Cardiovascular Risk Reduction in Adults: The Lifestyle Workgroup
Background and Methods

NHLBI-sponsored CVD Guidelines and National Partnership Programs

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Nutritionist
National Heart, Lung, and Blood Institutes

Institute of Medicine
Perspectives on Dietary Sodium and Health
December 05, 2012
To provide global leadership through research and education to enhance the health of all individuals so that they can live longer and more fulfilling lives.
CVD prevention in adults:
- Obesity (1998)

CVD prevention in children/adolescents:
- Cholesterol (1991)
- Integrated CV risk reduction (2011)
History of NHLBI CVD Adult Clinical Guidelines

Joint National Committee on Prevention, Detection, Evaluation, & Treatment of High Blood Pressure (JNC)

- JNC 7: 2003
- JNC 6: 1997
- JNC 5: 1992
- JNC 4: 1988
- JNC 3: 1984
- JNC 2: 1980
- JNC 1: 1976

Detection, Evaluation, & Treatment of High Blood Cholesterol in Adults (ATP, Adult Treatment Panel)

- ATP III Update: 2004
- ATP III: 2002
- ATP II: 1993
- ATP I: 1988

Clinical Guidelines on the Identification, Evaluation, & Treatment of Overweight and Obesity in Adults

- Obesity 1: 1998
New directions for CV guidelines derived from recommendations by several groups:

- **NHLBI Cardiovascular Disease Thought Leaders**
  - June 17, 2005
- **NHLBI Clinical Guidelines Users and Developers**
  - March 7, 2006
- **NHLBI Guidelines Leadership Group**
  - November 15, 2007
Updated NHLBI Approach

- Follow major recommendations:
  - Update risk factor guidelines (HTN, cholesterol, obesity)
  - Use evidence-based approach and systematic reviews
  - Develop integrated strategy for CV risk reduction

- New NHLBI guideline development process
  - Enable guidelines to remain “state of the art”
  - Use systematic reviews as basis for recommendations
  - Use methods that meet most of the new IOM standards
    - “Finding What Works in Health Care” (standards for SRs)
    - “Clinical Practice Guidelines We can Trust” (standards for developing trustworthy CPGs)
17 standards in 8 categories

1. Transparent process—details about process & funding
2. Conflicts of Interest managed—COI in group selection, disclosures, divestments, exclusions
3. Group composition—multidisciplinary and balanced
4. Based on systematic reviews
5. Recommendations rated for strength of evidence
6. Recommendations clearly written
7. External review by stakeholders and experts
8. Updated when new evidence is available

NHLBI process meets 75%-88% of the standards (depending on interpretation)
77 standards in 4 categories

1. Initiating the Systematic Review
   • Appropriate expertise, managed COI, formulation of topic, SR protocol

2. Standards for findings and assessing individual studies
   • Comprehensive search, grey literature, screen/select studies, document search, manage data collection, appraise each study

3. Synthesizing the body of evidence
   • Prespecified method to evaluate body of evidence, qualitative synthesis, consider quantitative synthesis (meta-analyses)

4. Reporting the systematic review
   • Structured format including exec summary, organize around key questions, include discussion, funding sources, COI, peer review

NHLBI process meets 76%-81% of standards (depending on interpretation)
NHLBI Systematic Review and Guideline Development Process

- **Topic Area Identified**
- **Resources Obtained; Expert Panel Established**
- **Critical Questions, Study Eligibility Criteria Identified by Panel**
- **Literature Searched**
  - **All Eligible Studies Identified**
- **Studies Quality Rated**
  - **Evidence Tables Developed**
- **Evidence Statements Written**
  - **by panel; Graded w/ Methodologist advice**
- **Recommendations Developed & Graded By Panel**
- **Draft Reports Written, Reviewed, Revised**
- **Reports Disseminated & Implemented**

*Blue portion is the Systematic Review
**Done by Contractors
Infrastructure: CVD Guidelines
Expert Panels and Work Groups

**BP Panel**
- **N=17**
- Evidence Review on BP Tx
- 3 CQs

**Cholesterol Panel**
- **N=15**
- Evidence Review on Cholesterol Tx
- 3 CQs

**Obesity Panel**
- **N=19**
- Evidence Review on Obesity
- 5 CQs

**Lifestyle WG**
- **N=15**
- Evidence Review on Diet & Physical Activity
- 3 CQs

**Risk Assessment WG**
- **N=16**
- Evidence Review & Risk Prediction Model
  + 2 CQs

5 reports being written

Total of 16 Critical Questions

**Implementation WG**
- **N=18**
- Implementability Guidance
- Implementation Science Review
Regarding charge #1:
Review of Adult CVD Guideline Reports

*Reviews That Occur Simultaneous
Two Review Steps Added based on IOM Standards (in red)

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Every review comment considered; reports modified to address issues.
About 60 expert volunteers serve on the committees as volunteers.
# Lifestyle Workgroup Members

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<th>Robert H. Eckel, MD</th>
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<td>Van S. Hubbard, MD, PhD</td>
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<td>Catherine M. Loria, PhD</td>
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<td>Susan Z. Yanovski, MD</td>
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Workgroup lead: Janet de Jesus, MS, RD
Evidence Review on Diet and Physical Activity (in the absence of weight loss) to be integrated with the recommendations of the Blood Cholesterol and Blood Pressure panels.
1. Effect of dietary patterns and macronutrient composition on blood pressure and lipids

2. Effect of dietary sodium and potassium on BP and CHD/CVD outcomes

3. Effect of physical activity on blood pressure and cholesterol
   - Looking at observational epidemiology studies and RCTs;
Critical Question 2:
Exclusion criteria

- Supplements in greater than dietary range and/or in pharmacologic doses.
- Non-oral routes of nutrient delivery
- Studies where the is weight change $\geq 3\%$
- Surgery
- Outcomes by measure of self-report (exempt from exclusion are studies that use structured methods that include self reporting such as validated diet records, food frequency questionnaires, diet histories.)
Methods
Literature Review Process

- Systematic search of the literature for each critical question using inclusion/exclusion criteria

- Initial screen of citations by title and abstracts, followed by full-text review

- All articles reviewed for inclusion independently by two trained reviewers

- If the reviewers do not agree about inclusion status, a 3rd reviewer.
Rating the Quality of Individual Studies

• The quality of each “included” study is rated by two independent reviewers
  ▪ Good, Fair, Poor

  ▪ If the raters do not agree, a 3rd rater with content and methodological expertise reviews and adjudicates

  ▪ Standardized NHLBI rating instruments with pre-specified criteria
Quality Rating Tools

- Controlled intervention studies (e.g., RCTs)
- Observational studies (cohort, case-control)
- Systematic reviews and meta-analyses
### NHLBI Evidence Quality Grading and Recommendation Strength

#### Evidence Quality (for Evidence Statements)
- **High**
  - Well-designed and conducted RCTs
- **Moderate**
  - RCTs with minor limitations
  - Well-conducted observational studies
- **Low**
  - RCTs with major limitations
  - Observational studies with major limitations

#### Recommendation Strength
- A – Strong
- B – Moderate
- C – Weak
- D – Against
- E – Expert Opinion
- N – No Recommendation

Similar to USPSTF grading system, with the addition of Expert Opinion.
### NHLBI Recommendation Strength

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<tr>
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<tr>
<td>A</td>
<td>Strong recommendation  &lt;br&gt;High certainty that the net benefit is substantial. Benefits are much greater than risks/harms.</td>
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<tr>
<td>B</td>
<td>Moderate recommendation  &lt;br&gt;Reasonable certainty that the net benefit is moderate to substantial or there is high certainty that the net benefit is moderate. Benefits are greater than risks/harms.</td>
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<tr>
<td>C</td>
<td>Weak recommendation  &lt;br&gt;At least moderate certainty that the net benefit is small. Benefits may slightly outweigh risks/harms.</td>
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<td>D</td>
<td>Recommendation against  &lt;br&gt;At least moderate certainty that it has no net benefit or that risks/harms outweigh benefits.</td>
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<tr>
<td>E</td>
<td>Expert opinion  &lt;br&gt;Net benefit is unclear. Balance of benefits and harms cannot be determined because of no evidence, insufficient evidence, or conflicting evidence, but the panel thought it was important to provide clinical guidance and make a recommendation. Further research is recommended.</td>
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<tr>
<td>N</td>
<td>No recommendation for or against  &lt;br&gt;Net benefit is unclear. Balance of benefits and harms cannot be determined because of no evidence, insufficient evidence, or conflicting evidence, and the panel thought no recommendation should be made. Further research is recommended.</td>
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New reports vs Previous reports

- New guideline reports won’t look like prior ones
  - All recommendations based on systematic reviews
  - Restricted to a few critical questions
  - More depth, less breadth

- Because of the different approach to evidence review and new evidence since the last reports:
  - Some recommendations will be different
  - There may be policy implications - TBD
New Program – NPRCR
New Integrated NHLBI-sponsored National Education Program

OLD

- National High Blood Pressure Education Program (NHBPEP) 1972
- National Cholesterol Education Program (NCEP) 1985
- NHLBI Obesity Education Initiative (OEI) 1998

NEW

National Program to Reduce Cardiovascular Risk (NPRCR) 2011
An Integrated Approach
Evidence-based collaborative effort to control CVD risk factors
NPRCR will engage partners in collaborating to:

- Detect and manage CVD risk factors through clinical services and outreach
- Assess evidence for approaches to reduce CVD risk
- Implement evidence-based guidelines and interventions
- Work toward harmonization
### Professional Organizations:
1. Academy of Nutrition and Dietetics  
2. American Academy of Family Physicians  
3. American Academy of Nurse Practitioners  
4. American Academy of Pediatrics  
5. American Academy of Physician Assistants  
6. American College of Cardiology  
7. American College of Physicians  
8. American College of Sports Medicine  
9. American Heart Association/American Stroke Association  
10. American Medical Association  
11. American Pharmacists Association  
12. American Public Health Association  
13. American Society of Hypertension  
14. Association of Black Cardiologists  
15. National Medical Association  
16. Preventive Cardiovascular Nurses Assn  
17. The Lipid Society  
18. The Obesity Society  

### Federal Agencies:
19. Agency for Healthcare Research and Quality (AHRQ)  
20. Centers for Disease Control and Prevention (CDC)  
21. Centers for Medicaid and Medicare Services (CMS)  
22. Department of Defense (DOD)  
23. Food and Drug Administration (FDA)  
24. Health Resources and Services Administration (HRSA)  
25. Indian Health Service (IHS)  
26. Office of Disease Prevention, NIH  
27. United States Department of Agriculture (USDA)  
28. Department of Veterans Affairs (VA)  

### Quality Care Organizations:
29. National Committee for Quality Assurance (NCQA)  
30. National Initiative for Children’s Healthcare Quality (NICHQ)
Some examples of Partners

- National Prevention Strategy
- HUD
- Healthy People
- American Society of Hematology
- American Health Association
- Community-Based Orgs.
- Regional Health Plan
- Healthy People
- Food & Drug Admin.
- Centers for Disease Control & Prevention
- Indian Health Service
- Indian Health Service
- Health Resources & Services Admin
- Health Resources & Services Admin
- Million Hearts
- Agency for Healthcare Research & Quality
- Agency for Healthcare Research & Quality
- Healthy People
- American Public Health Association
- Centers for Disease Control & Prevention
- American Public Health Association
Conclusion

- New NHLBI-sponsored CV prevention guidelines
  - Will translate hundreds of millions of dollars of research into a form useful in practice
  - Will be strongly evidence based
  - When implemented, will reduce CV risk and have a major impact on the health of the nation

- For more information:
  [www.nhlbi.nih.gov/guidelines/cvd_adult/background.htm](http://www.nhlbi.nih.gov/guidelines/cvd_adult/background.htm)
Thank you!