

START-UP AND IMPLEMENTATION OF AN OUTPATIENT CLINIC FOR MONITORING ORAL ANTICOAGULATION THERAPY

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ABSTRACT

The management of patients on oral anticoagulant therapy can be costly in both clinical resources and patient commitment. At Bend Memorial Clinic, physicians and laboratory staff sought to optimize patient care through the establishment of an independent outpatient anticoagulation clinic (OAC).

Methods: A representative group conducted a fact finding survey of area OAC and attended training sessions describing the general practices at these clinics. Specific dosing algorithms, policies and procedures were developed in consultation with the clinical staff and published guidelines. For optimal monitoring, several point of care PT monitors were evaluated based on correlation to the clinical laboratory, cost and ease of use. The HEMOCHRON® Jr. Microcoagulation System fingerstick PT was selected for use once the clinic opened in January 1999.

Results: During the initial seven weeks of operation, 40 to 50 patients were monitored daily. As part of the standard validation procedure, venous samples are drawn from 3 to 5 patients each week for a comparison of fingerstick and laboratory results. Samples obtained during a four week period (N=18) showed a high level of correlation with the laboratory (r=0.973) with no clinical differences and no systematic bias (mean difference = -0.09 INR). Presently, in the fifth month of operation, the clinic continues to increase patient enrollment through physician referrals.

Conclusions: The level of satisfaction with the OAC is high for both patients and nurses owing to the immediacy of results and dosage adjustment without phone calls. The laboratory continues to monitor performance and compliance with appropriate quality assurance policy. Bend clinic has successfully implemented a POC based OAC which optimizes patient care.

OBJECTIVE

To set up a free standing, independent outpatient oral anticoagulation clinic to service the central Oregon region.

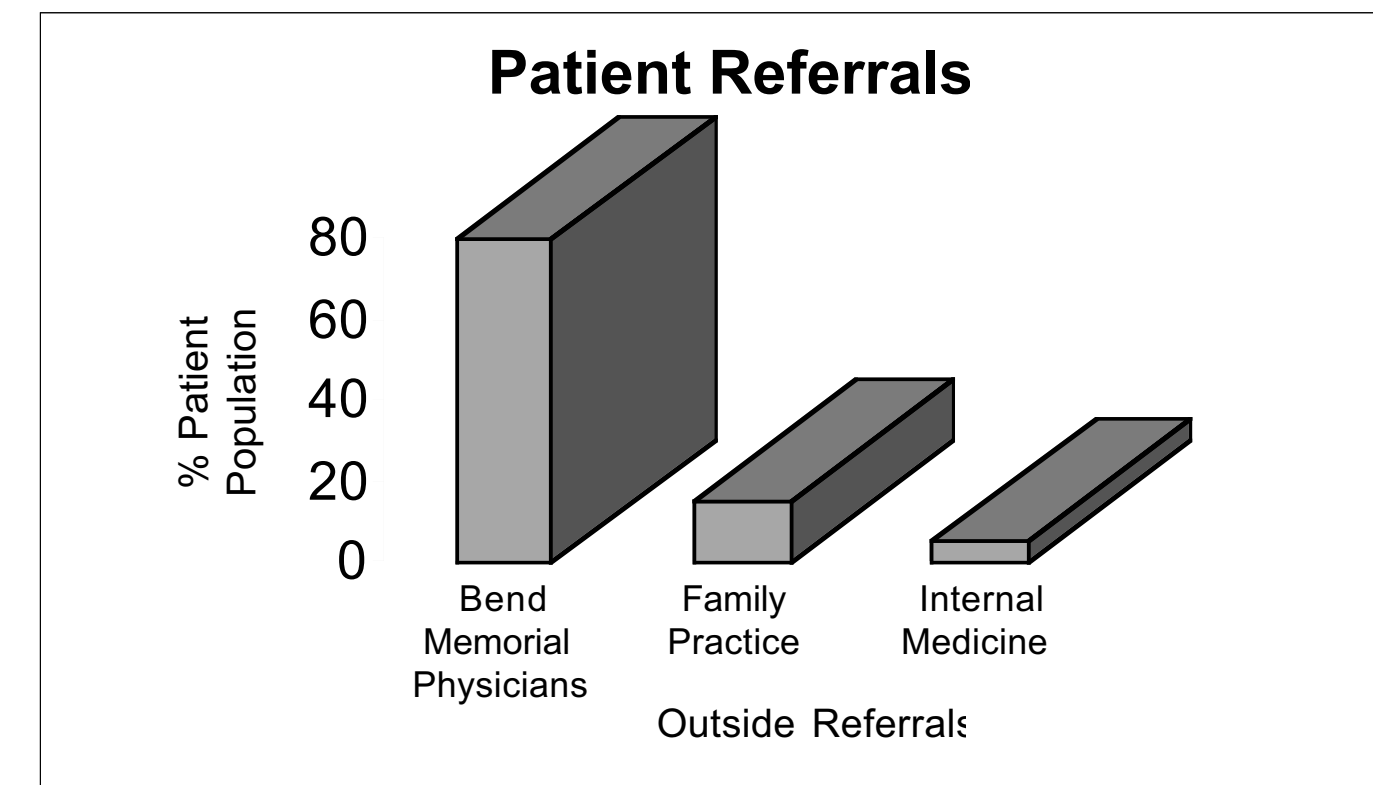
METHODS FOR ESTABLISHING THE INDEPENDENT CLINIC

- 1) Perceived need based upon clinical perspective
- 2) Management options explored
 - a) Committee formed.
 - i) Include clinicians, laboratorians, nursing staff
 - b) Fact finding
 - i) Visit existing OAC
 - ii) Attend regional training courses
 - iii) Identify physical facility needs
 - (1) Filing system, telephone/computer, patient interaction areas
 - iv) Identify personnel medical and administrative requirements
- 3) Establish clinic
 - a) Develop policies and procedures
 - i) Dosing algorithms
 - ii) Administration and billing
 - (1) Independent, direct billing
 - (2) Insurance claims coordinated with parent Bend Clinic facility
 - b) Select point of care analyzer
 - (i) Evaluate correlations to current laboratory
 - (ii) Evaluate ease of use
 - (iii) Evaluate costs, including PT tests, routine QC and time requirements
 - c) Select and train personnel
- 4) Train professional and lay communities
 - a) Mail letters describing program
 - b) Set up two community training days and two presentations/day
 - c) Describe clinic
 - d) Describe improvements reported from the use of free-standing clinics

5) Open clinic - January 1999.

Policies and Procedures

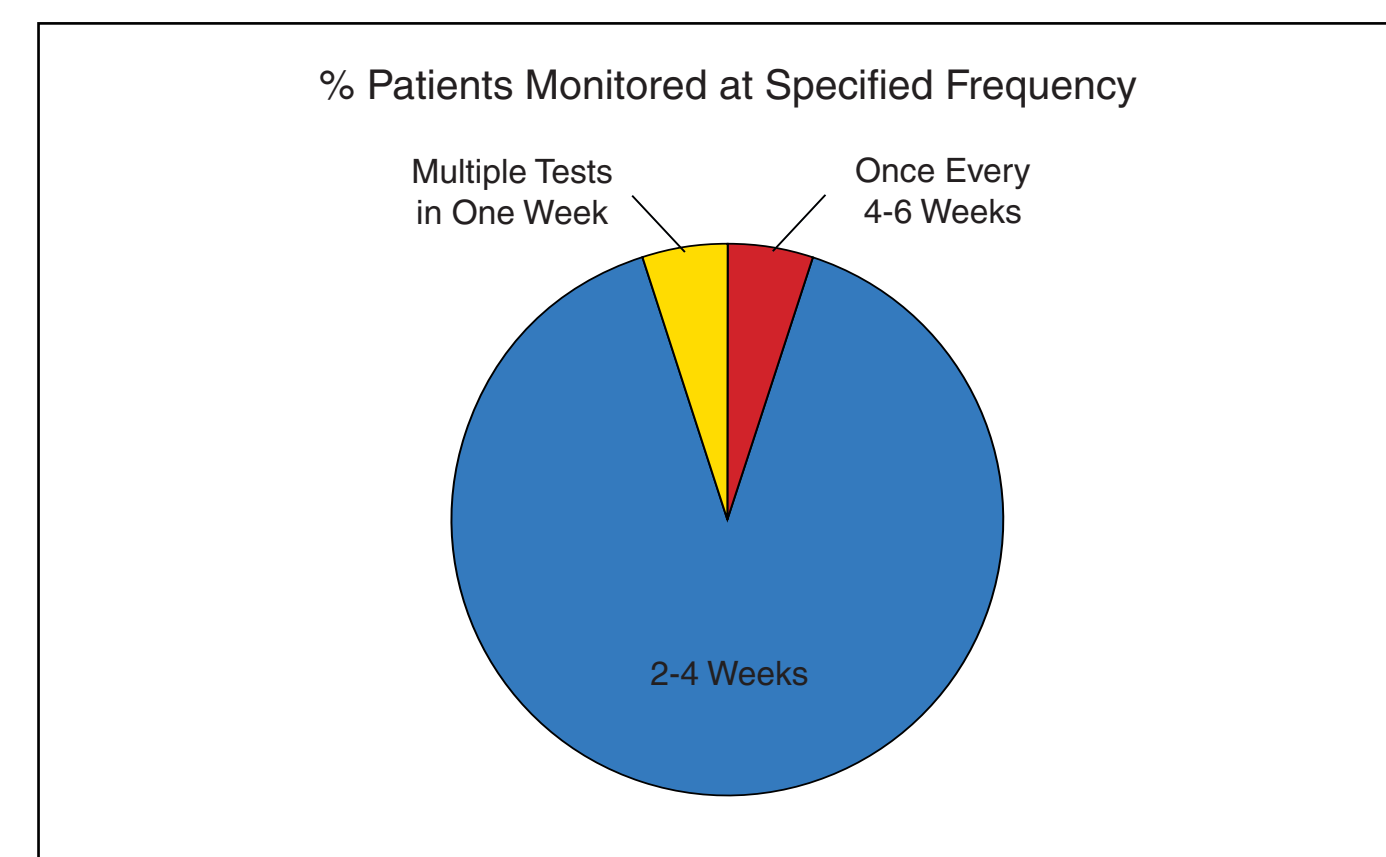
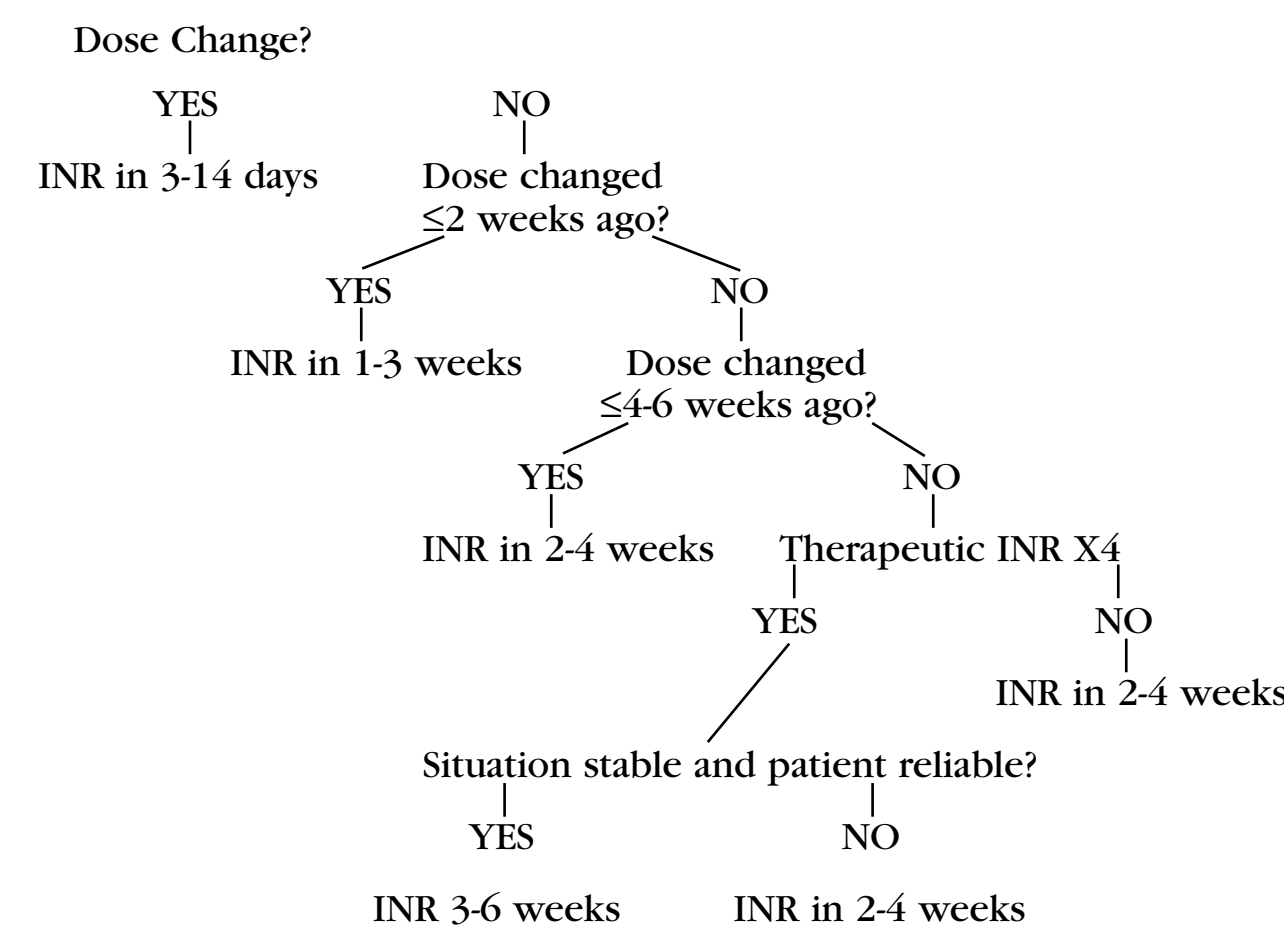
Upon referral, full patient management for anticoagulation therapy is transferred to the Bend Anticoagulation Clinic.



Most patients are referred from the Bend Memorial Clinic, a large multi-disciplinary practice of more than 70 physicians. Physician specialties include Family Practice, Internal Medicine, Cardiology, Oncology, etc. Patients referred from area physicians not associated with Bend Memorial are referred primarily by Family Practice and/or Internal Medicine doctors.

Patient education for oral anticoagulant therapy is standard for all new clients.

Maintenance Therapy Guidelines:



Upon initiation of therapy or temporary discontinuation for surgery or dental procedures, patients are monitored at least every three days.

RESULTS

Dosing Algorithms:

Required dose adjustments are explained to the patient at the time of anticoagulation clinic visit.

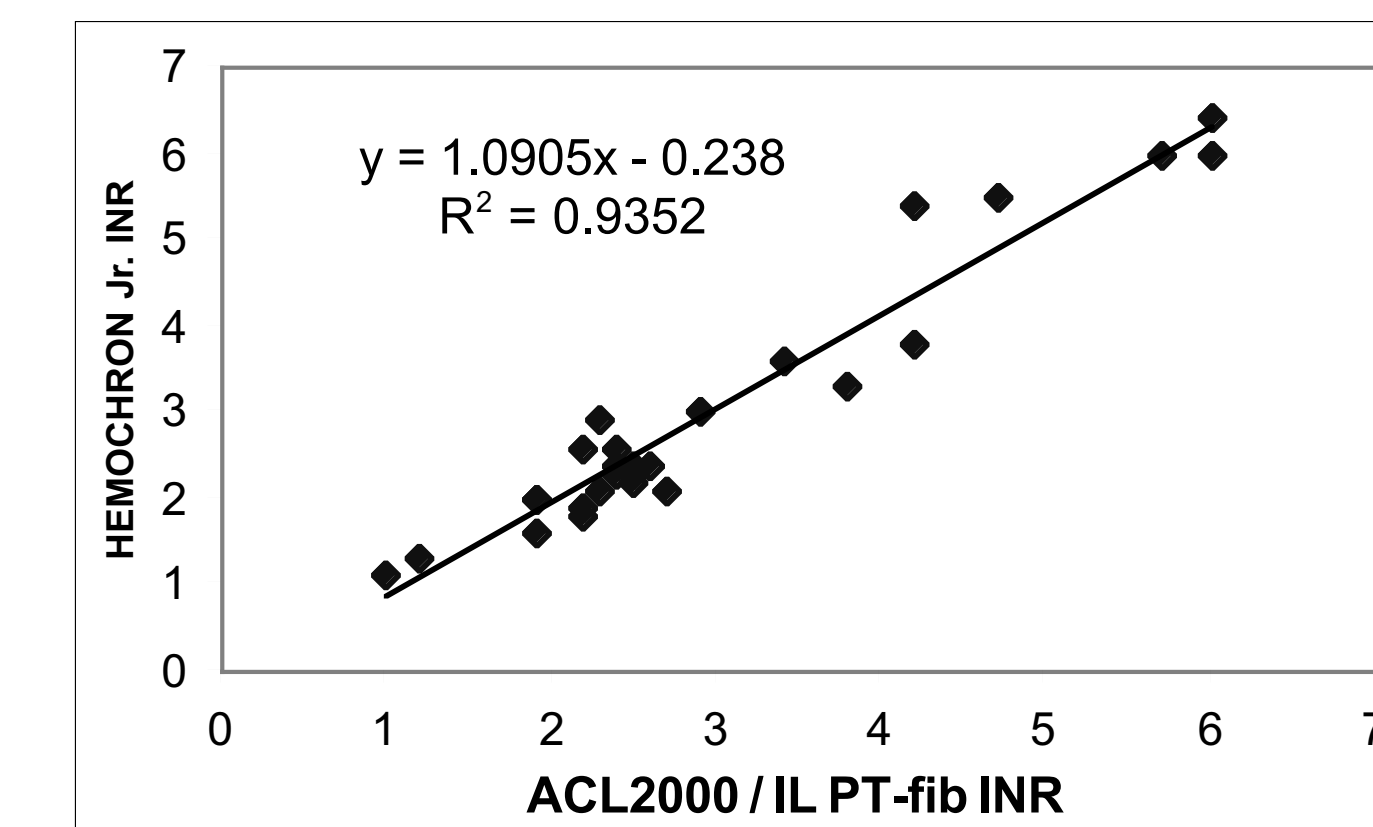
Low Intensity Anticoagulation — Target INR: 2.0 - 3.0						
INR ≤ 1.4	INR 1.5 to 1.9	INR 2.0 to 3.0	INR 3.1 to 3.5	INR 3.6 to 4.0	INR 4.1 to 4.9	INR ≥ 5.0
Increase by 10-15%	Increase by 5-15%	No Change	Decrease by 5-15%	Hold Next 0-1 Dose	Hold Next 1-2 Dose	Hold for Now
Add to 1st Day's Dose				Decrease by 10-15%	Decrease by 10-15%	Call M.D.

High Intensity Anticoagulation — Target INR: 2.5 - 3.5						
INR ≤ 1.9	INR 2.0 to 2.4	INR 2.5 to 3.5	INR 3.6 to 4.0	INR 4.1 to 4.5	INR 4.6 to 4.9	INR ≥ 5.0
Increase by 10-15%	Increase by 5-15%	No Change	Decrease by 5-15%	Hold Next 0-1 Dose	Hold Next 1-2 Dose	Hold for Now
Add to 1st Day's Dose				Decrease by 10-15%	Decrease by 10-15%	Call M.D.

Point of Care PT Monitor

Selection: Following clinical evaluation, the HEMOCHRON, Jr. (International Technidyne Corporation, Edison, NJ) was selected as the POC monitor. Selection was based on comparative correlation studies involving POC and laboratory personnel.

Quality Control: Electronic Quality Control is performed daily. Liquid Quality Control is performed at two levels (normal and abnormal) on each new box of test reagent.



Quality Assurance: Periodically, duplicate samples are drawn and sent to the main Bend Memorial Clinic Laboratory for reconfirmation of correlation. No clinically significant differences have been seen.

The Bend Anticoagulation Clinic was opened in January of 1999.

STAFF

Clinical staff:

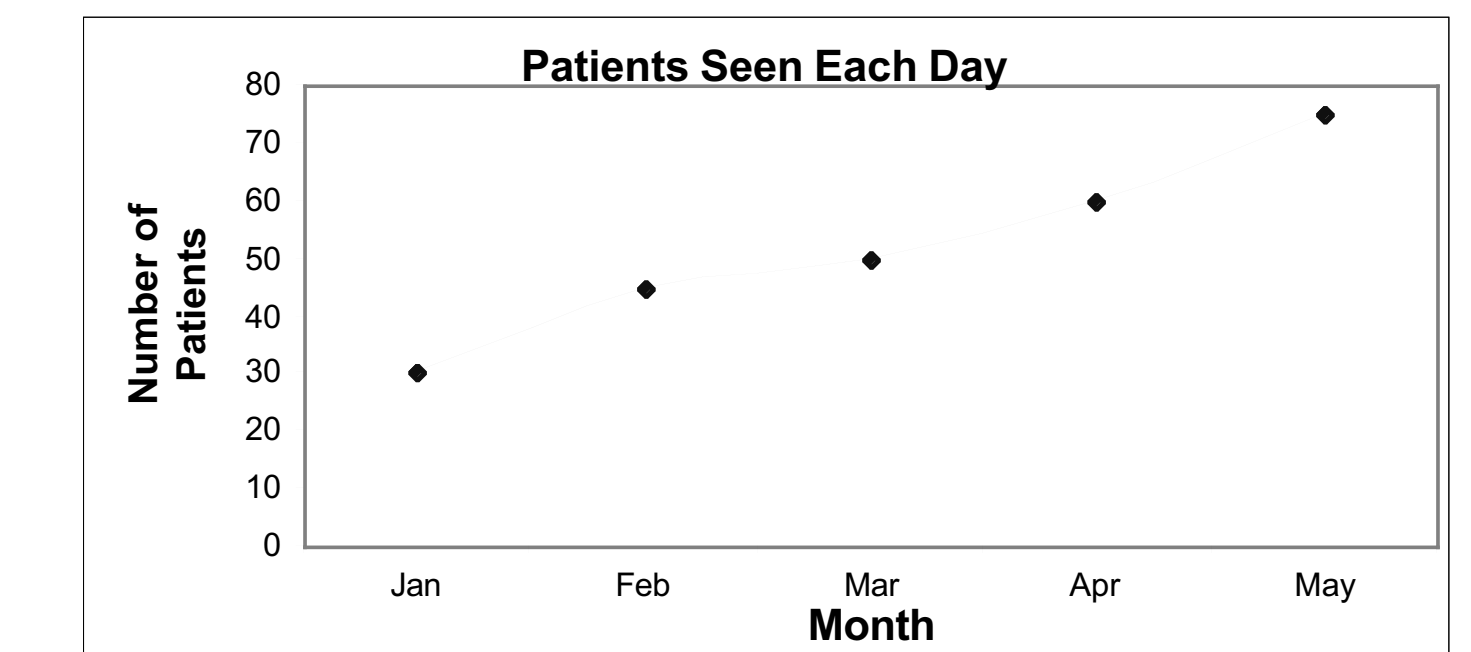
Two registered nurses and one medical assistant

Administrative staff:

Daily operations: One of the nurses also acts as the clinic administrator.
Laboratory oversight: Point of care coordinator in the main laboratory assures appropriate quality assurance and quality control procedures
Medical Director: Physician in the Bend Memorial Clinic.

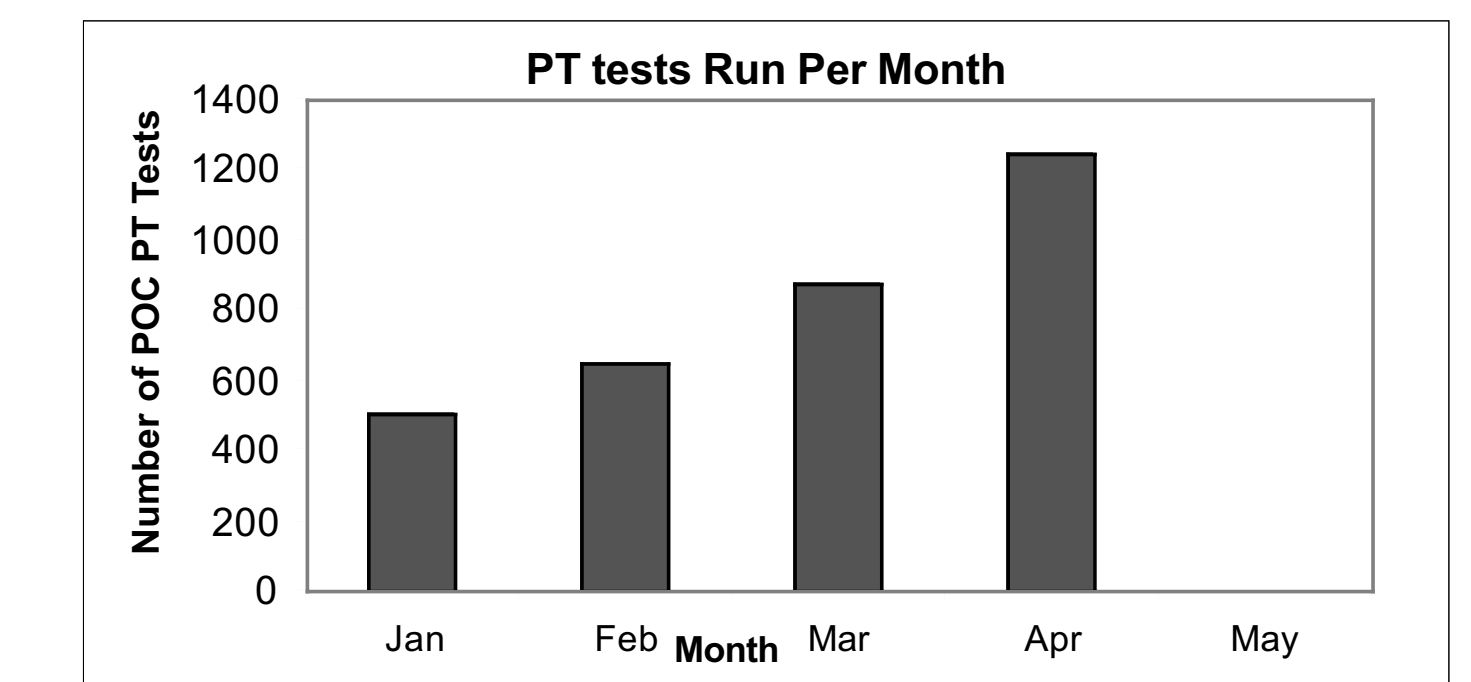
The clinic is self-sufficient

Patient's private doctor is advised if adverse event occurs.



Since opening, the number of patients referred to the clinic has grown every month. Referrals now come from as far as 200 miles away.

If a patient requires surgery or dental procedures, the clinic staff is advised and takes responsibility for initiating alternative anticoagulant therapy for the patient. Post-procedure, the clinic is responsible for returning the patient to a stable oral anticoagulation regimen.



The growing patient population has led to an exponential increase in the number of PT tests performed each month.

CONCLUSIONS

Clinician and patient satisfaction are very high.

Patients prefer:

- Fingerstick over venipuncture
- Immediate results over one hour turn around
- Immediate dose adjustment over telephone calls for dose changes

Doctors prefer:

- Knowing patients are appropriately trained and properly monitored
- Having experienced personnel manage their oral anticoagulant patients
- Obtaining appropriate adjustments pre and post procedures

Laboratorians prefer:

- Minimizing calls for STAT prothrombin time tests.
- Knowing the correlation between the POC device and the laboratory is not drifting.