

# The Anticoagulation Clinic Primer™

A Template for Improving Patient Care

## **Primer Contributors and Acknowledgments**

The Anticoagulation Clinic Primer was developed with the assistance of anticoagulation management specialists at the University of Massachusetts - Memorial Medical Center, Worcester, MA and the Jerry L. Pettis Memorial Veterans Administration Medical Center, Loma Linda, CA.

The following clinical advisors are extended special acknowledgement for their contributions to this work and to the development of anticoagulation management standards.

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# *Ground Rules for Establishing the Comprehensive Anticoagulation Clinic*

## **FORWARD**

Today, as medical science and economics converge, providing better care more efficiently and at a lower cost is paramount. The traditional role of private physicians in the management of anticoagulation therapy is giving way to regional centers as a more efficient, effective alternative for the future.

While the opportunity to establish Anticoagulation Clinic Services (ACS) exist in many regions, the job of start-up may seem daunting and risky to both healthcare professionals and administrators. It need not be.

This Primer was developed by ITC, a leader in point-of-care hemostasis testing, with the guidance and advice of clinical experts in this field, as a guide for professionals interested in establishing an ACS center. It provides a template for forming and managing the clinic service, including appropriate use of home-based testing, and explains how both medical professionals and patients will benefit. Optimizing anticoagulation management provides a unique opportunity to improve the use of medical resources and delivery of medical services, and improve patient care.

Frank M. LaDuca, Ph.D.

International Technidyne Corporation (ITC)

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## CHANGING THE STATUS QUO

### Moving from Routine Medical Management to Anticoagulation Clinic Services

Oral anticoagulation therapy with warfarin (coumadin®) is required for conditions in which the patient is predisposed to thrombosis or intravascular clotting. Effective anticoagulation is defined as a therapeutic range in terms of a desired International Normalized Ratio (INR). The INR is a standardized prothrombin time test, which is an effective measure of oral anticoagulation. The most common reasons for anticoagulation and the associated target INR are:

- |  |         |
|--|---------|
| ■ Prophylaxis and treatment of venous thrombosis | 2.0-3.0 |
| ■ Treatment of pulmonary embolism                | 2.0-3.0 |
| ■ Prevention of systemic embolism due to:        | 2.0-3.0 |
| • Tissue prosthetic heart valves                 |         |
| • Acute myocardial infarction                    |         |
| • Valvular heart disease                         |         |
| • Atrial fibrillation                            |         |
| ■ Mechanical prosthetic heart valves             | 2.5-3.5 |
| ■ Bileaflet mechanical valve in aortic position  | 2.0-3.0 |

Adapted from ACCP Consensus Conference Guidelines,  
Editors James Dalen, Jack Hirsh and Gordon Guyatt, Chest, 2001.

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In these conditions, maintenance of the proper effective anticoagulation level, as measured by the INR, is required to achieve benefit while minimizing the risk of bleeding or clotting complications.

“Patients on oral anticoagulants have long suffered from excessive complications because of problems with routine management. The literature is now rich with evidence that care can be improved by specialized anticoagulation services or patient self-monitoring.”

— Jack A. Ansell, M.D.

## Basic Types of Anticoagulation Management

### Routine Medical Management

**(RMM):** Care provided by a physician or physician group as part of the routine care of the patient, without any specialized anticoagulation service. Care can be directed by the family physician (general practitioner) or physician specialist (cardiologist, hematologist).

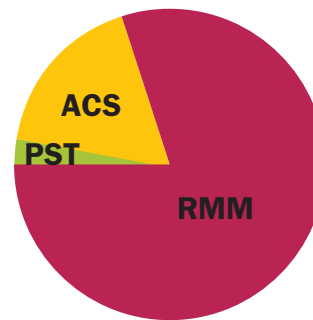
### Anticoagulation Clinic Services

**(ACS):** Care provided by a specialized comprehensive care facility, which includes access to a team of physician, nursing, and healthcare staff who provide comprehensive anticoagulation care.

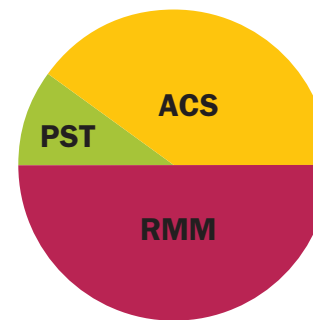
### Patient Self-Testing (PST):

Commonly referred to as “home care.” The physician or ACS trains the patient to perform his or her own INR testing at home using an approved coagulation monitoring device. The patient reports results to the provider and is given specific instructions for follow-up care.

Current Management Options



Desired Management Goals



## Utilization of Patient Management Options

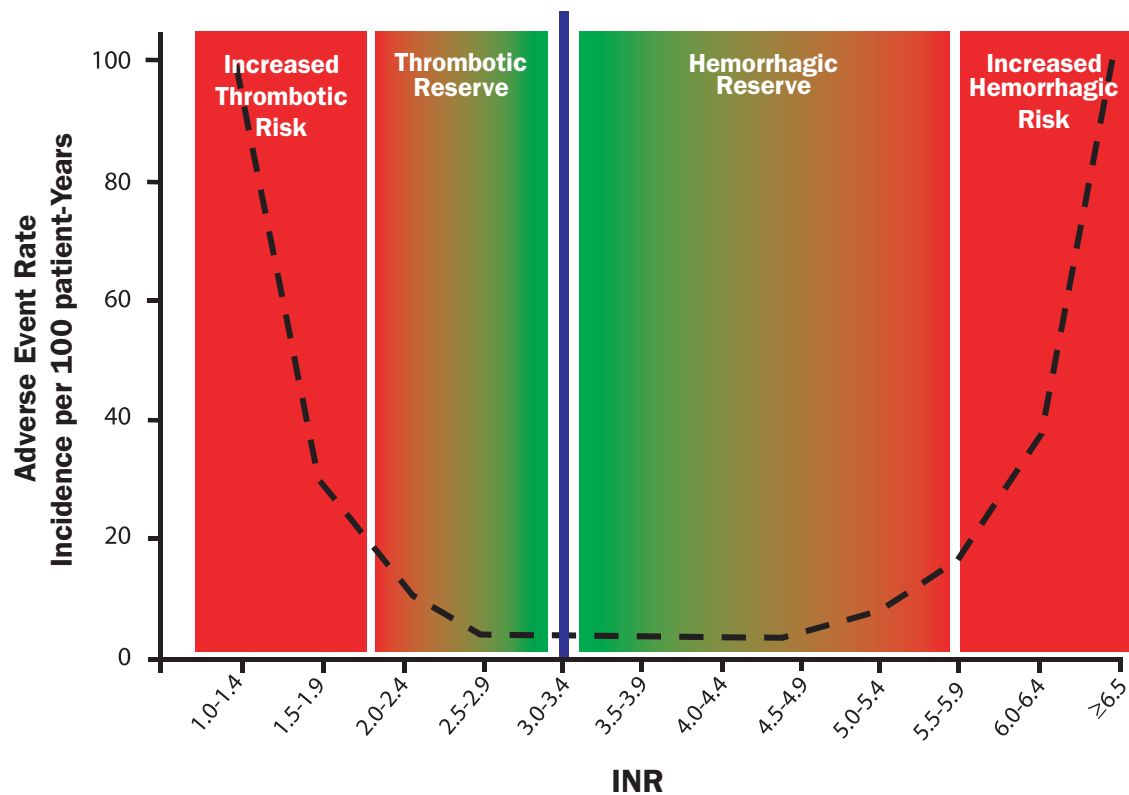
### Primer Briefs

- 2 million US patients are on long-term oral anticoagulation
- Less than 20% are managed by Anticoagulation Clinic Services
- Management of Oral Anticoagulation Therapy (OAT) under Routine Medical Management is inefficient for physicians and less than optimal for patients
- Patients managed through Anticoagulation Services benefit from improved care provided by “Anticoagulation Experts”

## BUILDING THE CASE

### The Perils of Oral Anticoagulation Management

Warfarin is a medication with a “narrow therapeutic index,” reflecting the tendency for clotting or bleeding events to occur when the target INR range is not achieved. There is a clear tendency to bleed with INRs greater than 5.0 and for unwanted clotting to occur when the INR is less than 2.0.

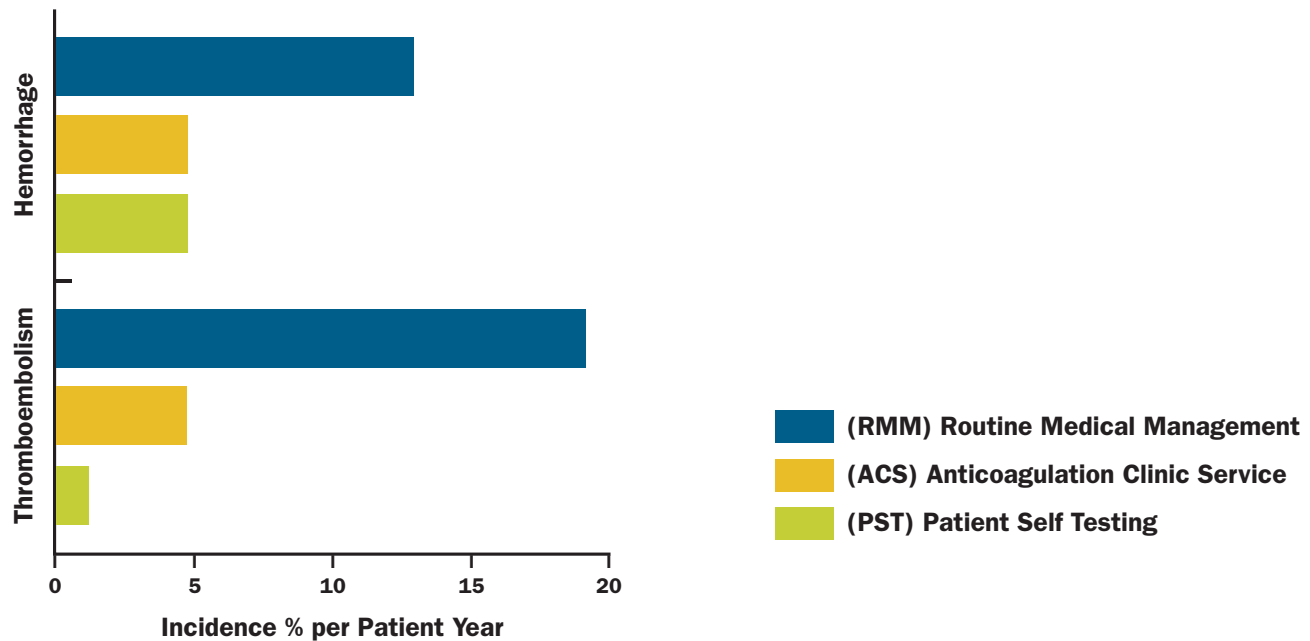


Adapted from Jacobson, AK, modification of Cannegeiter SC, N Engl J Med, 1995

## Clinical Benefits of Anticoagulation Clinic Services

Several studies have surveyed the impact of the type of anticoagulation management on effective patient outcome. While no single study exists, a composite of the improved patient outcome associated with movement of management from RMM to ACS and PST can be derived from reviews of the literature. The likelihood of an adverse event is customarily reported as an incidence expressed as percent per patient year.

### Improving Patient Outcome with ACS and PST



Adapted and modified from Ansell JE, J Thrombosis and Thrombolysis, 1998

## Impact on Health Care Delivery - Cost Effectiveness of ACS and PST

The cost to treat an adverse event associated with poorly managed anticoagulation therapy is significant. A wide range of costs exist, depending on the degree of complication and whether the complication leads to death, long term morbidity, or eventual resolution. Both direct and indirect benefits are associated with more effective anticoagulation management.

<b>Benefits of Properly Manged Anticoagulation</b>	
<b>Direct Benefits</b>	
	Reduction of adverse events
	Decreased use of hospital and medical services
<b>Indirect Benefits</b>	
	Patient compliance and satisfaction
	Increased patient productivity
	Increased quality of life

<b>Cost Associated with Mismanaged Anticoagulation</b>		
	<b>Approximate Cost Estimates</b>	
	<b>Bleeding Event</b>	<b>Thromboembolic Event</b>
Resolution	\$4,000	\$6,000
Death	\$8,000	\$12,000
Long Term Morbidity	\$14-24,000	\$21-26,000

Adapted from Eckman, MH et. al., Chest, November 1998

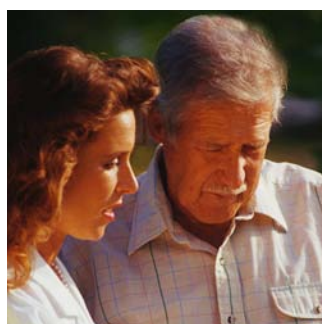
“Maintaining patients within a prescribed therapeutic range is critical to minimizing hemorrhagic and thrombotic complications. These adverse events are not only potentially devastating for the patient; they also place a tremendous burden on the healthcare system. Effective use of Anticoagulation Clinic Services has been proven to reduce the frequency of adverse events by 75%.”

— Alan K. Jacobson, M.D.

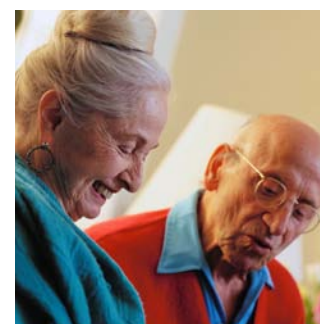
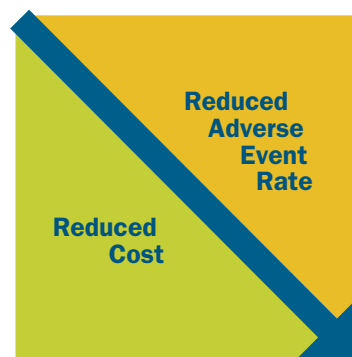
### Primer Briefs

- Patients managed in ACS remain in the desired therapeutic range more often than patients managed under RMM.
- Patients managed under ACS have fewer adverse events as a complication of anticoagulation treatment.
- ACS provides comprehensive programs for OAT patients, which includes:
  - INR testing, including optimal use of point-of-care testing (POCT)
  - Medical consultation
  - Patient education
- Promoting the movement of OAT management to ACS will decrease the cost of healthcare delivery.

### Advantages of Optimal Patient Management



**Optimal Patient Management**



**Improved Quality of Life**

# BLUEPRINT FOR SUCCESS - ESSENTIAL CONSIDERATIONS FOR THE ACS MODEL

## Operations

*Staffing* - The appropriate staffing model depends on the medical setting in which the ACS is established. For a hospital-based clinic, an often-used successful model, the staffing needs are best defined using a “unit clinic” size of 300 patients, and adjusted for clinics of larger enrollment.

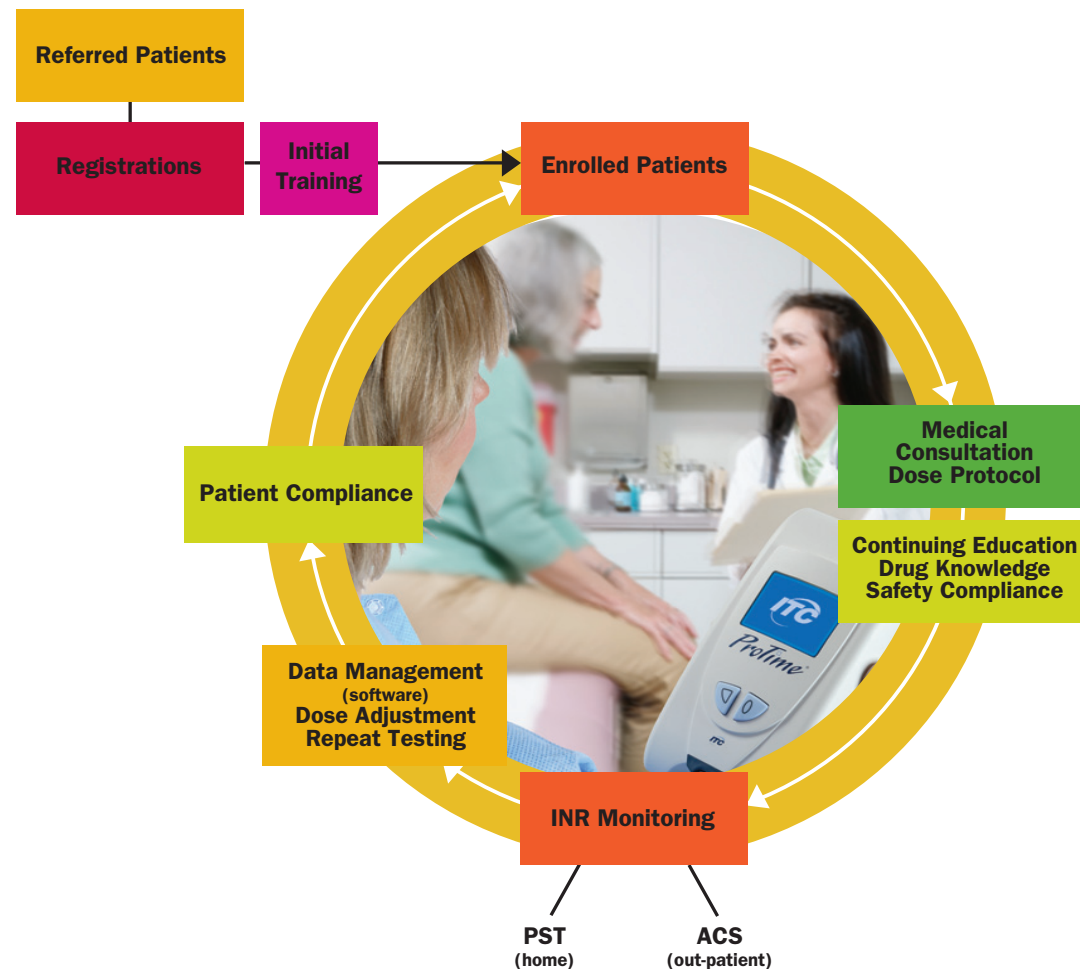
FTE for Clinic Staffing			
	Clinic Enrollment (No. of Patients)		
	300	300-600	600-1200
Professional Provider Pharm D, RN, or combination	1.0	1.5	2.0
Secretary or Administrator	0.5	1.0	1.5
POCT operator	0.8	1.5	2.0
Medical Director	0.1	0.2	0.3

*Patient Management Program* - Patients referred to the ACS, enter into a complete management program, which provides long-term monitoring and management of their condition. Patient education is a critical component, since it creates a broader understanding of the disease and its management, resulting in improved compliance. Suitable patients can be selected and trained to test their INR at home; thereby gaining greater access to care and providing an avenue to further improve their management and clinical outcome.

## Primer Briefs

- Optimize staffing for the number of clients using a combination of part-time and full-time staff.
- A client enrollment of 300 requires at least a full-time professional provider, with part-time administration assistance.
- Enrolled ACS patients enter into a defined patient management program in which education, INR testing and disease management are integral components.
- Point-of-Care Testing (POCT) provides efficient INR measurement and access to immediate patient consultation.
- Patient self-testing (PST) provides greater access to care for properly selected patients.
- Clinics are best served when a data management system is available that can effectively track patient INR results and dose adjustments, alert the medical staff to health issues or the need for further medical assessment.

## Patient Management Program

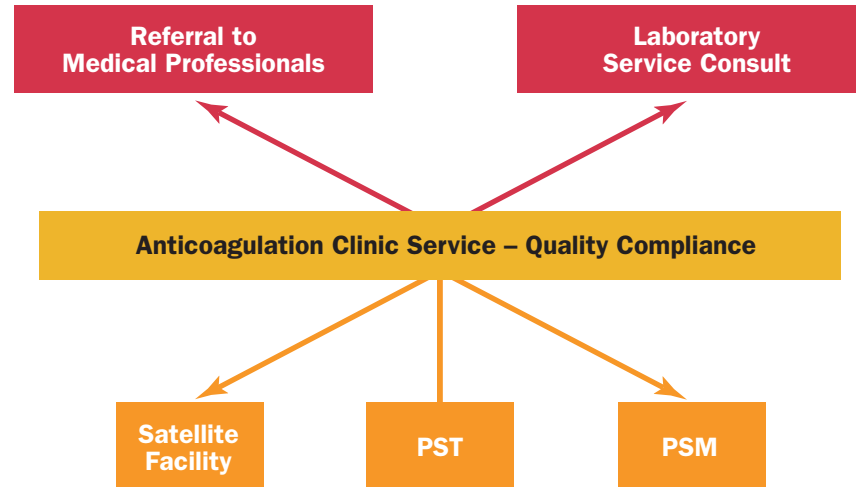


## Relationship to the Hospital and Laboratory Community

### Extending Patient “Access to Care” - The Outreach Program

The most effective ACS programs are associated with hospital medical professionals, and offer their services to the practitioners in community.

### Integration of ACS with Medical Services



### Expanding Patient Management Options

*Integration of ACS Services* - The ACS can receive patient referrals from the medical community alleviating potential difficulties of anticoagulation management encountered by the general practitioners or medical specialty clinics. Patients receive coordinated care, medical community resources are optimally utilized. A critical component of the ACS is INR measurement best performed using POCT. The hospital’s laboratory staff is usually responsible for quality assurance and quality control of INR testing. Reaching outward, the ACS can expand its community presence and the utilization of services through effective use of PST, PSM and establishing satellite facilities.

*Satellite Facility:* An INR testing facility remote from the core clinic, which services registered clinic patients, reports INR results to the core clinic, which then follows up with the patient.

*Patient Self-Testing (PST):* Selected patients test themselves (INR) at home at prescribed intervals, report results to the clinic and receive further medical direction. Patients are selected based on their ability to actively participate in their disease management and their anticipated level of compliance.

*Patient Self-Management (PSM):* An extension of the PST program in which patients are provided drug-dosing (i.e., management) guidelines based on INR results.

*“Anticoagulation Clinic Services provides a vital resource for community physicians, multi-specialty clinics and patients. This construct not only optimizes care, but establishes a framework for continuous quality improvement, outcome-based research, practice guideline development and achievement of ‘Best Practices’, as well. The model can also be used in other areas that have been shown to benefit from coordinated care including congestive heart failure and diabetes mellitus.”*

*— Richard C. Becker, M.D.*

### **Primer Briefs**

- Anticoagulation Clinic Services, managed as an independent facility, is linked to key hospital and laboratory services.
- Through an outreach program the Anticoagulation Clinic is able to provide improved access to care for a greater number of patients.
- Use of satellite testing facilities allows patients, remote from the core clinic, access to the ACS.
- Patient Self-Testing represents an effective model of care for properly selected ACS managed patients.
- PST provides a greater degree of patient participation in their disease management and a vehicle to further improve anticoagulation management.
- With further clinical verification, patients may participate in self-management programs, further improving the medical care outreach of ACS.

## Patient Management Components

**Dosing:** Dosing directions should be simple. It is desirable for patients to establish a fixed daily dose of warfarin based on standard tablet strength for example 5 mgs and to use easily understandable variations of that standard dose to achieve the desired weekly dose. For example if a patient does not achieve the desired INR on a 5 mg per day (35 mgs/wk) regimen and a more intense anticoagulation is desired, a simplify the dosing regimen to one 5 mg tablet every day and an additional one-half tablet every-other day for three days (i.e., Monday, Wednesday and Friday). Dose adjustments should be closely monitored with INR tests.

**INR Testing:** During the initiation phase of warfarin, frequent INR testing is appropriate to determine the correct daily dose to maintain the patient in the desired therapeutic range. Fluctuations of INR are particularly common during this phase. When the patient is more stable, usually after 3-6 weeks dose adjustments should be less frequent. Stabilization of the INR greatly depends upon the patient's attentiveness to diet and avoidance of other medications, which will influence the effectiveness of warfarin. This is where education is particularly important. Generally patients benefit from weekly testing, while some very stable patients may be tested less frequently. POCT is a valuable method for INR measurement in the clinic.

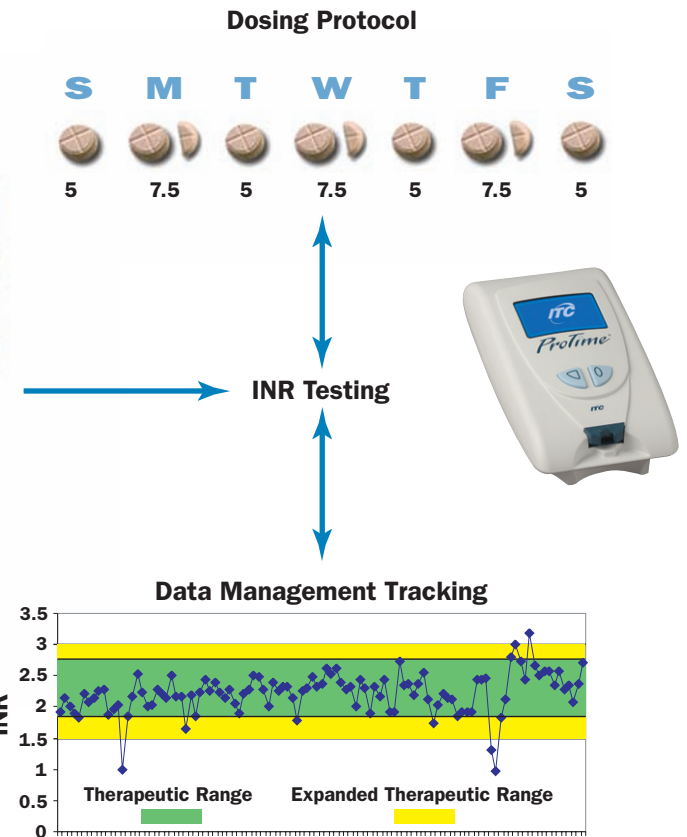
**Therapeutic Range (TR) Maintenance:** The therapeutic goal is to avoid a low INR, which predisposes the patient to clotting or a high INR, which may lead to bleeding. It is not always helpful to make minor dose changes in response to small deviations (i.e., 0.1-0.3 INR) from the desired INR range. In such cases, the concept of an "Expanded Therapeutic Range" (ETR) has been employed. In an ETR program, the patient is allowed to fluctuate slightly outside the lower or upper INR limits, and additional INR tests are used to closely monitor the patient. This avoids excessive dose adjustments, which may cause erratic and dangerous INR fluctuations. Each ACS should have the means to readily track patient INR results and dose directions. Several software programs are available for this purpose.

“ Individualizing the Therapeutic Range, or utilizing an Expanded Therapeutic Range, namely  $\pm 0.2$  INR units, is a frequently used patient management tool. Rigid algorithms that mandate dosage adjustment for all values outside a fixed range may lead to worsened instability in that those dosage adjustments may be made for random fluctuations rather than true changes in INR steady state. In most settings, we need more frequent testing - not more frequent dose adjustments. Improved access to INR measurement through clinic-based and home-based testing allows for increased test frequency and flexible dose adjustment algorithms. ”

— Alan K. Jacobson, M.D.

EDUCATION

CONSULTATION



## Primer Briefs

- Maintenance of the Therapeutic Range is the key to proper anticoagulation maintenance.
- Patient-specific “Expanded Therapeutic Range” serves to individualize patient therapy thus reducing unnecessary dose adjustments, which can result in erratic INR values.
- There is a clear correlation between the frequency of INR testing and maintenance of the therapeutic range.
- A basic dosing algorithm should be a part of the routine ACS protocol and individualized according to patient response.
- Automated dose management systems, which employ pharmacological dosing programs are available to help guide dose adjustments.
- Web-based software can provide small and large ACS operations with access to sophisticated patient management tools.

## Home-Based Care - Extending the ACS Program Through Patient Self-Testing

### History and Use of Home-Based Care

Home-based monitoring of INR is a management program with beginnings in Germany in the late 1980s. Initially a German student created her own “travel kit” which included a testing apparatus and a blood collection device. This provided her the freedom to continue her normal daily activities while conducting regular INR tests, ensuring that her INR remained within the desired therapeutic range. From these early programs, several formal programs for patient self-testing have been instituted worldwide.

For self-testing programs to be effective patients must be properly selected. Prospective candidates are those who are able to (1) comprehend the basic science of their disease, (2) learn and execute the procedures required to operate an INR testing device, and (3) are responsible and attentive to details to assure compliance; namely test at the prescribed interval, take the directed medications and maintain a consistent daily program of diet, exercise and the use of other medicines. When the appropriate patients are selected, conduct detailed training consisting of:

- General background on disease and the reason for oral anticoagulation
- Explanation of warfarin anticoagulation, including:
  - Mechanism of action
  - Need for INR testing
    - Influence of diet and other medications
- Instructions as to operation of the INR test device
- Review of symptoms related to insufficient or excessive anticoagulation
- Specific instructions for INR testing, reporting of results to the clinic
- Detailed instructions for dosing, including:
  - Time of day to take drug
  - Recovery from missed dose
- Individualized instructions for:
  - Pregnancy implications
  - Other diseased involvement

## Advantages of Patient Self-Testing

- Patients are more actively involved in the management of their disease
- Patients have increased access to care without needing to go to the clinic
- Mobile patients can remain closely monitored
- Physicians and healthcare workers can manage a greater number of patients
- Clinics can focus their direct patient contact on those patients most in need of such contact

*“Anticoagulation providers estimate that at least 50% of patients are potential candidates for patient self-monitoring. With proper training, this model of anticoagulation management has been shown to increase time-in-range and to decrease rates of major bleeding or recurrent thrombosis compared to routine medical management.”*

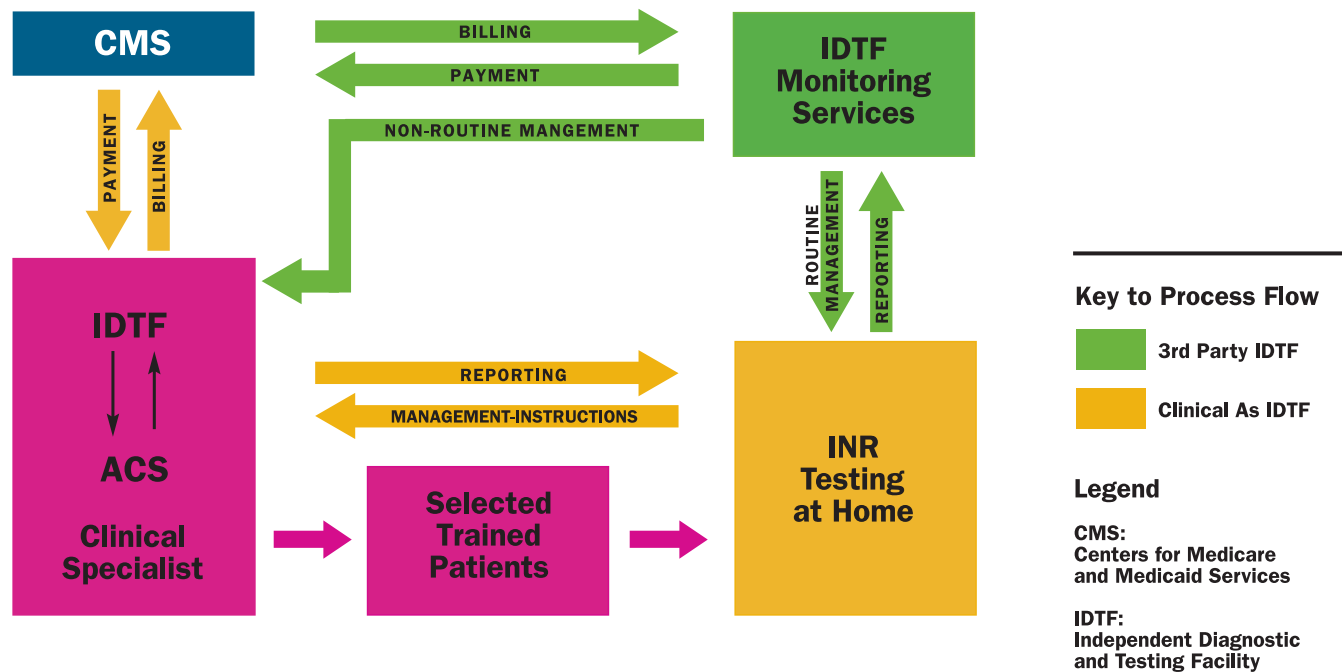
*— Jack A. Ansell, M.D.*

### Using PST to Expand the Clinic Program

The ACS is ideally suited to manage self-testing. The professional clinic staff can select, train and monitor appropriate patients. In the US many potential patients fall within the jurisdiction of the Medicare system, now named the Centers for Medicare and Medicaid Services (CMS). For those patients who do not fall under this insurance umbrella, most private carriers follow the guidelines of CMS when defining appropriate coverage and reimbursement programs.

### The CMS Paradigm for Providing Coverage and Reimbursement for PST

Under the CMS system for PST, management of patients is the responsibility of the primary healthcare provider. The designated intermediary between the healthcare provider and the CMS agency is the Independent Diagnostic and Testing Facility (IDTF). Under the IDTF program, the ACS has the option to use the services of an established IDTF or to develop its own self-contained IDTF program. The ACS can choose to have billing, reimbursement request and payment either flow directly from CMS to the ACS or through the IDTF pathway. Under IDTF management patients report directly to the technical staff at the IDTF who subsequently conveys patient status to the ACS. The ACS and IDTF determine the degree to which patient management is assumed by each party.



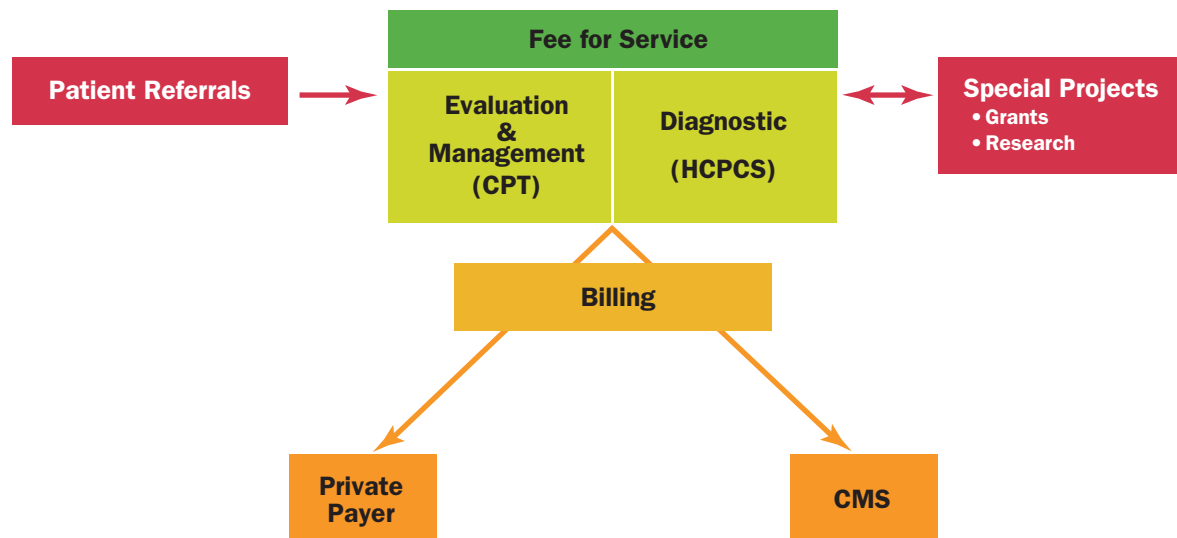
### Primer Briefs

- A comprehensive Patient Education Program is the key to patient compliance.
- PST patients must be properly selected - not all patients are candidates.
- Properly selected patients must receive suitable training.
- A designated clinical specialist at the ACS must manage the Home Care Program and the PST.
- Clinics may elect to serve as their own IDTF facilities to administer the Home Care Program or use the services of an independent third party.
- Telephone and Internet-based communications are critical components of the home-based PST program.

## ADMINISTRATIVE DETAILS

### Business Model

A business plan is essential to capture the numerous sources of revenue for the properly administered ACS. The primary source of revenue is the fee for services rendered. Additional funding can be obtained through awarding of grants and research studies.



“ The key to the successful Anticoagulation Clinic Service is defining an integrated business model which maximizes the utilization of existing resources, coordinates institutional strengths and acknowledges opportunities for both revenue generation and cost savings as a background of escalating patient satisfaction. ”

— Richard C. Becker, M.D.

## Payment for Clinic Based Services

**Billing and Coding:** In the clinical practice setting providers must submit a bill, which includes the ICD-9 Diagnostic Code and a CPT or HCPCS Code:

CPT	Current Procedural Terminology
ICD-9-CM	International Classification of Diseases, 9th Revision, Clinical Modifications
HCPCS	HealthCare Common Procedure Coding System

**CPT Codes:** Codes are based upon the degree of Evaluation and Management (E&M) required for a patient visit, whether the patient is new or established, and the degree of complexity of the exam and the medical decision.

<b>For New Patients</b>	
99201	Initial visit
99202	Focused history and/or exam and straightforward decision making
99203	Expanded history and/or exam and low complexity decision making
99204	Detailed history and/or exam and moderate complexity decision making
99205	Comprehensive history and/or exam and high complexity decision making
<b>For Established Patients</b>	
99211	Minimal problem - may not require a physician
99212	Focused history and/or exam and straightforward decision making
99213	Expanded history and/or exam and low complexity decision making
99214	Detailed history and/or exam and moderate complexity decision making
99215	Comprehensive history and/or exam and high complexity decision making

## Primer Briefs

- At the onset, the ACS must develop a business plan.
- The properly developed

HCPCS Code	Descriptor
G0248	Demonstration, at initial use, of home INR monitor for patient with mechanical heart valve(s) – includes demonstration of use and care of device, obtaining blood sample, instructions for result reporting, and training documentation
G0249	Provision for test materials, equipment for home monitoring – includes materials for patients with mechanical heart valve(s) who meet Medicare coverage
G02050	Physician review and interpretation of home monitoring tests – in groups of 4 tests – does not require face-to-face assessment

## Primer Briefs

plan anticipates revenues from a number of diverse sources and plans staffing expenses accordingly.

- Billing on a fee-for-service basis provides the key element of revenue generation
- Considerations must be made for private insurance payers, Medicare and patient self-payers.
- CPT Codes describe Evaluation and Management Services for established patients with an increased payment schedule for increasingly complex patient E&M services.
- HCPCS Codes provide provision for diagnostic services.
- Unique payment options are available under the National Coverage Decision for PST.
- Successful ACS programs develop reputable referral service programs, increasing patient enrollment.
- ACS programs have the potential to generate significant clinical research activities and secure appropriate external funding for staff and equipment.

## REFERENCES AND RESOURCES

### **The American College of Chest Physicians (ACCP) Consensus Conference on Antithrombotic Therapy ([www.chestjournal.org](http://www.chestjournal.org))**

On a biannual basis, this association publishes the proceedings of a symposium, which reviews a broad spectrum of anticoagulation and antithrombotic issues. Included are guidelines for target INR values for disease-specific indications.

### **Anticoagulation Forum ([www.acforum.org](http://www.acforum.org)),** organized and coordinated by Jack A. Ansell, M.D.

The Anticoagulation Forum web site is a publication of this unique community of medical and healthcare personnel, dedicated to improving anticoagulation management.

### **Centers for Medicare and Medicaid Services ([www.cms.hhs.gov](http://www.cms.hhs.gov))**

The CMS website offers a volume of information regarding reimbursement for anticoagulation services and the CLIA (Clinical Laboratory Improvement Act) Program, as relates to ACS operations.

### **Jerry L. Pettis Veterans Administration Medical Center, Anticoagulation Management Preceptorship,**

Alan K. Jacobson, MD, Program Director

The Jerry L. Pettis VAMC provides a comprehensive training and review course for healthcare professionals and publishes a compendium of reference material related to anticoagulation management.

### **Journal of Thrombosis and Thrombolysis,** Richard C. Becker, M.D., editor; Kluwer Academic Publishers

Published bi-monthly, this journal provides a forum for anticoagulation topics and publishes proceedings of the Anticoagulation Forum Scientific Meetings.

### **International Self-Monitoring Association for Anticoagulant Therapy ([www.ISMAA-int.org](http://www.ISMAA-int.org))**

An international group of experts dedicated to self-managed oral anticoagulant therapy.

Published bi-monthly, this journal provides a forum for anticoagulation topics and publishes proceedings of the Anticoagulation Forum Scientific Meetings.

### **International Technidyne Corporation Educational Services ([www.itcmed.com](http://www.itcmed.com))**

ITC maintains a number of relevant reference materials related to anticoagulation management, which are provided upon request.

### **Managing Oral Anticoagulation Therapy: Clinical and Operational Guidelines,** Jack A. Ansell, M.D., editor; Aspen Publishers

Published as a three-ring binder, this reference, currently in its third edition, provides a comprehensive review of literature and recommendations related to anticoagulation management.