



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

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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

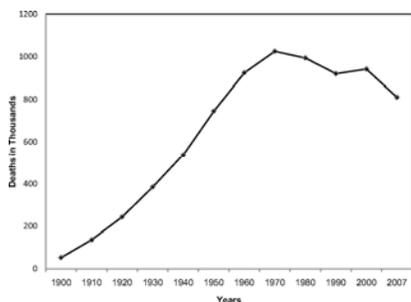


Specific Objectives for Attendees

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



Roger V. L. et al. Circulation. 2011;123:e18-e209

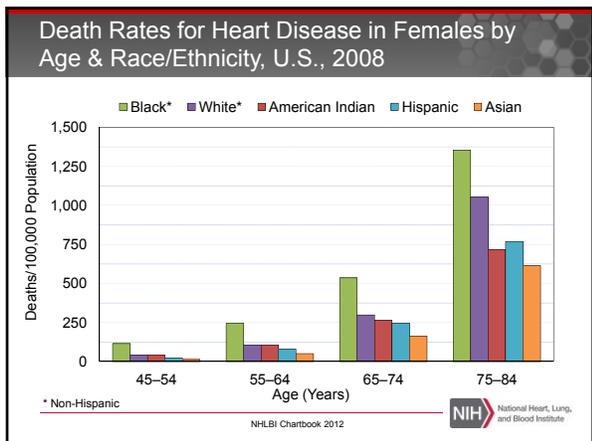


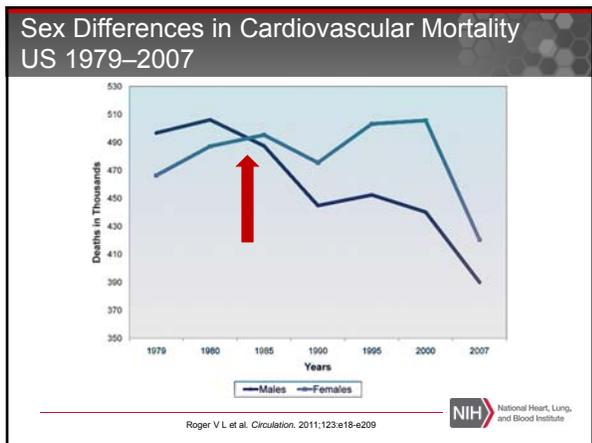
Life Expectancy by Race and Sex, US 2008

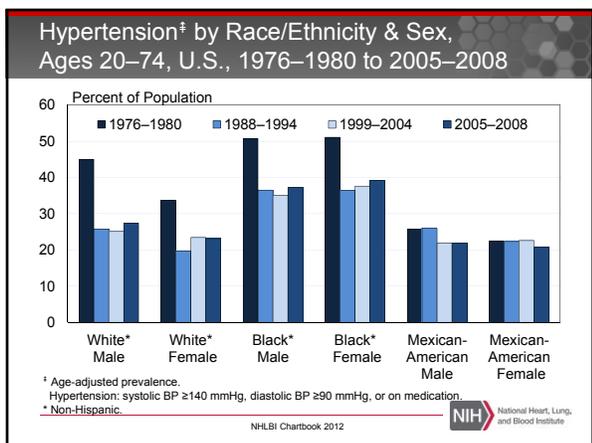
Age (Years)	Total	Male	Female	Total White	White Male	White Female	Total Black	Black Male	Black Female
Birth	78.9	75.5	80.3	78.4	75.9	80.8	74.3	71.9	77.4
15	83.8	81.3	86.1	84.0	81.6	86.3	80.6	77.2	83.6
35	44.7	42.6	46.7	44.9	42.8	46.9	41.8	39.0	44.3
65	18.7	17.2	19.9	18.7	17.3	19.9	17.5	15.5	18.9
75	11.7	10.6	12.5	11.6	10.6	12.4	11.3	10.0	12.2

NHLBI Chartbook 2012









Sex/Gender Differences in the Burden of CVD

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

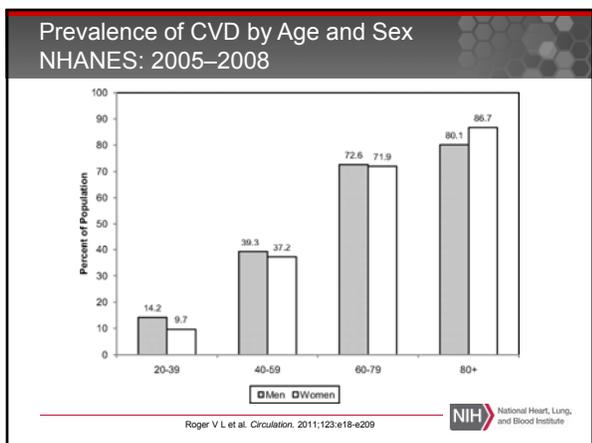
	Men	Women
Remaining lifetime risk for CVD at age 40 y	2 in 3	1 in 2
CVD		
Deaths - CVD and congenital heart disease (2007)	391,886	421,918
Age-adjusted CVD death rate per 100,000 (2007)	300.3	211.6
Prevalence of CVD (2008, age ≥20 y), in millions	39.9 (37.4%)	42.7 (35.0%)
Hospital discharges for CVD (2007)	3,016,000	2,874,000
Coronary Heart Disease		
Deaths caused by CHD (2007)	216,050	190,301
Age-adjusted CHD death rate per 100,000 (2007)	165.4	95.7
Prevalence of CHD (2008, age ≥20 y), in millions	8.8(8.3%)	7.5 (6.1%)
Hospital discharges for CHD (2007)	965,000	607,000
Stroke		
Deaths resulting from stroke (2007, all ages)	54,111	81,841
Age-adjusted stroke death rate per 100,000	42.5	41.3
Prevalence of stroke (2008, age ≥20 y), in millions	2.8 (2.7%)	4.2 (3.3%)
Hospital discharges for stroke (2007)	371,000	458,000
Heart failure		
Prevalence of heart failure (2008, age ≥20 y), in millions	3.1 (3.0%)	2.6 (2.0%)
Hospital discharges for heart failure (2007, all ages)	470,000	520,000

Risk Factor Burden by Sex

Risk Factor	Women	Men
Hypertension	29%	31%
Diabetes Mellitus	8%	7%
Total Cholesterol >240 mg/dl	16%	14%
Physical Inactivity	35%	30%
Obesity	64%	72%
Smoking	18%	23%

1. MMWR January 14, 1011 / 60(01):94-97
2. Mosca L et al. Circulation. 2011;124:2145-2154

NIH National Heart, Lung, and Blood Institute



Differences vs. Disparities

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

SOURCE: Games and McGuire. 2001 from IOM. *Unequal treatment: confronting racial and ethnic disparities in health care*. 2002.

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.

M W Massing et al, *BMC Cardiovascular Disorders* 2004, 4:15 doi:10.1186/1471-2261-4-15

Racial Disparity in Cholesterol Treatment

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.

M W Massing et al, *BMC Cardiovascular Disorders* 2004, 4:15 doi:10.1186/1471-2261-4-15

2013 ACC/AHA Cholesterol Guidelines

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.



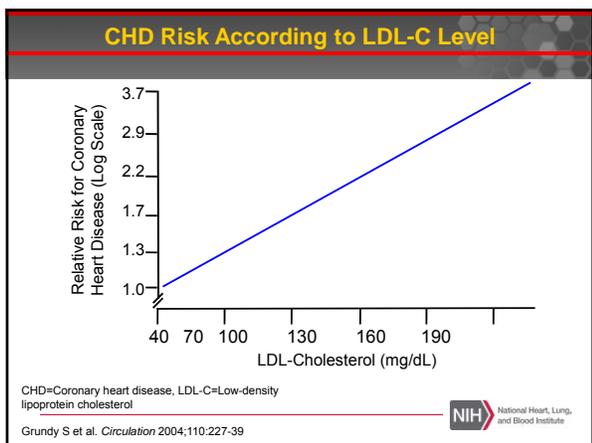
Decades of Research

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

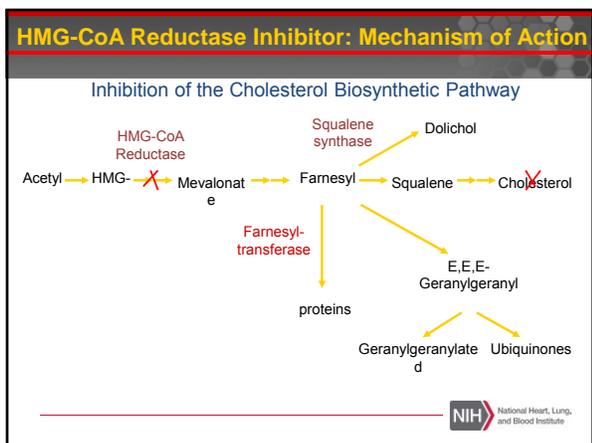


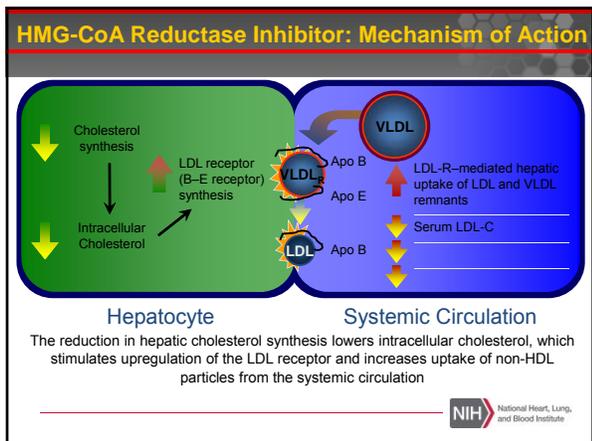


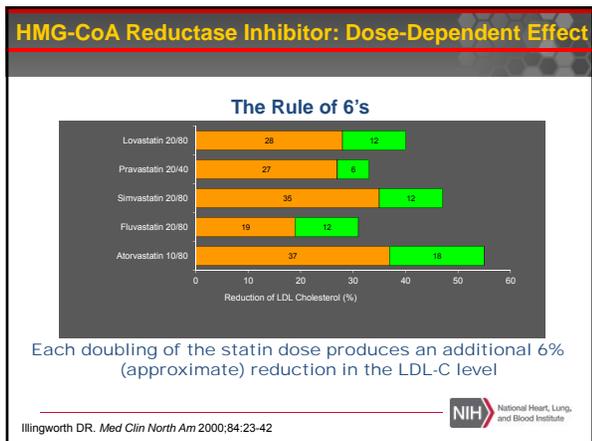
Therapies to Lower LDL-C

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

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- ### 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.
- NIH National Heart, Lung, and Blood Institute

Lifestyle and Risk Assessment Groups

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



Statin Safety Recommendations

Predisposition to statin toxicity:

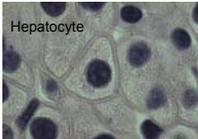
- Multiple serious comorbidities including impaired renal or hepatic function.
- History of previous statin intolerance
- Unexplained ALT >3X ULN.
- Patient factors or drug that affect statin metabolism.
- Age >75 years.
- Others: history of hemorrhagic stroke; Asian ancestry



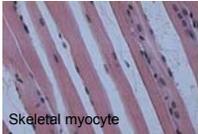
HMG-CoA Reductase Inhibitor: Adverse Effects

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)



Hepatocyte



Skeletal myocyte

*The rate of myalgias leading to discontinuation of atorvastatin in the TNT trial was 4.8% and 4.7% in the 80 mg and 10 mg arms, respectively.



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

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.

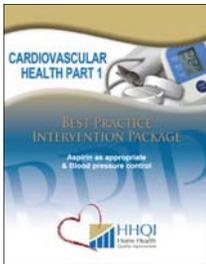


Questions?



Related HHQI Resources

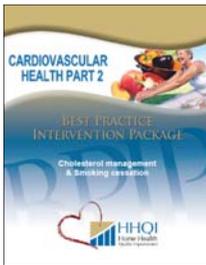
- Cardiovascular Health Part 1 BPIP
 - Aspirin as appropriate & Blood pressure control
- Look for an update next month related to the newer guideline updates for blood pressure



The image shows the cover of a document titled 'CARDIOVASCULAR HEALTH PART 1'. Below the title, it says 'BEST PRACTICE INTERVENTION PACKAGE'. A sub-heading reads 'Aspirin as appropriate & Blood pressure control'. At the bottom, there is the HHQI logo with the text 'Home Health'.

Related HHQI Resources

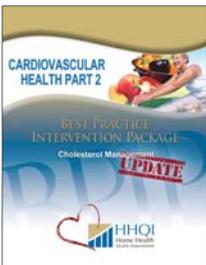
- Cardiovascular Health Part 2 BPIP
 - Cholesterol management & Smoking cessation
- Cardiovascular Health Part 2 Update (next slide)



The image shows the cover of a document titled 'CARDIOVASCULAR HEALTH PART 2'. Below the title, it says 'BEST PRACTICE INTERVENTION PACKAGE'. A sub-heading reads 'Cholesterol management & Smoking cessation'. At the bottom, there is the HHQI logo with the text 'Home Health'.

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



The image shows the cover of a document titled 'CARDIOVASCULAR HEALTH PART 2'. Below the title, it says 'BEST PRACTICE INTERVENTION PACKAGE'. A sub-heading reads 'Cholesterol Management UPDATE'. At the bottom, there is the HHQI logo with the text 'Home Health'.

HHQI Cardiovascular Data

- HHQI Cardiovascular Risk Reports
 - Available with general reports

HHQI Cardiovascular Data

- 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 BPPI

- Disease Management: **Heart Failure Focused BPPI**
 - 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!



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