Mitigating Cardiovascular Healthcare Disparities

New Guidelines for Cholesterol Treatment

presented by

The Home Health Quality Improvement National Campaign & The National Heart, Lung, and Blood Institute

Today’s Webinar

• Keynote Address
  — Patrice Desvigne-Nickens, MD
    • Medical Officer, Division of Cardiovascular Sciences
    • National Heart, Lung, and Blood Institute

• Cardiovascular Health Resources from HHQI
  — Misty Kevech, RN, BS Ed, MS, COS-C, CCP
    • HHQI Lead RN Project Coordinator

• Q&A: Send your questions to HHQI@wvmi.org
  — Shanen Wright, HHQI National Campaign Director

Questions & Answers

• Please send your questions and comments to HHQI@wvmi.org now or at any time

• We will address as many as time will allow during today’s live webinar broadcast

• You may also contact us at HHQI@wvmi.org at any time if you have questions or comments in the future
Mitigating Cardiovascular Healthcare Disparities: 2013 Guidelines for Cholesterol Treatment

Patrice Desvigne-Nickens MD,
Medical Officer
Division of Cardiovascular Sciences
National Heart, Lung, and Blood Institute

March 20, 2013

Atherosclerotic CVD

- Cardiovascular Diseases (CVD) represent the largest health burden to the American public despite substantial reductions in death rates since 1960.
- Research elucidating disease causing risks and subsequent treatments has and continues to offer opportunity to reduce CVD morbidity and mortality.
- Atherosclerotic CVD is the major component of CVD.
- Prevention of, or reducing the risk of, atherosclerotic CVD disease is an important strategy for reducing CVD morbidity and mortality, related healthcare costs and protecting the longevity and quality of life of Americans.

Objectives

- Review Cardiovascular Disease Burden
  - Sex, Race, and Ethnic Differences
  - Disparities in Treatment
- Review 2013 ACC/AHA Cholesterol Treatment Guidelines
  - ASCVD prevention through risk reduction
  - Lifestyle: Foundation for Risk Reduction
  - Statin Therapy
- Forecast Future Guideline Updates
Specific Objectives for Attendees

1. Identify and overcome obstacles to effective, equal treatment of atherosclerotic cardiovascular risk and disease.
2. Understand and apply new 2013 ACC/AHA Cholesterol treatment guidelines
3. Enable patients and providers to discuss treatment goals
4. Improve provider adherence to treatment guidelines and improve patient adherence to medical regimen and thus reduce/eliminate cardiovascular healthcare disparities.

Deaths from CVD: US, 1900-2007

Life Expectancy by Race and Sex, US 2008
Sex/Gender Differences in the Burden of CVD

Adapted from Mosca L et al. Circulation. 2011;124:2145-2154

<table>
<thead>
<tr>
<th>Sex/Gender Differences in the Burden of CVD</th>
<th>Women</th>
<th>Men</th>
</tr>
</thead>
<tbody>
<tr>
<td>Remaining lifetime risk for CVD at age 40 y</td>
<td>2 in 3</td>
<td>1 in 2</td>
</tr>
<tr>
<td>CVD</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Deaths - CVD and congenital heart disease (2007)</td>
<td>391,886</td>
<td>421,918</td>
</tr>
<tr>
<td>Age-adjusted CVD death rate per 100,000 (2007)</td>
<td>300.3</td>
<td>211.6</td>
</tr>
<tr>
<td>Prevalence of CVD (2005, age ≥20 y), in millions</td>
<td>38.9 (27.4%)</td>
<td>40.7 (30.5%)</td>
</tr>
<tr>
<td>Hospital discharges for CVD (2007)</td>
<td>3.036,000</td>
<td>2.874,000</td>
</tr>
<tr>
<td>Coronary Heart Disease</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Deaths caused by CHD (2007)</td>
<td>206,050</td>
<td>190,301</td>
</tr>
<tr>
<td>Age-adjusted CHD death rate per 100,000 (2007)</td>
<td>160.4</td>
<td>56.7</td>
</tr>
<tr>
<td>Prevalence of CHD (2008, age ≥20 y), in millions</td>
<td>6.88 (3.0%)</td>
<td>7.48 (3.1%)</td>
</tr>
<tr>
<td>Hospital discharges for CHD (2007)</td>
<td>905,000</td>
<td>807,000</td>
</tr>
<tr>
<td>Stroke</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Deaths resulting from stroke (2007, all ages)</td>
<td>56,111</td>
<td>67,641</td>
</tr>
<tr>
<td>Age-adjusted stroke death rate per 100,000 (2007)</td>
<td>42.5</td>
<td>41.3</td>
</tr>
<tr>
<td>Prevalence of stroke (2008, age ≥20 y), in millions</td>
<td>9.2 (3.7%)</td>
<td>4.2 (3.7%)</td>
</tr>
<tr>
<td>Hospital discharges for stroke (2007)</td>
<td>271,000</td>
<td>458,000</td>
</tr>
<tr>
<td>Heart failure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prevalence of heart failure (2008, age ≥20 y), in millions</td>
<td>2.1 (2.9%)</td>
<td>2.6 (3.1%)</td>
</tr>
<tr>
<td>Hospital discharges for heart failure (2007, all ages)</td>
<td>470,000</td>
<td>520,000</td>
</tr>
</tbody>
</table>

Risk Factor Burden by Sex

<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>Women</th>
<th>Men</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypertension</td>
<td>29%</td>
<td>31%</td>
</tr>
<tr>
<td>Diabetes Mellitus</td>
<td>8%</td>
<td>7%</td>
</tr>
<tr>
<td>Total Cholesterol &gt;240 mg/dl</td>
<td>16%</td>
<td>14%</td>
</tr>
<tr>
<td>Physical Inactivity</td>
<td>35%</td>
<td>30%</td>
</tr>
<tr>
<td>Obesity</td>
<td>64%</td>
<td>72%</td>
</tr>
<tr>
<td>Smoking</td>
<td>18%</td>
<td>23%</td>
</tr>
</tbody>
</table>

Prevalence of CVD by Age and Sex


1. MMWR January 14, 2011; 60(03):94-97
Differences vs. Disparities

- 2001 and 2010 IOM Reports
  - Sex and gender differences
- 2002 IOM Report Unequal Treatment
  - Race and ethnic disparities


Racial Disparity in Cholesterol Treatment

- Physicians and medical practices with high numbers of prescriptions for coronary artery disease medications were invited to participate in the Quality Assurance Program.
- Medical records were reviewed from a random sample of patients with coronary artery disease seen from 1995 through 1998.
- Data related to the detection, treatment, and control of dyslipidemia were abstracted from the medical record and evaluated in cross-sectional stratified and logistic regression analyses using generalized estimation equations.
- The study compared findings in ~1,000 blacks to 22,000 whites.

Findings:
- African-American patients were younger, more likely to be women and to have diabetes, heart failure, and hypertension.
- The low density lipoprotein cholesterol (LDL-C) testing rate for Caucasian men was over 1.4 times higher than that for African-American women and about 1.3 times higher than that for African-American men.
- Almost 60% of tested Caucasian men and less than half of tested African Americans were prescribed lipid-lowering drugs.
- Tested and treated Caucasian men had the highest LDL-C goal attainment (35%) and African-American men the lowest (21%).

Conclusions:
Although increased lipid testing is clearly needed for African Americans, improvements in treatment and control are also necessary to eliminate racial disparities in lipid management. Disparities in treatment and goal attainment must be better understood and reflected in policy to improve the health of underserved populations.
Lipid Therapy among Veterans with Diabetes and Dyslipidemia

Methods:
- A cross-sectional study of veterans serviced by the Veterans Health Administration in 2006 who had both diabetes and hyperlipidemia compared all female patients to age- and facility-matched males.
- Proportions of patients with any prescription for lipid-lowering therapy in the year was compared to those with elevated low-density lipoprotein cholesterol (LDL >100 mg/dL) and no prior treatment and initiation of lipid lowering therapy. Multiple logistic regression was applied to estimate odds ratios (AOR) and 95% confidence intervals (CI) adjusting for race, VA eligibility, health care utilization, CVD, mental health conditions, and comprehensive list of other comorbidities. We also performed the analysis stratified by age.

Findings:
- Women had higher LDL levels than men (110±38 vs. 101±36 mg/dL) and were less likely to be receiving lipid-lowering therapy (80% vs. 84%; AOR, 0.79; 95% CI, 0.76–0.82) or to be initiated on such therapy (57% vs. 62%; AOR, 0.87; 95% CI, 0.74–0.99).
- Differences were greatest in the youngest women (<45 years old) for both any lipid-lowering therapy (61% vs. 75%; AOR, 0.50; 95% CI, 0.45–0.56) and initiation of therapy (26% vs. 38%; AOR, 0.55; 95% CI, 0.42–0.73). Adjustment for potential confounders did not change the risk estimates.

Conclusion:
- Women veterans with diabetes and hyperlipidemia receive less aggressive lipid-lowering therapy than men, especially among younger age groups.
- This disparity is of concern because early intervention to control hyperlipidemia can reduce the later burden of cardiovascular disease among diabetic women.

Findings from Get with the Guidelines (GWTG) Quality Improvement Program

- To address reported disparities in application of evidence-based treatment guidelines for women and the elderly, treatment of 237,225 patients hospitalized with CAD was evaluated in the GWTG–CAD program from 2002 to 2007. Six measures: aspirin on admission and discharge, beta-blockers use at discharge, angiotensin-converting enzyme inhibitor or angiotensin receptor antagonist use, lipid-lowering medication use, and tobacco cessation counseling along with other care metrics.
- Over time, composite adherence on these 6 measures increased from 86.5% to 97.4% (+10.9%) in men and 84.8% to 96.2% (+11.4%) in women. There was a slight difference in composite adherence by sex that remained significant over time (P<0.0001), but this was confined to patients <75 years. Composite adherence in younger patients (<75 yrs.) increased from 87.1% to 97.7% (+10.6%) and from 83.0% to 95.1% (+12.1%) in the elderly (>75 yrs.) over time.

Conclusion: Quality Improvement Programs (GWTG) improve guideline adherence for all subgroups.

Eliminating Treatment Disparities

- Segue to new guidelines
- Focus on ASCVD risk reduction will treat at risk persons that will benefit. Attention to risk reduction heretofore has been under valued and will be helpful for women and minorities.
- Previous cholesterol targets, whether screening for initiation or target goal tended to exclude groups.
- Simple algorithm and emphasis on healthy lifestyle is easy for patient/provider satisfactory interaction.
Background:
- Previous ATP III Cholesterol Guideline was last released in 2001 and updated in 2004. Its approach is comprehensive and complex.
- In 2008 the National Heart Lung and Blood Institute (NHLBI) initiated new guidelines by sponsoring rigorous systematic evidence reviews.
- In 2011, responsive to the Institute of Medicine report focused on only the highest quality evidence and partnered with other organizations.
- Evidence after 2011 is not considered in the development of these guidelines, updates will begin in 2014.

2013 ACC/AHA Cholesterol Guidelines
- Limited in scope, based on highest quality evidence available, (randomized trials, meta-analyses and observational studies). If no evidence there is no recommendation.
- Text to support recommendation is succinct.
- Format is changed. Recommendations are mapped from NHLBI grading format to ACC/AHA Class of Recommendation/Level of Evidence. The alignment between the systems is imperfect.
- Released after independent expert review, scientific review and approval by partners and review and endorsement by professional groups.
- COI, specifically relationship with industry (RWI) is disclosed.

Decades of Research
Acknowledged
- Genetics
- Biochemical
- Animal models
- Pre-clinical studies
- Multiple targets; multiple drugs
- Established direct relationship and causal pathway for elevated LDL-C and ASCVD Guidelines focus on trials, meta analyses, observational studies
**CHD Risk According to LDL-C Level**

Relative Risk for Coronary Heart Disease (Log Scale)

- CHD=Coronary heart disease, LDL-C=Low-density lipoprotein cholesterol

**Therapies to Lower LDL-C**

<table>
<thead>
<tr>
<th>Drug(s)</th>
<th>Class</th>
</tr>
</thead>
<tbody>
<tr>
<td>3-Hydroxy-3-Methylglutaryl Coenzyme A (HMG-CoA) reductase inhibitors [Statins]</td>
<td>Atorvastatin (Lipitor)</td>
</tr>
<tr>
<td></td>
<td>Fluvastatin (Lescol XL)</td>
</tr>
<tr>
<td></td>
<td>Lovastatin (generic and Mevacor)</td>
</tr>
<tr>
<td></td>
<td>Pravastatin (Pravachol)</td>
</tr>
<tr>
<td></td>
<td>Rosuvastatin (Crestor)</td>
</tr>
<tr>
<td></td>
<td>Simvastatin (Zocor)</td>
</tr>
<tr>
<td>Bile acid sequestrants</td>
<td>Cholestyramine (generic and Questran)</td>
</tr>
<tr>
<td></td>
<td>Colesevelam (Welchol)</td>
</tr>
<tr>
<td></td>
<td>Colestipol (Colestid)</td>
</tr>
<tr>
<td>Cholesterol absorption inhibitor</td>
<td>Ezetimibe (Zetia)</td>
</tr>
<tr>
<td>Nicotinic acid</td>
<td>Nicotinamide</td>
</tr>
<tr>
<td>Dietary Adjuncts</td>
<td>Soluble fiber</td>
</tr>
<tr>
<td></td>
<td>Soy protein</td>
</tr>
<tr>
<td></td>
<td>Sterol esters</td>
</tr>
</tbody>
</table>

**HMG-CoA Reductase Inhibitor: Mechanism of Action**

Inhibition of the Cholesterol Biosynthetic Pathway

- HMG-CoA Reductase
- Mevalonate
- Farnesyltransferase
- Geranylgeranyl protein
- Ubiquinones
Hepatocyte

Systemic Circulation

The reduction in hepatic cholesterol synthesis lowers intracellular cholesterol, which stimulates upregulation of the LDL receptor and increases uptake of non-HDL particles from the systemic circulation.

HMG-CoA Reductase Inhibitor: Mechanism of Action

HMG-CoA Reductase Inhibitor: Dose-Dependent Effect

Each doubling of the statin dose produces an additional 6% (approximate) reduction in the LDL-C level.

2013 Cholesterol Guidelines (new perspectives)

New Guidelines:
- Direct focus on atherosclerotic cardiovascular (ASCVD) risk reduction.
- LDL-C, non-HDL-C targets are abandoned.
- Global Risk Assessment for primary prevention is an important consideration.
- There are safety recommendations.
- Role of Biomarkers and Noninvasive tests is included.
- Future Updates to this Cholesterol Guideline are anticipated.
Recommendations

- Lifestyle modification is foundation for ASCVD Risk Reduction:
  - Heart healthy diet – strong evidence to reduce salt and follow Mediterranean or DASH diet
  - Regular exercise – aerobic and strength building exercises for 30 minutes four times weekly
  - Avoidance of tobacco products
  - Maintenance of healthy weight

ASCVD risk reduction must include understanding and commitment to healthy lifestyle.

2013 Cholesterol Guidelines

- Non-statin cholesterol–lowering drugs have fewer trials and lack evidence for significant additional ASCVD event reduction and are not recommended.
- LDL-C and Non-HDL treatment targets, widely used over past 15 years are problematic and are not recommended
  - CTs lack evidence of specific target(s)
  - No evidence for ASCVD reduction by differential
  - Does not consider adverse effects from multi-drugs

2013 Cholesterol Guidelines cont’d

- Lowest is best – this approach is also abandoned because of potential AEs from multidrug regimens.
- Treat level of ASCVD Risk – a modified version of this approach is adopted.
- Lifetime risk approach was not taken because of paucity of data on long-term follow up of RCT’s over 15 years.
2013 Cholesterol Guidelines cont’d

- Four Major Statin Benefit groups:
  - Clinical ASCVD
  - Primary elevation of LDL-C >189mg/dL
  - Diabetics aged 40-75 years with LDL-C >70<189mg/dL
  - Individuals aged 40-75 years without ASCVD or DM with 1 year risk score at or above >7.5%

ASCVD includes coronary heart disease (CHD), stroke, and peripheral artery disease (PAD)

Cholesterol Treatment

- Treatment strategy is simplified to:
  1. high intensity (HI) or
  2. moderate (MI) statin therapy.

- Statin intensity is defined as
  - HI - Rosuvastatin (20-40 mgs) or Atorvastatin (80 mgs) to lower LDL-C by 50%
  - MI – statin to lower LDL-C by 30-50%

LDL measures remain important to monitor individual response to therapy and adherence.

Cholesterol Treatment cont’d

- Treatment by statin benefit group
  - Clinical ASCVD – HI
  - LDL-C > 189 mg/dL – HI
  - Diabetes, aged 40-75, LDL-C >70-189 mg/dL-MI
  - No diabetes or ASCVD, age 40-75, LDL~70-189, and 10 year risk at or greater than 7.5% -MI or HI

- Other considerations: family history of premature ASCVD in a first degree relative, high-sensitivity C-reactive protein (CRP) > 2mg/L, the presence of calcification on a coronary artery calcium (CAC) scan
Predisposition to statin toxicity:

- Multiple serious comorbidities including impaired renal or hepatic function.
- History of previous statin intolerance
- Unexplained ALT >3X ULN.
- Patient factors or drug that affect statin metabolism.
- Age >75 years.
- Others: history of hemorrhagic stoke; Asian ancestry

Statin Safety Recommendations

74,102 subjects in 35 randomized clinical trials with statins

- 1.4% incidence of elevated hepatic transaminases (1.1% incidence in control arm)
- Dose-dependent phenomenon that is usually reversible
- 15.4% incidence of myalgias* (18.7% incidence in control arm)
- 0.9% incidence of myositis (0.4% incidence in control arm)
- 0.2% incidence of rhabdomyolysis (0.1% incidence in control arm)

*Kashani A et al. Circulation 2006;114:2788-97

HMG-CoA Reductase Inhibitor: Adverse Effects

Treatment Guidelines

- Challenging time for healthcare in US
- 2013 Guidelines represent a dramatic change in approach. The resultant guidelines are practical, patient oriented focusing on available evidence to protect CV health of patients. This is good for the patient and managing health costs and disease burden.
- Future guidelines using quality evidence may address more complex patient
- Eliminating health disparities is doable and a moral imperative.
- Monitoring outcomes and safety by subgroups with quality improvement oversight is important to achieve best outcomes.
- Continued research to examine sex differences in pathophysiology and to address subpopulations with greater risk, disproportionate disease burden, and poorer outcomes is needed.
- Ongoing monitoring of health care system differences in treatment and outcomes of care is important and is best strategy for health equity.
Summary

- CVD is a remains a major health and economic burden.
- CVD Treatment has provided benefit to all Americans.
- Women and racial and ethnic minorities often are undertreated.
- Quality improvement programs narrow treatment gaps.
- 2013 ACC/AHA cholesterol guidelines focus on ASCVD risk reduction.
- A risk reduction strategy will benefit heretofore undertreated patients.

Conclusions

- Treatment disparities are reduced with quality improvement oversight.
- Reducing ASCVD risk is central to improving CV health and reducing CVD-related health care costs.
- 2013 ACC/AHA guidelines simplify therapy and focus on reduction of ASCVD events.
- Risk reduction will benefit heretofore undertreated groups.
- New guidelines and quality improvement programs promise to promote improved CV outcomes for all Americans.

Questions?
Related HHQI Resources

• Cardiovascular Health Part 1 BPIP
  – Aspirin as appropriate & Blood pressure control
• Look for an update next month related to the newer guideline updates for blood pressure

Related HHQI Resources

• Cardiovascular Health Part 2 BPIP
  – Cholesterol management & Smoking cessation
• Cardiovascular Health Part 2 Update (next slide)

Related HHQI Resources

• Cardiovascular Health Part 2 Update
  – Treatment of Blood Cholesterol
  – Assessment of Cardiovascular Risk
  – Lifestyle Management to Reduce Cardiovascular Risk
  – Management of Overweight and Obesity in Adults
HHQI Cardiovascular Data

• HHQI Cardiovascular Risk Reports
  – Available with general reports

• HHQI Cardiovascular Data Registry
  – Current focus is on:
    • Aspirin or other antithrombotic as appropriate for ischemic vascular diseases
    • Prevention, screening, and controlling hypertension
  – HHCDR Reports for those agencies abstracting
  – Numerous resources available on https://secure.homehealthquality.org/Resources.aspx

Upcoming BPIP

• Disease Management: Heart Failure Focused BPIP
  – To be released in April
The Gravity of Falls: Evidence-Based Preventative Strategies

- Tuesday, April 29, 2014 at 2-3 pm (ET)
- Topics
  - Discuss validated multi-factorial fall risk assessments
  - Examine your data findings and adjust your internal thresholds to identify high-risk patients in need of interventions
  - Identify fall prevention interventions for implementation by clinicians in the home
  - Discuss major classes of medications that either increase risk for falls or increase risk of injury from a fall
  - Review changes in metabolism of medications commensurate with aging
- Guest Speakers
  - Nancy Kimmons, BS, PT, Home Care Therapy Operations Manager, Rehab Affiliates, Division of Main Line Health, Philadelphia, PA
  - Michele James, BSN, MSS, RN-BC, Home Care Case Manager, The Home Care Network, Jefferson University Hospitals, Philadelphia, PA
  - Chuck Lally, RPh, Pharmacist, University Hospitals Home Care Services
  - Joanne M. Wile-Avenmarg, OTR/L, M.S., Director of Clinical Operations, University Hospitals Home Care Services

Thank You!

www.HomeHealthQuality.org
HHQI@wvmi.org

This material was prepared by the West Virginia Medical Institute, the Quality Improvement Organization supporting the Home Health Quality Improvement National Campaign, under contract with the Centers for Medicare & Medicaid Services (CMS), an agency of the U.S. Department of Health and Human Services. The views presented do not necessarily reflect CMS policy. Publication Number: 10228-WV-WMM-HHQI-031814.