Gender issues in cardiovascular guidelines

Peter Collins
Professor of Clinical Cardiology, Royal Brompton Hospital & Imperial College
London, UK
Many women and their physicians are unaware that cardiovascular disease (CVD) is the commonest cause of death in women.
Women’s Perceptions of Their Greatest Health Problems


- Breast Cancer: 34%
- Cardiovascular Disease: 27%
- Other Problems: 16%
- Don’t Know/No Answer: 7%

Causes of Death Among Women*

*Percentage of total deaths in 1999 among women aged 65 years and older.

- Heart Disease: 34%
- Other Cancers: 28%
- Cerebrovascular Disease: 15%
- Other: 10%
- Breast Cancer: 6%
- Diabetes: 3%
- Chronic Lower Respiratory Disease: 4%
- Other: 3%
Women Enrolled in Major Cardiovascular Trials

- 4S (Simvastatin) 20%
- CARE (Pravastatin) 14%
- WOSCOP (Pravastatin) 0%
- CHAOS (Vit E) 10%
- AIRE (Ramipril) 17%
- ISIS 3 (Streptokinase) 27%
- ISIS 4 (Mg, nitrate, captopril) 26%

Clinical Practice Guidelines

- systematically developed statements to assist practitioners with decisions about appropriate health care for specific patients’ circumstances
- Guidelines often assumed to be epitome of evidence-based medicine
- Guideline recommendations imply not only an evaluation of the evidence but also a value judgment based on personal or organizational preferences regarding the various risks and benefits of a medical intervention for a population
ACC/AHA Guidelines

- 20 years - American College of Cardiology (ACC) and American Heart Association (AHA) have released clinical practice guidelines to provide recommendations on care of patients with cardiovascular disease.


Scientific Evidence Underlying the ACC/AHA Clinical Practice Guidelines

Pierluigi Tricoci; Joseph M. Allen; Judith M. Kramer; et al.

JAMA. 2009;301(8):831-841
The joint cardiovascular practice guidelines of the American College of Cardiology (ACC) and the American Heart Association (AHA) have become important documents for guiding cardiology practice and establishing benchmarks for quality of care.

To describe the evolution of recommendations in ACC/AHA cardiovascular guidelines and the distribution of recommendations across classes of recommendations and levels of evidence.
Data Sources and Study Selection

• Data from all ACC/AHA practice guidelines issued from 1984 to September 2008 were abstracted by personnel in the ACC Science and Quality Division
• Fifty-three guidelines on 22 topics
• Total of 7196 recommendations

Data Extraction

• Number of recommendations and the distribution of classes of recommendation (I, II, and III) and levels of evidence (A, B, and C) determined
• The subset of guidelines that were current as of September 2008 was evaluated to describe changes in recommendations between the first and current versions as well as patterns in levels of evidence used in the current versions
### Classes of Recommendations

<table>
<thead>
<tr>
<th>Classes of Recommendations</th>
<th>Definition</th>
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</thead>
<tbody>
<tr>
<td>Class I</td>
<td>Evidence and/or general agreement that a given treatment or procedure is beneficial, useful, effective.</td>
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<tr>
<td>Class II</td>
<td>Conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of the given treatment or procedure.</td>
</tr>
<tr>
<td>Class IIla</td>
<td>Weight of evidence/opinion in favour of usefulness/efficacy.</td>
</tr>
<tr>
<td>Class IIlb</td>
<td>Usefulness/efficacy is less well established by evidence/opinion.</td>
</tr>
<tr>
<td>Class III</td>
<td>Evidence or general agreement that the given treatment or procedure is not useful/effective, and in some cases may be harmful.</td>
</tr>
</tbody>
</table>

### Levels of Evidence

| Level of Evidence A | Data derived from multiple randomized clinical trials or meta-analyses. |
| Level of Evidence B | Data derived from a single randomized clinical trial or large non-randomized studies. |
| Level of Evidence C | Consensus of opinion of the experts and/or small studies, retrospective studies, registries. |
Results

• Guidelines with at least 1 revision or update by September 2008 - number of recommendations increased from 1330 to 1973 (48%) from the first to the current version - largest increase observed in use of class II recommendations

• 16 current guidelines reporting levels of evidence, only 314 recommendations of 2711 total are classified as level of evidence A (median, 11%)

• 1246 (median, 48%) are level of evidence C

• Level of evidence significantly varies across categories of guidelines (disease, intervention, or diagnostic) and across individual guidelines

• Recommendations with level of evidence A are mostly concentrated in class I, but only 245 of 1305 class I recommendations have level of evidence A (median, 19%)

Clinical Practice Guidelines published by AHA/ACC/ESC

Disease Guidelines

Atrial fibrillation
Heart failure
Perioperative evaluation
Stable angina
Unstable angina
Valvular heart disease
### Change in recommendations and class in AHA guidelines

**Table 1.** Change in the Number of Recommendations and Distribution Across Classes of Recommendation Between First Guideline Version and Current Version*

<table>
<thead>
<tr>
<th>Guidelines by Year of Publication</th>
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<tr>
<td></td>
<td>No./Total (%)</td>
<td>Change, %</td>
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</tr>
<tr>
<td>Atrial fibrillation</td>
<td>46/65 (45.4)</td>
<td>-27.7</td>
<td>39/65 (60)</td>
</tr>
<tr>
<td>Heart failure</td>
<td>75/127 (59.0)</td>
<td>-11.0</td>
<td>32/127 (25.1)</td>
</tr>
<tr>
<td>Paroxysmal atrial fibrillation</td>
<td>8/29 (28)</td>
<td>-4.0</td>
<td>27/50 (54.0)</td>
</tr>
<tr>
<td>Stable angina</td>
<td>67/162 (41.6)</td>
<td>-10.7</td>
<td>94/255 (37.1)</td>
</tr>
<tr>
<td>Unstable angina</td>
<td>8/71 (11.2)</td>
<td>1.5</td>
<td>29/126 (22.7)</td>
</tr>
<tr>
<td>Valve heart disease</td>
<td>154/261 (59.1)</td>
<td>-11.1</td>
<td>44/139 (31.4)</td>
</tr>
<tr>
<td>Change in distribution across classes, median (IQR), %</td>
<td>-10.2</td>
<td>(-17.5 to -1.2)</td>
<td>16.7</td>
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### Change in recommendations and class in AHA guidelines

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<td>16.7</td>
</tr>
</tbody>
</table>

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**Notes:**
- *AHA guidelines* refer to the American Heart Association guidelines for the management of heart disease.
- Class I recommendations are strong recommendations, Class II recommendations are moderate recommendations, and Class III recommendations are weak recommendations.
- Numbers in parentheses indicate the percentage of total recommendations.
- Changes in recommendations are highlighted for emphasis.
Clinical Practice Guidelines
published by AHA/ACC/ESC

Interventional Guidelines

CABG
PCI
Pacemaker

Change in recommendations and class in AHA interventional guidelines

<table>
<thead>
<tr>
<th>Interventional guidelines</th>
<th>Class I</th>
<th>Change, %</th>
<th>Class II</th>
<th>Change, %</th>
<th>Class III</th>
<th>Change, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>CABG 1999</td>
<td>28/55 (50.9)</td>
<td>0</td>
<td>19/55 (35.5)</td>
<td>11/55 (19.6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2004</td>
<td>39/56 (69.6)</td>
<td>0</td>
<td>35/56 (62.5)</td>
<td>19.3</td>
<td>11/56 (19.6)</td>
<td>-33.3</td>
</tr>
<tr>
<td>Pacemaker 1999</td>
<td>27/87 (31.0)</td>
<td>0.4</td>
<td>29/87 (33.3)</td>
<td>31/87 (36.5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2008</td>
<td>36/122 (30.1)</td>
<td>0</td>
<td>52/122 (42.7)</td>
<td>23.0</td>
<td>34/122 (27.9)</td>
<td>-21.8</td>
</tr>
<tr>
<td>PCI 1999</td>
<td>20/99 (20.3)</td>
<td>0</td>
<td>27/99 (27.2)</td>
<td>23.0</td>
<td>22/99 (22.3)</td>
<td>-31.5</td>
</tr>
<tr>
<td>2005</td>
<td>39/136 (28.7)</td>
<td>-1.1</td>
<td>69/136 (50.7)</td>
<td>20.7</td>
<td>28/136 (20.6)</td>
<td>-35.4</td>
</tr>
</tbody>
</table>

Change in No. of recommendations: +43, -70, +9

Change in distribution across classes, median (IQR, %): 0 (0.0 to 0.2), 23.0 (21.2 to 25.4), -32.3 (~34.4 to -27.6)
Change in recommendations and class in AHA interventional guidelines

| Interventional guidelines | Class I | | Class II | | Class III | |
|---------------------------|---------|----------------|---------|----------------|---------|
|                           | No./Total (%) | Change, % | No./Total (%) | Change, % | No./Total (%) | Change, % |
| CABG                      | 26/56 (46.4)  | 19/56 (33.9) | 11/56 (19.6) |
| PCI                        | 27/87 (31.0)  | 20/87 (33.3) | 31/87 (36.8) |
| 2005**                    | 38/122 (31.1) | 50/122 (41.0) | 23/122 (27.9) |

Change in No. of recommendations

Change in distribution across classes, median (IQR): %

- Echocardiography: 0 (-0.5 to 0.2)
- Exercise testing: 23.0 (21.2 to 26.4)
- Radionuclide testing: 33.3 (-34.4 to -27.6)

Clinical Practice Guidelines published by AHA/ACC/ESC

Diagnostic Guidelines

Echocardiography
Exercise testing
Radionuclide testing
## Change in recommendations and class in AHA diagnostic guidelines

### Table 1: Change in Recommendations and Class in AHA Diagnostic Guidelines

<table>
<thead>
<tr>
<th></th>
<th>Class I</th>
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<th>Class II</th>
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<th>Class III</th>
</tr>
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<tbody>
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<td></td>
<td>No./Total (%)</td>
<td>Change, %</td>
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<td>No./Total (%)</td>
</tr>
<tr>
<td><strong>Diagnostic guidelines</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Echocardiography 1990&lt;sup&gt;1&lt;/sup&gt;</td>
<td>69/116 (59.3)</td>
<td>14.1</td>
<td>27/116 (23.0)</td>
<td>-21.9</td>
<td>21/116 (18.1)</td>
</tr>
<tr>
<td>Exercise testing 1999&lt;sup&gt;1&lt;/sup&gt;</td>
<td>6/52 (11.9)</td>
<td>15.9</td>
<td>6/52 (11.9)</td>
<td>11.2</td>
<td>15/71 (21.1)</td>
</tr>
<tr>
<td>Radionuclide imaging 1999&lt;sup&gt;1&lt;/sup&gt;</td>
<td>15/71 (21.1)</td>
<td>12.7</td>
<td>37/71 (52.1)</td>
<td>-11.2</td>
<td>15/71 (21.1)</td>
</tr>
<tr>
<td>2000&lt;sup&gt;1&lt;/sup&gt;</td>
<td>14/58 (24.6)</td>
<td>15.3</td>
<td>5/58 (8.6)</td>
<td>-28.3</td>
<td>6/58 (10.3)</td>
</tr>
<tr>
<td>Change in No. of recommendations</td>
<td>+10</td>
<td>+3</td>
<td>+6</td>
<td></td>
<td></td>
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<tr>
<td>Change in distribution across classes, median (ESR), %</td>
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<tr>
<td></td>
<td>14.1</td>
<td>-21.9</td>
<td>-12.5 to -1.7</td>
<td></td>
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<tr>
<td><strong>Summary of all guidelines</strong></td>
<td></td>
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<tr>
<td>Change in No. of recommendations</td>
<td>+215</td>
<td>+195</td>
<td>+65</td>
<td></td>
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<tr>
<td>Change in distribution across classes, median (ESR), %</td>
<td></td>
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<tr>
<td>0.2</td>
<td>-0.7 to 5.7</td>
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</table>

### Table 2: Change in Recommendations and Class in AHA Diagnostic Guidelines

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<td><strong>Summary of all guidelines</strong></td>
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<td></td>
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<tr>
<td>Change in No. of recommendations</td>
<td>+215</td>
<td>+195</td>
<td>+65</td>
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<tr>
<td>0.2</td>
<td>-0.7 to 5.7</td>
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CV Guidelines – general conclusions

• Most current articles called “guidelines” are actually expert consensus reports.

• Revisions of the American College of Cardiology (ACC)/American Heart Association (AHA) guidelines have shifted to more class II recommendations (conflicting evidence and/or divergence of opinion about the usefulness/efficacy of a procedure or treatment)

• 48% of the time, these recommendations are based on the lowest level of evidence (level C: expert opinion, case studies, or standards of care).

CV Guidelines - general

• This trend is especially disconcerting given the quantity of cardiovascular scientific literature published during the last decade

• Overreliance on expert opinion in guidelines is problematic

• All guideline committees begin with implicit biases and values, which affects the recommendations they make. However, bias may occur subconsciously and, therefore, go unrecognized

• Converting data into recommendations requires subjective judgments
CV Guidelines - general

Biases

• The most widely recognized bias is financial

• Guidelines often have become marketing tools for device and pharmaceutical manufacturers.

• While the ACC, AHA and ESC receive no industry funding for guideline development, they may receive industry support to disseminate guideline products such as pocket guides.

CV Guidelines - general

• ACC/AHA guidelines with at least 1 revision, the number of recommendations increased 48% from the first guideline to the most recent version

• Main messages tend to get lost in minutiae

• Guidelines are not patient-specific enough to be useful and rarely allow for individualization of care

• Most guidelines have a one-size-fits-all mentality and do not build flexibility or contextualization into the recommendations

• There are simply too many guidelines, often on the same topic
Women and Gender Issues in the ESC Clinical Practice Guidelines

Clinical Practice Guidelines published by AHA/ACC/ESC

Main Disease Topics
- Atrial fibrillation
- Heart failure
- Perioperative evaluation
- Stable angina
- Unstable angina
- Valvular heart disease
Clinical Practice Guidelines
published by ESC

Atrial fibrillation (2001 revised 2006)

Women mentioned 7 times: prevalence, incidence and prognosis

– Among men, the age-adjusted prevalence has more than doubled over a generation, while the prevalence in women has remained constant
– Stroke risk greater in women
– amiodarone-associated bradycardia is more common in women than in men

No gender treatment differences discussed

Clinical Practice Guidelines
published by ESC


Women mentioned 6 times: epidemiology, and pregnancy

– Studies show that the accuracy of diagnosis of HF by clinical means alone is often inadequate, particularly in women, the elderly, and the obese

No gender treatment differences discussed
Clinical Practice Guidelines published by ESC

Perioperative evaluation

Women mentioned twice: ageing population and pulmonary disease

No gender management differences discussed

Clinical Practice Guidelines published by ESC

Stable Angina 2006

Women mentioned 67 times!

Discussed extensively

Focus on differences in diagnosis, presentation, investigation and treatment

– “A considerable proportion of patients, especially women, who undergo coronary arteriography because of symptoms of chest pain do not have significant CAD”

– Also HRT discussed

Women discussed as a special subgroup
Women mentioned 60 times
Women discussed as a gender issue

- `The benefits of statins in healthy asymptomatic women are unproven’

Clinical Practice Guidelines published by ESC

The relationship of total cholesterol / HDL cholesterol ratio to 10 year fatal CVD events in men and women aged 60 yrs with and without risk factors, based on a risk function derived from the SCORE project.
Cardiovascular Risk Assessment - Methodology

SCORE Chart
Based on
- 12 European cohorts
- 250,000 patients
- 3 million person-years
- 7,000 fatal CV events

High CV risk = 5% risk of CV death over 10 years
Seville Guide 2008

ASSessment and Management of Cardiovascular Risks in Women
A Short Guide for Menopause Physicians

Chairs:
Professor Peter Gotlib
Clinical Chair
Seville Guide 2008

Faculty Members:
Esko H. (2008) [Chair]
Ernst A. (2008)

Acknowledgments:
Anecdotally, the editors of the Seville Guide (2008) express appreciation for the contributions of all the contributors. This guide was developed with the support of the European Menopause and Sexual Health Network (EMSH) and the European Menopause and Male Andrology Network (EMAN). The guide is intended to provide practical guidance for primary care physicians, gynecologists, and other health care professionals involved in the care of women in menopause.
WHICH PATIENTS CAN BE MANAGED FOR GLOBAL CARDIOVASCULAR RISK BY A MENOPAUSE PHYSICIAN?

- A woman with a high-risk profile or overt cardiovascular disease (CVD) requires intensive management, including drug therapy.
- Collaboration with a cardiovascular specialist is essential if global cardiovascular risk is high, or if cardiovascular disease is present.

Figure 3. Diagrammatic guide to determining patients suitable for cardiovascular risk management.

HOW TO MANAGE HIGH BLOOD PRESSURE

- Target: Systolic blood pressure: diastolic blood pressure <140/90 mmHg (non-diabetic patients) or <130/80 mmHg (patients with diabetes or chronic kidney disease).
- After the age of 45, blood pressure rises steeply in women, and by the age of 60, average SBP levels in women are higher than in men.
- In hypertensive postmenopausal women, only about one-third have effectively controlled blood pressure levels.
- High blood pressure is one of the most powerful modifiable risk factors for cardiovascular morbidity and mortality.
- A decrease is 80% of only 2-3 mmHg lowers the likelihood of death from stroke by 10% and from ischemic heart disease or other vascular cause by 7%.
- At each consultation, the blood pressure of women at highest risk of having raised blood pressure – especially peri-menopausal women – must be measured.
- Lifestyle changes help lower blood pressure if it is not seriously elevated (appropriate for women with SBP/DBP: blood pressure (SBP) 120–139/80–89 mmHg).
- A woman with no symptoms of cardiovascular disease requires antihypertensive therapy (blood pressure is high >140/90 mmHg).
- More vigorous control of blood pressure, using antihypertensive agents, is essential in a woman with additional cardiovascular risk factors, e.g. subclinical organ damage or diabetes.
- Modification of renin-angiotensin-aldosterone system (RAAS) activity might be important in blood pressure control of a hypertensive peri- or post-menopausal woman.
ACCURATE BLOOD PRESSURE MEASUREMENT — HOW TO AVOID SOME TYPICAL PITFALLS

- Ensure that the woman has been comfortably seated for several minutes in a quiet room.
- Advise the woman to avoid caffeine, exercise and smoking for 2-3 hours before measurement.
- Check that no tight clothing constricts the arm.
- Rest the woman's arm on a table, preferably with the brachial artery level with the heart.
- Use a standard cuff (12-13 x 35 cm); have larger and smaller cuffs available.
- The bladder should encircle at least 2/3 of the arm, (but not more than 100%)
- Check that any remaining air in the cuff is evacuated before putting it on the woman's arm.
- Inflate the cuff to >90 mmHg above the estimated SBP needed to occlude the pulse.
- Deflate slowly at a rate of 2-3 mmHg/sec until regular tapping sounds are audible.
- Use Korotkoff sounds to identify SBP and DBP; first hear when the cuff pressure equals the SBP and ceasing once the cuff has been deflated below the DBP.
- Take at least two measurements at an interval of 1-2 minutes; additional measurements are required if the first two vary markedly.
- At the first examination, blood pressure should be checked in both arms to detect possible differences due to peripheral vascular disease.
- If values vary in different arms, use the higher one.

THE MENOPAUSE AND HORMONE REPLACEMENT THERAPY

- The initiation or continuation of hormone replacement therapy (HRT) should be decided according to the individual patient.
- Progesterone should be added to systemic oestrogen in all women with an intact uterus, to prevent endometrial hyperplasia and cancer.
- Some progestins have additional, specific, beneficial effects on blood pressure and plasma lipid and plasma glucose profiles, for example.
- In a woman aged >40 years, recently menopausal, with menopausal symptoms and without symptomatic cardiovascular disease, the initiation of HRT does not cause early harm, and possibly confers long-term cardiovascular benefit.
- If a woman is at increased global cardiovascular risk, HRT is safe to use in the younger woman with indications.
- HRT should not be initiated solely for the prevention of cardiovascular disease and should not be regarded as a substitute for antihypertensive treatment.
- A woman aged >40 years should be counselled on the potential benefits and risks of HRT in women in their age group.
Clinical Practice Guidelines published by ESC

Hypertension - 2007

Women mentioned 45 times!
Discussed extensively

Treatment of HT as effective in men and women
Focus on treatment in women, pregnancy, pre-eclampsia

HRT and oral contraception discussed
Women discussed separately (7.7 Box 18)
Hypertension Control (%) in European Nations

STEMI - 2008

Women mentioned 6 times (dose variation of drugs and metabolic syndrome)

No gender treatment differences discussed

European Hypertension Control Study (Euroaspire). Lancet 2001;357:995-1001
Valvular Heart Disease

Women mentioned once
No treatment differences discussed

Clinical Practice Guidelines published by ESC

Interventional Guidelines
CABG
PCI
Pacemaker
CABG - 2004

Women mentioned 43 times (similar to stable angina guideline)
Discussed as a special group - extensive

Clinical Practice Guidelines published by ESC

PCI

Women mentioned twice
- Particular benefit in women for primary PCI
- Cardiogenic shock
Clinical Practice Guidelines published by ESC

Pacemaker

Women mentioned once
- Sleep apnoea!
- No discussion of gender differences

Evidence-Based Guidelines for Cardiovascular Disease Prevention in Women: 2007 Update

- Mosca, et al Circulation
- Very comprehensive but:
- Most recommendations IB or less (similar to other guidelines discussed)
- Again reinforcing a paucity of data
Conclusions

- Guideline statements are often not robustly evidence based
- Bias is prevalent
- Women and gender are often overlooked
- Lack of clinical trial data
- There is much work to do – there indeed is a need for action!