UMASS Memorial Health Care

Improving Patient Care Management

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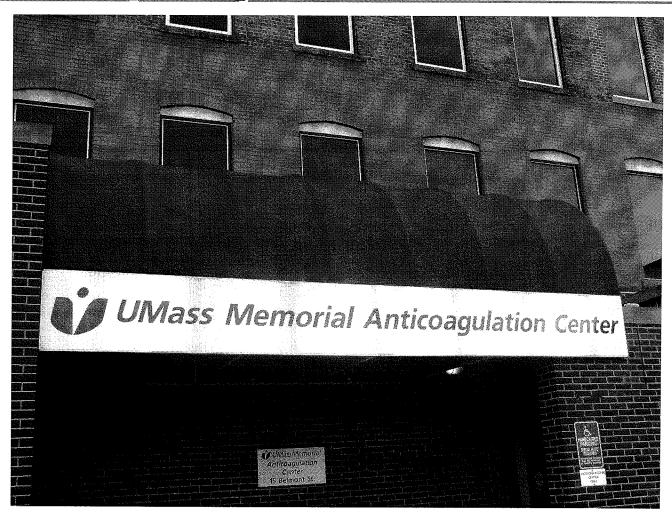
Presented November 4, 2008

Historical Perspective

- Coordinated Anticoagulation Clinics in United States Since 1950
- UMass Medical Center (UMMC) Established
 1970s
- Point of Care (POC) Testing 1980s approximately 250 patients
- Patient Self Testing (PST)/Patient Self Management (PSM) 1980s

14 patients/1 continues with PST/PSM

UMassMemorial Healthcare (UMMHC) Anticoagulation Center (ACC)



UMMHC ACC

- Warfarin /POC Testing
- Peri-Procedure/Operative
- Patient Self Testing
- Thrombophilia Screening
- High-Risk Pregnancy

UMMC ACC

- Approx 1650 active patients
 - 65% Point-of-care
 - 23% Lab draw/VNA
 - 12% patient self testers/pending

UMMC ACC

- Quality Measures
 - Time in Therapeutic Range (TTR)Benchmark: 66%
 - -Thrombotic/Hemorrhagic Events
 - PresGaney-Patient Satisfaction

Greater Rates of TTR

- Health Belief System
- Patient Education
- Communication
- Face-to Face Encounter

Greater Rates in TTRHealth Belief System

- Motivation
- Perceived Vulnerability
- Perceived Seriousness
- Perceived Costs/Benefits
- Cue to Action

Greater Rates of TTREducation

- Indication
- Rational
- INR Range
- Pill Strength/Color
- Weekly Dose
- Generic/Brand name

Provider Managing Therapy Writes Script

Greater Rates of TTRCommunication

- Provider/Patient
 - Verbal, Written, Contract, Access
- Patient/Provider
- Provider/Provider
 - Transition inpt/outpt
 - 1. Referral
 - 2. Medication Reconcilliation

Greater Rates of TTR Face-to-Face Encounter

- Assessment
- Non-Verbal Communication
- Verbal Prompts
- Real Time Management

Patient Self Testing (PST)

- Used in Europe since 1980's
- FDA approved
- Third party reimbursement has limited progress in United States

Objectives

- Empower patients to take control
- Promote patient satisfaction
- Improve quality of life
- Provide Safe care
- Provide mechanism for patients to test on a more frequent basis with less disruption in lifestyle

Insurance Timeline

- 2002-Medicare covers mechanical heart valves (MHV)
- 2002-Blue Cross/Blue Shield (BC/BS) MA covers MHV
- 2003-BC/BS anticoagulation to similar levels intensity (INR > 3.0) as MHV
- 2006-Harvard Pilgrim and Tufts cover all indications
- 2008-CMS, BCBS MA add Chronic AF, VTE

CMS Criteria

- 3 months warfarin therapy for MHV, chronic AF or VTE
- Initial face-to-face education and demonstrated use of the device
- Limited to no more than weekly testing
- Face-to-face verification by MD minimum of once/year (E/M visit)

Billing Codes

- G0248-Demonstration/training at initial use
 - **\$299.00** one time fee
- G0249-Provision of the test materials/equipment
 - **\$280.00** for 4 test results
- G0250-Physician review, interpretation and patient management
 - **\$9.00** per 4 tests

Active Approved Devices

- INRatioHemosense
- Protime MicrocoagulationInternational Technidyne
- CoaguchekRoche Diagnostic

Service Companies

- Quality Assured Services
 <u>www.QualityAssuredServices.com</u>
- Philips Cardiac Services (Raytel) www.philips.com www.inrselftest.com
- Tapestry Medical www.coagnow.com

Private Pay

Monitor\$1300.00 to \$1600.00

Supplies\$13 to \$25 a test

Patient Criteria

- Compliance*
- Physically Capable
- Mentally Competent
- Communication

*Possible patients are non-compliant d/t inconvenience of frequent blood tests

Education

Fingerstick

- Proper technique/location
- Increase blood flow (warming/gravity)
- 3. Application

Device

- 1. On/Off
- 2. Setting Date
- 3. Correlation Strips
- 4. Return Demonstration

Contract

UMMHC Anticoagulation Clinic Patient Totals By Indication

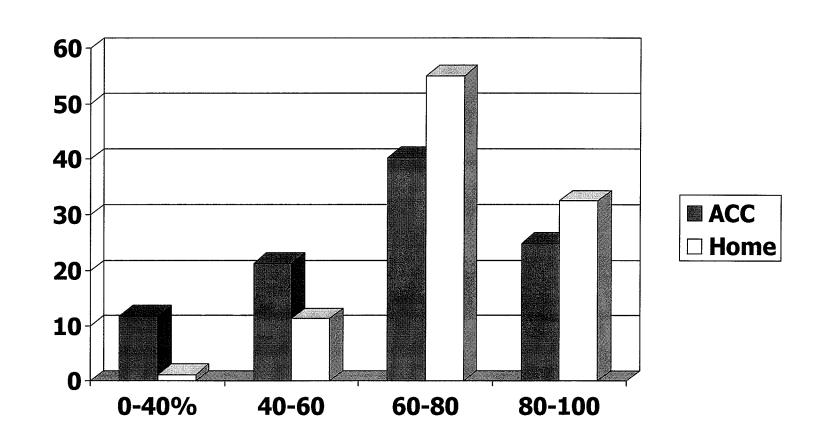
9/30/07 thru 9/30/08

	All	AF	DVT PE	MHV	CVA TIA	MI/ CHF	other
#Pt	2170	1022	531	225	84	45	263
% TTR	83	84.8	80.9	81.3	85	82.9	80.7

UMMHC Anticoagulation Clinic Patient Self Testing (PST) Program

- 115 patients
- 85 pending approval
- QAS, Raytel
- Protime, Hemosense and Coaguchek
- Education on site (G0248)
- Provider Interpretation (G0250)

UMMHC Anticoagulation Clinic TTR Comparison



UMMHC Anticoagulation Clinic

BRIDGING THERAPY

Objectives

 Provide a guideline for assessing thromboembolic and hemorrhagic risk.

 Utilize an algorithm to determine appropriate bridging strategy.

Definition

Bridging anticoagulation refers to the administration of therapeutic dose anticoagulation therapy with UF Heparin, LMWH or DTI for the 8 to 12 day period before and after surgery/procedure, during which time warfarin therapy is interrupted.

Options

- Continue Warfarin Therapy
- Withhold Warfarin Therapy
- Temporarily Withhold Warfarin and Provide a Short-Acting (Bridge)
 Anticoagulant

Experts

- Annual risk of thromboembolism is low, warfarin therapy may be held for 4 to 5 days before the procedure and restarted shortly thereafter. (American College of Chest Physicians)
- May be held for up to one week. (American College of Cardiology, American Heart Association, European Society of Cardiology)

Patient Selection

- No Universal Guidelines
- Moderate to High Risk for Thromboembolic Event
- Optional for Low Risk Patients

Bleeding Risk

- Very High Risk
 - Intracranial Surgery
 - Spinal Surgery
 - CABG
 - Valve Replacement

- High Risk
 - Pacer/Defibrillator
 - ProstateBiopsy/Surgery
 - Bowel Polypectomy
 - Total Knee
 - Total Hip
 - Bladder Tumor

Bleeding Risk

- Low Risk
 - Cataract
 - Skin
 - Endoscopy
 - Hernia
 - Gallbladder
 - Dental

Venous Thromboembolic Risk Scale

■ Low Risk

- DVT/PE >6 months without inherited thrombophilia or other risk factors
- Factor V Leiden/ProthrombinG 20210A
 gene mutation without prior event

Venous Thromboembolic Risk Scale

■ Intermediate Risk

- Factor V Leiden/ProthrombinG 20210A
 gene mutation with prior thromboembolic
 event > 12 months
- Protein C/Protein S/Antithrombin deficiency without prior event, but strong family history

Venous Thromboembolic Risk Scale

High Risk

- DVT/PE <6 months</p>
- Antiphospholipid antibody syndrome with prior thromboembolic event
- Factor V Leiden/ProthrombinG 20210A mutation with prior thromboembolic event < 12 months
- Protein C/Protein S/ Antithrombin deficiency with prior event

Arterial Thromboembolic Risk Scale

Low Risk

- Atrial Fibrillation (non-valvular)
- St. Jude Aortic Mechanical Heart Valve
- Dilated Cardiomyopathy

Arterial Thromboembolic Risk Scale

Moderate Risk

- Atrial Fibrillation with Valvular Disease
- Dilated Cardiomyopathy and Prior Thromboembolism (> 3 months)
- Anterior MI < 3 Months With No Other Risk Factors

Arterial Thromboembolic Risk Scale

High Risk

- Aortic St. Jude Mechanical Valve with AF or EF < 35%
- Mitral St. Jude Mechanical Valve
- Cardioversion < two weeks
- History of arterial thromboembolic event
- Antiphospholipid Syndrome plus prior event or additional risk factors
- Caged Ball Mechnical Heart Valves

CHADs

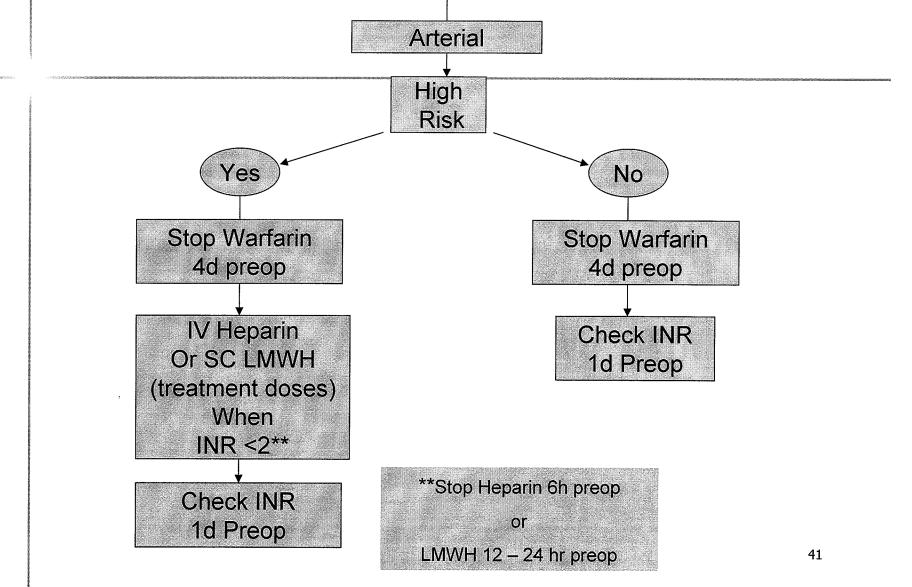
Nonvalvular Atrial Fibrillation

- Score calculated based on number of risk factors for stroke
- Prior CVA or TIA: 2 points
- CHF, HTN, Diabetes, age >75: 1 point each
- Bridging Recommended for score >5
- Consider Bridging >2
- Optional for < 2

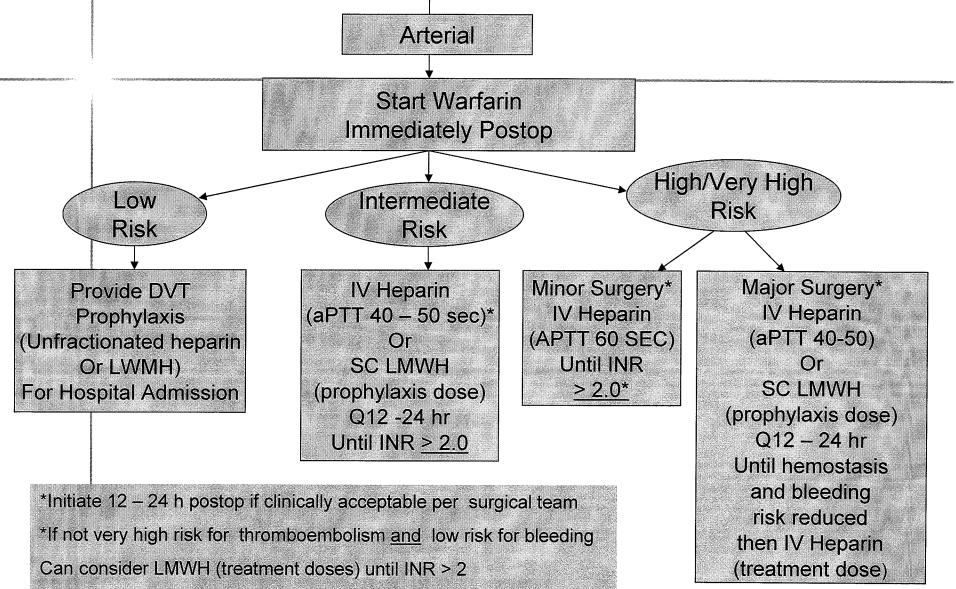
CHADS2

CHADS2 Score	Stroke Risk	% Annual Risk
0	low	1.9
1	low	2.8
2	moderate	4.0
3	moderate	5.9
4	moderate	8.5
5	high	12.5
6	high	18.5

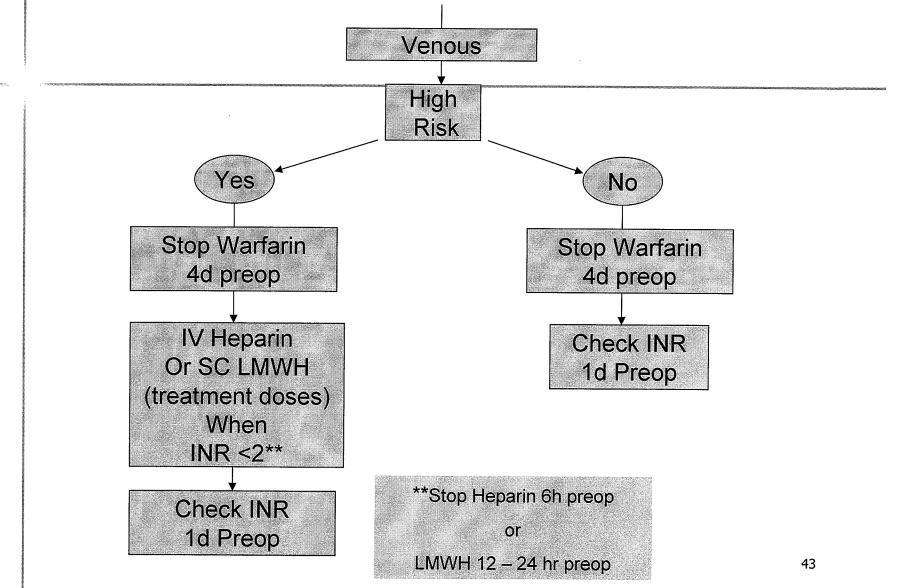
Preoperative Anticoagulation Indication for Warfarin - Arterial



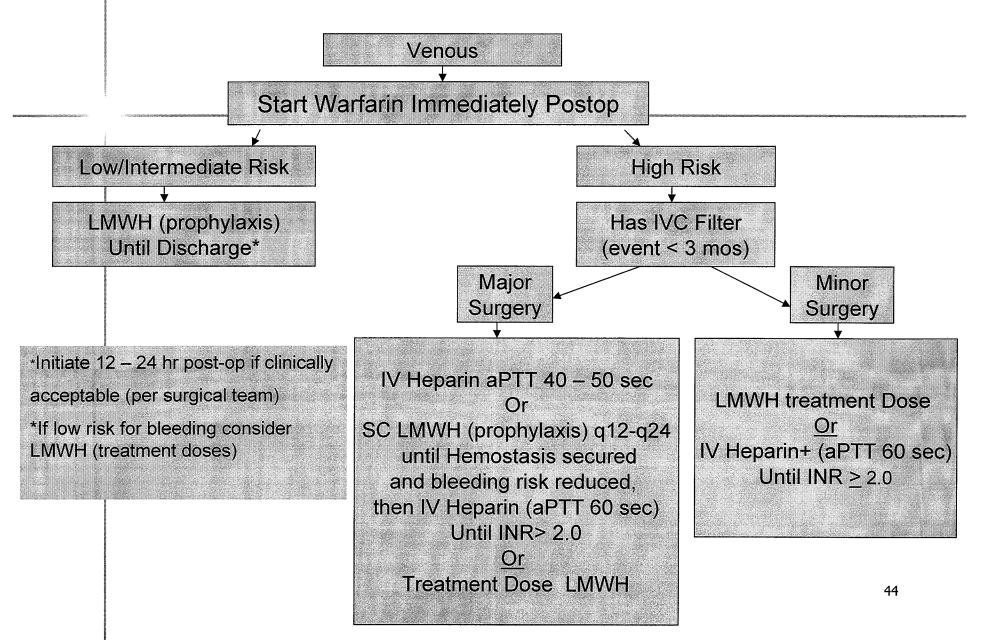
Postoperative Anticoagulation Indication for Warfarin - Arterial



Preoperative Anticoagulation Indication for Warfarin - Venous



Postoperative Anticoagulation Indication for Warfarin Venous



CONCLUSION

"It must be recognized that no alternative therapy has undergone the rigorous testing of large randomized controlled trials and that judgment must be made on the basis of available literature, expert opinion, a community standard, cost and patient preference."

Jack E. Ansell M.D.

THANK YOU

