

Applying Evidence-Based Therapies for Preventing and Treating Cardiovascular Disease: Role of Systems of Care

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Presenter and Program Disclosure Information

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Consultant, Honorarium: Medtronic, Novartis

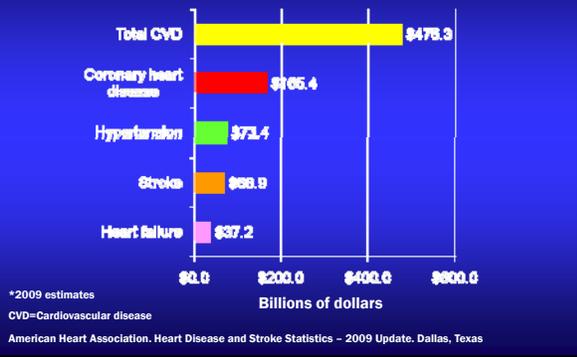
UNLABELED/UNAPPROVED USES DISCLOSURE:
None

Burden of Atherosclerotic Vascular Disease: CAD, CVD, PVD

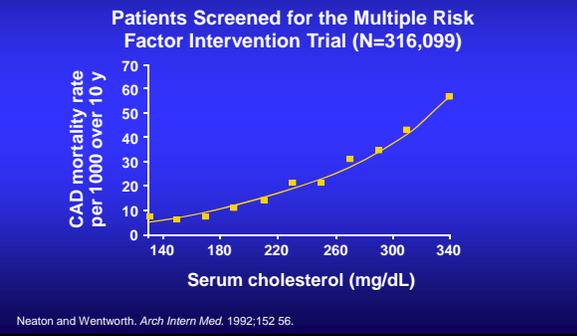
- Prevalence— 16 million in United States
- Annual rates
 - Myocardial infarction—1.4 million
 - Strokes-800,000
 - CVD Mortality—812,000 (every 30 seconds a death)
 - Cardiac catheterization—1.1 million
 - Percutaneous revascularization—1.1 million
 - Surgical revascularization—416,000
- Annual cost—>\$300 billion

American Heart Association. 2012 Heart and Stroke Statistical Update. At <http://www.americanheart.org>.

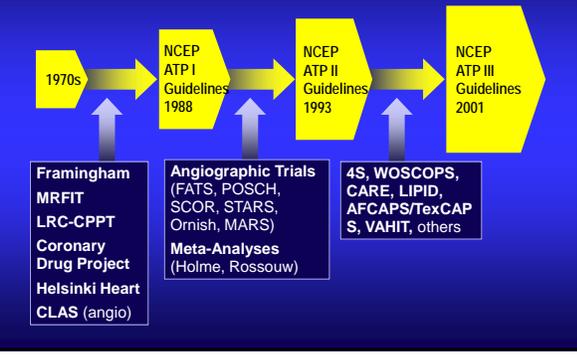
Cost of Cardiovascular Disease in the United States

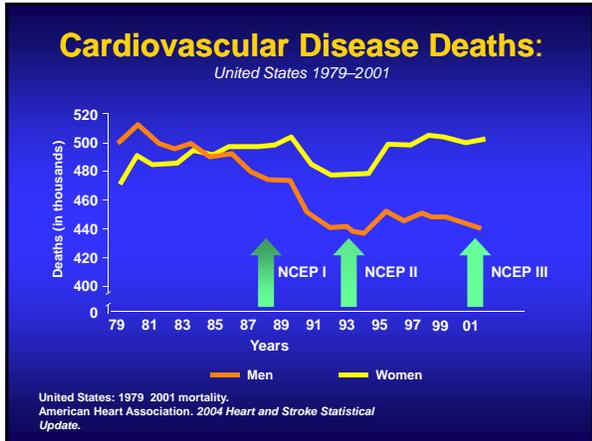


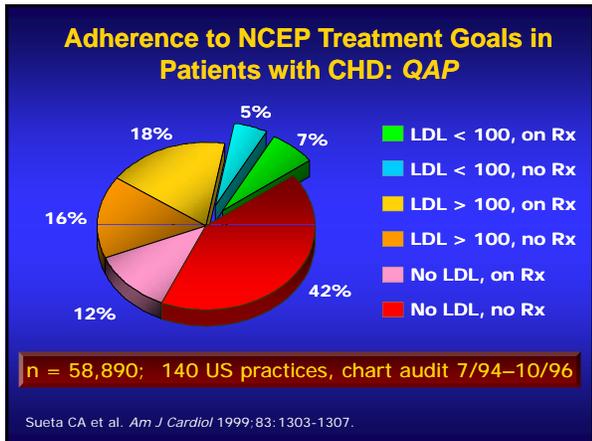
Total Serum Cholesterol and Cardiovascular Disease Risk

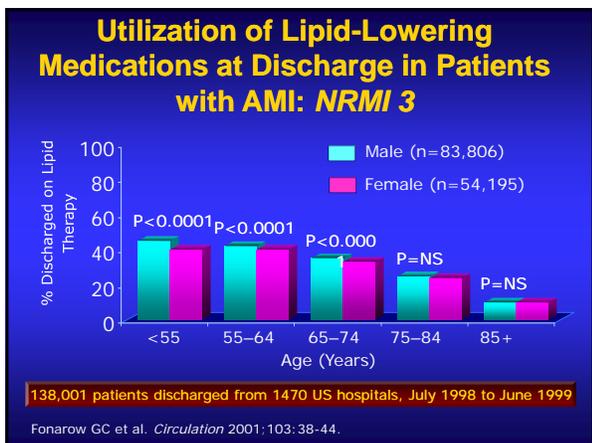


Evolution of the NCEP Guidelines

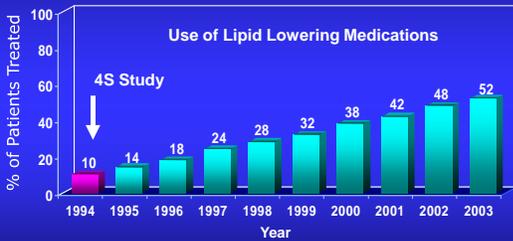








Slow Translation of Clinical Trials Results into Routine Clinical Practice



AMI/ACS patients discharged on lipid lowering medications
 NRMI 3/4, PRISM, PURSUIT, GUSTO II, TIMI-16, ACCEPT

Management of Coronary Artery Disease

Utilization Reported in Trials and Registries 1993-1996

| Type of Therapy | Mean (%) | Range (%) |
|-----------------------------|----------|-----------|
| Nitrates | 48 | 28-72 |
| Calcium channel blockers | 58 | 18-87 |
| Revascularization | 48 | 16-75 |
| Antiarrhythmic agents | 16 | 2-23 |
| Aspirin | 62 | 37-86 |
| Beta blockers | 32 | 12-68 |
| ACE inhibitors | 18 | 6-38 |
| Cholesterol lowering agents | 22 | 4-38 |

Trials: SAVE, CAVEAT, EAST, RITA, 4S, REGRESS, ISIS 4 ACME Registries: NRMI, SRS Database

Changing the Therapeutic Target for Coronary Artery Disease

Myocardial Ischemia as the Target



Antianginal Medications
 Calcium Blockers
 Nitrates
 Beta blockers
 Revascularization
 Angioplasty
 CABG

Risk factor modification

Atherosclerosis as the Target



Aspirin and/or Clopidogrel
 Statin
 Beta Blocker
 ACE inhibitor
 Exercise
 Smoking Cessation

Symptom control
 antianginal medications
 revascularization

Potential Therapies for Atherosclerosis



Atherosclerosis as the Therapeutic Target

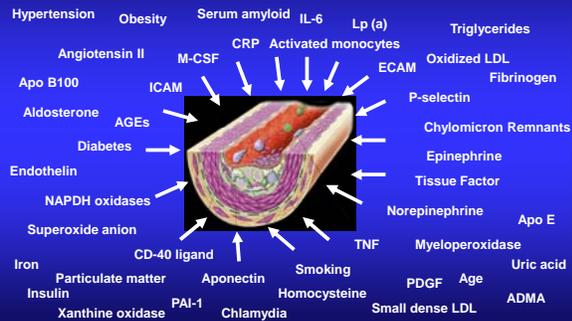
Therapies with Demonstrated Benefit

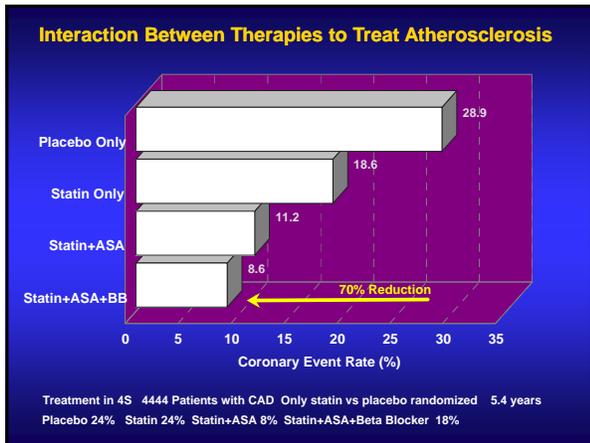


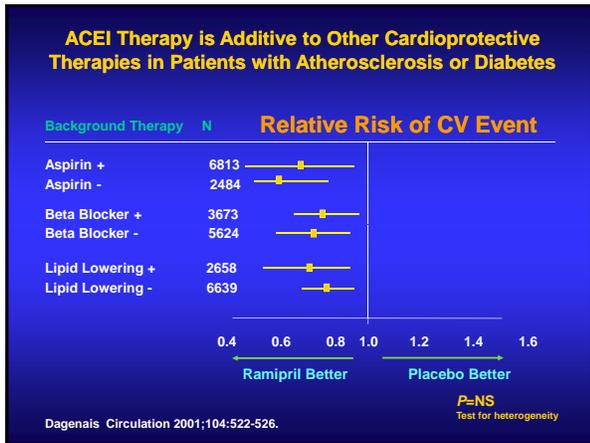
- **Anti-Platelet Therapy**
Aspirin
- **Neurohumoral Inhibition**
Beta Blockers
ACE Inhibitors
- **Lipoproteins / Inflammation**
Statins (irrespective of baseline LDL)
Omega-3 Fatty Acids
Exercise
Smoking Cessation

CHAMP 1994

Conceptual Basis for Combination Cardiovascular Protective Medical Therapy for Atherosclerosis





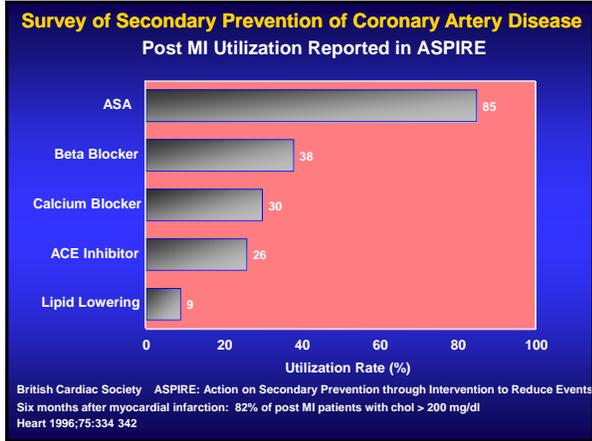


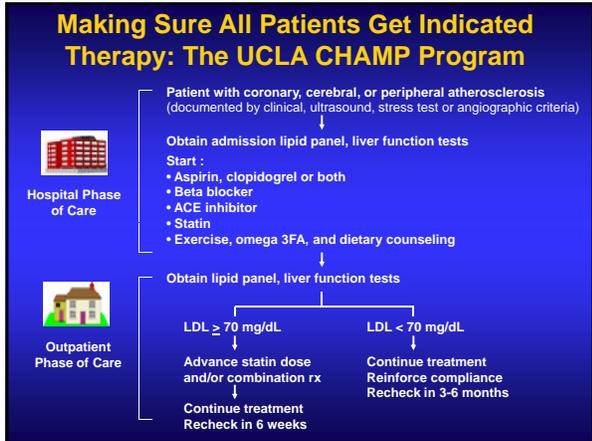
Cumulative Impact of Simple Cardiovascular Protective Medications

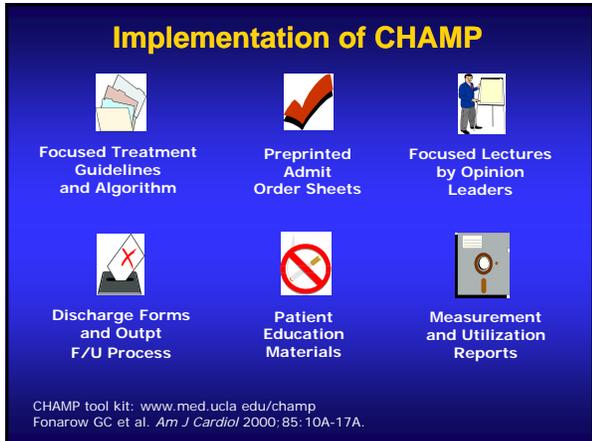
| | Relative-risk | 5yr CV event rate |
|--------------------|---------------|-------------------|
| None | -- | 20% |
| Aspirin | ↓ 25% | 15% |
| Beta blocker | ↓ 25% | 11.3% |
| ACE inhibitor | ↓ 25% | 8.4% |
| Lipid lowering Rx | ↓ 30% | 5.9% |
| LDL 100 → 70 mg/dl | ↓ 22% | 4.6% |

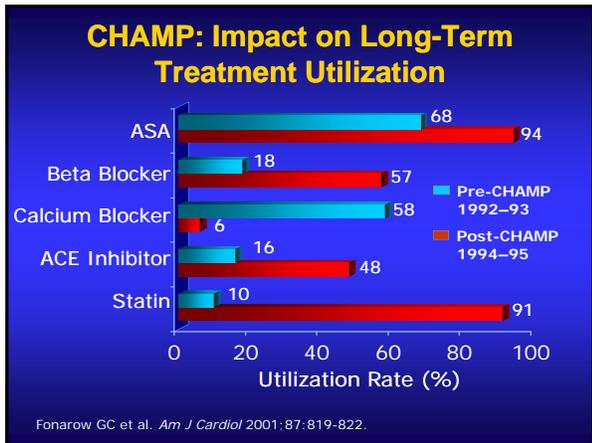
Cumulative risk reduction if all four therapies are used 77%
 Absolute risk reduction 15.4%, NNT = 6

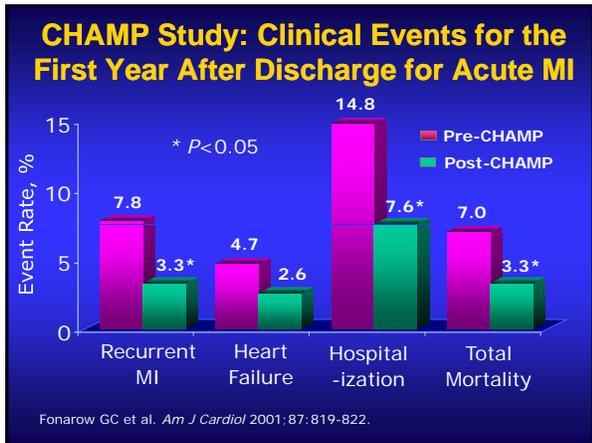
CV event CV death, MI, or stroke
 Fonarow Am J Cardiol 2001;85:10A 17A and Yusuf Lancet 2002;360:2 3

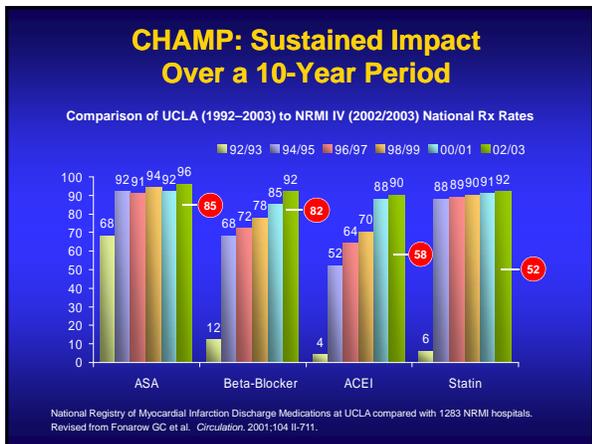


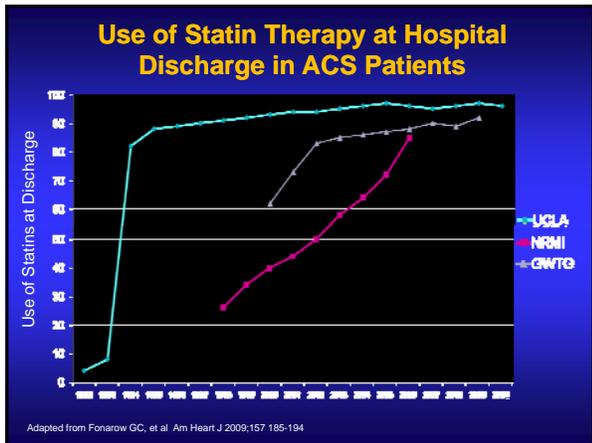


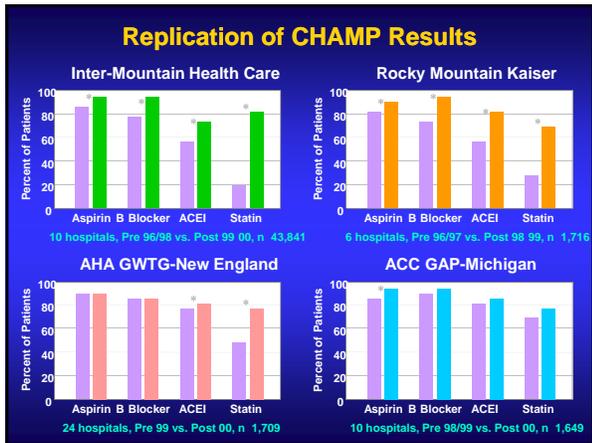


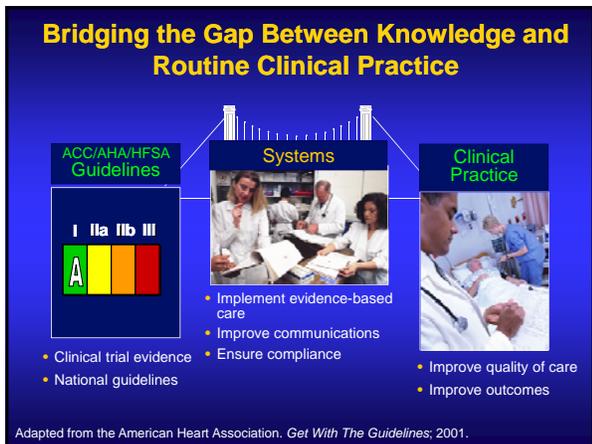




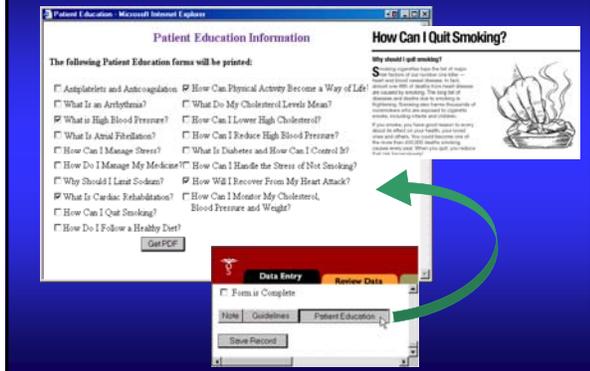








GWTG: AHA Patient Education Materials Tailored to the Individual Patient

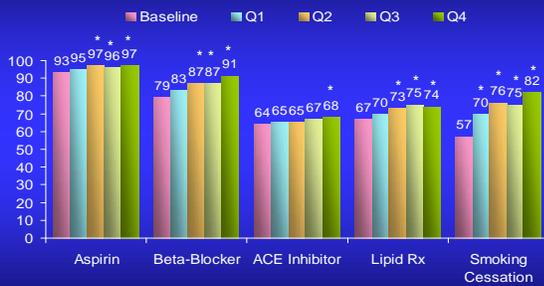


AHA GWTG Quality Measures

1. Aspirin within 24 hours in AMI/ACS
2. Aspirin at discharge in CAD patients
3. Beta blockers within 24 hours in AMI
4. Beta blockers at discharge in CAD patients
5. Smoking cessation counseling or advice in current smoker
6. ACE inhibitors at discharge in AMI patients
7. Lipid lowering medication treatment in all CAD pts
8. Lipid lowering medication treatment in CAD pts with LDL measured and > 100 mg/dL
9. Lipid measurement
10. Cardiac rehabilitation or exercise counseling
11. Blood pressure control \leq 140/90 mm Hg at discharge
12. Weight loss counseling, if indicated

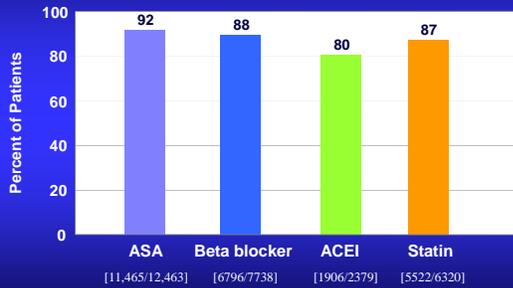
Patients with documented contraindication or intolerance were excluded from denominator of the quality measure

Impact of AHA GWTG-CAD Program on Quality of Care



GWTG-CAD 123 US Hospitals, n 27,825
LaBresh KA, Fonarow GC, et al. *Circulation*. 2003;108(suppl IV) 722.

Adherence Rates After Discharge for ACS if Therapy is Started In-Hospital



GRACE Registry: 21,408 patients, multinational, assessment at discharge and 6 months follow up
Eagle Am J Med 2004;117:73-81

In-Hospital Initiation of Cardiovascular Protective Therapies

- Therapy more likely to be initiated by physician
- Therapy more likely to be continued by physician long term
- Patients more likely to view therapy as essential (heart medication)
- Patients more likely to be compliant (lower discontinuation rates)
- Patient more likely to achieve treatment goals
- Early event reduction not missed

Fonarow Circulation 2001;103:2768

In-hospital Initiation of Lipid Lowering Medications: The New Standard of Care

The following national guidelines now recommend in-hospital initiation of lipid-lowering medications simultaneously with life-style modification, prior to hospital discharge:

NCEP-ATP III Guideline 2001

AHA/ACC Secondary Prevention 2001 update

ACC/AHA ACS Guideline 2002 update

ACC/AHA STEMI Guideline 2004 update

JAMA 2001;285:2486-2497; Circulation 2001;104:1577-9; Circulation 2002;106:1893-900

The Science of Implementation

- It is possible to create a hospital based system to implement atherosclerosis treatment
- In-hospital treatment rates are markedly improved
- It is safe to initiate lipid-lowering and other cardioprotective medications in the hospital
- In-hospital initiated treatments are continued by outpatient physicians
- In-hospital initiation of treatments markedly improves long term patient compliance
- In-hospital initiation of lipid lowering therapy results in more patients reaching a LDL < 100 mg/dl
- It reduces total medical costs
- In-hospital initiation of cardioprotective therapies reduces recurrent CV events and saves lives

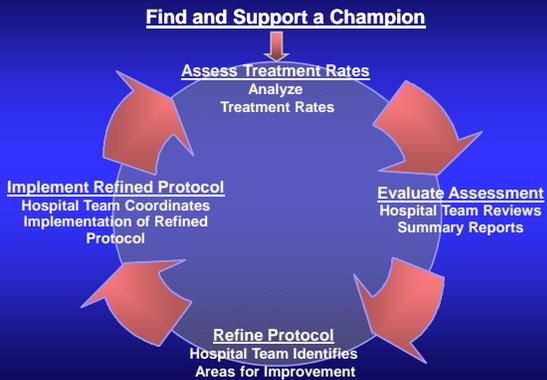
Building the Team



- Physicians
- Nurses
- Pharmacists
- Hospital Administrators
- Directors of Quality Improvement and Case Management
- Cardiac Rehab Team



Performance Improvement Process



Challenges to Implement a Hospital Performance Improvement System

"this will not work in a community setting"

"we can not get a consensus" "the cardiologists will not agree to this"

"the managed care organization will not pay for it"

"patients do not want to be on a lot of medications" "there is not enough time"

"it ma not be safe to start ACEI or BB medications in hos italized atients"

"it will cost too much" "this will benefit the competition"

"the hospital administration will not pay for it" "what about the liability"

"all my patients are too complex for this" "it will take too much time"

"it is too hard to get things through the hospital committee"

"the patients should all be followed in my office"

"the physicians at my hospital do not like cookbook medicine"

"we do not have anyone to do this"

ACC GAP Program: Use of Tools was Extremely Variable



Riba AL, et al. American College of Cardiology (ACC) acute myocardial infarction guidelines applied in practice Southern Michigan Expansion Project: a model of collaborative quality. Eur Heart J 2003; 24: 58

Key Elements to Quality Improvement

Why Do Some Hospitals Succeed?

- Access to current and accurate data on treatment and outcomes
- Physician champion, support among clinicians
- Have stated goals
- Administrative support
- Use of pre-printed orders, care maps
- Use of data to provide feedback

Bradley JAMA 2001;285:2604-2611

Cost of Atherosclerosis

13 million individuals in the United States with prevalent coronary disease
 6 million individuals with prevalent cerebral vascular disease
 5 million individuals with prevalent peripheral vascular disease

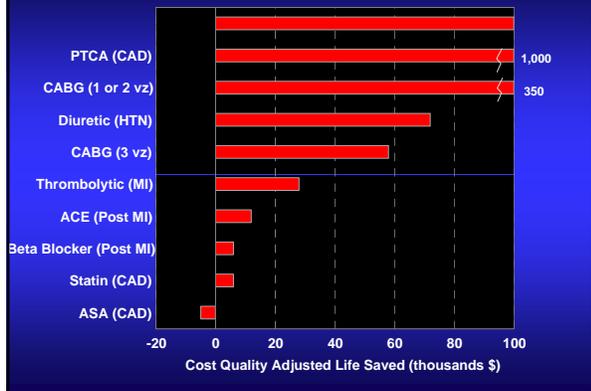
- 40 million office visits annually
- 5 million hospitalizations annually
- 226 billion dollars in direct costs in 2004
- 368 billion dollars in total costs in 2004

Average direct costs over a five year period

| | |
|-----------|-----------------|
| \$ 51,211 | MI |
| \$ 34,581 | Unstable Angina |
| \$ 9,780 | Sudden Death |
| \$ 62,524 | CABG |
| \$ 58,453 | PTCA |

Heart and Stroke Facts: 2004 Statistical Supplement, American Heart Association

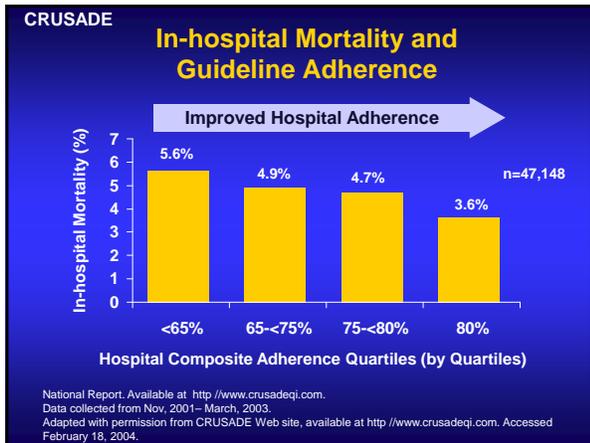
Cost Effectiveness of Therapies for CAD

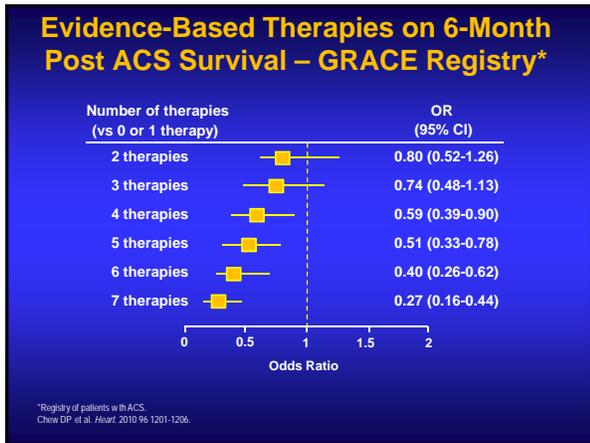


Variation in AMI Care Quality in 1085 Hospitals and It's Association with Mortality Rates

| Median Performance On Care Processes | Lagging Hospitals (n=271) | Leading Hospitals (n=271) |
|--------------------------------------|---------------------------|---------------------------|
| ASA < 24h | 73% | 93% |
| BB < 24h | 50% | 86% |
| Reperfusion | 50% | 71% |
| DC ACEI | 40% | 70% |
| DC Lipid Therapy | 58% | 80% |
| Smoking Advice | 7% | 65% |
| Mortality | 17.6% | 11.9% |

86,735 AMI patients in NRMII IV treated between 7/00 to 3/01. ACC/AHA Class I therapy
 Hospitals divided into quartiles to composites of quality
 Peterson Circulation 2002;106:II-722 Abstract





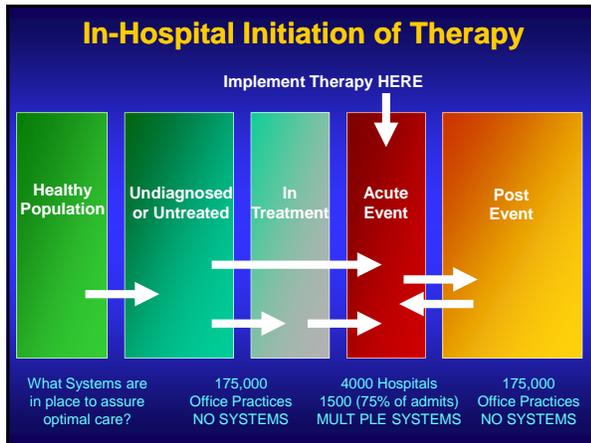
Population Level Impact: Declines in AMI and Other Cardiac Hospitalizations

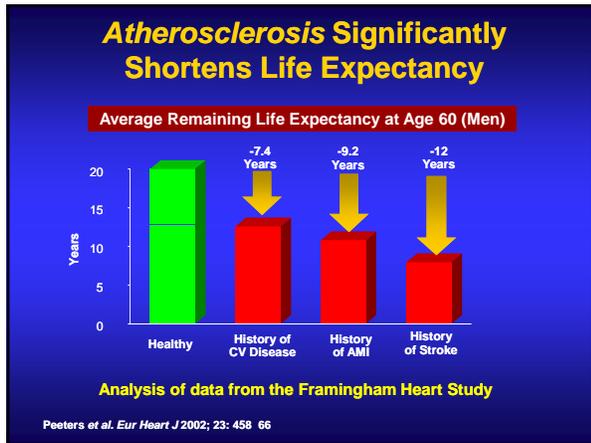
Annual Hospitalization Rate for AMI and Other Cardiac Conditions per 100,000 Medicare Fee-for-Service Beneficiaries 2002-2007

| Hospitalizations (ICD-9) | 2002 | 2003 | 2004 | 2005 | 2006 | 2007 | Change From 2002–2007, % |
|--------------------------|------|------|------|------|------|------|--------------------------|
| AMI (410) | 1131 | 1093 | 1021 | 961 | 893 | 866 | -23.4 |
| UA (411) | 136 | 108 | 90 | 75 | 63 | 55 | -59.2 |
| CAD (414) | 1744 | 1695 | 1692 | 1575 | 1506 | 1305 | -25.2 |
| HF (428) | 2152 | 2218 | 2195 | 2112 | 2015 | 1892 | -12.1 |

Extrapolated to the entire Medicare population of 45 million in 2007, this represents 1,390,000 fewer CV hospitalizations in 2007 compared to 2002 (~14 billion dollars a year in hospital costs avoided)

Chen J, et al. *Circulation*. 2010;121:1322-1328.





NCEP ATP III Guidelines, Levels of Risk, and Rationing of Care

| | Low Risk Yearly risk <1% LLA generally not indicated | Intermediate Risk Yearly risk 1-2% Consider LLA if LDL >130 | High Risk Yearly risk >2% LLA is generally recommended |
|----------------------|--|---|--|
| Relative RR | 32% | 32% | 32% |
| Absolute RR (5 year) | 1% | 2% | 4% |
| Absolute Hazard | 0.005% | 0.005% | 0.01% |
| NNT-benefit (5 year) | 100 | 50 | 25 |
| NNT-harm (5 year) | 20,000 | 20,000 | 10,000 |
| Statin | 40 mg ½ daily | 20 mg ½ daily | 10 mg daily |
| Cost/event avoided | \$25,000 | \$25,000 | \$25,000 |

Cost of Comprehensive Atherosclerosis Medical Therapy

Treatment Cost for 1 year

| Drug | | Daily Dose | Cost \$ |
|--------------------|---------------|------------|---------------|
| Aspirin | generic | 81 mg qd | 5.25 |
| Beta Blocker | Metoprolol XL | 100 mg qd | 40.00 |
| ACE inhibitor | Lisinopril | 20 mg qd | 40.00 |
| Statin | Simvastatin | 40 mg qd | 40.00 |
| Combination | | | 125.25 |

WallMart or Drugstore.com February 2012

Age at Which Risk of Cardiovascular Disease Becomes Moderate or High

| | Men | | Women | |
|---|---------------|------------------|---------------|------------------|
| | With diabetes | Without diabetes | With diabetes | Without diabetes |
| Heart disease defined as M /death | | | | |
| ■ Moderate risk | 38.6 | 54.8 | 46.1 | 61.7 |
| ■ High risk | 49.3 | 62.2 | 56.0 | 68.7 |
| Heart disease defined as M /stroke/ death | | | | |
| ■ Moderate risk | 34.5 | 54.1 | 44.6 | 60.5 |
| ■ High risk | 47.9 | 61.5 | 54.3 | 67.5 |
| Heart disease defined as M /stroke/ death/revascularization | | | | |
| ■ Moderate risk | 32.7 | 51.4 | 38.6 | 58.4 |
| ■ High risk | 41.3 | 58.8 | 47.7 | 65.4 |

Booth GL et al. *Lancet* 2006; 368: 29-36.

Moderate risk defined as a 10-year risk of 10%-19%.
High risk defined as a 10-year risk of 20% or greater.

LDL Level and Risk of Acute Coronary Syndromes

- 92% of patients with ACS have LDL < 160 mg/dL
- 77% of patients with ACS have LDL < 130 mg/dL
- 49% of patients with ACS have LDL < 100 mg/dL

136,905 patients hospitalized with acute coronary syndromes
Fonarow GC et al. *Am Heart J* 2009;157: 111-7.e2

Statins Have Been Shown to Reduce CV Risk in All the Following Circumstances:

- Older age
- Younger age
- Men
- Women
- Diabetes
- High LDL
- Low LDL
- High HDL
- Low HDL
- High Triglycerides

The Ultimate in Hi_hl Personalized Medicine:
 Person + Statin Rx = Benefit

- Hypertension
- No Hypertension
- Obesity
- No Obesity
- Current Smoking
- Former Smoking
- Never Smoking
- CAD Family History
- No CAD Family History
- Small Dense LDL
- Large Buoyant LDL
- High CRP
- Low CRP
- High Homocysteine
- Low Homocysteine
- Elevated Lp (a)
- Low Lp (a)

Primary Prevention Candidates for Statin Rx

If LDL > 50 mg/dL and no contraindications

Men Age 35 and Older

Women Age 45 and Older

Start earlier if:

- Smoker
- Family History
- Hypertension
- Diabetes or Metabolic Syndrome

Potential Impact of GWTG on Cardiovascular Patient Outcome in the United States

| Outcomes | Events Avoided |
|-----------------------|----------------|
| PTCA/CABG | 120,000 |
| Hospitalizations | 464,000 |
| Myocardial Infarction | 216,000 |
| Strokes | 44,800 |
| All Deaths | 83,400 |

Annual events avoided if 90% compliance with asa, bb, ACEi, statins in patients with CAD
 4S/LIPID/HOPE/Antiplatelet and Beta Blocker Meta-analysis and Bahit et al AHA 2000
 Fonarow Curr Atheroscler Rep. 2002;4:99-106

National Cardiovascular Care Quality Improvement: The Time is NOW

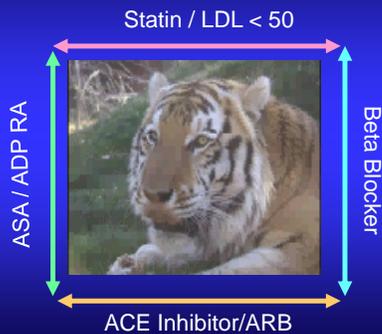
Now is the time to ensure that
Each and every patient we see is treated
Each and every colleague we work with is treating
Each and every hospital and outpatient practice
we work in has a treatment system in place and is
monitoring treatment rates

Fonarow Circulation 2001;103:2768-2770

Conclusions

- Comprehensive application of primary and secondary prevention therapies is highly effective in reducing the risk of cardiovascular events
- Despite the clinical trial evidence and national guidelines, large number of eligible patients are not receiving one or more of these recommended therapies
- As such, large number of patients are having CV events that could be avoided if there was better implementation
- Every effort should be made to bridge the cardiovascular risk reduction gap

Get With The Guidelines



Questions for the Group

1. What further steps could you take to engage participating health systems, hospitals, practices, health care providers, employers, and community leaders to incentive participation?
2. Are you sure you have the right process of care goals and metrics, as HEDIS measures are often out of date, omit key metrics, and may not be well linked to desired outcomes?
3. What more could you do to engage and incentivize individuals and families, to provide them benchmarked feedback on their cardiovascular health status, progress to goals, and maintenance of goals?
