We are pleased to publish in this issue the proceedings of the 1996 Hammersmith Perfusion Workshop, held on 6 December 1996. The topic for the workshop was ‘Safety, standards and education’.

The delegates and the speakers made this a truly international occasion. The papers presented stimulated wide-ranging discussion, highlighting the very considerable interest in these aspects of perfusion practice.

Professor KM Taylor
Editor
Health technology assessment – principles, pointers and problems

Successful health and safety management

John P Doidge The Royal Society for the Prevention of Accidents, Edgbaston Park, Birmingham

Safety: a manufacturer’s perspective

Elisabeth J Wierenga Medtronic Ltd, Kerkade
Perfusion standards and guidelines

Aaron G Hill and Mark Kurusz The Virginia Heart Center at The Fairfax Hospital, Falls Church, Virginia and Department of Surgery, The University of Texas Medical Branch, Galveston, Texas

Introduction

Standards of practice in perfusion were previously reviewed in 1994. The purpose of this report is to update activities in the area of standards and guidelines affecting perfusion practice. Standards and related topics will again be defined, past work in this area by professional organizations in the USA will be summarized and future implications of standards development on practice will be discussed.

The word ‘standard’ has 28 different meanings according to the Random House dictionary of the English language. Standards may be classified into: general standards, specific standards, and performance standards. It is important to distinguish between these different types of standards. General standards are a set of guidelines that provide a framework for the development of specific standards and performance standards. Specific standards are detailed guidelines that provide specific guidance for the implementation of general standards. Performance standards are used to measure the performance of individuals or organizations against specific standards.

The American Society of Extra-Corporeal Technology (AmSECT) started the examination process under the guidance of James Dearing and Louis Toth in 1972. In 1975, the American Board of Cardiovascular Perfusion (ABCP) was formed as an independent entity to administer the examination process and supervise the accreditation of perfusion training programmes. Prior to this time, the ABCP had been a part of AmSECT. The use of a formal examination process was one of the first attempts by the perfusion community to adopt a standard credentials procedure. In 1977, the Joint Review Board (JRB) was established to accredit training programmes in perfusion. The JRB is the only body that can grant accreditation to training programmes in perfusion.

The roles of the ABCP and AmSECT are still very important to the perfusion community. The ABCP is responsible for administering the examination process and supervising the accreditation of perfusion training programmes. AmSECT is responsible for maintaining the standards for perfusion practice and for continuing education programs for perfusionists.
Standards and Guidelines: are they the same?

Rob Baker
Flinders Medical Centre
and Flinders University
Adelaide Australia
Disclosures

• Over the last 12 months

• Terumo: Research and Travel Support
• Cellplex: Research and Travel Support
• AmSECT: Travel Support
“Words like guidelines and standards may mean one thing to clinicians, another to purchases, and yet another to attorneys”
Outline of Talk

• Background
  – USA (AmSECT) and the UK
• Definitions
• Examine Standards
• Examine Guidelines
• Current Standards and Guidelines
  – ABCP
  – Spanish Perfusion Society
  – ANZCP
Background

• Early standards in response to perfusion training
  – 1972 (AmSECT)
  – 1975 (ABCP), independent
  – 1977 Joint Review Committee for Perfusion Education
    • Combined standards of AmSECT and the ABCP in the Council on Allied Health Education and Accreditation (CAHEA) format
Standards & Guidelines

At the heart of the CAAHEP accreditation system are our nationally recognized Standards. All CAAHEP Standards have certain elements in common, however the Standards for each discipline contain specific requirements for training entry level practitioners in that profession. The Standards are approved by the CAAHEP Board of Directors and are subject to review every five years. The Standards review process is a rigorous one that includes input from the communities of interest, a public open hearing, and approval by the Committee on Accreditation (CoA) and its sponsoring organization(s).

The Standards review and revision process requires that proposed Standards be posted on the CAAHEP website at least 30 days prior to the date of the open hearing. Please check News and Announcements for current notices of open hearings. If you would like to comment on proposed standards for any of the CAAHEP professions, please email mail@caahep.org

To review the Standards and Guidelines for a specific profession, please select the appropriate profession below (Please note in some instances there may be more than one set of Standards for the profession, if this is the case please contact the appropriate CoA to determine which set of Standards currently applies to your program):

- Anesthesiologist Assistant
- Cardiovascular Technologist
- Cardiovascular Technologist (New Standards effective April 1, 2009)
- Cytotechnologist
- Diagnostic Medical Sonographer
  (Please note. If you are looking for the 1996 version of the Diagnostic Medical Sonographer Standards, they can be found by clicking here)
- Electroneurodiagnostic Technologist
- Emergency Medical Technician-Paramedic
- Exercise Physiologist
Commission on Accreditation of Allied Health Education Programs

Standards and Guidelines
for the Accreditation of Educational Programs in Perfusion

Essentials/Standards initially adopted in 1980; revised in 1989, 1994, 2000, and 2005 by the:

American Academy of Cardiovascular Perfusion
American Association for Thoracic Surgery
American Board of Cardiovascular Perfusion
American Society of Extracorporeal Technology
Perfusion Program Directors’ Council
Society of Cardiovascular Anesthesiologists
Society of Thoracic Surgeons
and
Commission on Accreditation of Allied Health Education Programs

The Commission on Accreditation of Allied Health Education Programs (CAAHEP) accredits programs upon the recommendation of the Accreditation Committee – Perfusion Education (AC-PE).

These accreditation Standards are the minimum standards of quality used in accrediting programs that prepare individuals to enter the Perfusion profession. The accreditation Standards therefore constitute the minimum requirements to which an accredited program is held accountable.

Standards are printed in regular typeface in outline form. Guidelines are printed in italic typeface in narrative form.
Acceptance of Standards

- Slow
- 1976 “standards Committee AmSECT proposed a standard perfusion record
  - Voted down by BOD
- 1976 American Society for Artificial Internal Organs draft standard for oxygenators
- 1981 multidisciplinary approach “standardising CPB” at the AACP
- 1987 AACP “position statement “standards of practice”
- 1995 AMSECT “Guidelines for perfusion practice”
  - 1993 “Essentials”
How were they established?

• US National Survey 1993\(^1\)
  – All known open-heart surgery programs
  – Quality committee validated data
  – 64% (270426 cumulative cases)
    • Demographics
    • Documentation
    • Personnel
    • Conduct of CPB
    • Equipment
    • Administrative policies
    • Quality management

AmSECT Perfusion Life 1994;42-45
<table>
<thead>
<tr>
<th>Essentials</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
</tr>
<tr>
<td>II</td>
</tr>
<tr>
<td>III</td>
</tr>
<tr>
<td>IV</td>
</tr>
<tr>
<td>V</td>
</tr>
<tr>
<td>VI</td>
</tr>
<tr>
<td>VII</td>
</tr>
<tr>
<td>VIII</td>
</tr>
<tr>
<td>IX</td>
</tr>
<tr>
<td>X</td>
</tr>
<tr>
<td>XI</td>
</tr>
<tr>
<td>XII</td>
</tr>
</tbody>
</table>
The Society of Clinical Perfusion Scientists
OF GREAT BRITAIN AND IRELAND

and

The College of Clinical Perfusion Scientists
OF GREAT BRITAIN AND IRELAND

Standards of Practice Document

AGREED OCTOBER 1999
Recommendations for Standards of Monitoring during Cardiopulmonary Bypass

The Society of Clinical Investigation Scientists of Great Britain and Ireland

Standards of Practice Document

AGREED OCTOBER 1999
Development of Aussie Standards and Guidelines

• Leave to Jane!
More recent Guideline Work

• Leave to Tomorrow
Definitions

• What are we really talking about?
• Is standard synonymous with guideline?
What are Standards then?

• Standards: multiple variable definitions
  – “something considered by authority or by general consent as a basis of comparison; an approved model”
    – Random House Dictionary of the English Language

What are Standards then?

• Standards: multiple variable definitions
  – “something considered by authority or by general consent as a basis of comparison; an approved model”
    – Random House Dictionary of the English Language¹
  – “something set up or established by an authority as a rule for the measure of quantity, weight, extent, value or quality”
    – Merriam-Webster Medical Dictionary, 2009

STANDARDS OF QUALITY: are authoritative statements of
(1) minimum levels of acceptable performance or results,
(2) excellent levels of performance or results, or
(3) the range of acceptable performance or results.

IOM 1992
As for Guidelines?

The *Random House Dictionary of the English Language* (1987) dates the American origin of *guideline* to 1775 – 1785 in its literal usage as a:

“rope or cord that serves to guide one’s steps especially over rocky terrain, through underground passages, etc.”
The Random House Dictionary of the English Language (1987) dates the American origin of guideline to 1775 – 1785 in its literal usage as a:

As for Guidelines?

"rope or cord that serves to guide one's steps especially over rocky terrain, through underground passages, etc."
What are Guidelines then?

• Practice Guidelines
  – “systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances”
  – Institute of Medicine 1990
GUIDELINES FOR PERFUSION PRACTICE

ESSENTIAL 1

An accurate perfusion record must be maintained according to an established protocol.

PRACTICE GUIDELINES

A. The perfusion record should include the following patient information:
   1. Hospital ID
   2. Age
   3. Gender
   4. Height
   5. Weight
   6. Body Surface Area (BSA)
   7. Allergies
   8. Blood Type
   9. Pre-op Laboratory Data
   10. Diagnosis/History

B. Additional procedure information should include:

...
Regulations and Guidelines for Perfusionists
So what should we be looking for?

What are the “standards” and “guidelines” we should be following, developing, and challenging?
Protocols, guidelines, and standards are no substitute for common sense and experience. However, they have been useful in promoting safe conduct of CPB. Perhaps in its simplest form an institutional protocol outlines the selection of circuit components and required priming volumes.....

- Ch 26, Davis, Kurusz & Conti, Conduct of CPB, Gravlee 2008
Standards

Standards of Practice Document
Recommendations for Standards of Monitoring during Cardiopulmonary Bypass
Standards of Practice

1. Preamble

1.1 When a society of individuals involved in clinical work prefers to call itself a 'profession', it must set for itself standards of conduct, behaviour and competence for all aspects of its work, that are worthy of the term 'professional'. Such standards should encompass such diverse aspects of the work as:

1.1.1 Clinical competence.

1.1.2 The safety and well-being of patients and colleagues.

1.1.3 The utmost honesty and integrity as far as clinical and research responsibilities are concerned.

1.1.4 The utmost honesty and integrity as far as financial and business dealings are concerned.

1.1.5 The maintenance of the strictest confidentiality as far as patients, colleagues and other health-care professionals are concerned (within the confines of legal requirements to disclose information).
Standards of Practice

1. Preamble

1.1.1 Clinical competence.

1.1.2 The safety and well-being of patients and colleagues.

1.1.3 The utmost honesty and integrity as far as clinical and research responsibilities are concerned.

1.1.4 The utmost honesty and integrity as far as financial and business dealings are concerned.

1.1.5 The maintenance of the strictest confidentiality as far as patients, colleagues and other health-care professionals are concerned (within the confines of legal requirements to disclose information).
Standards of Practice

1.1.4 The utmost honesty and integrity as far as financial and business dealings are concerned.

1.1.5 The maintenance of the strictest confidentiality as far as patients, colleagues and other health-care professionals are concerned (within the confines of legal requirements to disclose information).
1.2 A society of professionals should be prepared to set and to regulate such standards with a Code of Conduct that is of sufficient precision and clarity that ambiguity is avoided, whilst setting the general tenor of behaviour for situations and conditions not specifically envisaged.
1.3 Such a code of conduct should be binding on all members and be enforceable by the appropriate professional body.

1.4 This is a working document, to be discussed and refined in the light of experience.
Recommendations for Standards of Monitoring and Alarms During Cardiopulmonary Bypass

Derriford Hospital, Plymouth, United Kingdom
Background...

• Lack of acceptable monitoring and safety standards
• Discrepancy of monitoring standards during periods on and off Cardiopulmonary Bypass
• Requirement for practice regulation
• Desire to improve patient safety and care standards

Courtesy of M. Weatherall
Starting Point...

• Survey current clinical practice
• Review survey data
• Review other reference material
• Convene a multi-disciplinary working party

Courtesy of M. Weatherall
Postal survey...

- Sent to the Principal Clinical Perfusionist at 53 NHS centres in the United Kingdom & Ireland
- Initial response was poor
- Repeat questionnaires sent to non-responders
- Final response rate was 43% (23/53)

Courtesy of M. Weatherall
Survey Results Summary...

- Activated Clotting Time 23/23
- Arterial Line Pressure 23/23
- Level Sensor (With Pump Cut Out) 22/23 (11)
- Bubble Sensor (With Pump Cut Out) 19/23 (9)
- Arterial Blood Gases (Offline) 22/23
- Arterial Oxygen Tension (Continuous) 18/23
- Venous Oxygen Saturation (Continuous) 16/23
- Fresh Gas Oxygen Content (Continuous) 14/23
- Haematocrit 11/23
- Trans-Membrane Pressure Gradient 7/23
- Trans-Filter Pressure Gradient 6/23
- Exhaust Gas Agent 6/23
- Exhaust Gas Capnography 5/23

Courtesy of M. Weatherall
Other Reference Material...

- Publication by Cockroft (1992)
- Publication by Weatherall & Sherry (2000)
- SCPSGBI Standards of Practice
- AmSect Guidelines for Perfusion Practice
- Association of Anaesthetists G.B & I
- U.K Department of Health Guidelines
- COSHH

Courtesy of M. Weatherall
Document Development...

• Multi-Disciplinary Committee Meetings
• Peer Review
• Draft Document Circulation
• Membership Consultation

Courtesy of M. Weatherall
Timescale...

- Introduction (2001)
- Implementation (By 2004)
- Review (2005)

Courtesy of M. Weatherall
“Only an accredited Clinical Perfusion Scientist registered with the College of Clinical Perfusion Scientists of Great Britain & Ireland can undertake or supervise the conduct of Cardiopulmonary Bypass. A named and accredited Clinical Perfusion Scientist not distracted by other clinical commitments, in close proximity and freely available must supervise a trainee undertaking a Cardiopulmonary Bypass procedure.”

Statement...

“The recommended monitors and alarms that should be used during Cardiopulmonary Bypass are considered by the Society of Clinical Perfusion Scientists of Great Britain & Ireland, the Association of Cardiothoracic Anaesthetists & the Society of Cardiothoracic Surgeons of Great Britain & Ireland to be the minimal monitoring requirements during Cardiopulmonary Bypass. All centres undertaking cardiac surgery involving Cradiopulmonary Bypass should plan to institute these standards of monitoring and alarms by the 1st January 2004.”

Courtesy of M. Weatherall
Clinical Parameters...

- Electrocardiograph (ECG)
- Systemic Arterial Pressure
- Central Venous Pressure
- Core Body Temperature
- Urine Output
- Pulse Oximetry
- Expired Carbon Dioxide Tension/Concentration

Courtesy of M. Weatherall
Bypass Circuit Monitoring...

- Venous Oxygen Saturation
- Arterial Oxygen Tension or Saturation
- Fresh Gas Flow Continuity
- Fresh Gas Oxygen Content
- Blood Flow Rate
- Arterial Line Pressure
- Cardioplegia Delivery Line Pressure
- Blood Temperature
- Water Temperature (Heater/Cooler Unit)
- Activated Clotting Time
- Filtrate Volume

Courtesy of M. Weatherall
Near Patient and On Site Testing..

- Blood Gases
- Red Cell Concentration (Hb or Hct)
- Serum Potassium
- Blood Sugar
- Clotting Studies
- Serum Calcium
- Serum Lactate
- Serum Magnesium

Courtesy of M. Weatherall
Safety Devices...

- Mains power failure alarm
- Bubble detector
- Low level alarm
- Anaesthetic gas-scavenging apparatus
- Out of range temperature alarm

Courtesy of M. Weatherall
Conclusion...

- Reduced risk
- Increased awareness
- Increased safety
### Membership of the working party (2007)

<table>
<thead>
<tr>
<th>Name</th>
<th>Organization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ian Curle</td>
<td>Society of Clinical Perfusion Scientists of Great Britain and Ireland</td>
</tr>
<tr>
<td>Fiona Gibson</td>
<td>Association of Cardiothoracic Anaesthetists</td>
</tr>
<tr>
<td>Jonathan Hyde</td>
<td>Society for Cardiothoracic Surgeons in Great Britain and Ireland</td>
</tr>
<tr>
<td>Alex Shipolini</td>
<td>Society for Cardiothoracic Surgeons in Great Britain and Ireland</td>
</tr>
<tr>
<td>David Smith</td>
<td>Association of Cardiothoracic Anaesthetists</td>
</tr>
<tr>
<td>J. P. van Besouw</td>
<td>Association of Cardiothoracic Anaesthetists</td>
</tr>
<tr>
<td>Kate Wark</td>
<td>Association of Cardiothoracic Anaesthetists</td>
</tr>
<tr>
<td>Mike Weatherall</td>
<td>Society of Clinical Perfusion Scientists of Great Britain and Ireland</td>
</tr>
<tr>
<td>David Whitaker</td>
<td>Association of Cardiothoracic Anaesthetists</td>
</tr>
</tbody>
</table>

*This document is available on the following websites:*

<table>
<thead>
<tr>
<th>Organization</th>
<th>Website</th>
</tr>
</thead>
<tbody>
<tr>
<td>Society of Clinical Perfusion Scientists of Great Britain and Ireland</td>
<td><a href="http://www.scps.org">www.scps.org</a></td>
</tr>
<tr>
<td>Association of Cardiothoracic Anaesthetists</td>
<td><a href="http://www.acta.org.uk">www.acta.org.uk</a></td>
</tr>
<tr>
<td>Society for Cardiothoracic Surgeons in Great Britain and Ireland</td>
<td><a href="http://www.scts.org">www.scts.org</a></td>
</tr>
</tbody>
</table>
Introduction

The aim of this document is to determine standards of monitoring during cardiopulmonary bypass for adult and paediatric surgery. These standards are considered by the Society of Clinical Perfusion Scientists of Great Britain and Ireland, the Association of Cardiothoracic Anaesthetists and the Society for Cardiothoracic Surgeons in Great Britain and Ireland to be the minimal monitoring required during cardiopulmonary bypass. This includes monitoring for the onset of and weaning from

All centres undertaking cardiac surgery involving cardiopulmonary bypass should plan to institute these recommendations of monitoring by 6 months from the date of publication.

The safe conduct of cardiopulmonary bypass is the joint responsibility of surgeons, anaesthetists and clinical perfusionists and requires a high level of communication between the team members. Whilst it is considered best practice during the
Guidelines

“systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances”

Institute of Medicine 1990
Guidelines
Guidelines

Methodology Manual for ACC/AHA Guideline Writing Committees
What are guidelines meant to be?

Who are they meant to help?
Guidelines not new

• Medical organisations have been developing for over 50 years
• “Appropriate care recommendations date back to ancient times”
• Now emphasis on systematic, evidence based guidelines
• Interest in process, effective use and evaluation of guidelines
Attributes of Good Guidelines

- Development
- Intervention
- Evaluation

IOM 1992
Purposes for guidelines

(1) **Assisting** clinical decision making by patients and practitioners.

(2) **Educating** individuals or groups.

(3) **Assessing** and **assuring** the quality of care.

(4) **Guiding** allocation of resources for health care.

(5) **Reducing** the risk of legal liability for negligent care.
So, if guidelines are so important?
What assumptions underlying their importance?

1. Need scientific evidence to serve as the foundation.

2. Support to develop guidelines
   • Organized,
   • Funded, and effectively
   • Managed
   Such that valid, usable guidelines

3. Disseminated to wide numbers of interested parties such that change can occur.

IOM 1992
What assumptions underlying their importance?

4. Such changes will be broad and intense enough to improve health outcomes.

5. On balance, guidelines will lead to more cost-controlling than cost-increasing behaviour

6. The body of guidelines will continually expand to cover new areas so that net rates of increase in health care costs and absolute levels of expenditures will be lower than they would otherwise be.

IOM 1992
Terminology used to describe guidelines
VALIDITY

When followed, they lead to the health and cost outcomes projected for them, other things being equal.

A prospective assessment of validity will consider:

The projected health outcomes.

The relationship between the evidence and recommendations.

The substance and quality of evidence cited.

The means used to evaluate the evidence.
If given the same evidence and methods for guidelines development – another set of experts would produce essentially the same statements.

If given the same circumstances – the guidelines are interpreted and applied consistently by practitioners or other appropriate parties.
CLINICAL APPLICABILITY

• Practice guidelines should be as inclusive of appropriately defined patient populations are scientific and clinical evidence and expert judgement permit, and they should explicitly state the populations to which statements apply.
CLINICAL FLEXIBILITY

• Practice guidelines should identify the specifically known or generally expected exceptions to their recommendations.

CLARITY

• Practice guidelines should use unambiguous language, define terms precisely, and use logical, easy-to-follow modes of presentation.
MULTIDISCIPLINARY PROCESS

• Should be developed by a process that includes participation by representatives of key affected groups.
SCHEDULED REVIEW

• Should include statements about when they should be reviewed proportional to new evidence and changing practice

DOCUMENTATION

• The methodology must be described.
Where are guideline now?
What does your patient expect?
Evidence-Based Medicine

In the 1990s, evidence-based medicine emerged as a way to improve and evaluate patient care. It involves combining the best research evidence with the patient's values to make decisions about medical care. Looking at all available medical studies and literature that pertain to an individual patient or a group of patients helps doctors to properly diagnose illnesses, to choose the best testing plan, and to select the best treatments and methods of disease prevention. Using evidence-based medicine techniques for large groups of patients with the same illness, doctors can develop practice guidelines for evaluation and treatment of particular conditions. In addition to improving treatment, such guidelines can help individual physicians and institutions measure their performance and identify areas for further study and improvement. The February 25, 2009, issue of JAMA includes an article about the importance of using evidence-based medicine to develop practice guidelines. This Patient Page is based on one published in the September 6, 2006, issue of JAMA.

**LOOKING FOR EVIDENCE IN MEDICAL LITERATURE**

Systematic reviews of the medical literature, large randomized controlled trials (the best way to assess the efficacy of a treatment), and large prospective studies (followed up over time) are types of research published in the medical literature that can be helpful in providing evidence about tests and treatments. Reports of the experiences of individual patients or small groups usually provide less reliable evidence, although they may provide important clues about possible adverse effects of treatments.

**USING EVIDENCE-BASED MEDICINE**

Practice guidelines developed using evidence-based medicine have helped to reduce mortality (chance of dying) from heart attacks. Evidence-based medicine guidelines have also improved care for persons with diabetes and other common medical problems. Evidence-based medicine does not replace physicians' judgment based on clinical experience. Any recommendations taken from evidence-based medicine must be applied by a physician to the unique situation of an individual patient. Sometimes there is no reliable research evidence to guide decision making, and some conditions are rare enough that there is no way to do large studies.

**IMPROVING YOUR HEALTH**

- Many evidence-based medicine guidelines are publicly accessible. You can use these guidelines to search the medical literature, which can be accessed through the Internet. For example, PubMed (http://www.ncbi.nlm.nih.gov/pubmed/) is a searchable database of biomedical literature maintained by the National Library of Medicine. You can search the literature using keywords such as "diabetes care," "heart disease," or "cancer screening." Other websites, such as the Cochrane Library (http://www.cochranelibrary.com/) and the Centre for Evidence-Based Medicine (http://www.cebm.net/), also provide access to evidence-based guidelines and other resources for improving health care.

**FOR MORE INFORMATION**

- National Institutes of Health
  www.nih.gov
- The Cochrane Collaboration
  www.cochrane.org
- Centre for Evidence-Based Medicine
  www.cebm.net

**INFORM YOURSELF**

To find this and previous JAMA Patient Pages, go to the Patient Page link on JAMA's Web site at www.jama.com. Many are available in English and Spanish. A Patient Page on randomized controlled trials was published in the June 21, 2006, issue; one on medical journals was published in the April 19, 2006, issue; one on medical research was published in the
Practice guidelines developed using evidence-based medicine have helped to reduce mortality (chance of dying) from heart attacks. Evidence-based medicine guidelines have also improved care for persons with diabetes and other common medical problems. Evidence-based medicine does not replace physicians’ judgment based on clinical experience. Any recommendations taken from evidence-based medicine must be applied by a physician to the unique situation of an individual patient. Sometimes there is no reliable research evidence to guide decision making, and some conditions are rare enough that there is no way to do large studies.
What does your patient expect?

**IMPROVING YOUR HEALTH**

- Many evidence-based medicine guidelines are publicly accessible. You can use these guidelines to improve your health and make good choices about your medical care.

- Together, you and your doctor can make the best evaluation and treatment plans based on the available medical evidence.

- Understanding why your doctor recommends certain tests or treatments based on evidence from the medical literature will help you make good health care and lifestyle choices.
Current Status of Guideline Writing: Positives and Negatives

• Pluralism
  + Wide base
  + Develop different approaches
  - Limited resources fragmented
  - Goals divided
  - Topic selection haphazard
Positives and Negatives

• Enthusiasm
  + Encouraged activity
  + Societal support

• Credibility
  + Expectations and process
  + Examination

• Relationship to quality and efficiency
Positives and Negatives

- Quality Control of Methodology
- Evaluation of Impact

Implementation processes need to be anticipated as guidelines are first disseminated, used, and evaluated.
Positives and Negatives

- Quality Control of Methodology
- Evaluation of Impact
Conclusions: Recommendations issued in current ACC/AHA clinical practice guidelines are largely developed from lower levels of evidence or expert opinion. The proportion of recommendations for which there is no conclusive evidence is also growing. These findings highlight the need to improve the process of writing guidelines and to expand the evidence base from which clinical practice guidelines are derived.
Scientific Evidence Underlying the ACC/AHA Clinical Practice Guidelines

Pierluigi Tricoci, MD, MHS, PhD
Joseph M. Allen, MA
Judith M. Kramer, MD, MS
Robert M. Califf, MD
Sidney C. Smith Jr, MD

Context 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.

Objective 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, including a total of 7196 recommendations, were abstracted.

Data Extraction The number of recommendations and the distribution of classes of recommendation (I, II, and III) and levels of evidence (A, B, and C) were 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.

Results Among guidelines with at least 1 revision or update by September 2008, the number of recommendations increased from 1330 to 1973 (+48%) from the first to the current version, with the largest increase observed in use of class II recommendations. Considering the 16 current guidelines reporting levels of evidence, only 314 recommendations of 2711 total are classified as level of evidence A (median, 11%), whereas 1246 (median, 48%) are level of evidence C. Level of evidence significantly varies across categories of guidelines (disease, intervention, or diagnostic) and across individual recommendations.
Conclusions: Recommendations issued in current ACC/AHA clinical practice guidelines are largely developed from lower levels of evidence or expert opinion. The proportion of recommendations for which there is no conclusive evidence is also growing. These findings highlight the need to improve the process of writing guidelines and to expand the evidence base from which clinical practice guidelines are derived.

Context: 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 review and update. The increasing complexity and volume of guidelines have raised concerns about their quality, impact, and use. The process of guideline development involves multiple stakeholders, including healthcare professionals, researchers, and patients, and requires transparent methods and rigorous evidence assessment.

Pierluigi Tricoci, MD, MHS, PhD
Joseph M. Allen, MA
Current use of the term guideline has strayed far from the original intent of the Institute of Medicine. Most current articles called “guidelines” are actually expert consensus reports. It is not surprising, then, that the article by Tricoci et al in this issue of JAMA demonstrates that revisions of the American College of Cardiology (ACC)/American Heart Association (AHA) guidelines have shifted to more class II recommendations … and that 48% of the time, these recommendations … are based on the lowest level of evidence (level C: expert opinion, case studies, or standards of care). This trend is especially disconcerting given the quantity of cardiovascular scientific literature published during the last decade.
Reassessment of Clinical Practice Guidelines
Go Gently Into That Good Night

Terrence M. Shaneyfelt, MD, MPH
Robert M. Centor, MD

In 1990, the Institute of Medicine proposed guideline development to reduce inappropriate health care variation by assisting patient and practitioner decisions. Unfortunately, too many current guidelines have become marketing and opinion-based pieces, delivering directive rather than assistive statements.

Current use of the term guideline has strayed far from the original intent of the Institute of Medicine. Most current articles called “guidelines” are actually expert consensus reports. It is not surprising, then, that the article by Tricoci et al in this issue of JAMA demonstrates that 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) and that 48% of the time, these recommendations are based on the lowest level of evidence (level C: expert opinion, case studies, or standards of care). This trend is especially disconcerting given the quantity of cardiovascular guidelines. Of 44 guidelines, 87% of the guideline authors had some form of industry tie.

Other biases are also important. The specialty composition of a guideline panel likely influences guideline development. Specialty societies can use guidelines to enlarge that specialty’s area of expertise in a competitive medical marketplace. Federal guideline committees may focus on limiting costs; committees influenced by industry are more likely to shape recommendations to accord with industry needs.

Guidelines have other limitations. Guidelines are often too narrowly focused on single diseases and are not patient focused. Patients seldom have single diseases, and few if any guidelines help clinicians in managing complexity. Paradoxically, guidelines are also often too comprehensive, covering every possible intervention that could be appropriate for a patient with that single disease. Tricoci et al found that in ACC/AHA guidelines with at least 1 revision, the number of recommendations increased 48% from the first guideline to the most recent version. If there is a main message in such guidelines, it is likely to be lost in the minutiae. Guidelines are not patient-specific enough to be useful and rarely allow for individualization of care. Most guidelines are more useful for determining the need for further information than for providing evidence-based recommendations.
What to we need to be wary off?

- Guidelines  →  consensus statements
- Bias inherent in writing groups
- Specialities
- Participants
- Data needs to be interpreted to make recommendations
- Narrow focus
- Over reliance in performance assessment
- Need to revert back to stronger relationship with the IOM principles
Standards and Practice Guidelines are different; however both are extremely important in providing the medical profession (perfusion) the opportunity to provide the best possible outcomes for our patients.