Linking Clinical Evidence and Clinical Practice: Stroke Prevention and Atrial Fibrillation

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Center mission

The mission of the Duke Center for Clinical Health Policy Research (CCHPR) is to encourage the formation and implementation of sound clinical health care policies.

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Formation of clinical policy

Elements involved with the formation of clinical health policy include: (a) understanding what the decision maker (doctor, patient, administrator) requires in order to make an informed decision, (b) synthesizing and interpreting available evidence in a way that addresses those information needs, and (c) establishing new research efforts to fill in gaps in existing knowledge.

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Implementation of clinical policy

Implementation of clinical health policy involves (a) analyzing current practices, (b) comparing current practices with optimal practice, (c) designing strategies for practice improvement, and (d) evaluating the effects of these intervention strategies.

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Implementation of clinical policy

CCHPR addresses the entire spectrum of clinical health policy from its development using evidence-based approaches to strategies for optimal implementation. Our goal is to bridge theory and practice in a way that both advances the state of the scientific theory and is sufficiently pragmatic to actually improve health care practice.

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The Duke Evidence-Based Practice Center

- Designated by the Agency for Healthcare Research and Quality (AHRQ)
- Commissioned evaluations of medical practices
- Major contract to work with the Centers for Medicare and Medicaid Services

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The Duke Evidence-Based Practice Center

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- Commissioned evaluations of medical practices (by federal and public entities)
- Major contract to perform technology assessments for the Centers for Medicare and Medicaid Services (CMS)

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Clinical topic areas

- Disabling neurological disorders (e.g., stroke and cerebrovascular disease, multiple sclerosis, Alzheimer's disease, headache)
- Women's health (e.g., cervical cancer screening and treatment,fibroids)
- General medicine (e.g., anticoagulation, advanced chronic kidney disease, COPD)

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Background

- The central role of scientific evidence is clear
  - Historical trend
  - The concept of "evidence-based medicine" is established
- Yet, there are troubling discrepancies between scientific evidence and practice

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Wonderful practice improvement ideas

- RCT catalogue
- Decision/cost-effectiveness analysis
- Clinical guidelines
- Variations research
- Outcomes research
- TQM/CQI

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The 7-step model

The PORT integrative approach

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The 7-step model

- Step 1. Identify the potential target of opportunity
  - *A potential target of opportunity is a condition with high morbidity, prevalence and cost*

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Atrial fibrillation (AF) and stroke

- AF places individuals at substantially increased risk for stroke (5-6 x increased risk with AF; 15% of stroke attributable to AF)
- AF is common (5% of >65yo) and becoming more common
- AF-associated stroke cost ≈ $4 billion

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The 7-step model

- Step 2: Synthesize information about optimal practice
  - approaches include literature and meta-analysis, decision and cost-effectiveness analysis

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Illustration: Stroke Policy Model

- First version developed in 1993 by Stroke PORT, funded by AHCPR
- Goals of stroke PORT:
  - Summarize epidemiology of stroke
  - Describe best stroke prevention practices
  - Describe current practices, and test methods for improving practice

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Modules

- **Natural history module** -- generates patient histories
- **Cost module** -- attaches costs to patient histories
- **Utility module** -- attaches QOL to patient histories
- **Intervention module** -- modifies natural history parameters

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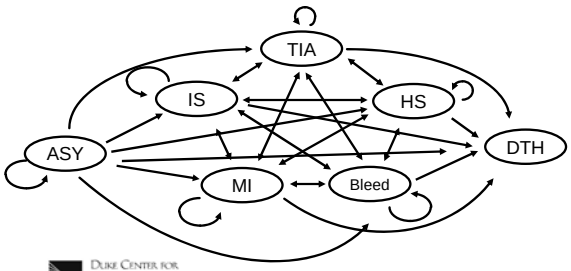
SPM Structure



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SPM Data Sources

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Known

- Warfarin is effective and cost effective if managed well
- Warfarin is underutilized
- Quality of management can be poor

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Warfarin is effective

- Warfarin, if given in a broad range of AF patients, reduces stroke risk by 2/3rds
- 20 to 25 strokes or MIs are avoided per major bleed

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Warfarin is cost-effective

Strategy	Cost	QALY	Δ Cost	Δ QALY	Δ CE
No Treatment	$87,181	9.081	--	--	--
Aspirin	$88,036	9.097	$855	0.0154	$55,633
Warfarin	$90,097	9.87	$2,062	0.7736	$2,665

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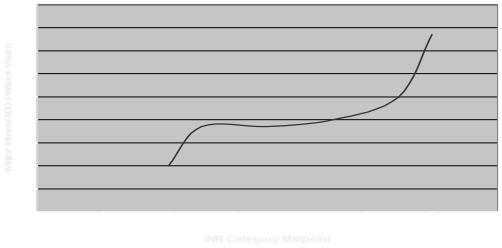
…if managed well: bleeding rates



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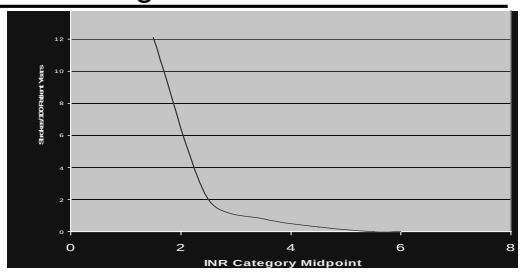
INR/Bleeding Relationship
(6085 Patient Years, 1003 Events)
From: van der Meer et al

…if managed well: TE rates



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INR/Stroke Relationship in
6475 Patient Years, 43 Events) From:
Cannegieter et al.

The 7-step model

- Step 3: Synthesize information about current practice
  - *sources include literature, other external data, administrative files, and chart audits*

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Warfarin use in AF is sub-optimal

- Less than 1/2 of individuals who are candidates for warfarin receive the drug
- Individuals receiving warfarin are in target range for INR less than 1/2 the time

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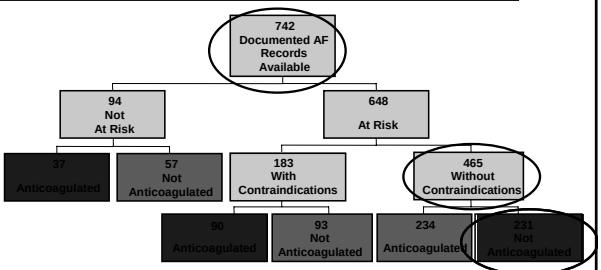
Warfarin is underutilized



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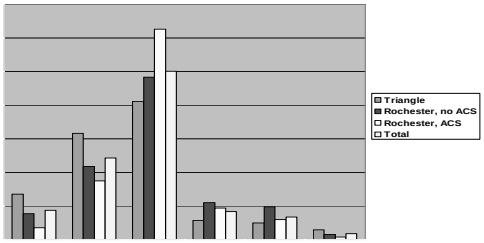
31% of AF pts. NOT TREATED

50% of appropriate pts. NOT TREATED

Distribution of INR days (n=34,297 days)



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- Step 4: Identify reasons for discrepancies between current and optimal practice
  - *sources include literature, focus groups and interviews, and experts*

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Primary barrier to optimal warfarin use in AF is need to improve coordination and follow-up

- Fear of bleeding
- Inconvenience
- Complex interactions of illness, drugs, diet, idiosyncrasies

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- Step 5: Develop a strategy for practice improvement
  - *Define the intervention functionally, develop a toolbox of implementation options, engage clinicians and administrators*

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Anticoagulation service: rationale

- The basic idea is for AC management to become one person's job, to be performed according to protocol, and to benefit from specialization and economies of scale
  - Physicians like to delegate the hassles
  - Patients like the extra attention

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Anticoagulation Service: Functional definition

- Management by a responsible individual
- Accountability to primary physician
- Use of a standard treatment protocol
- Maintenance of standardized records
- Patient education

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Anticoagulation Service Toolbox

- Structure options: physical, virtual, circuit-rider
- ACS manager training
- Role of referring MD
- Education options: who and where
- Educational materials: patient and MD
- Record keeping: paper, computer

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- Step 6: Assess effectiveness and cost-effectiveness of the practice improvement strategy
  - *Assessment options range from nothing to comparison with external benchmarks, pre-post comparisons and randomized comparison*

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ACS Assessment: MAST

- Randomize practice clusters
- Implement functional definition - confirm success with a checklist
- Investigators focus on assuring that sites satisfy scientific requirements, not micro-managing the ACS
- Outcomes measured pre/post and with concurrent controls

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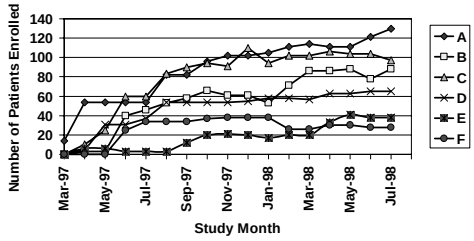
Uptake of ACS at MAST sites



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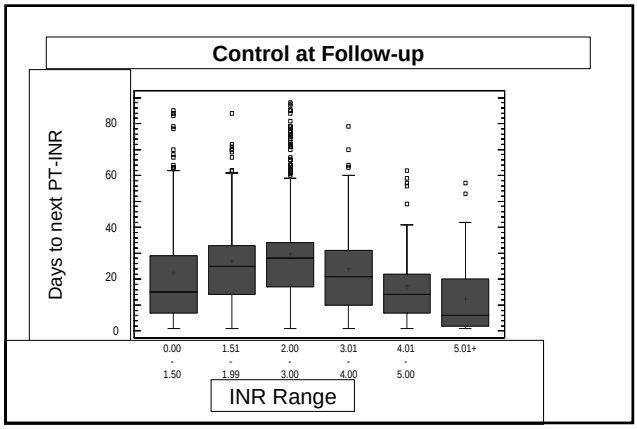

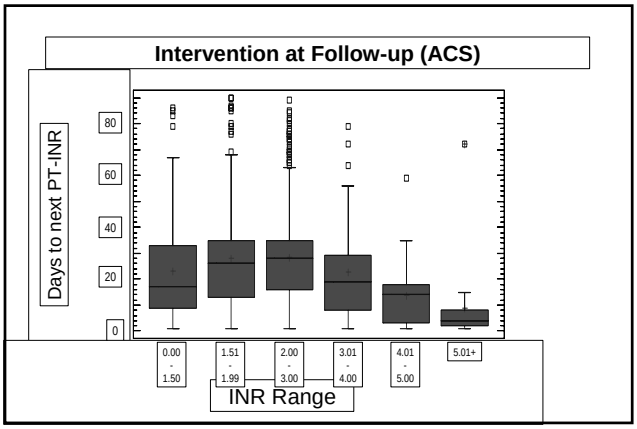

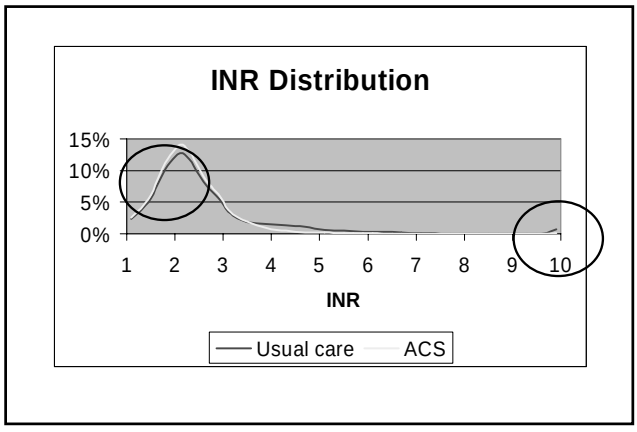

The 7-step model

- Step 7: Determine whether or not the practice improvement strategy should be implemented
  - *Develop a scorecard of gains and losses from perspective of the parties affected by the intervention to assist in determining whether to implement the practice improvement strategy*

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Per 1,000 patient-years	AC Care Scenario			
	No AC Available	Only Usual Care	ACS Available	PST/PSM Available
AC care				
Patients treated (N)	**0**	**400**	500	700
Management	$0	$93,656	$122,786	$148,073
Testing	$0	$33,965	$48,528	$146,647
Medication	$0	$97,824	$122,280	$171,192
Total care costs	**$0**	**$225,445**	**$293,593**	**$465,912**
Events				
Bleed				
Major GI (n)	0.39	3.03	2.67	2.33
Hemorrhagic stroke (n)	0.04	0.34	0.30	0.26
Minor (n)	4.36	33.72	29.70	25.90
Bleed cost	$7,228	$55,911	$49,237	$42,943
TE				
TE (n)	125	90	82	63
TE cost	$8,606,620	$6,219,921	$5,674,832	$4,305,406
Total event costs	$8,613,978	$6,275,956	$5,724,181	$4,348,438
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Patient self-management: rationale

- Frequent testing is likely to increase quality of anticoagulation
- Self-testing and self-management empowers the patient

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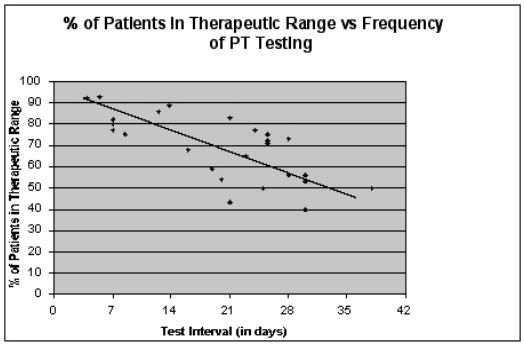

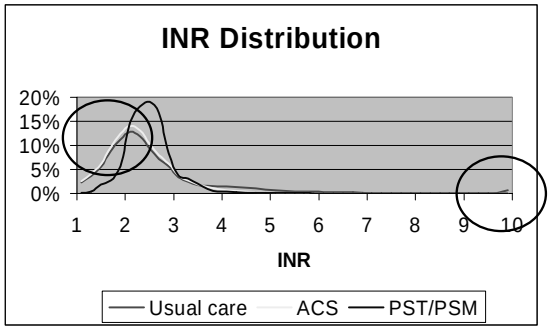

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Summary

- Evidence/evidence synthesis is one part of the puzzle in practice improvement activities
- Success of national efforts at identifying "best practice" depends on local implementation
  - the link is the functional definition and the toolbox
- Evaluation can be scientifically credible and practical

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Future considerations

- Limits of the "disease management strategy": seek alternatives, e.g., based on patient involvement, new technologies/ information systems
- Promote projects linking the products of evidence synthesis to practice improvement

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