

Medication Safety: Anticoagulation Management

Carla S. Huber, ARNP MS
Community Anticoagulation Therapy (CAT)
Clinic
Cedar Rapids, IA 52401
515-558-4046
chuber@pcofiowa.com
www.crhealthcarealliance.org



Working Together for Patient Safety.

September 10, 2008

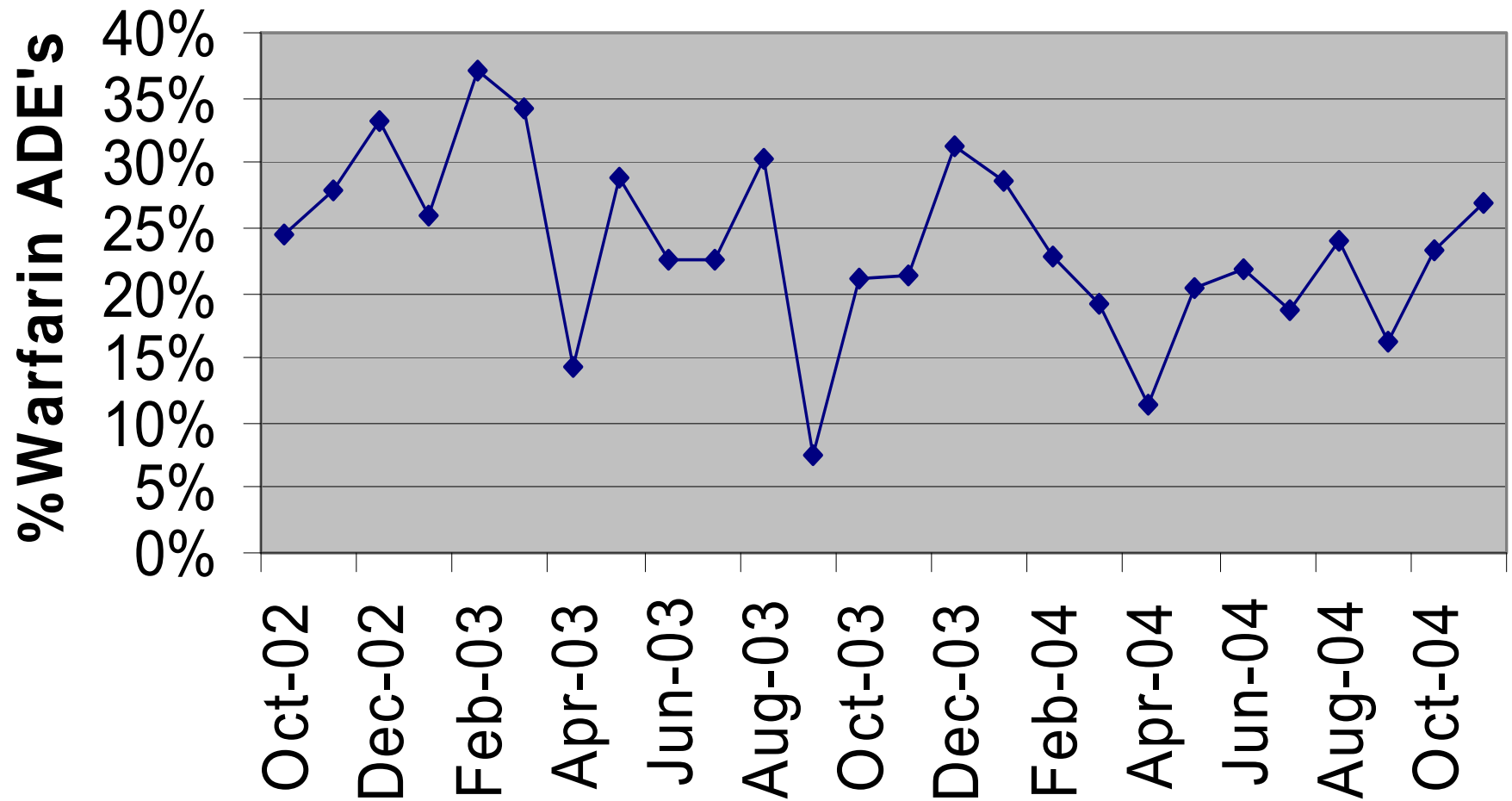
Objectives

- Identify the challenges and barriers to implementing medication safety tools
- Explain the importance of utilizing evidence-based guidelines for managing warfarin therapy
- Explain the importance of education for patients taking warfarin
- List the advantages of a dedicated anticoagulation clinic

PIPS Grant

- Specific Aims
 - Education and training in principles of ISO 9001 quality management systems
 - Establish the anticoagulation clinic
 - Determine other uses of ISO framework within the healthcare community

% Warfarin of All ADE's 04/02 through 11/04



National Quality Forum (2004)

- Safe Practices:
 - #1 - Creation of a healthcare culture of safety
 - #18 – Utilization of dedicated anti-thrombotic services that facilitate coordinated care management

Medication Statistics

- 60% of older Americans use five or more different medications per week
- 20% of older Americans take 10 different medications per week
- Americans older than 65 have more than 175,000 emergency room visits/year for adverse drug events

Source CDC

Medication Statistics

- In the US age >65 comprise 15% of population and buy 30% of all prescription drugs and 40% of OTC meds http://www.webmd.com/content/article/6/1680_51638.htm retrieved 1/22/07
- Up to 60% of all medications prescribed are taken incorrectly or not at all
- 90% of elderly patients make some medication errors
- 35% of the elderly make potentially serious errors <http://www.itaa.org/isec/events/presentations> retrieved 1/12/07

Anticoagulation Clinics

- Dedicated service to manage patients on anticoagulation medications
- Use evidence based guidelines to make dosing decisions
- Specially trained nurses, pharmacists
- Decrease complications of anticoagulants and decrease ER visits and hospital admissions
- Pts. are in INR range greater percent of the time
- Improve physician and staff efficiency

Why dedicated anticoagulation clinics?

- Use of evidence-based guidelines – American College of Chest Physicians
- Improved outcomes
 - Increased time in INR range
 - Decreased bleeding and clotting events
 - Decreased hospitalizations related to anticoagulation events

Patient Safety Goal

- Joint Commission 2009 National Patient Safety Goal #3:
 - Improve the safety of using medications
 - Anticoagulation therapy, 3.05.01
 - Reduce the likelihood of patient harm associated with the use of anticoagulation therapy

Policies and Procedures

- The organization needs to identify and determine which additional procedures need to be documented to create consistent processes.
- Physicians' Clinic of Iowa currently has over 400 documented policies and procedures.
- The Community Anticoagulation Therapy Clinic (CAT Clinic) currently has over 70 documented policies and procedures.

Note the:

Format and color

Document
number

Purpose

Definition

Procedure or
flowchart

DOCUMENT-TITLE	NUMBER	REV
Patient Flow in Anticoagulation Clinic	3032CATC	2

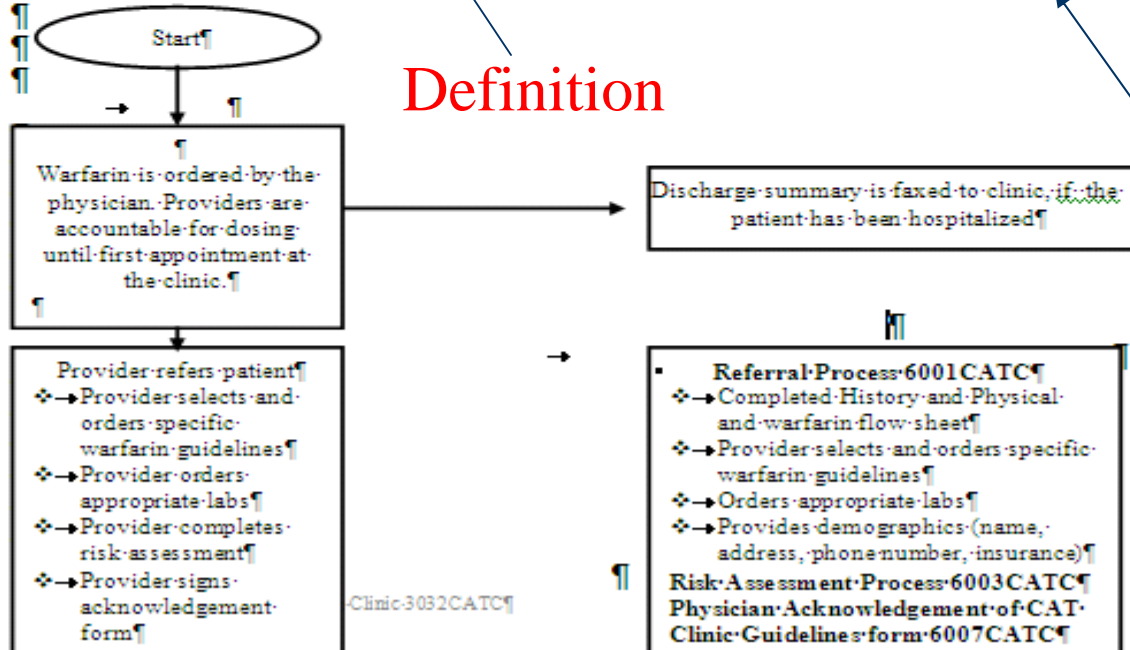
PURPOSE: (outline the intent or objective of the document)

Used to identify Patient Flow Process/Procedures in the Community Anticoagulation Therapy Clinic (CATC).

DEFINITIONS AND ACRONYMS: (provide clear understanding to words, abbreviations that may be ambiguous)

The Community Anticoagulation Therapy Clinic provides centralized care to patients receiving warfarin therapy.

PROCEDURE/FLOWCHART: (describe the steps in which work objectives are achieved; include statements, to the extent necessary, that explain the why, what, when, where, who and how)



Community

Anticoagulation

Therapy

Clinic

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Patient notified of results and short assessment of any changes completed



Encounter and next lab date entered into Warfarin Patient Management System



Visit report sent to referring physician via e-mail or fax

RECORDS (results or evidence of work performed)

Patient Agreement (4502CATC), Warfarin Guidelines (6511CATC or 6512CATC or 6502CATC), Warfarin Error Reporting Form (3034CATC), and patient record file.



REVISION HISTORY

Rev#	Description of Change	Approval	Date
0	Initial document	J. Levett, MD	12/16/05
1	Changed protocol to guidelines	J. Levett, MD	2/24/06
2	Moved risk assessment to referral form, removed compliance score, added Knowledge Assessment, added documentation in Warfarin Patient Management System, added report sent to referring physician via e-mail or fax	J. Levett, MD	8/25/06

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DOCUMENT TITLE	NUMBER	DATE
Master List	3002CATC	7/05/07

Document Title	Number	Approval Date	Revision
Administration	1000		
• Accounting	1500		
• Human Resources	2000		
• Job Description Process	2001CATC	12/16/05	0
• Training Competency Process	2002CATC	12/16/05	0
• Training Competency Template	2003CATC	12/16/05	0
• Nursing Training Competency Record	2004CATC	2/24/06	1
• Clerical Training Competency Record	2005CATC	12/16/05	0
• Quality Improvement	2500		
• Quality System	3000		
• Document Numbering Procedure	3001CATC	12/16/05	0
• Master List	3002CATC	See Above	0
• Control of Documents	3003CATC	12/16/05	0
• Document Template Form	3004CATC	12/16/05	0
• Document Approval Process	3005CATC	12/16/05	0
• Document Request Approval Form	3006CATC	12/16/05	0
• Customer Comment Process	3008CATC	12/16/05	0
• Comment Form	3009CATC	12/16/05	0
• Control of Records	3010CATC	12/16/05	0
• External Document Master List	3014CATC	08/15/06	0
• Internal Audit Procedure	3016CATC	12/16/05	0
• Internal Audit Attributes	3017CATC	12/16/05	0
• Internal Audit Schedule	3018CATC	12/16/05	0
• Internal Audit Plan Form	3019CATC	12/16/05	0
• Internal Audit Checklist	3020CATC	12/16/05	0
• Internal Audit Opening Meeting Agenda Checklist	3021CATC	12/16/05	0
• Internal Audit Closing Meeting Agenda Checklist	3022CATC	12/16/05	0
• Internal Audit Attendance Log	3023CATC	12/16/05	0
• Nonconformance Form	3024CATC	12/16/05	0
• Internal Audit Report Form	3025CATC	12/16/05	0
• Operating Procedure Action Procedure	3026CATC	12/16/05	0

Flow of current clinic processes

- Completed a process flow of current (2005) anticoag clinic processes
- Lots of variation – several nurses providing information about dose changes to patients
- Little use of evidence-based guidelines
- Waiting for lab results
- Pt. satisfaction low
- Pt. education 15 minutes

Community Anticoagulation Therapy (CAT) Clinic

- Provide patient education 60-90 minutes and ongoing
- Patients go to lab of their choice, POC testing, home INR monitor
- INRs faxed to CAT Clinic or provided via web
- Pt. notified of results same day and dosing decision made based on guidelines
- Referring physician notified of all results and changes in warfarin therapy

ACCP Guidelines

- Why use guidelines to manage anticoagulation?
 - To reduce gaps in knowledge
 - To reduce safety issues surrounding anticoagulation
 - Both of the above promote standardization in the practice of managing patients taking warfarin

Guidelines

- Maintenance Therapy
 - Make small changes to warfarin – increase or decrease dose 5-15%, if INR between 1.0 and 5.0
 - Calculate the weekly dose and adjust according to the total weekly dose. If patient taking 5mg/day=35mg/week. If dose increased or decreased by 10% = 3.5mg/week
 - Check INR every 4 weeks at a minimum
- Give the warfarin time to work- may take 48 hours to see a change in INR

What affects how warfarin works?

- Other medications – antibiotics, herbs, aspirin products, chemotherapy, NSAIDs, amiodarone (decrease warfarin by as much as 30%)
- Diet – amount of vitamin K in foods
- Alcohol – warfarin is synthesized in the liver
- Exercise
- Stress

What does all of this mean?

- Each time the patient has an INR (especially if elevated or low), ask about changes in medication, OTCs, alcohol, diet, stress, missed/extra doses
- Each face-to-face or telephone visit is a great opportunity to reinforce (anticipatory guidance)
- If dose is changed, ask pt. to repeat instructions; clarify dose vs. pill size (5mg = 1 pill)

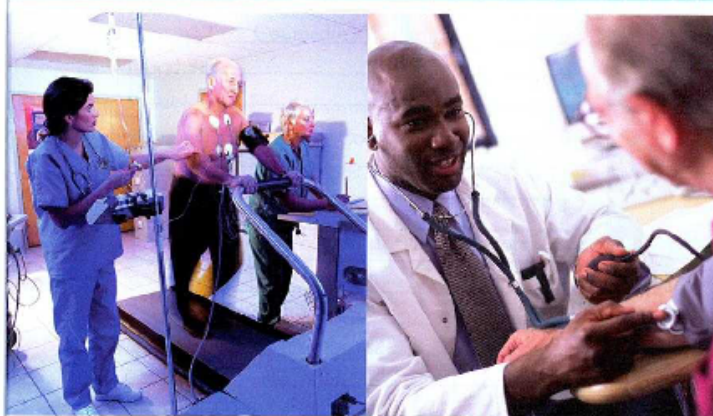
What does all of this mean?

- It takes time to educate – more than a 10 or 15 minute office visit

Education and Communication

- Educate, Educate, Educate
 - Health Literacy – 50% of adult population reads below 8th grade level
 - Joint Commission National Patient Safety Goal #13 - *Encourage patients' active involvement in their own care as a patient safety strategy.*
 - Find patient friendly materials such as “Your Guide to Coumadin®/Warfarin Therapy”
-
- Teach back – ask “Just so I know I explained things correctly, can you tell me 3 signs of bleeding that you need to report to your Dr.”

Your Guide to Coumadin®/Warfarin Therapy



Agency for Healthcare Research and Quality
Advancing Excellence in Health Care • www.ahrq.gov

Medical Record

- CAT Clinic utilizes a web-based electronic medical record www.inrpro.com
- Automatic list of patients due for INRs
- Warfarin log – easy to read
 - Control Chart
 - Next apt. date
 - Sent to referring physician
- Reports at the click of a button

Testing Site MMCLP

Patient's Name: [REDACTED]

Phone Number: [REDACTED]

Physicians Name: [REDACTED]

Diagnosis: NUT R1 MR 2-3

Tablet Size

10mg

Date	Return Appointment	FT/Ratio/INR	Physician Orders	Notified Pt. Initials
1/20/05		11.9 1.1/1.0 5.5 mmol	10 SSIT	Brian
3/11/05			notified 10 mg PT drawn	
3-28-05	received 3-30-05	15.4 1.72 12.5 QD 60 p		Brian/KR
4-11-05		20.6 3.10 10 mg QD rev 6 days		Brian/KR
4-28-05		15.9 1.83 10 mg QD rev 1 WK		Brian/KR
5-10-05		14.8 1.4 15 mg QD 1 WK		Brian/KR
5-10-05		18.5 2.9 10 mg QD 1 WK		Brian/KR
5-10-05		31.5 6.8 40 mg QD 1 WK		Brian/KR
5-13-05		18.7 2.5 10 mg QD 1 WK		Brian/KR
5-23-05		12.8 1.2 15 mg QD 1 WK		Brian/KR
5-31-05		26.0 4.67 40 mg QD 1 WK		Brian/KR
6/27/05		14.2 1.9 10 mg QD 1 WK		Brian/KR
7-22-05		19.7 2.7 10 mg QD 1 WK		Brian/KR
8/10/05		11.3 1.9 10 mg QD 1 WK		Brian/KR
9-13-05			pt total to get protimedone	
9-14-05		10.0 1.0 10 mg QD 1 WK		Brian/KR
9-27-05		15.3 1.7 10 mg QD 1 WK		Brian/KR
10-12-05		23.8 3.9 10 mg QD 1 WK		Brian/KR
10/20/05		16.4 1.9 10 mg QD 1 WK		Brian/KR
11/11/05		15.3 1.7 10 mg QD 1 WK		Brian/KR
12-24-05		22.5 3.5 10 mg QD 1 WK		Brian/KR
1-13-06		total pt to do protimedone		Brian/KR
1-19-06		17.8 2.2 15 mg QD 1 WK		Brian/KR
2-21-06		26.1 4.5 10 mg QD 1 WK		Brian/KR
2-24-06		13.7 1.3 10 mg QD 1 WK		Brian/KR
3-7-06		15.3 1.6 10 mg QD 1 WK		Brian/KR
3-22-06		15.5 1.7 10 mg QD 1 WK		Brian/KR
4-12-06		14.2 1.4 15 mg QD 1 WK		Brian/KR
4-21-06		22.2 3.3 15 mg QD 1 WK		Brian/KR
5-9-06		13.8 1.3 15 mg QD 1 WK		Brian/KR
5-26-06		21.7 3.2 10 mg QD 1 WK		Brian/KR



Working Together for Patient Safety

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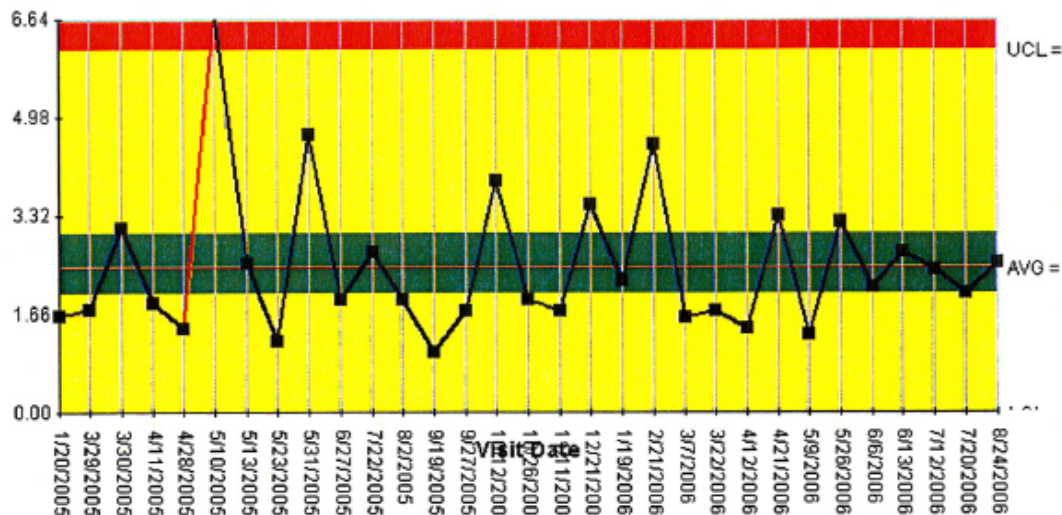
Office: 319.558.4046

Fax: 319.558.4049

Community Anticoagulation Therapy (CAT) Clinic
Patient INR History

1/19/2006	Prior Visit	2.2	flag	0		
2/21/2006	Prior Visit	4.5	flag	0		
3/7/2006	Prior Visit	1.6	flag	0		
3/22/2006	Prior Visit	1.7	flag	0		
4/12/2006	Prior Visit	1.4	flag	0		
4/21/2006	Prior Visit	3.3	flag	0		
5/9/2006	Prior Visit	1.3	flag	0		
5/26/2006	Prior Visit	3.2	flag	0		
6/6/2006 5:04:57 PM	Scheduled Visit	2.1	flag	0	Warfarin	Pt. reports no changes to diet or signs of bleeding. He did go to Dr. today re: head going numb and red leg. Dr. prescribed Levaquin for 10 days for cellulitis of leg. Pt. verbalized understanding to continue warfarin 85 mg/week and to recheck protime/INR on 5/9/06 due to Levaquin.
6/13/2006 4:39:05 PM	Scheduled Visit	2.7	flag	0	Warfarin	Left a message on cell phone to continue warfarin 85 mg/week and recheck protime/INR in one month. 6/13/06 at 4:58 PM received phone call from pt. He reports 3 more days of Levaquin and lower leg is still swollen and sore. Verbalized understanding to remain on warfarin 85 mg/week and recheck protime/INR in one month. Reluctant to call Dr. Justice to report increased swelling and pain in leg.
7/12/2006 10:58:25 AM	Scheduled Visit	2.4	flag	0	Warfarin	7/11/06 at 4:30, pt. reports redness and swelling of left lower leg. He reports he is on his way to St. Luke's ER. 7/12/06 at 9:48 AM pt. reports visit to ER included checking for DVTs. He reports the ER physician diagnosed cellulitis in both lower legs. Prescribed Levaquin, Doxycycline, and lasix. Verbalizes understanding to continue warfarin 85 mg/week and recheck protime/INR on 7/21/06.
7/20/2006 6:31:21 PM	Scheduled Visit	2	flag	0	Warfarin	Pt. denies changes to diet or signs of bleeding or clotting. Continues on Doxycycline. Verbalizes understanding to continue warfarin 85mg/week and recheck protime/INR in one month.
8/24/2006 8:24:23 PM	Scheduled Visit	2.5	flag	0	Warfarin	8/25/06 at 1:26 PM, pt. verbalizes understanding to continue warfarin 85mg/week and recheck protime/INR in one month.

INR Results for [REDACTED] [451.19 Deep Vein Thrombosis, DVT]



Green area denotes recommended patient INR range [2 - 3]
 Yellow area denotes readings that are outside of INR range, but within individuals' typical INR range of readings
 Red area denotes readings that are outside of individuals' typical INR range of readings

Average INR (calculated) = 2.45
 Std Dev INR = 1.23
 Upper Control Limit (UCL)* = 6.14
 Lower Control Limit (LCL)* = 0
 * based on 3 standard deviations

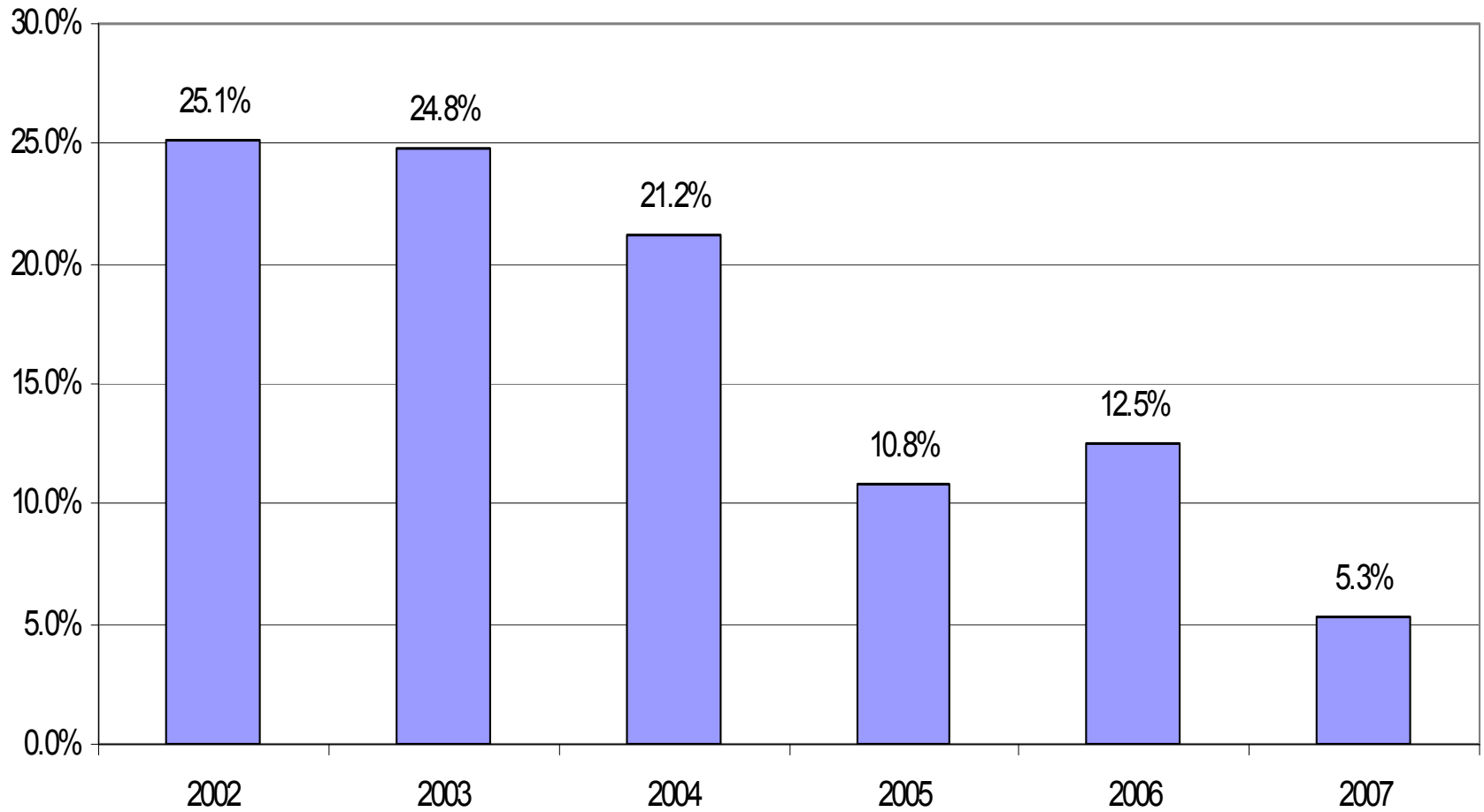
Percent Within Range (Green Area) = 25.81% [8/31]
 Percent Above Range (Yellow and Red Area) = 25.81%
 Percent Below Range (Yellow and Red Area) = 48.39%

Total Dosage Amount per week (last change) = 85 mg

Dosage Change History

Date	SUN	MON	TUE	WED	THU	FRI	SAT	Total
5/31/2006 [delete]	10	15	10	15	10	15	10	85
2/21/2006 [delete]	10	10	10	10	10	10	10	70
1/19/2006 [delete]	15	15	15	15	15	15	15	105
12/21/2005 [delete]	10	10	10	10	10	10	10	70
10/12/2005 [delete]	10	15	10	0	10	15	10	70

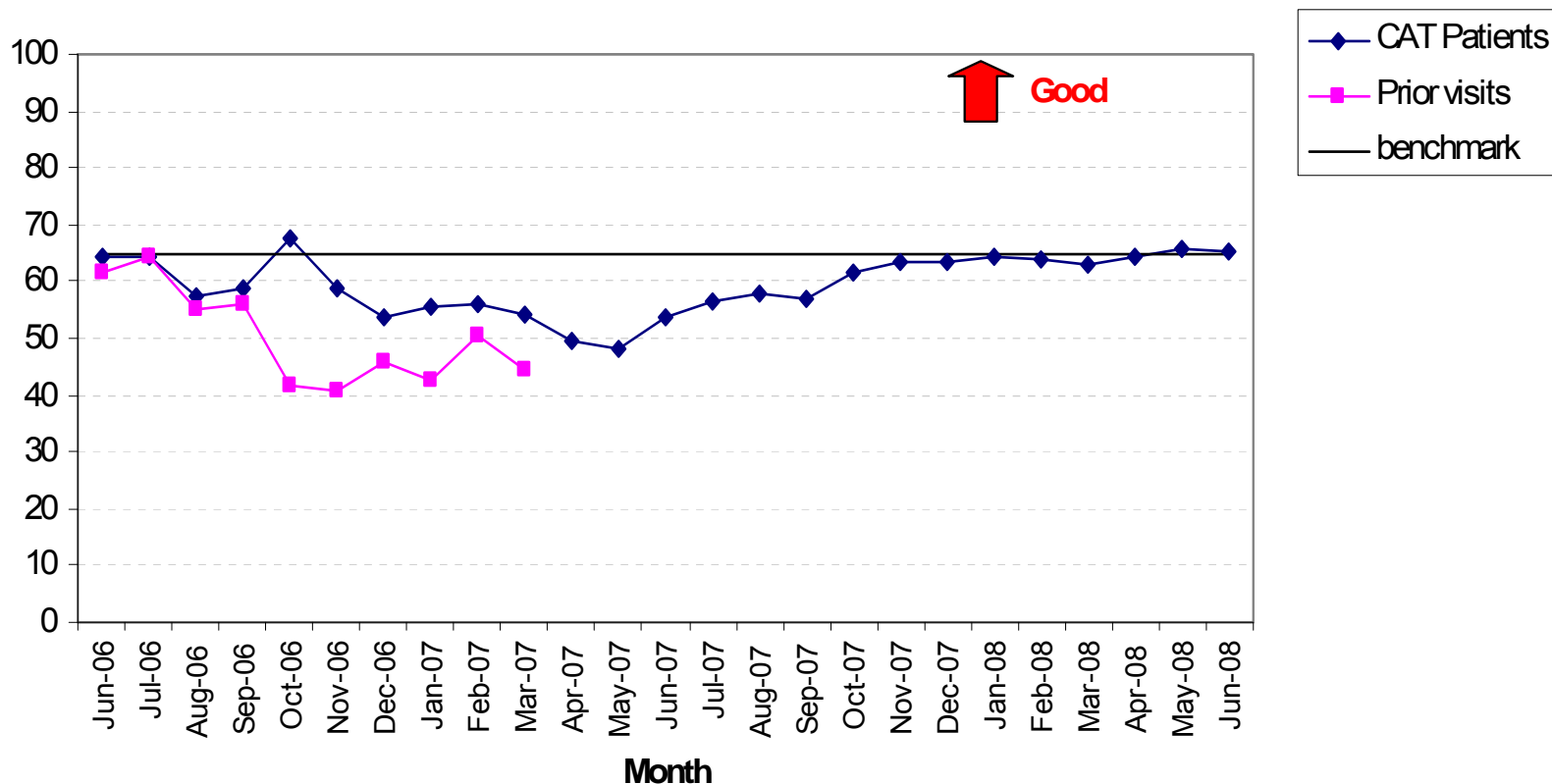
Percent of total inpatient ADEs related to warfarin (St. Luke's)



Start Date: <input type="text"/> (mm/dd/yyyy)	All Primary Diagnosis <input type="text"/>
End Date: <input type="text"/> (mm/dd/yyyy)	All Secondary Diagnosis <input type="text"/>
Patient Age >= <input type="text"/> and < <input type="text"/>	All Referring Physicians <input type="text"/>
All Visits <input type="text"/>	All Labs <input type="text"/>
Active Patients Only <input type="text"/>	All Physician Groups <input type="text"/>
All Patient Genders <input type="text"/>	All Pharmacies <input type="text"/>
All Patients <input type="text"/>	All Physicians Reviewing INR data <input type="text"/>
All Data Entered by Users <input type="text"/>	

<p align="center">Preferred Methods for Calculating Therapeutic Time in Range</p> <p align="center">Displays calculations using following three methods: Traditional [% visits in range], Rosendaal [% days in range], and Cross Section [last visit in range]</p> <p align="center">Expand INR range <input type="text"/> 0.0 on high and low end (ex: expanding 0.15 changes 2-3 range to 1.85 and 3.15)</p> <p align="center">Ignore first <input type="text"/> 14 days after first test result</p> <p align="center"><input type="button" value="Run Report"/></p>	
<p>Multiple Patient Visits within the Month</p> <p align="center"><input type="button" value="Run Report"/></p>	<p>Patient Visit Activity by Hour</p> <p>Activity: <input type="text"/> -- Select One -- <input type="text"/></p> <p align="center"><input type="button" value="Run Report"/></p>
<p>Quantity of Visits per Day</p> <p align="center"><input type="button" value="Run Report"/></p>	<p>Percent Breakdown of Patient Age</p> <p align="center"><input type="button" value="Run Report"/></p>
<p>Percent Breakdown for Poor INR Readings</p> <p align="center"><input type="button" value="Run Report"/></p>	<p>Percent Breakdown of Primary Diagnosis</p> <p align="center"><input type="button" value="Run Report"/></p>
<p>High and Low 'Out of Range' Breakdown (Traditional Method)</p> <p align="center"><input type="button" value="Run Report"/></p>	<p>Patient Priority for Improvement (Most Out of Range Visits)</p> <p align="center"><input type="button" value="Run Report"/></p>
<p>Patient Response Time reports</p> <p align="center"><input type="button" value="Run Report"/></p>	<p>Patient Referrals</p> <p>Number of patients referred by medical contact</p> <p align="center"><input type="button" value="Run Report"/></p>
<p>Average CAT Scores by Patient</p> <p align="center"><input type="button" value="Run Report"/></p>	<p>Average Pre/Post Test Scores by Patient</p> <p align="center"><input type="button" value="Run Report"/></p>
<p>Missed Visits by Patient</p> <p>Number of Days Late: <input type="text"/> 2</p> <p align="center"><input type="button" value="Run Report"/></p>	<p>Dose Changes per 100 Days of Patient Therapy</p> <p align="center">Entering Start Date in filter above is Recommended</p> <p align="center"><input type="button" value="Run Report"/></p>
<p>% Physicians Contacted per Visit</p> <p align="center"><input type="button" value="Run Report"/></p>	<p>Complications Requiring Hospital Admissions</p> <p align="center"><input type="button" value="Run Report"/></p>

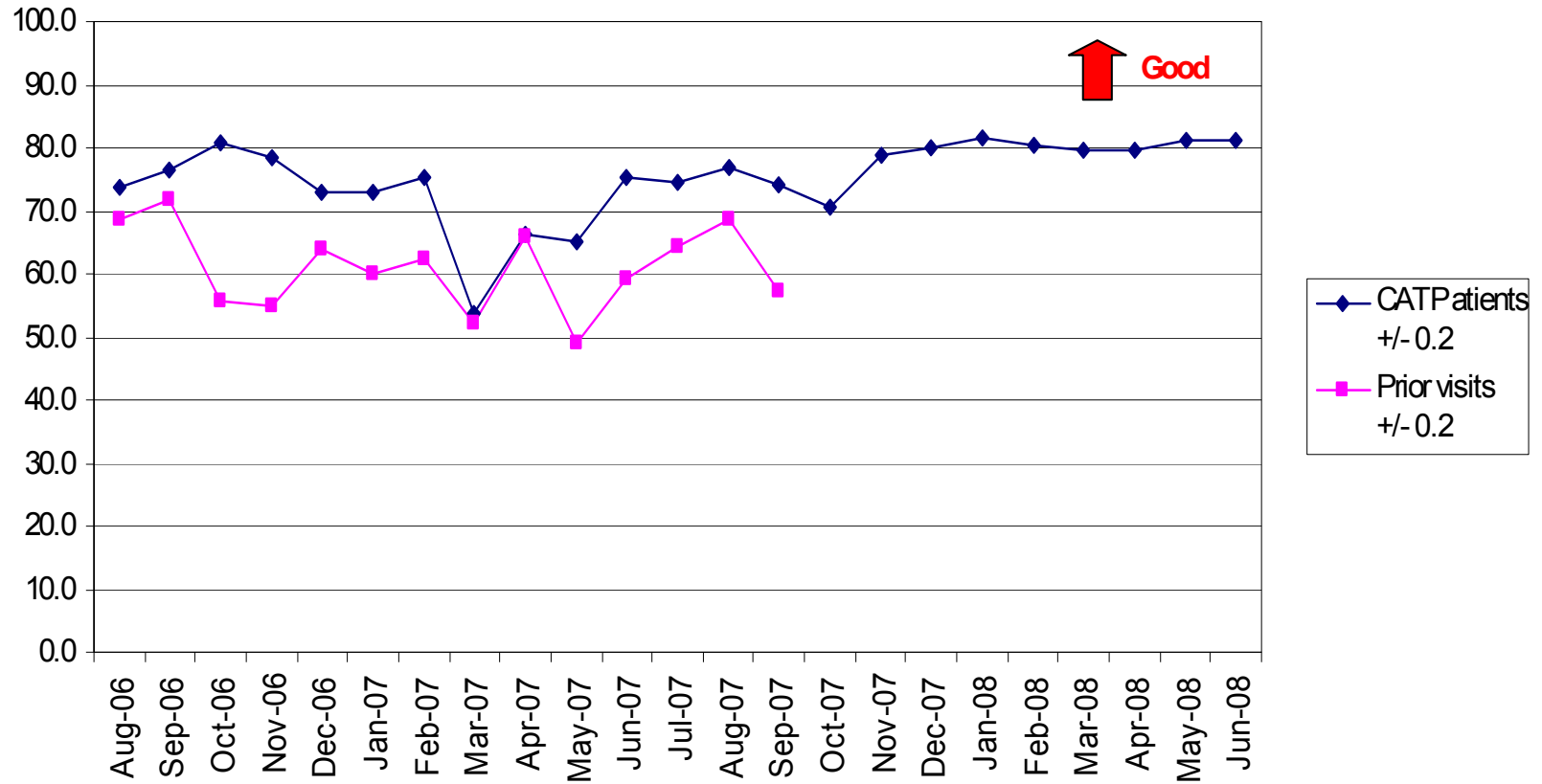
Percent of Time Patients in INR Range Rosendaal



Median % of Time in INR Range (CAT Clinic) = 59%

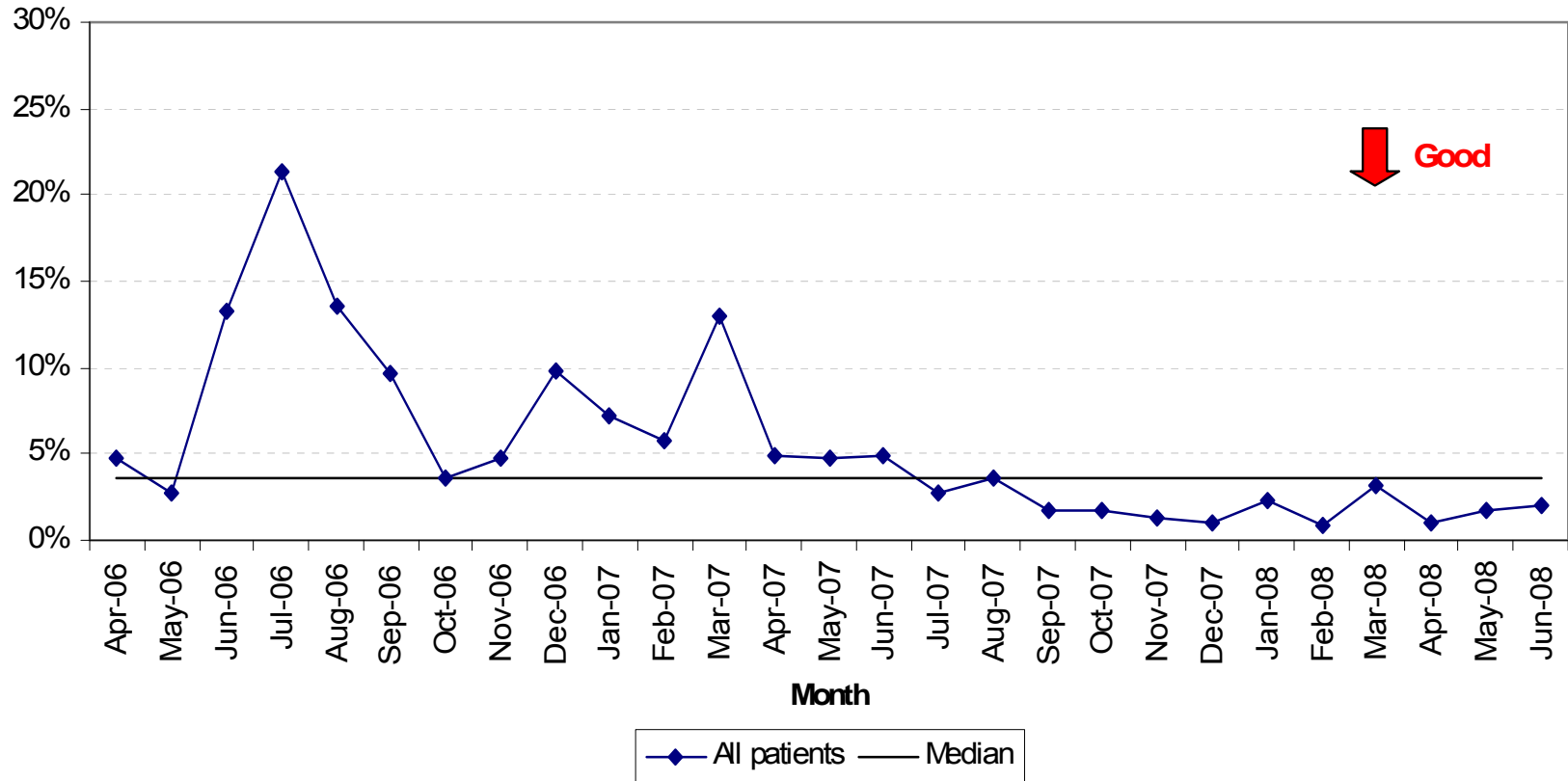
Benchmark - JCAHO, Journal of Quality
and Safety, Vol. 29 (12), 2003 and
AC Forum 2007.

Percent of Time Patients in INR Range ± 0.2



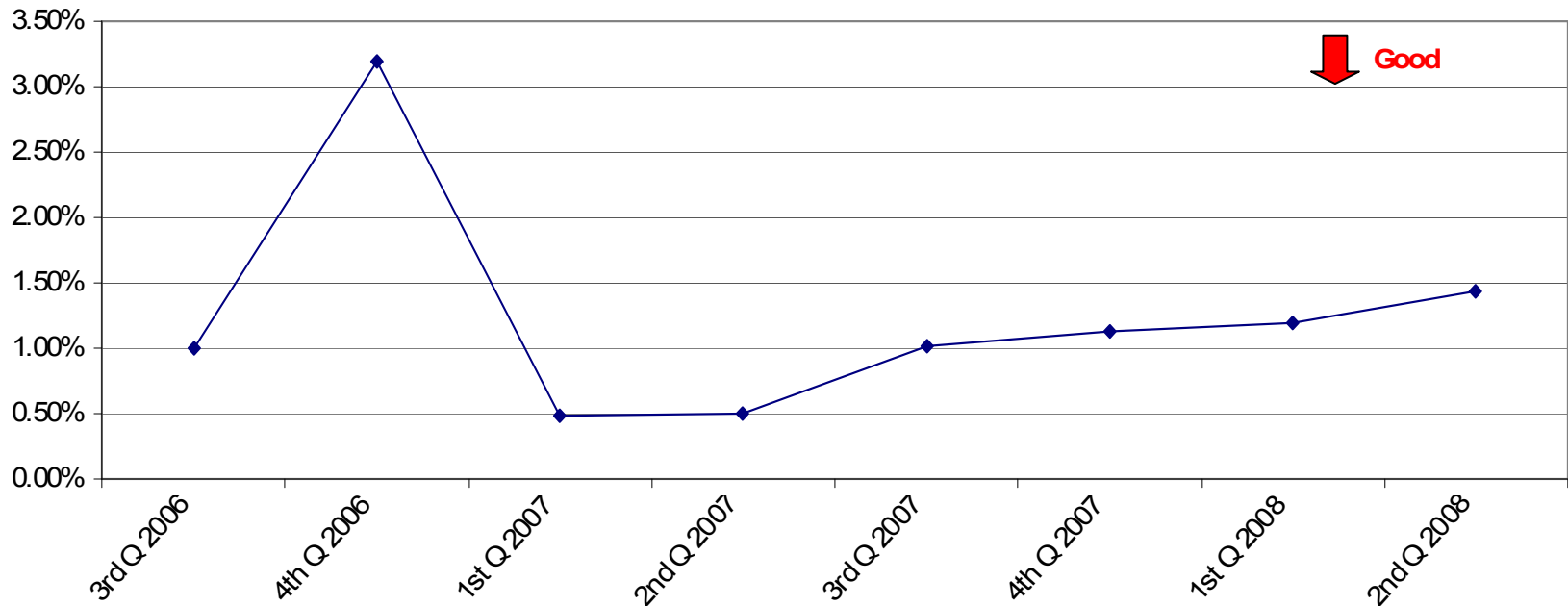
CAT Clinic patients in tighter range

Physician Contacts



This graph shows a decrease in the number of physician contacts (the number of times the CAT Clinic nurse needs to contact the referring physician). This number should decrease as patients are in INR range a greater percent of the time.

%of INRs > 5

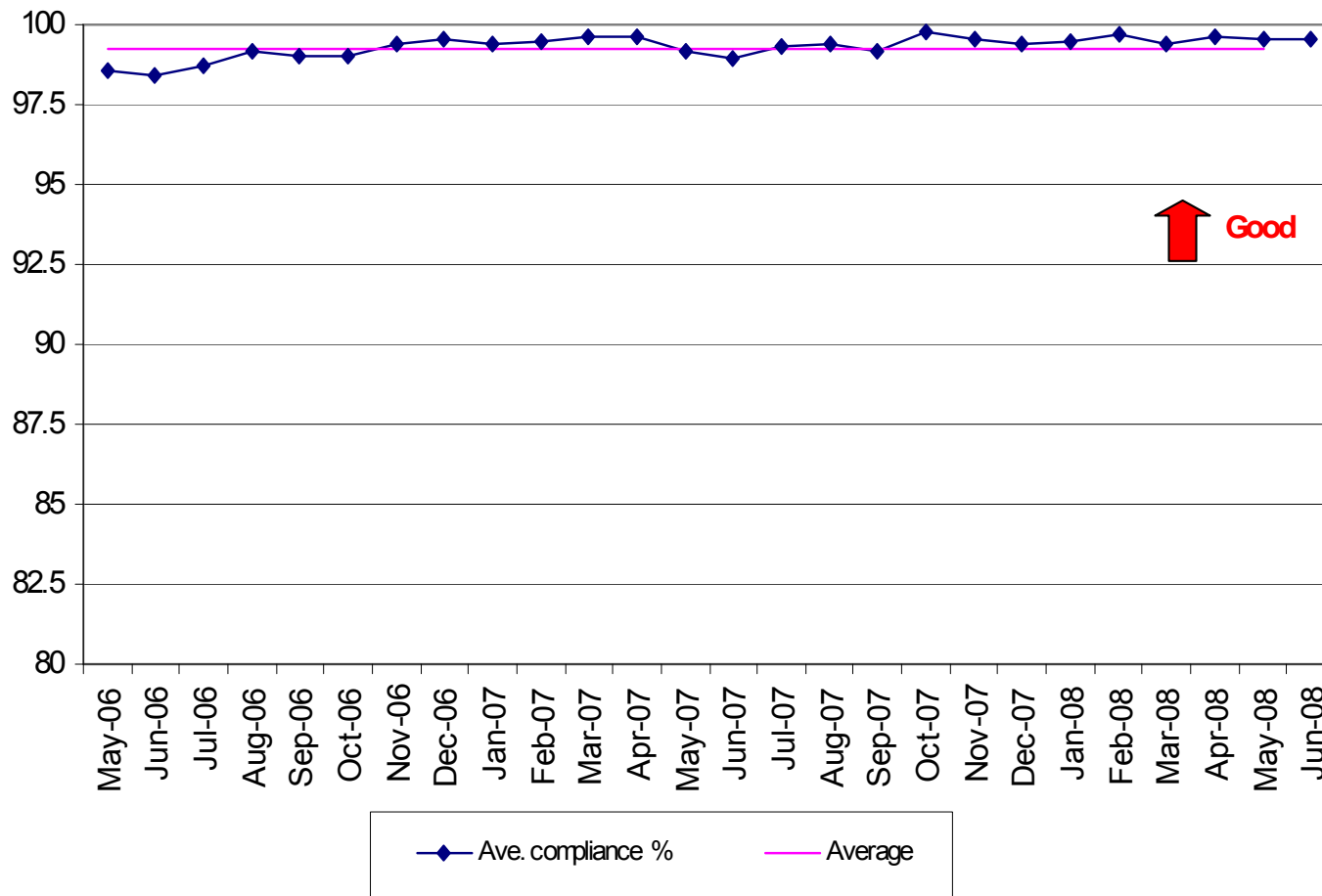


The graph shows the percent of INRs greater than 5. There have been two associated major bleeds in 2007 (GI bleeding, requiring hospitalizations, one pt. taking NSAID, another pt. taking ASA and started on Amiodarone) with the INRs greater than 5.

Benchmark 7%, Chiquette, Amato, Bussey, 1999.

Warfarin Compliance Assessment Scale - #6515CATC		
	Points	Patient Score
Missed doses (not prescribed)		
•→ Missed one dose in a week	1	
•→ Missed two doses in one week	2	
•→ Missed 3 or more doses	3	
Additional doses (not prescribed)		
•→ Took 1 extra dose	1	
•→ Took 2 extra doses	2	
•→ Took 3 or more doses	3	
	Points	Patient Score
Diet: How has your diet changed over the past week?		
•→ Ate 1—2 more servings than usual of Vitamin K foods	1	
•→ Ate 3—4 more servings than usual of Vitamin K foods	2	
•→ Ate 4 or more servings than usual of Vitamin K foods	3	
•→ Ate 1—2 less servings than usual of Vitamin K foods	1	
•→ Ate 3—4 less servings than usual of Vitamin K foods	2	
•→ Ate 4 or less servings than usual of Vitamin K foods	3	
Alcohol consumption		
•→ Drank the usual amount of alcohol in the past week	0	
•→ Drank more than your usual amount of alcohol this past week	1	
•→ Binged (drank excessive amounts) of alcohol 1 or more times this past week	2	
Medication		
•→ Started or stopped an antibiotic in the past week	Yes--1 No--0	
•→ Started or stopped an herbal supplement in the past week	Yes--1 No--0	
•→ Started or stopped an aspirin-containing product or an NSAID in the past week	Yes--1 No--0	
•→ Started or stopped <u>amiodarone</u> or another medication this week	Yes--1 No--0	
Total Score		
Compliance Assessment Scale created by CAT Clinic 2006		

Average Compliance Score



Toolkit Items

- ISO Executive and Staff Training Modules
- INRPro Database – www.inrpro.com
- Organized Document System – 70 documents
- Compliance Assessment Scale
- Patient Education – *Your Guide to Coumadin®/Warfarin Therapy*
- Staff Education Modules

Summary

- Identify the challenges and barriers to implementing medication safety tools
- Explain the importance of utilizing evidence-base guidelines for managing warfarin therapy
- Explain the importance of education for patients taking warfarin
- List the advantages of dedicated anticoagulation clinics

References

- www.crhealthcarealliance.org Cedar Rapids Healthcare Alliance
 - www.chest.org Most recent anticoagulation management guidelines
 - My Guide to Warfarin Therapy
www.crhealthcarealliance.org
 - Your Guide to Coumadin[®]/Warfarin Therapy
-
- www.inrpro.com



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Carla S. Huber, ARNP MS

CAT Clinic

600 7th Street SE

Cedar Rapids, IA 52401

319-558-4046

chuber@pcofiowa.com

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