MICHIGAN MEDICINE
UNIVERSITY OF MICHIGAN

Shared Decision Making

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What Is Shared Decision Making?

Increase the likelihood that patients receive the care they need in a manner consistent with best available research evidence and their values and preferences.

Seaburgh, Hess P, et al. Circ 2014

Shared Decision Making?

- Shared Decision-making is an open communication process between provider and patient
- An effective means of arriving at an agreement upon the best treatment strategy for many non-emergency health conditions
- Provider offers personalized information about treatment options, risks and benefits, and the patient communicates to the provider his/her values, preferences and concerns related to these variables

Health Literacy

Health Literacy: **The degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions**

N = 502 Veterans (22-82 years old)

Low Literacy = 29%

Marginal Literacy = 26%

Adequate Literacy = 45%

Rodriguez V, Andrade A, et al J. of Health Comm 2013

Ratzan and Parker, 2000

Numeracy

Half of adults in U.S. unable to accurately calculate a tip.

20% of college educated adults do not know which risks are higher:

1% 5% 10%

(NEED CITATION)

How To Clearly Communicate Risk To Patients

1. Present Statistical Info Using Absolute Risk

- Relative Risk: Statin will decrease risk of MI by 30%
- Absolute Risk: Risk of MI will decrease from 10% to 7%

2. Highlight the incremental risks associated distinctly from baseline risk

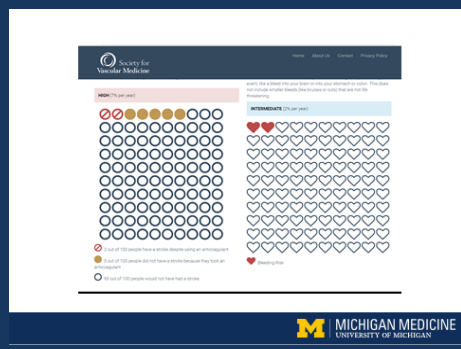
-Aspirin and anticoagulant and risk of bleeding
-Aspirin alone increases risk of bleeding.

Min 6 and Fagerlin A, 2014 Shared Decision Making

Communicating Risk

Use pictographs to communicate risk and benefit info

- Use of pictographs help all patients (regardless of numeracy) better comprehend info.
- More effective than bar graphs and tables.
- Equally effective to pie graphs.



Shared Decision Making

Patient Empowerment

CMS Innovation Project

- December 8, 2016 – CMS: 2 new models from the CMS Innovation Center to increase patient engagement in decisions
- Beneficiary Engagement and Incentives (BEI) Models are the Shared Decision Making Model (SDM Model) and the Direct Decision Support Model (DDS Model).
- BEI models will test different approaches to shared decision making, acknowledging that:
  - patients make decisions regarding treatment options in a variety of ways
  - facilitating a better understanding of their health and health care decisions is key towards improved patient engagement

Patient and Family Centered Care

- An approach to the planning, delivery and execution of health care
- A partnership between health care providers, patients and families
- Patients on teams, councils, and committees
- Empowers patients to ask questions, be involved and actively participate in programs/councils to improve care being provided to all patients

Shared Decision Making

- 1982: first coined the term "shared decision making," - process to improve physician-patient communication and informed consent in health care
- 30 years later, patient preferences and values about medical treatment choices are still routinely left out of important discussions between practitioner and patient

Principles of Shared Decision Making

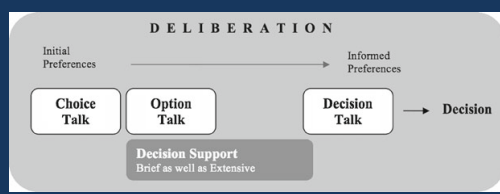
Individual Self determination:
Patient makes choice (Autonomy)

Clinicians support patient to achieve self-determination

Essential Process Elements in SDM

1. Define and explain problem
2. Present options
3. Discuss pros and cons/risks and benefits
4. Patient values and preferences
5. Discuss patient ability and self efficacy
6. Offer knowledge/communication
7. Check/clarify understanding
8. Make or defer decision
9. Arrange follow-up

Shared Decision Making: A Model for Clinical Practice



Choice Talk
Offer choice
Justify choice
Check reaction

Option Talk
Check knowledge
Describe options
Harms/Benefits
Provide patient decision support

Decision Talk
Focus on preferences
Move to a decision
Offer review

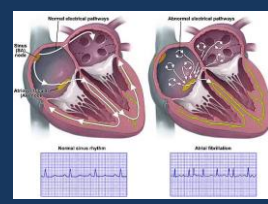
Shared Decision Making Decision Aid In NVAF Patient In DOAC Era

Background:

- Prevalence of AF – treatment options
- Focus on stroke risk and treatment
- DOACS have emerged as alternatives to warfarin
- Guidelines and experts recommend shared decision making when determining best OAC.
- Most decision aids don't include "values assessment"

Atrial Fibrillation and Anticoagulation

- A-fib represents a loss of normal contraction of the atria (upper chambers)
- Blood can become stagnant within the atria resulting in clot development
- Clots can break free and travel to the rest of the body
- In 2005, there were an estimated 3 million cases of A-fib, and it is projected that by 2050 there will be over 7 million cases.
- 70% of cases are patients over 65.
- 10% of patients over 80 have A-fib.



Afib Guideline, *Circulation 2006;114:e257-e354*

Outcomes

- After the diagnosis of atrial fib in the older adult, mortality is the most frequent major outcome in the first 5 years
- Heart Failure is the most common non-fatal cardiac event

Treatment is focused on

- Rate control
- Rhythm control
- Stroke prevention
- Management of comorbidities and risk factors

Prevalence of Stroke

- >85 years of age make up 17% of all stroke patients, of which 66.2% are women
- Among people 65 to 84 years of age, 53.4% of stroke patients were women
- Very elderly patients have a higher risk-adjusted mortality, have longer hospitalizations, receive less evidenced-based care, and are less likely to be discharged to their original place of residence

AHA Statistical Fact Sheet – 2013 Update

✓ Based on the Framingham Study, atrial fib is a risk factor in 1/6th of all strokes

Treatment Options . . .

Dependent upon:

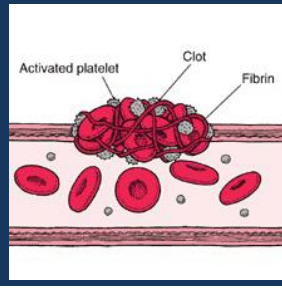
- Comorbidities
- Underlying cardiac disease
- Patient and provider preference

In the elderly, medications are complicated by:

- Comorbidities
- Diminished drug clearance
- Decrease in body mass → reduction in dose
- Compliance issues/polypharmacy

What is Coagulation?

- Coagulation – the process by which blood clots



What is coagulation?

•complex process by which blood forms clots

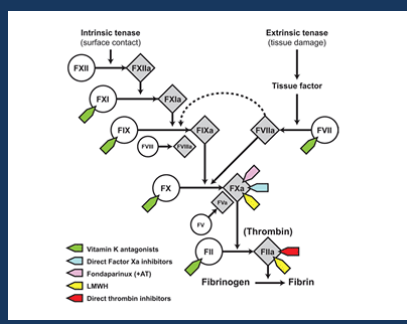
•Disorders of coagulation can lead to an increased risk of bleeding (hemorrhage) or clotting (thrombosis).

•involves both a cellular (platelet) and a protein (coagulation factor) component

What is an anticoagulant?

- a substance that stops blood from clotting (thrombosis).
- Primary/Secondary prevention of:
  - Deep vein thrombosis
  - Pulmonary embolism
  - Myocardial infarctions
  - Strokes
  - Embolus from atrial fibrillation

What is Anticoagulation?

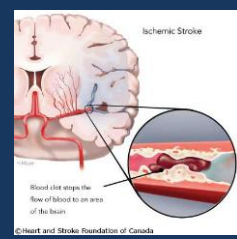


Anticoagulants vs Antiplatelets

- To form a clot, platelets clump together and the clotting cascade activates to produce fibrin to stabilize the clot.
- Anticoagulants such as warfarin and heparin block thrombin activity which blocks the formation of fibrin
- Antiplatelets such as aspirin and clopidogrel (Plavix) block platelet activity

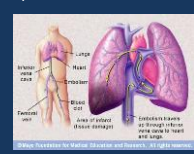
Atrial Fibrillation and Anticoagulation

- Embolic/Ischemic stroke is most dangerous consequence of A-fib
- Depending on co-morbidities, untreated A-fib patients can have a yearly stroke risk of >10%
- $CHADS_2$ and CHA_2DS_2-VASc scores are used to calculate risk
- Anticoagulants reduce risk by around 66% by preventing development of clots in the atria



DVT/PE (VTE)

- Deep vein thrombosis (DVT)= blood clot in a vein deep within the body, usually the leg
- Pulmonary Embolism (PE)=blood clot has travelled to the lungs and now blocks an artery in the lungs
- Together, these conditions are called venous thromboembolism (VTE)
- 50% of patients with DVT end up having a PE if untreated
- PE accounts for approx. 300,000 deaths a year
- 15% of sudden death cases are caused by PE

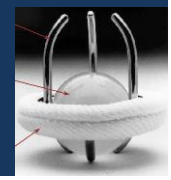


Tapson NEJM 2008

Other Indications for Anticoagulation

- Prevention of VTE (post-hip and knee surgery)
- Immobilization (e.g. hospitalized patients)
- Mechanical Heart Valves
- Mechanical Heart (LVAD)
- High risk conditions for clotting

(e.g. antiphospholipid syndrome)



Spyropoulos CHEST 2005
Levine et al NEJM 2002

Anticoagulation Options

- Injectable thrombin and/or factor Xa inhibitors
  - Heparin
  - Low molecular weight heparin (LMWH)
    - Lovenox® (enoxaparin)
- Oral vitamin K antagonists
  - Coumadin®(warfarin)
- Oral factor Xa inhibitors
  - Xarelto® (rivaroxaban)
  - Eliquis® (apixaban)
  - Savaysa® (edoxaban)
- Oral direct thrombin Inhibitor
  - Pradaxa® (dabigatran)

- "Warfarin alternatives"
- "New agents"
- Novel Oral Anticoagulants (NOACs)
- Target-Specific Oral Anticoagulants (TSOACs)
- Direct Oral Anticoagulants (DOACs)

Warfarin (Coumadin®)

- Initially a rat pesticide
- Vitamin K Antagonist
  - Inhibits production of several coagulation factors
- Monitor with international normalized ratio (INR)
- Difficult to manage!
- 34 million people take in U.S.[1]
- 21st most prescribed medication in the U.S. [1]

[1]IMS Institute for Healthcare Informatics. The Use Of Medicine in the United States in 2011

International Normalized Ratio (INR)

Laboratory test to measure how quickly blood will clot

Sub-therapeutic | Therapeutic | Supra-therapeutic

Typical INR target ranges:
- 2-3 (A-fib, VTE)
- 2.5-3.5 (artificial valves)

Narrow Therapeutic Range

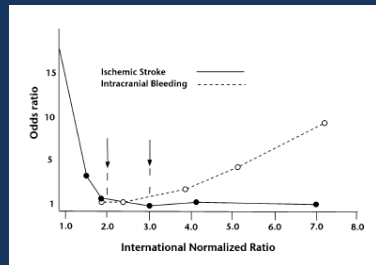


Fig. 4 Adjusted odds ratios for ischemic stroke and intracranial bleeding in relation to the intensity of anticoagulation. (Reprinted with permission from Fuster V et al. Circulation 2006;114:e257–354)

DOACs

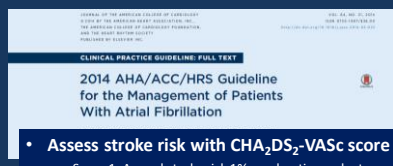
Xarelto® (rivaroxaban), Eliquis® (apixaban), Pradaxa® (dabigatran), Savaysa® (edoxaban)

- Same dose every day
- No INRs needed
- No food interactions and very few medication interactions
- Quick onset/offset (no bridging necessary)
- Can't easily measure whether patient is taking as directed
- Reversal agents coming (Praxbind, Andexanet Alpha)
- Can't be used for valvular a-fib

Anticoagulants can be dangerous and expensive

- First or second most common cause of adverse drug event related ED visits
- >100,000 ED visits/year
- 68% of ED visits for adverse drug events are related to acute bleeding
- 40% of these ED visits for bleeding resulted in hospitalizations
- 5 out of 12 deaths from adverse drug events are related to warfarin

Thromboembolism in Patients with AF



- **Assess stroke risk with CHA_2DS_2-VASc score**
  - Score 1: Annual stroke risk 1%, oral anticoagulants or aspirin may be considered
  - Score ≥2: Annual stroke risk 2%-15%, **oral anticoagulants are recommended**
- **Balance benefit vs. bleeding risk**

Calculating Risk

CHA_2DS_2-VASc Score

HAS-BLED Score

Risk Factors for Stroke in Atrial Fibrillation

Risk Factor	Relative Risk
Old Stroke/TIA	2.5
Hypertension	1.6
CHF	1.4
Increased age	1.4/10 years
DM	1.7
CAD	1.5

Arch Intern Med 1994; 154: 1449-1457

Calculating Stroke Risk using CHA_2DS_2-VASc Score

Risk Factor	Points
C: Hx of CHF or LVEF ≤ 40%	1
H: Hx of Hypertension	1
A2: Age ≥ 75 yr old	2
D: Diabetes mellitus	1
S2: Stroke/TIA/TE	2
V: Vascular disease- CAD,MI PAD	1
A: Age 65-74 years	1
Sc: Sex category -Female	1

Calculating Stroke Risk

CHA_2DS_2-VASc Score	Stroke Risk
0	0.2%
1	0.6%
2	2.2%
3	3.2%
4	4.8%
5	7.2%
6	9.7%
7	11.2%
8	10.8%
9	12.2%

Europace 2016. 2016 Oxford University Press

Case Study:

- 70 yr old female
- New onset atrial fib, currently rate controlled
- Per echo – EF 60%; stress test negative
- HTN – borderline controlled
- Diabetes
- Lives with her husband
- Likes to garden, does the wash and prepares meals

	PTS
C: Hx of CHF or LVEF ≤ 40%	0
H: Hx HTN	1
A2: Age ≥ 75 yr old	0
D: DM	1
S2: CVA /TIA/TE	0
V: Vascular disease- CAD,MI PAD	0
A: Age 65-74 yrs	1
Sc: Sex category -Female	1
Total	4.8%

Stroke Risk

Determining Stroke Risk

CHA_2DS_2-VASc Scoring Table	
Condition	Points
Congestive heart failure	1
Hypertension	1
Age ≥ 75 years	2
Diabetes mellitus	1
Stroke/TIA or thromboembolism (prior)	2
Vascular disease (MI, PAD, or aortic plaque)	1
Age 65-74 years	1
Sex Category (Female)	1
Total score=	

CHA_2DS_2-VASc Score	Yearly Stroke Risk (%)		
	No Warfarin	With Aspirin	With Warfarin
0	0	0	0
1	1.3	1.0	0.5
2	2.2	1.8	0.8
3	3.2	2.6	1.1
4	4.0	3.2	1.4
5	6.7	5.4	2.3
6	9.8	7.8	3.4

CHA_2DS_2-VASc Risk Stratification			
Score	Risk	ESC Recommendation	AHA/ACC/HRS Guidelines
≥2	High	Anticoagulate	Anticoagulate (Class Ia rec.)
1	Intermediate	Anticoagulate	Consider oral anticoagulant or aspirin (Class IIb rec.)
0	Low	Don't Anticoagulate	No antithrombotic (Class IIa rec.)

Assessing Bleed Risk

- HASBLED Score
- High Risk Occupations/Professions
- High Fall Risk
- Cognitive Impairment
- Intolerance to OAC
- Increased bleeding risk (e.g., thrombocytopenia, cancer, or risk of tumor associated bleeding in case of systemic anticoagulation)

Calulating Bleed Risk with HAS-BLED Score

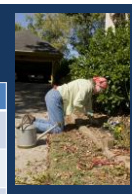
Risk Factor	Points
Hypertension History (uncontrolled, >160 mmHg systolic)	1
Abnl Renal Disease (Dialysis, transplant, Cr >2.6 mg/dL or >200 µmol/L)	1
Abnl Liver Disease (Cirrhosis, Bilirubin >2x Nl, AST/ALT/AP >3x Nl)	1
Stroke History	1
Prior Major **B**leeding or Predisposition to Bleeding	1
Labile INR? (Unstable/high INRs)	1
Elderly Age ≥65 yrs	1
Drug Use Predisposing to Bleeding (Antiplatelet agents, NSAIDs)	1
Alcohol Usage History	1

Risk of Major Bleeding

HAS-BLED score	n	Bleeds,n	Bleeds/100 pts
0	789	9	1.13
1	1286	13	1.02
2	744	14	1.88
3	187	7	3.7
4	46	4	8.7
5	8	1	12.5
Any score	3071	48	1.56

Pisters R, Lane DA, Nieuwlaat R, de Vos CB, Crijns HJ, Lip GY.

Case Study:



Risk Factor	Points
Hypertension History (uncontrolled, >160 mmHg systolic)	1
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Labile INR? (Unstable/high INRs)	1
Elderly Age ≥65 yrs	1
Drug Use Predisposing to Bleeding (Antiplatelet agents, NSAIDs)	1
Alcohol Usage History	1

Bleed Risk → **3.7%**

Hemorrhage with Anticoagulation

- Minor bleeding such as nose bleeds and increased bruising are common
- About 2-4% of patients per year will experience major bleeds requiring urgent medical attention and blood transfusions
- Intracranial hemorrhage is most dangerous bleed

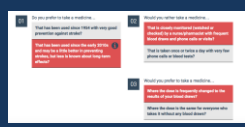
Decision Aids

Improves decision-making process by:

A. Increasing knowledge
B. Increasing risk communication
C. Decreasing decisional conflict
D. Increasing participation in care
E. Increasing value congruence

Shared Decision Making Tool: Patients

- CHAD-VASc, HAS-BLED Scores



- Followed by personal preferences questionnaire

www.mybloodclots.org - Society for Vascular Medicine

Shared Decision Making In NVAF: Development of Decision Aid

- Provider interviews
- Patient focus groups
- Semi-structured interviews

- Led by: Geoff Barnes MD, MSc

Shared Decision Making Tool: Providers

A. Determine stroke risk using CHADS-VASc

B. Determine bleeding risk using HAS-BLED

C. Mechanical valve?

Development of SDM Tool Patients

- 1. Will a co-pay of > $10 per month be prohibitive?
- 2. Would you rather take a drug that:
  - A. Used for > 50 years , lots of experience
  - B. New – little better at preventing strokes, less is known about long term effects
  - A. Requires close monitoring with blood draws
  - B. Taken once or twice daily with no monitoring
  - A. Dose adjusted frequently
  - B. Same dose for everyone
  - A. Easily reversible
  - B. Not reversible (yet) but less bleeding strokes

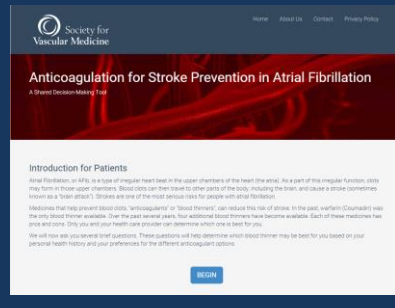
SDM Tool
Patients

- Which of the prior 4 questions is most important to you?:
  - 1. Lots of experience vs new
  - 2. Close monitoring (call and blood draws) vs no monitoring
  - 3. Frequent changes in dose vs one dose for all
  - 4. Reversible vs non-reversible

Shared Decision Making Tool: Patients

1. Cost
2. Food-Drug Interaction
3. Food-Food Interaction
4. Side Effects
5. Convenience of Clinic/Lab Location
6. Other Barriers to Compliance (support system, language barriers)

www.mybloodclots.org - Society for Vascular Medicine



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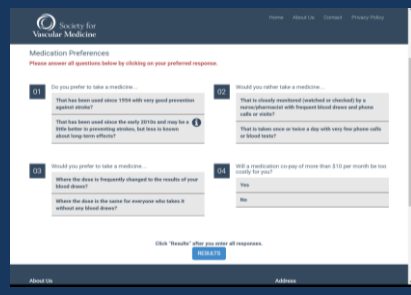

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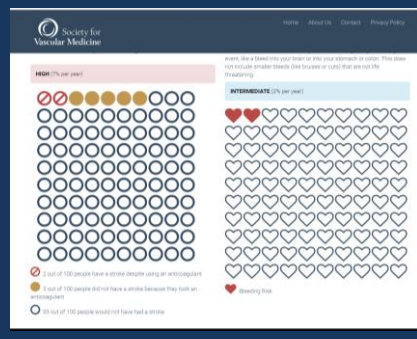

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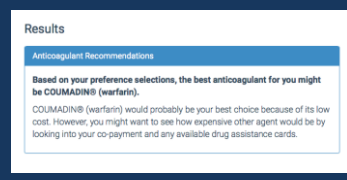
Shared Decision Making Tool: Patients



- Receive a personalized anticoagulant recommendation based on demographic information, comorbidities, and personal preferences.

www.mybloodclots.org - Society for Vascular Medicine

Assessing the Impact of the Shared Decision Making Tool

- Patient surveys administered at one and 3-12 months.
- Primary outcome: congruence of values
  - Questions and OAC choice.
- Secondary:
  - Persistence of values questions.
  - Associations between degree of decision regret and likelihood to choose DOAC.

MAQI2 Introduction

MAQI²

MICHIGAN ANTICOAGULATION QUALITY IMPROVEMENT INITIATIVE

Participating Sites

Patient Education Projects

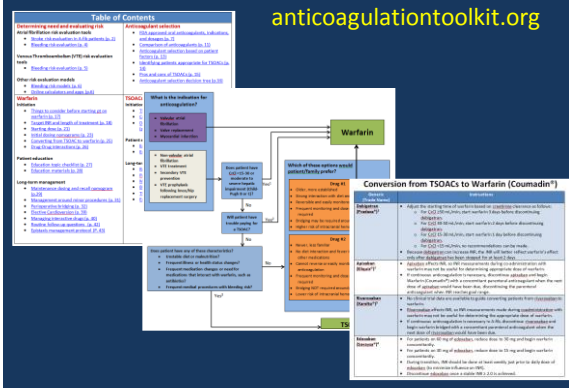
Initially focused on warfarin – now DOACS

Patient knowledge
- Need for anticoagulation
- Food interactions
- Drug interactions
- When to notify clinic
- Ways to improve INR stability

Decreased adverse events and cost
- Higher TTR
- Appropriate use of ED
- Higher compliance

MAQI² Anticoagulation Toolkit

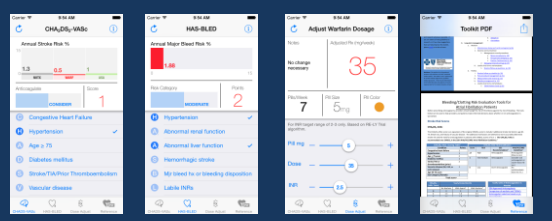
anticoagulationtoolkit.org

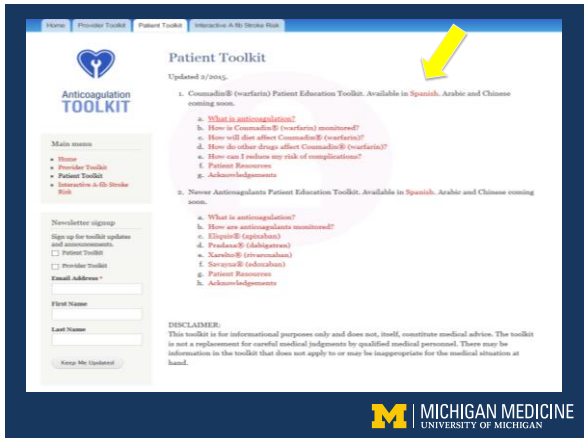


MAQI² Anticoagulation Toolkit

anticoagulationtoolkit.org

Mobile app: search "MAQI" in App Store





Decision support tools

In Conclusion

- Atrial fibrillation is associated with an increased risk for stroke
- There are tools available to assess for risk of stroke and bleed in NVAF
- There are tools available to assist patients/providers in making a shared decision regarding care

In Conclusion

- **Shared Decision Making = Patient Empowerment**
- Health decision with choices/risks/benefits
- Risk assessment
- Decision tools to help illustrate risk
- Discussion re: choices
- Decision by patient w/ provider support

Websites for SDM Tools/Information

ACC's AF Decision Aid for Anticoagulation for Non-Valvular AF *https://www.acc.org/tools-and.../anticoagulation-shared-decision-making-tool*

Strategies for Chronic Care: Provider Resources *www.strategiesforchroniccare.com*

The SHARE Approach *https://www.ahrq.gov/professionals/education/curriculum-tools/shareddecisionmaking/*

Mayo Clinic Shared Decision Making National Resource *Centershareddecisions.mayoclinic.org/*