Instituting Patient-Self Test Meters in Adults on Warfarin in a Cardiology Practice

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by

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INSTITUTING INR PATIENT-SELF TEST METERS IN ADULTS ON WARFARIN IN A CARDIOLOGY PRACTICE

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INSTITUTING INR PATIENT-SELF TEST METERS IN ADULTS ON WARFARIN IN A CARDIOLOGY PRACTICE

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**Background:** Warfarin is the oral anticoagulant that is most commonly used to control and prevent thromboembolic disorders. It requires meticulous testing and dosing adjustments to attain therapeutic international normalized ratio (INR) levels. Patient self-testing (PST) is associated with a reduced risk of all-cause mortality and lower rates of thromboembolism and bleeding. PST meters offers convenience and promotes self-initiative of care.

**Purpose:** The purpose of the project is to evaluate the effectiveness of INR PST in adult patients diagnosed with atrial fibrillation, deep vein thrombosis, and mechanical heart valve on warfarin therapy in a Cardiology practice compared to traditional laboratory methods, or usual care.

**Description of Design:** Chart reviews were conducted to identify patients on warfarin (for greater than six months) with the medical indication of atrial fibrillation, deep vein thrombosis, and mechanical heart valve. Data obtained from medical records included INR lab values, age, gender, medical indication, method of testing, and insurance carrier. INR lab values were analyzed over a four-year time period (August 2010 – August 2014) for control of INRs based on method of testing.

**Outcomes:** Pre- and post- data reveal patients had tighter INR control after PST initiation. A statistically significant trend is noted at the three-month point from date of initiation, where the group experienced less therapeutic control, however control of INRs continued to be tighter compared to usual care.

**Statement of Conclusions:** The data suggests adult patients on warfarin utilizing PST method of INR testing showed tighter control of INRs as compared to usual care.

**Implications for practice:** Based on the data obtained, the six months following the three month PST initiation suggested provider follow-up after three months of initiation to re-evaluate testing frequency and goals.
**Background & Evidence for problem**

Warfarin is the oral anticoagulant that is most commonly used to control and prevent thromboembolic disorders. According to the Joint Commission improper monitoring of anticoagulants resulted in loss of function and deaths in 26% of the nation. Warfarin is a medication that requires meticulous testing and dosing adjustments to attain therapeutic International Normalized Ration (INR) levels. An INR level is a crucial laboratory measurement to make certain the blood will not put the patient at risk for bleeding or clotting. The goal of warfarin management is to administer a therapeutic dose to provide the patient protection against clotting conditions and minimizing the risk of bleeding. Signs of warfarin overtreatment are increased bruising, excessive bleeding, and presence of blood in stool and emesis. The increase danger of bleeding further complicates safety awareness in older patients. Under treatment may increase the risk for blood clots, which may dislodge into small arteries in the brain or heart causing stroke or myocardial infarction. Challenges of usual laboratory testing are time and scheduling inconveniences, separate visits for blood draw and result interpretation, possible return to the lab for system error, therefore possible delay in treatment, multiple medical consultations, and lack of independence.

The main challenge observed in this cardiology practice has been an increase of patients on warfarin who have acquired complications from non-therapeutic INR’s and required immediate intervention including hospitalization.

**Evidence-based intervention**

The intended population in this a cardiology clinic are adults who are currently receiving warfarin management. The utilization of patient-self testing (PST) is the planned intervention to maintain a therapeutic INR. Evidence discussed has shown PST
is just as accurate as conventional laboratory methods (Garcia-Alamino et al., 2012). The PST is a portable device allowing convenience of INR testing in the comfort of the patients’ own home. The meter is very similar to glucometers used for diabetic patients. A sample of blood is collected from a fingerstick using a lancet. The test strip is inserted into the pocket-sized device and blood is dropped on to the strip. The result is available immediately. The device works by measuring thromboplastin-mediated clotting time, then converted to plasma PT and expressed as an INR value. The health care provider will receive the INR reports from the meter vendor providing PST service as results become available.

PST would allow for more frequent monitoring, better treatment adherence, and fewer thromboembolic or hemorrhagic complications (Heneghan, 2012). An estimated 19,380 strokes and 916 bleeds would be prevented each year by home INR testing (Caro, 2004). “A conservative economic model estimated a Medicare savings of $1.14 billion annually through maintaining patients eligible for anticoagulation on therapeutic doses of warfarin” (Caro, 2004).

**Evidence of Accuracy in Patient Care Settings**

There is strong evidence that PST meters are just as accurate as laboratory findings and are effective to utilize in practice. In a systematic review by Christensen & Larsen (2012), analyzing 22 randomized control studies, PST meters were found to have adequate precision in the clinical setting. A randomized control trial conducted by Sobieral-Teague, Daniel, Farelly, Coghlan, and Gallus monitored daily INR until INRs were “2.0” for two consecutive readings. The purpose of this study was to determine correlation of PST meters to laboratory testing. This study compared two point-of-care
devices from the same manufacturer and compared them to traditional methods. Nearly all (99.4%) of PST INR’s were within 0.8 units of laboratory INR’s (Sobieral-Teague, Daniel, Farelly, Coghlan, & Gallus, 2009).

In another randomized control trial study performed by Donaldson, Sullivan, and Norbeck in 2010, two point-of-care devices were compared with laboratory methods. INR’S of 52 patients receiving oral Warfarin therapy were measured using both devices and during the same visit a blood sample was taken from each patient for lab analysis. Values from PST meters and laboratory were within 0.4 units of each other 67% of the time (Donaldson, Sullivan, & Norbeck, 2010).

Bardacki et al. studied 105 patients undergoing open-heart surgery for mechanical valve replacements. Patients were placed on vitamin k antagonists along with low molecular weight heparin. Patient-self test and laboratory techniques were used to obtain INR results daily after surgery until therapeutic INR range was achieved. INR values correlated strongly with lab methods by the 2nd and 5th postoperative days (Bardaki et al., 2013). Testing occurred daily, using both methods and resulted in similar results.

Evidence of Improved INR Maintenance and Reductions in Bleeding Complications

A systematic review evaluated by Garcia-Alamino et al. (2012) examined effects of self-monitoring and self-management of oral anticoagulant therapy and compared results to standard monitoring. The Cochran Central Register of Controlled Trials, MEDLINE, EMBASE, and CINAHL were databases used to search for 18 randomized trials, incorporating a total of 4,723 participants. Twelve out of 18 trials reported improvement in percentage of mean INR measurements in therapeutic range (Garcia-Alamino, et al., 2012). “Trials of self-mangement using CoaguChek meters showed
significant reductions in thromboembolic events and all-cause mortality; reduced major hemorrhages” (Garcia-Alamino, et al., 2012, p.2).

Heneghan et al. completed a large meta-analysis of 11 randomized control trials consists of 6,417 adults and analyzed the effect of self-monitoring or self-management versus standard monitoring on thromboembolic events, major bleeding, and mortality as well as measurements within therapeutic range. Searches were limited to EMBASE (1980-2009) and MEDLINE (1966-2009). The review indicated a 55% reduction in thromboembolic events, 35% reduction in bleeding, and a 39% reduction in all-cause mortality (Heneghan, Ward, Perera, & the Self-monitoring Trial Collaboration, 2012). Heneghan et al. also found improvements on INR measurements within therapeutic range in patients that were self-monitoring.

**Implementation**

The purpose of the project is to evaluate the effectiveness of INR PST in adult patients diagnosed with atrial fibrillation, deep vein thrombosis, and mechanical heart valve on warfarin therapy in a Cardiology practice compared to traditional laboratory methods, or usual care. The selection of patients to participate in this study was provided by the practice and gathered by a computer generated list using the ICD-9 code for patients on anticoagulant therapy. Data were obtained from two groups of patients on oral warfarin: 1) patients testing INR’s levels via usual care and 2) patients currently utilizing PST meters. The practice had 13 patients on PST meters. Inclusion criteria include warfarin therapy for six months or longer, diagnosis of atrial fibrillation, mechanical heart valve, and/or history of deep vein thrombosis. All data were obtained from medical records. Data obtained from the patients’ medical records, over a four-year time period
(August 2010-August 2014), including INR lab values, age, gender, medical indication, method of testing, and insurance carrier.

Although 4 years of data was collected, three phases of PST monitoring were identified. The three phases of PST monitoring that were closely evaluated were: six months prior to initiation of PST, the first three months of initiation of PST, and the last six months following the three month initiation. All INR data were documented into the patient chart, regardless of testing method, either usual care or PST meters.

**Evaluation Results**

![Average INR Values Pre- Post- Patient-Self Testing](image)

**Figure 1. Average INR Values Pre- Post- PST**
The PST patient population included 13 patients, 10 over the age of 65 with ten male patients and three female patients. There were eight patients with the diagnosis atrial fibrillation (afib), two patients with diagnosis of deep vein thrombosis (DVT), one patient with both afib and DVT, and two with mechanical heart valves.

INR lab values were analyzed over a four-year time period (August 2010 – August 2014) for control of INRs based on method of testing. A X bar (Figure 1) and R (Figure 2) control chart were created using QI Macros software to evaluate the INR values over the total number of patients, thereby controlling for volume. The X bar indicates INR values averages for the group for the four-year period (August 2010 – August 2014). The break in values (see red arrows), indicate initiation of PST. The control limits for the data values before the break have a wider control, which means there is a high variability and data fluctuation. The control limits after the break or after
PST initiation shows a much narrower control, which means data values was less variable and tighter control of INR levels. However, the data values after the three-month initiation period (purple arrows) show increase and wider control once again. The PST group experienced less therapeutic control, however control of INRs continued to be tighter compared to usual care.

Figure 2 provides information about how consistent the INR values are among the group. The red data points seen in the R control chart indicate statistically significant, undesirable trend showing lessening of therapeutic control, or more variation among values. The red data points are observed outside of the control limits.

Figure 3. PST group’s Pre-Post Implementation Percent in Therapeutic Range

In Figure 3, the PST group, showed excellent control within the first three months of initiation. After the three-month adjustment period, monitoring was not as frequent and resulting in less control. One patient was not testing frequently pre-PST and post-PST. This patient’s data affected the average percent in time of the PST group. For five of the
patients, their post- PST results were worse than their pre-PST results. The groups’ INR average percentage in therapeutic range Pre-PST was approximately 53% and Post-PST was approximately 58%.

![Usual Care: Percent in Therapeutic Range](image)

**Figure 3. Percent in therapeutic range of usual care patients.**

Patients in the usual care group had unpredictable and varying INR values. There were no specific patterns observed. INR’s were tested at least monthly. These patients were in therapeutic range approximately 50% of the time.

**Cost Implications**

There were no extra costs spent by the practice prior to implementation. Medicare remains the top insurer for adults in this population. Fortunately, Medicare covers PST meters for patients, reimburses the practice for the initial PST education prior to implementation as well as use of PST monitoring monthly (Bloomfield, 2011).
Conclusions

According to the evidence, PST meters are an effective INR evaluation method and preventing clotting and bleeding complications from warfarin. The usual care group showed fluctuations in INR data and exhibited lack of consistency in therapeutic range. This study revealed tighter control in the PST group after initiation of meters. There was an undesirable trend observed through data collection after the three-month initiation period, which suggests need for follow-up intervention.

Implications for Clinical Practice and Sustainability

PST INR testing method is easily sustainable in this practice setting. Appropriate provider follow-up and support are the foundations of successful patient outcomes for patient self-testing. This study suggests a three month follow-up visit may be needed to reinforce testing frequency and compliance. During this visit it is crucial to identify and correct any possible barriers to testing.

Discussion

New anticoagulants have recently been introduced as an alternative to warfarin. These medications do not require close monitoring with INR testing, provide convenience of standard dosing, and have fewer bleeding and stroke risks (Buller et al., 2013). Examples of these medications are clopidogrel, ticagrelor, rivaroxaban, and edoxaban.

The Rocket AF trial compared effectiveness of rivaroxaban and warfarin to prevent stroke or systemic embolism in patients with nonvalvular atrial fibrillation. Rivaroxaban proved less frequent intracranial and fatal bleeding than warfarin and appeared to match effectiveness of warfarin in prevention of stroke and embolism (P<
0.001). Edoxaban is a newer anticoagulant in the same pharmaceutical category. It is primarily given to prevent venous thromboembolism. In a study by Buller et al., Edoxaban resulted in 3.3% rate of recurrent venous thromboembolism while warfarin resulted in 6.2% recurrence rate.

The PLATO study compared ticagrelor to clopidogrel to determine superiority on prevention of vascular events and death in patients with an acute coronary syndrome. The study resulted in a significantly reduced rate of death from vascular causes, myocardial infarction or stoke without an increase in rate of major bleeding for patients taking ticagrelor. (CITE)

Warfarin is a sensitive medication that requires meticulous management to prevent adverse complications. With the development and release of newer anticoagulant medications, warfarin may be used less. In the meantime, INR monitoring while on warfarin remains to be a crucial aspect of care. PST meters have been proven to be as effective as usual care modalities and should be considered with patients on warfarin.
References


INSTITUTING INR PATIENT-SELF TEST METERS IN ADULTS ON WARFARIN IN A CARDIOLOGY PRACTICE

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Background: Warfarin is the oral anticoagulant that is most commonly used to control and prevent thromboembolic disorders, it requires meticulous testing and dosing adjustments to attain therapeutic international normalized ratio (INR) levels. High rates of patients in non-therapeutic INR ranges are generally caused by failure of the provider to adjust INR doses based on monitoring. Patient self-testing (PST) is associated with a reduced risk of all-cause mortality and lower rates of thromboembolism and bleeding. PST meters offers convenience and promotes self-initiative of care.

Purpose: The purpose of the project is to evaluate the effectiveness of INR PST in adult patients diagnosed with atrial fibrillation, deep vein thrombosis, and mechanical heart valve on warfarin therapy in a Cardiology practice compared to traditional laboratory methods, or usual care.

Description of Design: Chart reviews were conducted to identify patients on warfarin (for greater than six months) in the practice with the medical indication of atrial fibrillation, deep vein thrombosis, and mechanical heart valve. Data obtained from medical records included INR lab values, age, gender, medical indication, method of testing, and insurance carrier. INR lab values were analyzed over a four-year time period (August 2010 – August 2014) for control of INRs based on method of testing.

Outcomes: Pre- and post-data reveal patients on warfarin had tighter INR control after PST initiation. A statistically significant trend is noted at the three-month point from date of initiation, where the group experienced less therapeutic control, however control of INRs continued to be tighter compared to usual care.

Statement of Conclusions: The data suggests adult patients on warfarin utilizing PST method of INR testing showed tighter control of INRs as compared to usual care.

Implications for practice: Appropriate provider follow-up and support are the foundations of successful patient outcomes for patient self-monitoring.
Instituting INR Patient-self Test Meters in Adults on Warfarin in a Cardiology Practice

Melvyn Rabanal RN, BSN, DNP Student
Karen Macauley, PhD, DNP, FNP-BC

BACKGROUND
- Warfarin is the most commonly used oral anticoagulant to prevent thromboembolic disorders.
- Requires multiple testing and dosing adjustments to attain therapeutic international normalized ratio (INR) levels.
- Deaths have occurred from improper monitoring of anticoagulants (Joint Commission, 2008).

Setting: Adult population, Cardiology Practice
- Many of the patients in this setting on Warfarin acquired complications from non-therapeutic INR and required immediate intervention.

EVIDENCE
- Patient-self testing (PST) has shown significant reductions in thromboembolic events and mortality (Gutkin, Martin, et al., 2012).
- PST has shown:
  - 50% reduction in thromboembolic events
  - 39% reduction in hospitalization
  - 39% reduction in all-cause mortality
- Heneghan et al. also found improvements in INR measurements when therapeutic range in patients that were self-monitoring.
- Roche Diagnostics: estimated 19,300 strokes and 9,166 deaths would be prevented each year by PST INR testing (Roche Diagnostics).

PURPOSE
The purpose of the project is to evaluate the effectiveness of INR PST in adult patients diagnosed with atrial fibrillation, deep vein thrombosis, mechanical heart valve, and/or history of deep vein thrombosis.

PRACTICE INNOVATION
- The selection of patients was based on a computer generated list using the INNOS tool for oral anticoagulant therapy.
- 28 patients identified using traditional laboratory methods (usual care).
- 13 patients identified using PST meters.
- Inclusion criteria include adult patients on warfarin therapy for six months or longer, diagnosis of atrial fibrillation, mechanical heart valve, and/or history of deep vein thrombosis.
- INR values (traditional laboratory or PST) were reviewed by chart review for a total of 37 patients.

EVALUATION METHODS
- Data obtained from the patients' medical records were INR lab values, age, gender, medical indication, method of testing, and insurance carrier.
- Data over a four year time period (August 2010-August 2014) was obtained.
- Three phases of PST implementation that were significant for monitoring:
  - Pre-Data: the first three months of initiation of PST
  - Peak-Data: the last six months following the three month initiation
- The last six months following the three month initiation.

TABLE I. Graphs
- Average INR Analysis Pre-Post Patient Self Testing
- Consistency of INR Values Pre-Post Patient Self Testing

RESULTS
- Pre- and post- data on 37 adult patients on warfarin with tighter INR control after PST initiation.
- A statistically significant trend is noted at the three-month point from date of initiation, where the group experienced less therapy in control.
- The PST group showed excellent control within the first three months of initiation. After the three-month adjustment period, monitoring was not as frequent and affected INR results.

CONCLUSION
- Tighter control in the PST group up after initiation of monitors was achieved.
- There was an undeniable trend observed through data collection after the three-month initiation period, which suggests need for physician intervention.

IMPLEMENTATION OF PRACTICE
- Based on this study re-education at three month point may necessary to improve compliance and therapeutic control.
- Converting all patients on Warfarin to PST meters may improve overall therapeutic control.

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  http://www.coagulcheck.com/content/docs/coagulcheck/
  coagulcheck_patient.pdf/Coagulcheck_patient.pdf
Patient Self-Test Meters Implementation to Improve INR therapeutic time

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PROBLEM STATEMENT

- Warfarin is the second most common drug, after insulin, implicated in emergency room visits for adverse drug events (Budnitz, Pollock, Weidenbach, et al., 2006)

- According to the U.S. Food and Drug Administration (FDA), hemorrhage during warfarin therapy is a leading cause of death in Western countries and related adverse events account for 1 in 10 hospital admissions.

- Such events generate a mean hospital stay of 6 days and healthcare costs of $16,000 per admission per year, resulting in poor clinical outcomes and over 1 billion dollars in health care services (Fanikos, Grasso-Correnti, Shah, et al., 2005)

- 9/34 deaths or loss of function patients occurred from improper monitoring of anticoagulants (Joint Commission, 2008).

PICO QUESTION

- Does the use of Patient-self test (PST) meters in a cardiology clinic result in better maintenance of therapeutic INR levels as compared to usual care performed by traditional laboratory methods?

EVIDENCE-BASED INTERVENTION & BENCHMARK

- The purpose of this project is to improve time in therapeutic range using PST meters, decrease complications from non-therapeutic INR’s, and increase quality of life of patients on warfarin.

BACKGROUND AND SIGNIFICANCE

- Warfarin is the treatment of choice for preventing thromboembolism.

- Non-therapeutic International Normalized Ratio’s (INR) cause thromboembolic or hemorrhagic events.

- Home monitoring would allow for more frequent monitoring, better treatment adherence, and fewer thromboembolic or hemorrhagic complications (Heneghan, 2012).

- An estimated 19,380 strokes and 916 bleeds would be prevented each year by PST testing (Caro, 2004).
SETTING ASSESSMENT

- Medical director of cardiology practice stated the main challenge observed in his office is coagulation.

- A large number of patients on Warfarin have acquired complications from non-therapeutic INR and required immediate intervention, including hospitalization.

SYNOPSIS OF EVIDENCE

- Twelve out of 18 trials reported improvement in percentage of mean INR measurements in therapeutic range (Garcia-Alamino, et al., 2012)

- Systematic review by Christensen & Larsen (2012) Patient-self test meters were found to have adequate precision in the clinical setting.

- Meta-analysis by Heneghan et al. (2012) indicated a 55% reduction in thromboembolic events, 35% reduction in bleeding, and a 39% reduction in all-cause mortality.
EBP MODEL

- Stetler model of Evidence-base Practice

PROJECT PLAN PROCESS

- Pre and post INR results obtained and analyzed from patient chart reviews
  - patients on warfarin (for greater than six months)
  - medical indication of atrial fibrillation, deep vein thrombosis, and mechanical heart valve
- August 2010 – August 2014
- 13 Patients using PST meters
- 23 Patients Usual Care

EVALUATION RESULTS
Conclusion

- INR monitoring while on warfarin remains to be a crucial aspect of care.
- PST meters have been proven to be as effective as usual care modalities and should be considered with patients on warfarin.
- New Medications replacing warfarin requires less monitoring and less bleeding/clotting events.
Cost-Benefit Analysis

- Information of inpatient hospitalization unknown.
  - Cost of hospitalization vs. PST meter

- MEDICARE and PPO’S cover PST
- CPT code: 85610
- Reimbursement $5.40/ PT/INR

Implications for Practice

- Data suggests intervention is needed after the initial phase of initiating PST.

- The poor control seen after the initiation of PST could be better managed by follow up by provider via office visit after the initial three months of PST implementation to re-evaluate testing frequency.
  - Also, during this visit it is crucial to identify and correct possible barriers to testing
REFERENCES


REFERENCES
