

# APPENDIX 5

# Sharing Safety Stories

Volume 1 – October 2013

## THE PATIENT: THE STORY OF MR. VIP

Mr. VIP, a 71 year old high risk patient with multiple chronic conditions, including heart and lung disease and diabetes, is housed in the OHU at one of our state prisons. Early in 2013, he was prescribed Coumadin to treat his cardiovascular problems, including atrial fibrillation and a suspected blood clot in his heart.

From January through April of 2013, Mr. VIP's anticoagulation therapy was managed by multiple providers in the institution's Coumadin Clinic. His therapeutic goal was set at 2.5 in the International Normalizing Ratio (INR), and he had INR testing weekly. During this four-month period, only 1 of 17 INR results came close to his therapeutic goal.

Mr. VIP's co-morbidities made him a complex patient to manage. In particular, the light-headedness, low blood pressure, and low blood sugar he sometimes experienced as complications of his other chronic conditions placed him at risk for falls, which is dangerous for a patient who may bleed easily because of anticoagulation.

In early April of 2013, Mr. VIP fell and had to be treated in the TTA for his injuries. A month later, he fell again. His cellmate found him on the floor of their cell, with his left eye swollen. His INR was 10.0, indicating that his blood was dangerously thin. The day following his second fall, Mr. VIP was sent to the hospital, where it was discovered that he had suffered a brain hemorrhage. Mr. VIP survived the bleeding in his brain and is now under close monitoring.

While identifying information for this patient has been modified, this case describes actual health care events for one of our patients. See Attachment 1 for specific clinical detail. Mr. VIP is one of 481 patients currently receiving anticoagulation therapy in California prisons.

## COUMADIN CARE AS A PATIENT SAFETY PRIORITY

Management of patients on anticoagulation therapy is a patient safety concern for any health care organization. As all providers know, Coumadin has a narrow therapeutic window. Too little and a patient can have serious, even fatal, thrombotic (blood clotting) complications, and too much can result in serious, or even fatal bleeding complications.

## ANTICOAGULATION CARE

When we look at avoidable hospitalizations and other performance trends, we see that many of our institutions struggle with anticoagulation management.

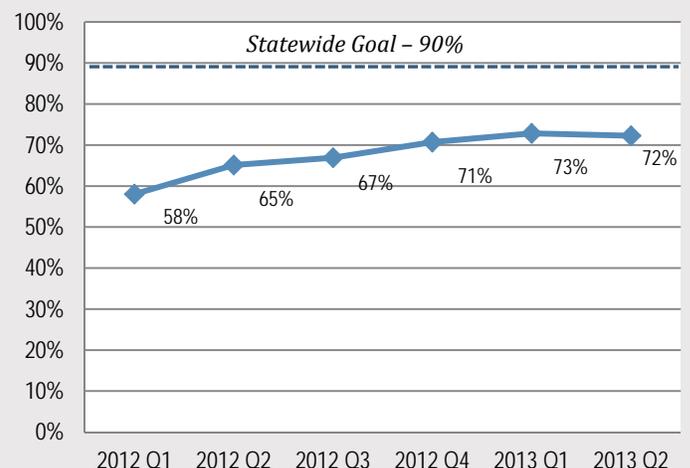
For these reasons, the CCHCS Statewide Performance Improvement Plan includes a population management outcome measure for anticoagulation:

**Population Management – Anticoagulation**  
By December 31, 2013, 90% or more of all patients on Warfarin will have most recent INR result within 30 calendar days at therapeutic levels.

### Population Management: How Well Are We Doing in Coumadin Care?

Over the past year and a half, CCHCS has steadily improved in the management of Coumadin patients, though we are still eighteen percent (18%) shy of the statewide performance objective of ninety percent (90%) of Coumadin patients attaining and maintaining a therapeutic INR (Figure 1).

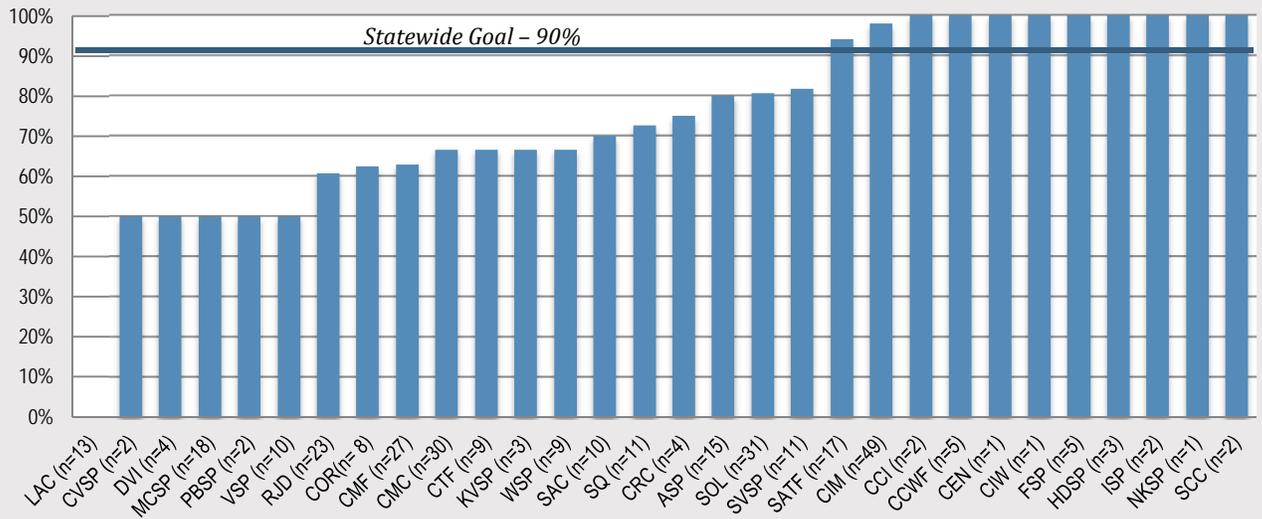
Figure 1. Percentage of CCHCS Coumadin Patients With a Most Recent INR Within Therapeutic Levels By Quarter, January 2012 - June 2013



Performance from institution to institution on this measure varies widely, from 0% at one institution to 100% therapeutic INRs at nine others (Figure 2). (Note: The population size for this measure was less than ten patients at 16 institutions.)



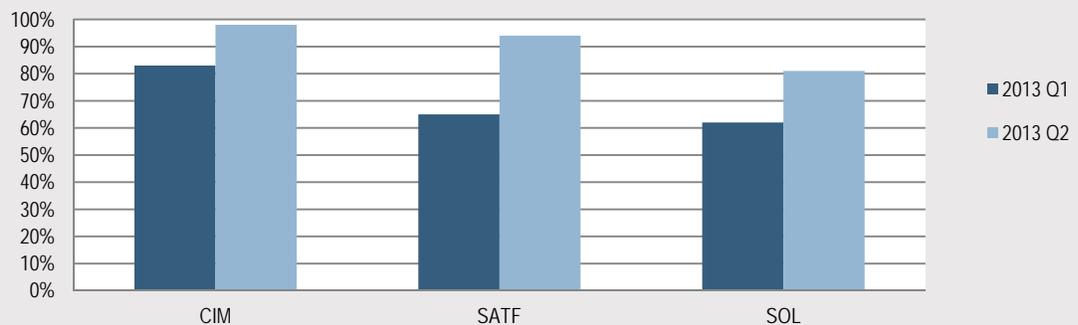
Figure 2. Percentage of CCHCS Coumadin Patients With a Most Recent INR Within Therapeutic Levels by Institution  
2nd Quarter 2013



Some institutions have demonstrated significant improvement from the most recent reporting period to this one by instituting local improvement activities focusing on Coumadin care. Two institutions, SATF and SOL, improved performance more than 20% from the first quarter of 2013 to the second quarter. The third institution, CIM, achieved ninety-eight percent (98%) of patients at therapeutic INRs, exceeding the statewide performance objective despite having the largest population of patients on Coumadin (Figure 3).

There are common themes in the strategies these three institutions used to improve Coumadin care, as described in brief in the “Process Improvement/Best Practices” section below. Detailed information about these institutions’ programs is provided in Attachment 2.

Figure 3. Percentage of CCHCS Patients With a Most Recent INR Within Therapeutic Levels  
Three Institutions With the Most Positive Change  
1st Quarter of 2013 vs. 2nd Quarter of 2013



### PROCESS IMPROVEMENT AND BEST PRACTICES

Institutions that have been able to achieve high performance in Coumadin care have created reliable processes to communicate and coordinate care among care team members and have leveraged the skills of other members beyond the primary care provider to include nurses and pharmacists, and make good use of available resources to manage, monitor and modify treatment for Coumadin patients.

In addition, executive leaders at high performing Institutions plan their work and work their plan through the PIWP and local QMC. The next section outlines specific strategies and tools used by these institutions.

## Population and Care Management

It is important to use an evidence-based standardized protocol and patient registries for all patients treated with warfarin. Institutions with high performance identified Coumadin patients from the moment they arrived at the institution and set up processes to coordinate care when patients moved from one care setting to another (such as transfers to and from community hospitals).

- Formalize a standard process to track warfarin patients and identify transfers of care/changes in level of care as these “hand-offs” greatly increase risk.
  - Identify patient upon arrival at institution.
  - Track patient as he or she transfers between care teams.
  - Track patient upon return from higher level of care (especially high risk patients because warfarin dose may need to be adjusted to new medications or change in health condition).

There are several resources available to CCHCS to assist in the safe and effective management of patients on warfarin. These resources include:

- **CCHCS Anticoagulation Care Guide** provides detailed information including how to adjust warfarin doses and patient education materials.
- **Warfarin Registry** includes an updated list of all patients at an institution prescribed warfarin and the two most recent INR results from the Quest Diagnostics system.

**Care Teams** - Institutions with high performance established a consistent relationship between the assigned PCP and their patient panel, created reliable processes to communicate and coordinate care among care team members as well as leverage the skills of members beyond the primary care provider to include nurses and pharmacists.

### Suggested Tools

Master Registry  
Warfarin Registry

**Readily Accessible Health Information** - Institutions with high performance ensured that care teams have ready access to important clinical information for Coumadin patients.

- Formalize a standard *process* to track when labs are due and then a *process* to review labs and adjust dose as needed. Ensure redundancies and back-ups so that staff is aware of missing and abnormal results immediately.
- Formalize a standard *process* to ensure that patients receive appropriate information regarding warfarin, especially signs that their dose may be too high, but also the importance of not missing doses.
  - Promoting self-management/engagement will empower the patient to speak up sooner if things fall through the crack, especially at hand-offs.
- Formalize a standard process to ensure communication of important changes in the patient's condition, adherence or medication dosing to all involved staff.
  - Primary Care Provider
  - Pharmacist
  - Licensed Vocational Nurse
  - Registered Nurse

### Suggested Tools

Master Registry  
Warfarin Registry  
HQ Central Pharmacy Notification  
CCHCS Anticoagulation Care Guide

## Models of Care

All paths lead to Advanced Primary Care Processes to ensure:

- Prepared Consistent Care Team
- Timely Access to Clinicians, Labs and Meds
- Proactive, Planned Population Management
- Targeted Case Management
- Timely Health Information Exchange
- Seamless Care Transitions (“Hand-offs”)

Successful institutions use various models of anticoagulation management including:

### CIM

Using a Pharmacist as the population manager for patients on Coumadin, CIM exceeded statewide goals for anticoagulation management at 98% compliance.

### SATF

Created routine processes to review patient registries by the Primary Care Team and order labs and administer medications which improved anticoagulation performance results from 65% to 94%.

### SOL

Nurse Case Managers carefully monitor and manage warfarin patients resulting in performance improving from 62% to 81%.

## Attachment 1 – The Story of Mr. VIP

### Clinical Details

#### Case

A 71 year old man on warfarin with multiple co-morbidities was followed in the Coumadin clinic. Over a 5 month period his INR's varied widely with a range of 1.1-10.4. His goal INR was 2.5 (range 2.0-3.0). Of the 17 INR's he had during this period, one was in range, eight were subtherapeutic and eight were suprathematic with four INR values over 5.0. Within this 5 month period his warfarin dose was adjusted by seven different providers primarily in the Coumadin clinic and TTA.

During a particular two week period he presented three different times to the TTA, once for a fall, once for low blood sugar, and once for low blood pressure. Shortly thereafter he sustained a more serious fall presenting with a hematoma over his left eye. He was evaluated in the TTA and found to have an INR of 10.0 and was given Vitamin K. The following day he was found to be confused and was sent out to the community ED where a diagnosis of subarachnoid hemorrhage was made.

#### Details

Mr. VIP is prescribed warfarin because of a history of atrial fibrillation and a ventricular thrombus. He has multiple co-morbidities including COPD, CAD, CHF with LVEF 26%, AICD, and diabetes type 2 on insulin. His goal INR is 2.5.

He resides in the OHU and his PCP is Dr. Sugar. His warfarin is managed by other providers in the "Coumadin Clinic". In the first 3 months of the year he had INR's of 3.4, 1.6, 1.7, 1.2, 1.1 and 6.8 and his weekly dose varied between 24.5 mg/week and 31 mg/week. During that time his warfarin dose was adjusted by a total of 4 providers primarily in the Coumadin clinic, but most recently by the TTA provider who ordered Vit K 2.0 mg and a warfarin dose decrease of 15% because of the INR of 6.8.

Over the ensuing 5 weeks Mr. VIP's INRs were 1.7, 5.4, 4.2, 1.6, 4.2, and 2.7. During this time he was seen by three different providers in the OHU and Coumadin clinic. His warfarin dose was decreased to 21 mg/week. He was seen in the TTA for a fall in early April but his OHU PCP made no mention of it when he saw the patient a week later.

In early May the patient refused to be seen at the Coumadin clinic and later that day an INR

## **Attachment 1 – The Story of Mr. VIP**

### **Clinical Details**

returned 10.4. The patient refused to go to the TTA to be evaluated by the TTA provider Dr. Dixon. Orders were written to give the patient Vit K 10 mg and do an INR in the a.m.

The following day the patient's cellmate informed custody that the patient was sweaty and confused and he was found to have a blood sugar of 23. He was treated by the nurses and saw his PCP later that day. The PCP addressed the hypoglycemia and mentioned the "Hyper - coagulation" and noted that the warfarin was discontinued and would be managed by the Coumadin Clinic. The patient was simply told to watch his diet.

Over the next week, the patient was seen twice in the TTA, once for another episode of hypoglycemia and 2 days later for low blood pressure. His INR's were 1.5 and 1.8. Warfarin was restarted at the prior dose (21 mg/week). Two days after seeing the TTA nurse for hypotension he was added to the OHU provider's clinic schedule because of low blood pressure. The patient shared that he occasionally felt light-headed when he got up. There was no mention of patient's anticoagulation. Later that day an INR returned at 4.7. The on-call provider, Dr. Modesto, wrote orders to hold the warfarin for a day and restart at a slightly smaller dose 20 mg/week.

The following day the patient was found on the floor by his cellmate and was evaluated. He was found to have an INR of 10.0 and his left eye was swollen. The warfarin was held and he was given Vitamin K 5 mg. The next day he was found to be confused and was sent out by Dr. Oliver and found to have a subarachnoid hemorrhage.

The above is a real case and while there are things that went right in Mr. VIP's care, there are several things that were not ideal in his care.

## Attachment 2 – Best Practices

### Pharmacist Run Coumadin Clinic

**CIM is an intermediate facility with approximately 70 patients on warfarin. They developed a Pharmacist run Coumadin Clinic model for monitoring these patients.**

- A clinical pharmacist provides day-to-day monitoring and treatment using a protocol.
- Eligible patients are identified:
  - Upon arrival at CIM, through the medication reconciliation process.
  - By referral from the PCP or PC nursing staff when warfarin is prescribed.
  - Through ongoing monitoring of GuardianRx reports (e.g. patients receiving anticoagulation therapy), and CCHCS's Master and Warfarin Registries.
- To initiate treatment, the assigned PCP evaluates the patient and signs off on a written protocol, specifying, among other information, the patient's INR goal.
- The clinical pharmacist conducts a thorough chart review, specifically looking for potential complications or relative contraindications for anticoagulation therapy (e.g. drug-drug interactions, drug-condition interactions).
- The clinical pharmacist interviews the patient, documents a detailed history and educates the patient (using education materials taken from the CCHCS Anticoagulation Care Guide) regarding:
  - Importance of adhering to the medication regimen
  - Risks of non-adherence
  - Symptoms that the patient should elevate to the pharmacist.
- The pharmacist makes an initial determination about the mode of delivery for the patient (KOP vs. DOT) and may modify the mode of delivery depending on the patient's adherence.
- The clinical pharmacist monitors patients through:
  - Ongoing laboratory studies per the protocol.
  - Regular encounters with patients.
  - Daily conversations with health care staff in contact with the patient, such as:
    - Medication nurses who can report on patient compliance during medication lines
    - Laboratory staff who know whether or not the patient has abnormal values requiring immediate intervention or if the patient is reporting for blood draws as scheduled.

## Attachment 2 – Best Practices

- Conferences with the assigned PCP/PC Team and institution medical leadership for patients where compliance is an issue or clinical factors dictate consideration of alternative therapeutic options.
- Health care staff (e.g., medication nurses, phlebotomists) is trained to contact the clinical pharmacist to report any problematic sign or symptoms or non-compliance with the lab monitoring or medication regimen.
  - Supervisory staff is trained in the new program and appropriate circumstances for elevation to the clinical pharmacist
  - Clinical pharmacist reinforces the need for reporting in day-to-day communication with line staff.
- The clinical pharmacist promotes a safe atmosphere for patients to truthfully disclose their health status and actions they may have taken that impact effectiveness of treatment.
- To prevent two-to-three-day delays in medication processing that often occur with standard medication orders:
  - Dosage changes are communicated directly from the pharmacist to the medication nurse via fax, with receipt confirmed over the phone.
  - Documentation of specific staff names of all communications was made a requirement for accountability.
- Patients whose INR remains supra- or sub-therapeutic despite dosage changes and careful monitoring are subject to a strict DOT regimen and even closer monitoring.
- Program performance is reported monthly to the local P&T Committee, Medical Program Subcommittee, and Quality Management Committee.

### Primary Care Team

**SATF has chosen to have the PC Team/PCP be responsible for managing their warfarin patients.**

- Each PCP chooses 1 day/month to see ALL of their warfarin patients.
  - Before the chosen clinic day each month, the lab does an INR on each patient so it is ready for review by the PCP on the designated clinic day.
  - If patient is not therapeutic the PCP will see the patient for additional visits.
- The CME monitors the CCHCS Warfarin Registry regularly, contacts PCP if there are problems, and continues to follow those patients to ensure their INR reaches at goal.
- SATF also uses alerts from the Central Pharmacist. Both the CME and PIC receive these emails, and after review they forward to the alerts to the PCP/PC Team.

## Attachment 2 – Best Practices

- Warfarin is given at the noon pill line. Nursing staff at SATF evaluated compliance in the various pill lines and determined that at their institution delivering warfarin at the noon pill line had the best compliance rate.
  - Patients who “no show” to the pill line are called to the clinic immediately for counseling and once at the clinic they will usually take their medication.

Currently SATF’s noncompliance rate with warfarin medication is < 1%.

- At SATF, nursing, pharmacy and the physicians have worked cooperatively to reduce medication errors associated with warfarin.
  - PROBLEM: In the past, physicians would often order different strengths of warfarin each day of the week or on specific days of the week (for example: 7.5 mgs on Monday, Wednesday and Friday and 6 mgs on Tuesday Thursday Saturday and Sunday).

The warfarin doses needed to be dispensed to the clinic in 1 mg and 2 mg tabs and the nurses had to mix and match to equal that days correct dose.
  - SOLUTION: SATF physicians attempt to dose patients using a weekly “total milligrams needed” and divide that dose as equally as possible over each day so that there is consistency in dosing.
  - PROBLEM: The sig printed out by the pharmacy was very confusing.
  - SOLUTION: The Pharmacy created standardized labeling to give clear directions to the nursing staff, and it dispenses the minimum amount of tablets to achieve the appropriate dose for each patient.
- SATF tracks the warfarin compliance rate and medication error rate weekly.

### RN Case Managers

#### **SOL has chosen a nurse Case Manager model to monitor warfarin patients.**

- Each yard has an assigned RN Case Manager.
  - The RN Case Manager (CM) works closely with the PCP to monitor high-risk patients, which includes patients on warfarin.
  - The CM has warfarin patients referred through several avenues:
    - R&R nurse refers on arrival from other institutions
    - TTA nurse refers patients returning from hospital or specialty appointments who have been started on warfarin.

# Attachment 2 – Best Practices

- PCP/PCRN refers patients started on warfarin in the PC clinic.
  - The CM nurse monitors the Master Registry and Warfarin Registry on a regular basis looking for patients new to the institution and who are on warfarin that may have been missed.
- The CM meets with each patient as he enters the case management program to provide education on warfarin using the CCHCS Anticoagulation Care Guide.
  - The CM nurse will see the patient in person every 90 days or sooner if needed to assess compliance and answer any questions.
- The CM nurse monitors the INR results for each patient in his or her yard using the Warfarin Registry and Quest Diagnostics.
- The CM attends the huddle every day.
  - One particular CM orders labs to be done the same day each week so that she knows to expect the results and is able to follow-up with the PC Team/PCP in the huddle the following day.
- The CM nurses work closely with the Pharmacists around dosing (using the CCHCS Anticoagulation Care Guide) and medication compliance to determine when a patient is a good candidate for KOP dosing.

Correction of Supratherapeutic Anticoagulation Caused by Warfarin			
Bleeding Severity	INR *	Warfarin	Vitamin K (Do not expect reversal for at least 16-24 hours)
No significant bleeding	<5.0	Decrease or omit dose	NA
	5.0-8.9	Omit 1-2 doses and decrease dose If bleeding risk is high, omit 1 dose and give Vitamin K 1-2.5 mg	1-2.5 mg by mouth If rapid reversal is required because of urgent surgery, may give ≤5 mg by mouth If INR is still high, can give additional 1-2.5 mg by mouth
	≥9.0	Hold, give Vitamin K and decrease dose	5-10 mg by mouth
Serious bleeding at any elevation of INR	NA	Hold, give Vitamin K p.o. and send out	Once hospitalized, 10 mg IV by slow infusion; may repeat every 12 hours (IV Vitamin K given in monitored setting only)
Life-threatening bleeding	NA	Hold, give Vitamin K p.o. and send out	Once hospitalized, 10 mg IV by slow infusion; repeat if necessary depending on INR (IV Vitamin K given in monitored setting only)

\* If INR >5, recommend recheck every 24 hours until stabilized. Adapted from: Ansell, Jack; Chest 2008; 133:160-198