Implementing and Improving an Inpatient Anticoagulation Service: the Role of Management

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Objectives

- Identify prudent steps to take when implementing an inpatient anticoagulation service
- Describe strategies in refining and expanding the service
- List possible future roles for inpatient pharmacists practicing in anticoagulation

Step 1: Review the Literature and Networking

- Take a close look at the articles already presented
  - Which hospitals seem similar to your situation?
  - Which articles deal with issue that your hospital is struggling with?
- Closely evaluate the Bond and Raehl article
  - Can be used to postulate a financial benefit to the hospital
- Talk to colleagues at other hospitals who have services like you are contemplating
  - Site visits are a very good idea to see a service first hand

Step 2: Plan the Anticoagulation Service

- Successful programs will have support from:
  - All of pharmacy
  - Medical staff
  - Hospital administration
  - Nursing
- Think about things from their perspective and assure those issues are addressed

Where to start?

- Appoint a program manager tasked with planning
- Identify a medical staff champion
  - Well respected physician
    - hematologists, cardiologists, hospitalists, general internists
    - should be involved in planning
- Form a planning team

Who should be on the team?

- Anticoagulation program manager (team leader)
- Pharmacists, preferably those that would be providing the service on a day to day basis
- Director of pharmacy
- Pharmacy technician
  - more distributive duties may need to be handled by technicians
- Medical staff champion
- Nursing representative where the service will likely be heavily utilized
- Others….

Start at the end…..

- Engage the team a form a vision of what the end product will look like
  - Focus on problem areas
  - MUE, research may help identify biggest targets
  - Avoid “nay” saying; focus on the vision and worry about how to get there later

Issues that **MUST** be tackled by the planning team

- Role of the service
  - Direct patient care only?
  - Or does it also have a policy role?
    - evaluate new anticoagulation medications as they emerge, standardize the use of vitamin K, recombinant factor VIIa, or other reversal agents, assure anticoag labs seen, electronic prompts, how to manage HIT
- How will the practice be incorporated into daily pharmacist duties?
- Assure job descriptions are up to date
  - Is direct patient care covered in the job description?
  - Must clearly set expectations for those providing the service

Issues that **MUST** be tackled by the planning team

- Who is responsible for addressing performance?
  - Program as a whole
  - Individual pharmacists
- Will the pharmacists have face to face interactions with the patients they are serving?
  - Highly recommended
  - Supports the ASHP 2015 initiative
- Which pharmacists will provide the service?
- How will pharmacists be trained?
- What chart documentation will take place?

What patients should initially be covered by the service?

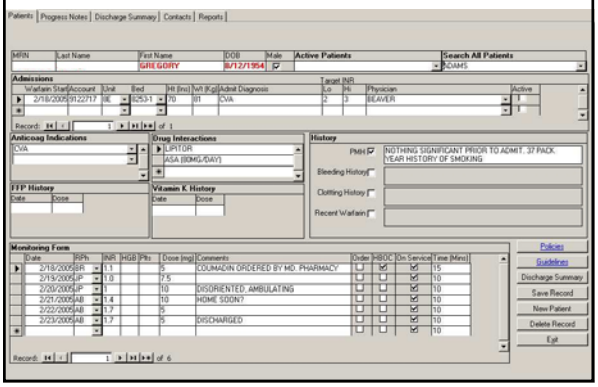
- Patient groups who are considered as receiving unsafe care
- Patients who request a pharmacist to be involved in their care
- Pediatric/geriatric patients with defined specific ages
- Critical care patients receiving anticoagulation therapy
- Physician consult
- Specific units where the physicians have a strong desire for pharmacist help in management
- Patients that are on a high number of concurrent medications
- Patients who are suspected of not adhering to anticoagulation therapy

Adapted from Galt K. *Developing Clinical Practice Skills for Pharmacists*. Bethesda, MD: American Society of Health-System Pharmacists; 2006.

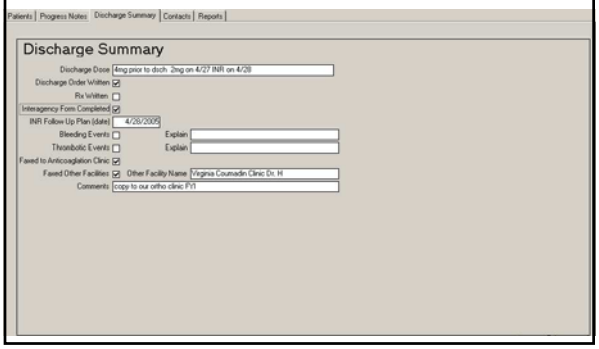
Data tracking

- How will your service be organized?
- How will the quality of the service be managed?
- How will the service assure all patients can easily be identified?

St. Mary’s Warfarin Software



St. Mary's Warfarin Software



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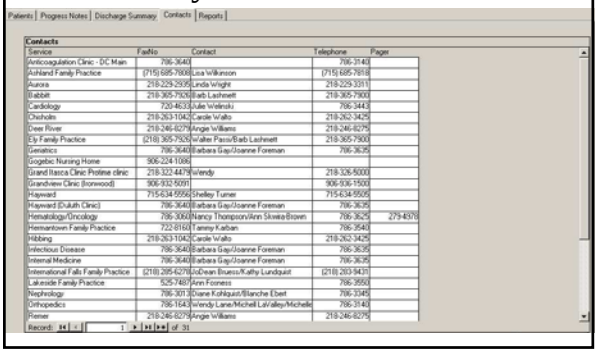
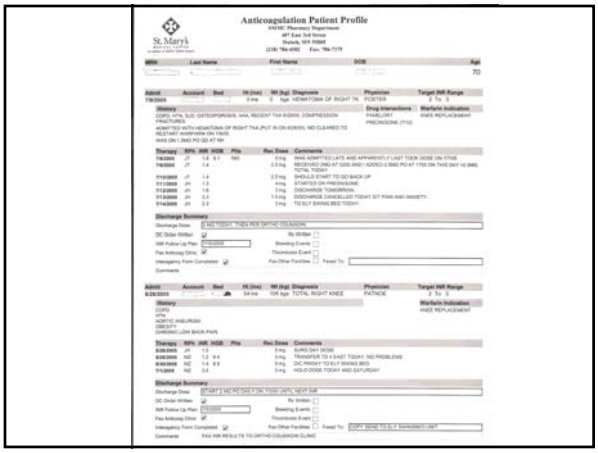


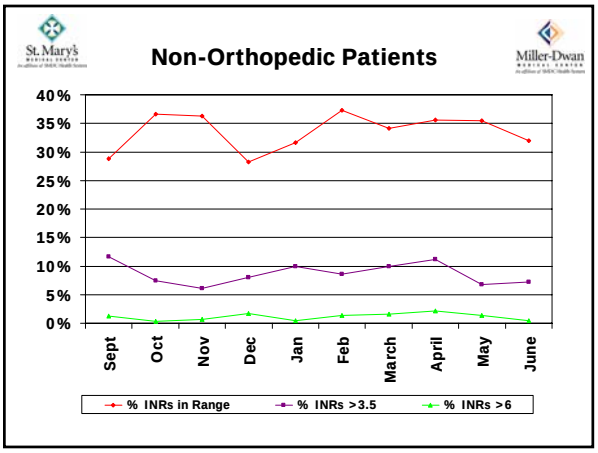
Transitional care

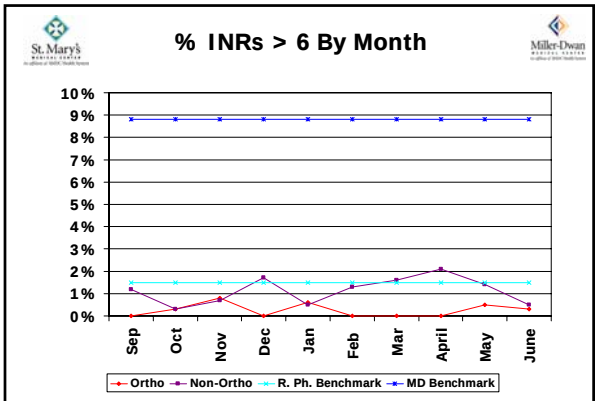
- How will our service facilitate smooth transitions in care
  - Outpatient to inpatient
  - Inpatient to outpatient

SMDC Epic Anticoagulation Flowsheet

Anticoagulation	Diagnosis	INR Goal	Result Date	INR	INR/Lab	Tab Size	Wkly Dose	Dose Text mgs
7/29/2005	atrial fibrillatio	2.0-3.0	07/29/2005	2.7		5	17.5	2.5 daily (mgs)
7/7/2005	atrial fibrillatio	2.0-3.0	07/07/2005	2.2		5	17.5	2.5 daily (mgs)
6/20/2005	atrial fibrillatio	2.0-3.0	06/20/2005	1.1		5	17.5	2.5 daily (mgs)
5/26/2005	atrial fibrillatio	2.0-3.0	05/26/2005	2.2		5	17.5	2.5 daily (mgs)
5/5/2005	atrial fibrillatio	2.0-3.0	05/05/2005	3.9		5	17.5	2.5 daily (mgs)
4/14/2005	atrial fibrillatio	2.0-3.0	04/14/2005	3.7		5	20	5 W & 2.5 ROW (mgs)
3/9/2005	atrial fibrillatio	2.0-3.0	03/09/2005	1.8		5	22.5	5 MF & 2.5 ROW (mgs)
2/3/2005	atrial fibrillatio	2.0-3.0	02/03/2005	2.2		5	22.5	5 MF & 2.5 ROW (mgs)
1/3/2005	atrial fibrillatio	2.0-3.0	01/03/2005	2.3		5	22.5	5 MF & 2.5 ROW (mgs)
12/10/2004	atrial fibrillatio	2.0-3.0	12/10/2004	1.6		5	22.5	5 MF & 2.5 ROW (mgs)
11/18/2004	atrial fibrillatio	2.0-3.0	11/18/2004	1.5		5	20	5 W & 2.5 ROW (mgs)
10/27/2004	atrial fibrillatio	2.0-3.0	10/27/2004	2.1		5	20	5 W & 2.5 ROW (mgs)
10/7/2004	atrial fibrillatio	2.0-3.0	10/07/2004	2.4		5	20	
9/30/2004	atrial fibrillatio	2.0-3.0	09/30/2004	1.8		5	20	
9/16/2004	atrial fibrillatio	2.0-3.0	09/16/2004	2.2		5	20	
9/10/2004	atrial fibrillatio	2.0-3.0						
9/9/2004	atrial fibrillatio	2.0-3.0	09/09/2004	3.2	3.2 (H)	5	20	
8/26/2004	atrial fibrillatio	2.0-3.0	08/26/2004	3.4		5	22.5	
8/19/2004	atrial fibrillatio	2.0-3.0	08/19/2004	2.9		5	25	







Other tidbits….

- Flowcharting the service could be helpful to prospectively identify potential problems
- If the team thinks a service is important to patient care, the question becomes not "if" but "how"
- But don't ignore the elephant hiding under the table

Staffing

- Can technicians be used for more dispensing duties?
  - Tech check tech?
- Can the department better utilize automation?
- Are local pharmacy students available to hire?
  - Can help pharmacist work through clinical duties
- How about starting a residency program?
- But you may need more pharmacists….

Step 3: Gain Formal Approval of the Program

- The pharmacy and therapeutics committee will likely need to approve all programs, protocols, and guidelines
  - What policies and procedures are needed?
- Make sure your political homework is done BEFORE the meeting
- Be sure to think of it from the physicians perspective

Step 4: Launch the Program and Address Unanticipated Issues

- Be sure to do careful planning prior to launch, but
- Be careful not to "over plan"
  - Not having the service in place could be the bigger issue
  - Piloting is an excellent way to avoid this
- Once "bugs" are worked out, expand to other areas

Step 5: Monitor Program Quality and Strive for Improvement

- Then, brag very loudly about the excellent care your pharmacists are delivering
  - You need to publicly recognize the performance of your pharmacists
- Don't let quality issues go
  - Address system issues that need to be addressed
  - Provide individual, one on one, feedback when individual pharmacists do not perform adequately and strive to improve their skills

Step 6: Expand into New Arenas as the Patient Need Arises

- If you institution starts with warfarin, what other types of quality problems are occurring with:
  - Heparin
  - LMWH
- What is the department's role with rVIIa?
- Is an inpatient "antithrombosis" program the next step?

Why the Iron is Hot

- Pharmacist involvement in dosing warfarin and heparin may soon be mandated in hospitals
  - Was in draft 2007 national patient safety goals from JCAHO
- Proposed core measures for the systematic prevention and treatment of venous thromboembolism also open up opportunities
  - Who will screen for VTE risk?
  - How will you assure heparins and warfarin are used correctly to meet the standard?
- So what are YOU going to do with this information?

Clinical Leadership

- I believe that inpatient anticoagulation services clearly improve care
  - Data
  - Experience
- We need people with clinical backgrounds to lead this charge

Excerpts from Sarah White's 2006 Harvey A. K. Whitney Lecture

- "Thus, a leader is a pioneer, a pathfinder, who continually faces the unknown, exploring new territories, and dealing with unforeseen challenges."
- "Seeing challenges as opportunities, replacing problems with solutions, and overcoming failure are essential to successful leadership and organizational influence."

Managing Anticoagulation Patients in the Hospital: the Inpatient Anticoagulation Service

- Dr. Dager and I have signed a contract to write the above book for ASHP
- Bill Dager, Edith Nutescu, Scott Neel, and Jill Strykowski are other prominent anticoagulation pharmacists who are contributing authors
- Look for this text during the first half of 2007

Thank you for your attention!

Unique Challenges for Initiating Anticoagulation in Inpatients

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Objectives

- Describe the challenges of managing anticoagulation in the hospital
- Identify risk factors for bleeding and thrombosis in patients requiring anticoagulation
- Summarize the literature supporting inpatient pharmacists managing anticoagulation

How should anticoagulation be managed?

- "We recommend that physicians who manage oral anticoagulation therapy do so in a systematic and coordinated fashion, incorporating patient education, systematic INR testing, tracking, follow-up, and good patient communication of results and dosing decisions." **Grade 1C+**

CHEST 2004; 126: 204S-233S.

What is "systematic and coordinated" care?

- According to Dr. Jack Ansell, systematic coordinated anticoagulation care consists of:
  - Assisting in determining the appropriateness of care
  - Providing anticoagulant dosing
  - Assuring regular monitoring and patient evaluation
  - Provision of repeated patient education
  - Communicating with other patient care providers that are involved in the patients care
- But these are just outpatient issues, right?

Ansell JE. The Value of an Anticoagulation Management Service. In: Ansell JE, Oertel LB, Wittkowsky AK, eds. *Managing Oral Anticoagulation Therapy*. ASPEN; 2000.

NO!

- Assisting in determining the appropriateness of care
  - Picking the right parenteral antithrombin agent for the disease, renal function, patient history, etc.
- Providing anticoagulant dosing
  - Dosing heparin, LMWH, warfarin, argatroban, etc.
- Assuring regular monitoring and patient evaluation
  - Designing policies to assure coagulation labs are drawn when needed; consulting on individual patients
- Provision of repeated patient education
  - Assuring hospital education on warfarin, LMWH, etc.
- Communicating with other patient care providers that are involved in the patient's care
  - Helping surgeons and hospitalists communicate regarding the risks vs. benefits of therapy and picking the right option

Reasons anticoagulation services are also needed in the hospital

- Why are patients in the hospital?
  - They are sick!
  - Examples: decompensated heart failure, renal failure, poor nutrition status, etc.
- Interruption of anticoagulation for surgical procedures
  - Big role is assure appropriate bridge therapies are utilized
- Heparin administration medication errors
  - An anticoagulation program can change the "systems" in how heparin is delivered
- Medication changes are frequent!

Preventable disaster #1

- A patient is admitted with decompensated heart failure and is also on warfarin for stroke prophylaxis due to atrial fibrillation. The INR is not checked for at admission or for 2 days. The patient, while out walking, falls and hits his head. The patient has a large intracranial hematoma. An INR is finally checked and it is 10.

Preventable disaster #2

- A patient is taken off warfarin for a colonoscopy with the possibility of biopsies. The patient undergoes the procedure successfully, but the next day has a massive stroke. When reviewing the records, it is found the patient had a mechanical mitral valve and did not receive appropriate “bridge” therapy with a heparin product.

Preventable disaster #3

- A patient is started on enoxaparin after a total knee replacement for deep vein thrombosis prophylaxis. Two days later, the patient begins losing sensation in his legs. The patient, that same day, had an epidural catheter pulled that had been used post op for pain control. The loss of sensation progresses to permanent paralysis and an epidural hematoma is found to be the cause.

Preventable disaster #4

- A patient in the hospital, who is also on warfarin, is started on sulfamethoxazole/trimethoprim for uncomplicated cystitis. Three days later, the patient has gross amounts of blood in their stool and a low blood pressure. The INR is found to be 10.

Preventable disaster #5

- A patient with an in range INR with a mitral mechanical heart valve is admitted to the hospital with a new hip fracture. The patient is given 10 mg po of oral vitamin K to lower her INR for surgery the next day. After her procedure, she remains in the hospital 7 days as clinician attempt to get her INR back into range since she is not an appropriate candidate for outpatient LMWH therapy.

Preventable disaster #6

- A nurse in a hospital caring for a patient on heparin receives the results the first aPTT after the heparin is started. She is startled to see the result in > 200 seconds and that the entire heparin bag has been infused. When investigating the cause, she finds that the pump was set at 900 ml/hour when the order was for 900 units/hour.

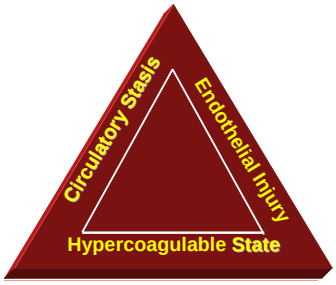
The clinical challenges of managing inpatient anticoagulation

- Patients are sick!
  - They call it acute care for a reason….
  - And they are constantly changing
- The frequency of needed therapy interruptions
- Much more than just warfarin….
- And as Johnny Cash would say, "I Walk the Line"

Walking the anticoagulation line

- Constantly need to be weighing the risk of thrombosis versus the risk of bleeding
- Good idea is to always ask yourself what am I most worried about in this patient at this time?
  - Do this daily
- Really need a good sense of thrombosis and bleeding risk factors

Virchow's Triad



DVT thrombosis risk factors

- Surgery
- Trauma
- Immobility
- Malignancy
- Cancer therapy
- Previous VTE
- Increased age
- Pregnancy and postpartum
- Estrogen medications
- Estrogen receptor modulators
- Obesity
- Acute medical illness
- Heart or respiratory failure
- Inflammatory bowel disease
- Nephrotic syndrome
- Myeloproliferative disorders
- Paroxysmal nocturnal hemoglobinuria
- Smoking
- Varicose Veins
- Central venous catheterization
- Inherited or acquired thrombophilia

CHEST 2004; 126: 338S-400S.

Atrial fibrillation thrombosis risk factors

- "$CHADS_2$"
  - Cardiac failure (heart failure or LV dysfunction < 35%)
  - Hypertension
  - Age 75 year-old or greater
  - Diabetes mellitus
  - Stroke or transient ischemic attack (TIA) (doubled)
- Rheumatic mitral stenosis
- Prosthetic heart valve

Circulation 2006; 114: 700-752.

Mechanical valve risk factors for thrombosis

- 1st generation (like ball and cage) vs. newer valves (St. Jude, etc.)
- Position of valve (mitral vs. aortic)
- Multiple valves
- Atrial fibrillation
- Left atrial enlargement
- Poor LV function
- Age > 70 years old
- History of prior embolism

CHEST 2004; 126: 457S-482S

Risk factors for bleeding

- Warfarin
  - Intensity of anticoagulation effect
    - Don't forget about "unintended" increased intensity
  - Patient age (greater than 75 years-old)
  - Bleeding history
  - Serious comorbid conditions like:
    - Treated hypertension
    - Cerebrovascular disease
    - Ischemic stroke
    - Serious heart disease
    - Renal insufficiency
  - Concomitant medications
  - Initiation time period

CHEST 2004; 126: 287S-310S.

Risk factors for bleeding

- Heparins
  - Intensity of effect as measured by aPTT?
    - Conflicting data
  - Intermittent IV heparin likes to more bleeding than continuous infusion
    - Why it is not used
  - Comorbid conditions
    - Recent surgery or trauma singled out
  - Concomitant medications
    - Antiplatelet agents, lytics
  - Renal failure
  - Age > 70 years-old

CHEST 2004; 126: 287S-310S.

So can pharmacist's to this?

- YES!!!
- Dr. Dager has been doing it for years!
- Our pharmacists at St. Mary's Medical Center are doing it as I speak
- But how about the data…..

Heparin articles

- Pawloski et. al. assessed pharmacist dosed heparin using new weight based protocol (n=29) vs physician (n=14) in a 69 bed community hospital
  - Earlier aPTT in target range ($p<0.001$), higher infusion rates utilized ($p<0.01$), and fewer rate changes ($p<0.001$)
  - No demographic comparison noted in study

Hospital Pharmacy 1992; 27: 703-706

Heparin articles

- Rivey and Peterson assessed pharmacist adjusted heparin (n=42) vs. physician managed (n=42)
  - Pharmacist management achieved first aPTT ration value $\geq$ 1.5 earlier, shorter time to first aPTT 1.5 – 2 times normal, and fewer patients with aPTT values < 1.5 or > 3 times normal. All p values <0.05.

AJHP 1993; 50: 279-84.

Heparin articles

- Kershaw et. al. evaluated pharmacy based, computer assisted heparin dosing (n=131) vs. historical cohort (n=57)
  - In historical control, 62% of patients achieved a therapeutic aPTT during the first 24 hours and 17% failed to reach therapeutic levels in 48 hours
  - In the computer assisted group, 90% reached a therapeutic aPTT during the first 24 hours and only 3% failed in 48 hours

Arch Intern Med. 1994; 154: 1005-1011.

Warfarin article

- Ellis et. al. evaluated pharmacist involved warfarin dosing consultation (n=52) vs. previous usual care (n=97)
  - Decreased number of aPTT or PT assays requested per day (p=0.02)
  - Increased PT values in target range and decreased supertherapeutic PT values at first outpatient follow-up (p significant for both)

AJHP 1992; 49: 387-94.

Warfarin article

- Rivey et. al. evaluated protocol driven dosing by pharmacist (n=151) vs physician independent of protocol (n=41) in orthopedic surgery patients.
  - Similar duration of inpatient therapy, no difference in complication rates.

AJHP 1995; 52: 1310-6.

Warfarin article

- To and Pearson assessed pharmacist assisted warfarin dosing protocol (n=41) compared to physician directed dosing (n=46) prior to implementation
  - Decreased INR values > 4 per patient (p=0.0059)
  - Other data was similar between groups
  - Cohorts unequally matched for anticoagulation indication

Can J Hosp Pharm 1997; 50: 169-175.

Warfarin article

- Dager et. al compared usual physician directed warfarin dosing (n=60) to pharmacist consultation (n=60) matched for anticoagulation indication.
  - Decreased critical INR values (> 3.5 or > 6.0; p<0.001)
  - Length of hospital stay (p=0.009)
  - INR more likely in the target rang (2-3) at discharge

Ann Pharmacother 2000; 34: 567-72.

Warfarin article

- Boddy compared pharmacist dosed (n=74) warfarin 4 days after initiation vs junior physicians (n=64) with access to same protocol
  - Improved INR control (58% vs. 15%; p<0.001) with reduction in values > 6 or < 2
  - Fewer INR values requested with improved control associated with pharmacist involvement

Pharm World Sci 2001;23:31-5.

LMWH and warfarin article

- Bridges evaluated inpatient pharmacist involved in a collaborative DVT prevention process for trauma patients
- Utilized LMWH as a bridge to warfarin
- n=108 in pharmacist group and compared to historical control of n=69
  - Matched for injury severity in trauma
  - Reduced length in stay (p<0.002) and inpatient days on warfarin (p<0.0001)

J Trauma 2004; 54: 232-235.

Heparin and warfarin article

- Mandami et. al. evaluated usual physician directed care (n=50) vs. pharmacist management (n=50) of heparin and warfarin
  - UFH: Increase aPTT values in (p=0.05) or below (p=0.03) the target range; supertherapeutic the same
  - Warfarin: Decreased time to initiate therapy (p=0.05)
  - Reduction in total hospital costs (p=0.05) in pharmacist managed group.
    - $1594 vs. $2014 in 1997 dollars

Pharmacotherapy 1999; 19(9): 1064-1074.

The BIG one….

- Bond and Raehl evaluated the potential impact of pharmacist management of heparin and warfarin
- 1995 Medicare and the National Clinical Pharmacy Services Databases from 955 hospitals comparing data from hospitals that have the service to those that don't

Pharmacotherapy 2004; 24(8): 953-963.

Heparin results

- If a hospital did not have a heparin service (relative):
  - 11.41% higher death rates
  - Length of stay was 10.05% higher
  - Medicare charge were 6.6% higher
  - Bleeding complications were 3.1% higher
  - Transfusion for bleeding was 5.47% higher

Pharmacotherapy 2004; 24(8): 953-963.

Warfarin results

- If a hospital did not have a warfarin service (relative):
  - 6.2% higher death rates
  - Length of stay was 5.86% higher
  - Medicare charge were 2.16% higher
  - Bleeding complications were 8.09% higher
  - Transfusion for bleeding was 22.49% higher

Pharmacotherapy 2004; 24(8): 953-963.

Conclusion

- Inpatients need systematic, coordinated anticoagulation care
- The unstable nature of inpatients can make management challenging
- Inpatient anticoagulation pharmacists are always "walking the line" between thrombosis and bleeding
- Pharmacists have shown they can provide systematic, coordinated anticoagulation care in the inpatient setting