekly INR results, and health care practitioners may choose from several options, depending on their preferences and needs.

An answering machine phone line may be dedicated to PST patients calling in results, or e-mail or fax may be used if the retrieval system is reliable. An alternative method is to use a third-party patient management vendor who would receive results from patients and communicate them in real time to the practitioner. Health care practitioners implementing PST may schedule different patients for testing on different days of the week or all on the same day, depending on the office schedule and number of patients performing PST. There should be a protocol for contacting patients for whom a result is not received on the day it was expected, and the practitioner should review the INR results within a reasonable time frame and develop an individual office protocol for contacting patients regarding dose adjustments. Alternatively, the practitioner may prescribe INR-based dose adjustment instructions for patients. Patients and practitioners should maintain appropriate documentation of communication with each other, and to the extent possible, redundancy should be built into the program so that patient records can be cross-checked periodically. Voice-response software is available to facilitate the collection and real-time transmission of results without an increase in telephone activity. With these systems, patients call a toll-free number and enter a unique identifier and their weekly INR result. The system then asks the patient to confirm the data, and promptly transmits the information to the practitioner's designated system.

The many options for communications systems enable practitioners to select one that will allow their offices to function efficiently and prevent an increase in nonurgent

TABLE 3
Options for patient self-testing (PST) communications

Communication system	Possible patient advantages	Possible practitioner advantages
Dedicated auto-answer line or voice response answering line	Simple, easily accessed	Results can be promptly accessed throughout the day without interrupting patient care
E-mail or fax; electronic uploading of results	May be preferred for patients with speech or hearing impairments	Written copy of communication can be added to the record
Third-party management service	Simple, easily accessed; toll-free number	Results transmitted to practitioner's designated system in real time; may facilitate ease of practitioner review process

phone calls while still receiving INR results promptly and reliably. Patients may be instructed to call the office with out-of-range results (may be specifically predetermined by the practitioner) so they can be managed appropriately in those situations. Practitioners should ensure the method they select is HIPAA-compliant. Table 3 outlines some advantages for different PST communication options.

Accuracy of INR devices

The ease of use and portability of whole-blood INR devices has made home testing by patients or their caregivers a feasible option for monitoring warfarin therapy, and home testing has been demonstrated to result in increased time in therapeutic range; improved outcomes, including lower rates of thrombotic and bleeding complications; and increased survival relative to usual care

TABLE 4
Profile of CLIA-waived INR instruments for patient self-testing (PST)

	INRatio (HemoSense Inc.)	ProTime (ITC)	CoaguChek XS (Roche Diagnostics)
INR range	0.7–7.5	0.8–9.9	0.6–8.0
Sample	1 drop capillary blood	1 drop capillary blood	1 drop capillary blood
ISI	1.00	1.00	1.00
Clot detection principle	Change in impedance	Cessation of blood flow	Icon-based LCD and amperometric PT determination
Analysis time	1–1.5 min.	3–5 min.	1 min.
Correlation coefficient	0.96	0.95	0.96
QC	Internal	Internal	Internal
Memory	60 tests	50 tests	100 tests



CLIA=Clinical Laboratory Improvement Act, INR=international normalized ratio, ISI=international sensitivity index, LCD=PT=prothrombin time, QC=quality control.

and anticoagulation clinic management (Heneghan 2006, Ansell 2005, Koertke 2007). There are three Clinical Laboratory Improvement Act (CLIA)-waived INR devices that have been FDA-approved for POC home testing. The devices vary with regard to clot-detection method and testing materials, but all require a drop of whole blood applied to a test strip or cuvette, and the INR result is available within minutes. Most devices have onboard quality control and self-diagnostics that simplify their use by patients and caregivers.

Variations among results obtained on different instruments, or even identical instruments, are to be expected, and these variations do not invalidate the results of either method or instrument. Likewise, INR devices, like other POC testing devices, are not expected to produce results identical to those of a citrated plasma-based assay, and different sample types will yield statistically different results even on the same instrument. Rather, the devices have been shown to correlate adequately to the reference method within an acceptable range prior to FDA approval (Ansell 2005). Although parallel testing between INR devices and central laboratory methods should not routinely be needed, the panel does recommend periodic parallel testing between a patient's INR device and the office INR device to document a patient's continued ability to perform the assay correctly. Table 4 shows some of the CLIA-waived INR instruments available for PST.

Training

The recent CMS decision to expand PST-related reimbursement for patients with AF or DVT/PE stipulates that patients complete a one-time, face-to-face training program and demonstrate correct use of their INR device. This one-time device training is separate from ongoing patient education on medication, diet, and other aspects of oral anticoagulation therapy management that practitioners routinely provide during regular office visits to all patients, regardless of whether they participate in PST. Topics that should be included in this initial device training are the technique for fingerstick blood collection, device setup and operation, performance of the assay, recording and communicating the INR result, obtaining supplies, and care and storage of the device and supplies. Patients must demonstrate correct operation of the device prior to beginning a home testing program.

Ongoing follow-up

In addition to regular INR monitoring, a systematic, high-quality, comprehensive patient management system requires periodic visits to a knowl-

Summary of consensus panel recommendations

Warfarin therapy requires a systematic method of management and follow-up, including regular INR testing

Point-of-care testing and PST are enabling technologies that facilitate high-quality management of patients receiving long-term oral anticoagulation therapy

Patient self-testing enables more frequent testing that has been shown to improve INR control and reduce the incidence of bleeding and thrombotic complications

There is compelling evidence supporting PST in the context of a comprehensive anticoagulation management plan:

- Increased time in therapeutic range
 - Reduction of hemorrhagic and thrombotic complications
 - Overall cost-effectiveness
 - Improved quality of life for patients and their families
-

PST is not an alternative to regular care provided by a medical practitioner; PST provides additional data that allows practitioners to make more informed patient-care decisions

An increase in the demand for high-quality management of oral anticoagulation therapy is anticipated in the near future, and the current management methods may be inadequate to provide high-quality care to all the patients who require treatment

Medicare reimbursement, although imperfect, is changing in response to the growing body of clinical data supporting PST, and in response to the input of practitioners who understand the value and cost-effectiveness of PST

There are many options regarding all aspects of PST, allowing practitioners to tailor implementation to their needs and preferences

Elements that are important to successful implementation of PST include:

- Standardized patient selection process that focuses on the medical necessity for those patients or their caregivers who are willing and able to reliably perform PST as prescribed; reliable phone service or other means of communicating with the practitioner
- Initial and ongoing patient education and specific INR device training prior to initiating PST
- Clear, consistent communication between patients and practitioners regarding expectations of patients performing PST and consequences for nonadherence
- A readily accessible means for patients to communicate results to the practitioner's office
- An office system for managing patient communication and follow-up
- Ongoing patient education and specific INR device training prior to initiating PST

edgeable health care practitioner for patient assessment and follow-up, ongoing patient education regarding anticoagulant therapy and the patient's disease state, and oversight of the therapy in the context of any comorbidities. Ongoing, age-appropriate patient education during regular office visits should include basic principles of coagulation that pertain to anticoagulation therapy, the effects of foods and medications on therapy, symptoms of bleeding and thrombotic events, and topics related to travel, nutrition, and other issues that may arise. Periodically, the practitioner may choose to observe the patient perform INR testing during an office visit to ensure continued correct use of the device.

A call to action

PST has been shown to result in significant benefits for patients and their families, health care practitioners, and health care systems. Although effective, warfarin therapy has been associated with an increased risk of bleeding complications that can be reduced by implementing evidence-based programs, such as PST and PSM, that facilitate optimum INR control.

The 2008 Joint Commission National Patient Safety Goals include reducing the likelihood of harm associated with the use of anticoagulants. The Goals specifically state that the implementation of standardized practices that include patient involvement may be useful in reducing the risk of anticoagulant therapy. To comply with the requirements, the Joint Commission has set a year-long implementation period during which organizations must phase in standardized programs to reduce the risk of complications with anticoagulant therapy. Complete implementation is expected by Jan. 1, 2009. Elements of such a program include the use of a defined anticoagulant management program that allows for the provision of individualized care; use of approved dosing protocols for initiation and maintenance; provision of education about anticoagulation therapy to staff, patients, and their families; and evaluation of anticoagulation practices (Joint Commission 2008). Implementing PST may fulfill the Joint Commission requirements for standardizing oral anticoagulant therapy to reduce the likelihood of bleeding or thrombotic complications associated with over- or under-dosing of warfarin.

PST also provides a way to improve patients' lives, reduce costs to the health care system, and allow practitioners a more efficient and effective way to manage their patients.

The growing clinical evidence supporting PST and the changing landscape of health care delivery are driving a paradigm shift in the management of patients receiving oral anticoagulant therapy. Many practitioners view PST as an important tool to help them respond to these changes and improve the standard of care for their patients. They also understand the importance of PST in

responding to emerging evidence-based guidelines and the changing requirements of accrediting organizations, and to the increasing demand by patients to participate more fully in their own care.

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