

National Academy of Clinical Biochemistry Laboratory Medicine Practice Guidelines: Biomarkers of Acute Coronary Syndrome and Heart Failure

DRAFT GUIDELINES TO BE DISCUSSED AT THE 2004 BECKMAN CONFERENCE

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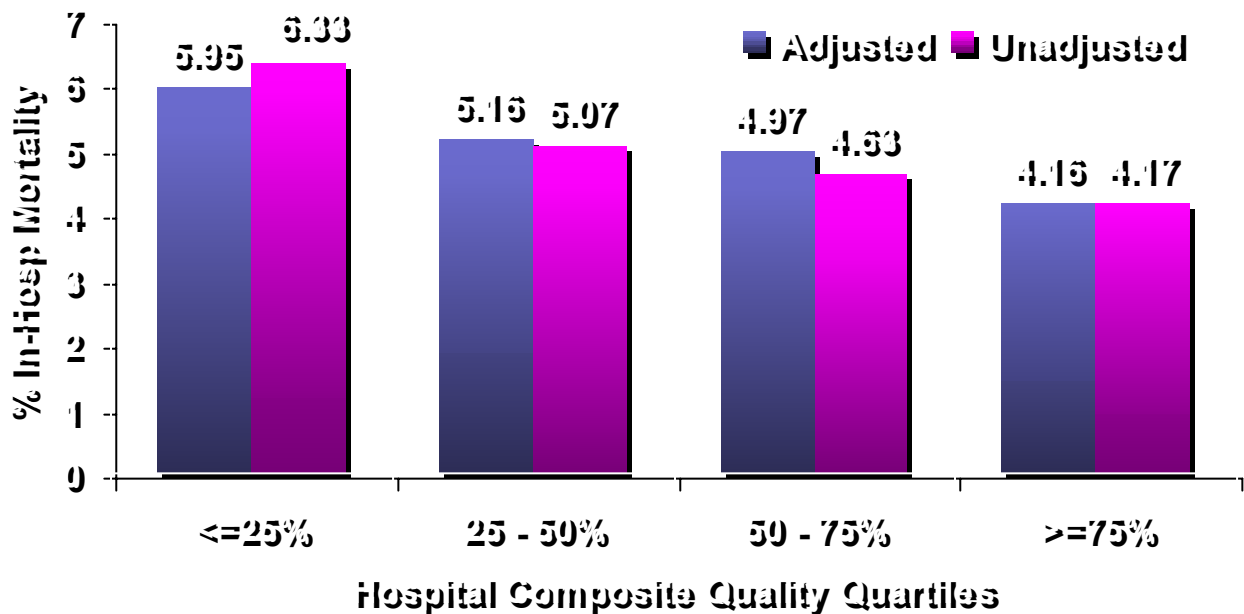
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Introduction

Establishing guidelines for clinical care is important. When the guidance provided and implemented, there is benefit in patient outcomes. The impact of guidelines, and adherence, is demonstrated by the following data from the CRUSADE initiative



Link Between Overall Guidelines Adherence and Mortality



Every 10% improvement in guidelines adherence leads to an 11% decrease in mortality (OR=0.89, 95% CI: 0.81-0.98). Peterson et al. ACC 2004

According to a report from the U.S. Institute of Medicine, “clinical practice guidelines are systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances.” (1). Clearly an important component of appropriate guidelines is the use of evidence-based medicine. However because addressing all relevant question and topics, in all patient populations is not always feasible using high quality evidence “tools” such as randomized trials, well-designed cohort studies or other appropriate strategies, expert consensus must be recognized as an important component of guidelines.

Expert consensus must be guided by input from stakeholders in the laboratory and clinical communities. Towards meeting part of this fundamental goal, the **NACB Laboratory Medicine Practice Guidelines on Biomarkers of Acute Coronary Syndrome and Heart Failure** is the spearheading the 2004 Beckman Conference to be held in Boston on May 21 & 22, 2004. In formation on attending this meeting can be found at (<http://www.aacc.org/meetings/beckman/program.stm>). For those unable to attend the conference written comments can be sent by email to rchristenson@umm.edu.

Guidelines have particularly high impact for diseases with high prevalence, such as the acute coronary syndromes and heart failure. The acute coronary syndromes are a continuum of ischemic heart disease that spans from unstable angina, associated with reversible injury, to frank myocardial infarction with large areas of cardiac necrosis. The acute coronary syndromes are the biggest killer in the western world, accounting for approximately 500,000 deaths annually in the U.S. alone. Until recently the magnitude and impact of this disease on women was largely under appreciated. However the acute coronary syndromes by far account for greater mortality among women than any other cause. The economic impact of acute coronary syndromes is estimated at between 3 and 10 billion dollars annually.

The heart is a very efficient pump; this organ ‘beats’ about 100,000 cycles per day. Over the past decade it has been increasingly recognized that in addition to being a fabulous pump, the heart is also an important endocrine organ. As part of its endocrine function, the heart releases the hormones B-type natriuretic peptide (BNP) and atrial natriuretic peptide. These hormones and their associated metabolites are collectively termed the ‘natriuretic peptides’. The natriuretic peptides perform an important physiological role in regulating fluid balance, and also function in vasodilation, antimitogenesis and myocardial remodeling (2). The natriuretic peptides are natural antagonists to the renin-angiotensin-aldosterone system and their role in regulating fluid balance appears to be particularly important in patients with hemodynamic stress such as heart failure.

Congestive heart failure (CHF) is the most common discharge diagnosis among patients over 65 years of age. The impact of CHF on U.S society is huge; there are 400,000 to 700,000 new cases per year, 3.5 million hospitalizations and 250,000 deaths, for a total cost burden estimated at 30 billion dollars. CHF is an insidious, progressive disease; 50% of patients are symptomatic, so many affected individuals are in the relatively late stages of disease by the time they are diagnosed and treated. This profile of late presentation translates into grim mortality statistics. After the first hospitalization for CHF, the 5-year survival rate is only 30% for men 67-74 years of age, about 20% for men 75-84 years old, and 15% in those >85 years (1). The survival for women is slightly better (1), suggesting the possibility of important gender differences in the disease.

Specific recommendations in this Monograph are based whenever possible on relevant published information. The strength of scientific data supporting each recommendation is characterized using the scoring criteria adopted from the American Heart Association / American College of Cardiology, as summarized in Table 1. For each recommendation, the designations I, IIa, IIb and III describe the indications, and the upper case letters A through C describe the weight of evidence.

Table 1: American College of Cardiology / American Heart Association Classifications	
Summary of Indications	
I	Conditions for which there is evidence and/or general agreement that a given procedure or treatment is useful and effective
II	Conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of a procedure or treatment.
	IIa Weight of evidence/opinion is in favor of usefulness/efficacy
	IIb Usefulness/efficacy is less well established by evidence/opinion
III	Conditions for which there is evidence and/or general agreement that the procedure/treatment is not useful/effective and in some cases may be harmful.
Weight of Evidence	
A	Data derived from multiple randomized clinical trials that involved large numbers of patients
B	Data derived from a limited number of randomized trials that involved small numbers of patients or from careful analyses of nonrandomized studies or observational registries
C	Expert Consensus was the primary basis for the recommendation

The **NACB Laboratory Medicine Practice Guidelines on Biomarkers of Acute Coronary Syndrome and Heart Failure** needs your feedback. Again, all comments are welcome, and all feedback will be carefully examined by the committee. We hope to interact with you at the [2004 Beckman Conference in Boston](#). For those who are unable to attend, please examine the following draft chapters of the guidelines document and email any comments and feedback to rchristenson@umm.edu.

Draft Chapters:

1. Acute Coronary Syndromes (*Morrow*, Newby, Jesse, Ravkilde, Storrow, Christenson)
2. Heart Failure (*Tang*, Francis, Cannon, Jesse, Newby, Storrow, Christenson)
3. Analytical Issues for Biomarkers (*Apple*, Christenson, Wu, Newby, Ravkilde, Jesse)
 - a. Biomarkers of acute coronary syndromes
 - b. Biomarkers of heart failure
4. Point of Care Testing and Logistics (*Storrow*, Wu, Christenson, Apple, Jesse, Francis)
5. Clinical Trials (*Newby*, Morrow, Apple, Christenson, Cannon, Ravkilde, Wu, Francis)
6. Other Etiologies (*Wu*, Apple, Newby, Jesse, Christenson, Francis)