

Foreword

History of guidelines for unstable angina/non-ST-elevation MI

Organizations at the national or international level have often been called upon to define a standard of care in the management of unstable angina (UA) or myocardial infarction (MI). In 1994, the United States Agency for Health Care Policy and Research (AHCPR) issued a set of guidelines for unstable angina that were very well received, and considered to be comprehensive in light of the data and treatment modalities available at the time^[1]. Considerable progress over the last decade, however, has altered the standard management of both UA and MI, and has prompted a global effort to create updated guidelines for these conditions.

Most cardiologists are now familiar with the concept of unstable coronary disease as a spectrum of conditions known collectively as the acute coronary syndromes (ACS), in which the most important patients to identify are those with atherosclerotic plaque rupture and subsequent intracoronary thrombus formation. While older guidelines have focused on either 'angina' or 'myocardial infarction', currently available guidelines — and those in preparation — now focus on the continuum of ACS, with the pathophysiology reflected in the nature of a patient's symptoms, physical exam findings, ECG findings, and blood tests. Thus, UA is now considered to have more in common with MI than with stable angina: but in contrast to MI, with UA the acute occlusion is in many cases not sufficient to result in necrosis. As laboratory testing for cellular damage becomes more sensitive, the line between UA and MI is shifting and will continue to shift, further obscuring the boundaries among different presentations of ACS. It is therefore logical for clinical practice guidelines to encompass both UA and MI, especially since early management decisions may need to be made prior to a definitive diagnosis.

A more easily defined boundary exists between ACS presenting *with* or *without* persistent ST-segment elevations. While MI was once considered as either 'transmural' or 'non-transmural', defined by whether or not pathological Q-waves developed on the ECG, it is now recognized that there are not always direct correlations between the severity of occlusion, initial ECG findings, extent of myocardial necrosis, and permanent electrocardiographic changes. Because not every patient with ST-elevations develops Q waves — particularly if there is a successful early intervention — and because an infarct involving the entire thickness of the myocardium can develop from a variety of presentations, newer guidelines refer to either ST-elevation or non-ST-elevation MI (STEMI, NSTEMI), which are easily distinguished at the time of presentation. This newer classification is more useful for trial enrolment as

well, because entry criteria correspond to findings at presentation, and not to presumptive discharge diagnoses.

Most notably, the division between STEMI and NSTEMI is useful in determining optimal therapy. The decision to use thrombolytics is a major branch-point in the initial management of MI, and it is hoped that thrombolytics are administered prior to the development of Q waves — indeed, that massive necrosis and Q-wave development are prevented from occurring at all. While thrombolytics have proved efficacious in STEMI, particularly when administered soon after the onset of symptoms, there is evidence that these agents are not useful in NSTEMI or unstable angina^[2]. Because the administration of lytic agents is such an important decision in the early management of ACS, other clinical presentations warranting thrombolysis (such as new left bundle branch block) are often grouped with STEMI in guideline documents or in the enrolment criteria for clinical trials.

In September 2000, a Joint Task Force of the American College of Cardiology and American Heart Association (ACC/AHA) published updated guidelines for the diagnosis and management of those acute coronary syndromes presenting without ST-segment elevations — namely UA and NSTEMI. The document in part builds upon the 1994 AHCPR guidelines for UA, and contains sections on initial evaluation and management (including risk stratification), hospital care (including anti-ischaemic and anticoagulant therapy), coronary revascularization, and discharge care. In addition there are appendices on special patient populations, such as the elderly. The full-length ACC/AHA guidelines are 93 pages in length^[3], as published in the *Journal of the American College of Cardiology*. A 17-page Executive Summary was published in *Circulation* at the same time^[4]. Also in September 2000, a Task Force of the European Society of Cardiology (ESC) issued its own set of guidelines^[5], published in the *European Heart Journal*. This 27-page document includes sections on pathophysiology, diagnosis, and risk-assessment; a section examining each of the available pharmacotherapies; a discussion of coronary revascularization; and a section summarizing a general management strategy in ACS. There is also a brief section on long-term management, and an appendix on Prinzmetal-variant angina.

The ACC/AHA guidelines include formal recommendations set in bold, and each recommendation that is made is assigned both a class and a level of evidence (Table 1).

The class of each recommendation corresponds to whether a treatment is deemed useful or effective, ranging from treatments which are useful and effective for all patients, to treatments which may be harmful. The level of evidence corresponds to the strength of available

Table 1 Definitions of classes and levels of evidence for ACC/AHA recommendations

Class I:	Conditions for which there is evidence and/or general agreement that a given procedure is useful and effective
Class II:	Conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of a procedure or treatment
Class IIa:	Weight of evidence/opinion is in favour of usefulness/efficacy
Class IIb:	Usefulness/efficacy is less well established by evidence/opinion
Class 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
Level of Evidence A:	Data derived from multiple randomized clinical trials that involved large numbers of patients
Level of Evidence 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
Level of Evidence C:	Expert consensus

data, ranging from overwhelming data from multiple randomized controlled trials, to expert opinion unsupported by randomized trial data. The ESC recommendations are assigned a level of evidence along similar lines to those of the ACC/AHA, but much of the European Society of Cardiology document consists of more descriptive text, without formal, codified recommendations.

The guideline documents described here are just two of many such documents coming into existence worldwide, as numerous countries have issued or are in the process of issuing guidelines for the management of UA and/or NSTEMI, not just in North America and Europe. Australia, Argentina, and South Africa, for example, are just a few of the other countries that have published or will soon publish their own guidelines. This supplement will focus on the North American and European guidelines, however, as the most widely read documents, and as some of the earliest available in this global wave of guideline revisions.

Issues in guideline implementation

The purpose of clinical practice guidelines is to improve clinical outcomes, but delay or failure to adopt evidence-based recommendations means that the benefits of newer treatments are not available to all patients. Registries as well as numerous retrospective studies indicate that many patients with coronary artery disease receive suboptimal therapy^[6-9]. Investigators have defined numerous barriers to implementation, and resulting discrepancies between ideal, standard-of-care medicine, and what takes place in a real-world setting^[10-11]. In one study, cardiologists were more likely than internists to implement guidelines for treatment of unstable angina^[12]; and, in a retrospective study of patients with MI, physicians participating in clinical trials were more likely to implement the results of clinical trials than physicians in routine practice^[13]. In some cases, active programs to disseminate information and familiarize physicians with clinical practice guidelines have

been shown to have positive influences on practice patterns^[14]. Other issues complicating guideline implementation include resource limitations; variable interpretation of, or disagreement with, guidelines; newer data rendering guidelines obsolete; and areas where evidence to guide treatment is simply lacking.

Large-scale registries are valuable in uncovering divergences between daily practice on the one hand and either guideline documents or the results of randomized clinical trials (RCTs) on the other^[15]. Registries can also provide information about the impact of guidelines—that is, whether adherence to guidelines actually improves clinical outcomes^[16]. Similarly, registries that determine the uptake of RCT results into routine practice can measure whether the treatment effects seen in clinical trials are recapitulated in an uncontrolled setting. The GRACE (Global Registry of Acute Coronary Events) registry is an ongoing prospective observational study that is documenting international treatment practices across the entire spectrum of ACS^[17]. GRACE is expected to provide insight into current management practices in a wide variety of settings, identify discrepancies with treatment guidelines, and determine how management practices correlate with clinical outcomes.

Although well-designed registries are valuable resources that can rigorously document patterns in clinical practice, they inevitably reflect events of the past. Given the diversity of institutional settings, and the constant input of new data from recent clinical trials, communication between practitioners should be encouraged. Focused discussions, such as those sponsored by the International Cardiology Forum, can serve as useful interim supplements to registries.

The International Cardiology Forum

The International Cardiology Forum (ICF) was founded in 1997 with the mandate of translating the results of clinical trials into the daily practice of cardiology. The ICF consists of 18 prominent cardiologists

from Europe, North America, South America, New Zealand and Japan. Its activities include annual experts' meetings and the publication of monographs and teaching aids meant for global distribution. In 1998, the ICF International Experts' meeting focused on the 1994 AHCPR guidelines for UA, specifically those areas where the most progress had occurred; suggestions for guideline revisions were then published in multiple cardiology journals worldwide^[18].

With the global publication of new guidelines for ACS, the ICF continues its active role in helping to translate trial data into clinical practice. In September 2000, 242 cardiologists, representing over 50 countries on six different continents, convened in Budapest, Hungary for the ICF's 4th Annual Experts' Meeting. The meeting focused on the new North American and European guidelines for UA/NSTEMI, and included workshops in which cardiologists from a variety of geographical regions and institutional settings analyzed the guidelines with respect to their own practices, the resources in their countries, and the available data. The workshops were divided into five separate but inter-related areas of patient management: risk stratification, antithrombin therapy, antiplatelet therapy, interventional management, and discharge therapy. In each area, differences between the North American and European guidelines were identified, as well as areas where the guidelines were most consistent or inconsistent with available data, and areas where more data are needed to define optimal therapy. Participants also looked at case studies of typical UA/NSTEMI patients, comparing how these patients might be treated in their own practices with the recommendations of the two guidelines.

In order to characterize the workshop participants, attendees of the Experts' Meeting were asked to fill out a questionnaire prior to the meeting. The questionnaire focused on the size and facilities of the participants' institutions, as well as their personal and institutional practices vis-à-vis UA/NSTEMI. Of the 242 attendees, 198 responded to the survey (82%), and at least 193 responded to any individual question.

Some key survey results are given in Tables 2 and 3. Institutions of all sizes were represented, from small hospitals with few beds devoted to cardiology, to large tertiary care complexes. The majority of participants, but not everyone, had access to at least a single room equipped for coronary intervention, and 72% had emergency surgical backup at their facilities. Most respondents had troponin testing available to them, but only half had access to a quantitative test.

Similarly, there was a diversity of practice related to pharmacotherapy. In the setting of acute ischaemia, most participants reported the routine administration of aspirin, β -blockers, and intravenous nitrates, and a more selected approach to both angiotensin converting enzyme (ACE) inhibitors and calcium-channel blockers. The majority reported routine use of low-molecular-weight heparin, reserving glycoprotein (GP) IIb/IIIa receptor antagonists for selected patients. A sizeable minority (22%) reported never using GP IIb/IIIa

Table 2 Size and available facilities of represented institutions

Total beds	
<250	9
250-499	37
500-749	23
750-999	15
≥1000	17
Cardiology beds	
<25	15
25-49	39
50-74	21
75-99	17
≥100	8
Facility or test	
Specialized Chest Pain Unit (distinct from ER or CCU)	27
At least one room equipped for percutaneous coronary intervention	92
Multiple rooms equipped for PCI	53
Cardiothoracic surgery	72
Electrophysiology	73
Intravascular ultrasound	54
Troponin testing	
Quantitative	51
Qualitative	10
Both available	28
Neither available	11

Table 3 Pharmacotherapy prescribing for UA/NSTEMI

Medication	Frequency of use (percent respondents)		
	Never	In selected patients	Routinely
In hospital			
Aspirin	0	0	100
β -blockers	1	12	87
IV nitrates	1	27	72
ACE inhibitors	4	84	13
Ca ⁺⁺ channel blockers	33	65	3
LMWH	3	33	64
GP IIb/IIIa inhibitors	22	74	4
After discharge			
Aspirin	0	0	100
β -blockers	0	14	87
Nitrates	6	58	36
'Statins'	5	51	45
Warfarin	67	33	0

receptor antagonists for UA/NSTEMI, partially accounted for by lack of availability of these agents (data not shown). As for discharge therapy, there was fairly routine use of aspirin and β -blockers, but a diversity of practice patterns related to ACE inhibitors, HMG-CoA reductase inhibitors ('statins') and oral anticoagulation with warfarin.

Workshop results

The articles contained in this supplement present highlights of the new UA/NSTEMI guidelines, and summarize the commentary from the individual workshops. In general, workshop participants found the new guidelines to be valuable updates that will be helpful in guiding clinical practice. However, the lively discussions that took place indicate the difficulty of formulating definitive recommendations, given the pace of research and the spectrum of resource availability that exists throughout the world. In several workshops, new data presented shortly before the ICF meeting, including the results of GUSTO IV ACS^[19], generated debate over the optimal use of GP IIb/IIIa receptor antagonists, the role of troponin measurement in risk stratification, and the advantages of early invasive management. Economic constraints, including restrictions on the use of newer pharmacotherapies and limited access to catheterization facilities, are barriers to guideline implementation that many clinicians must face. The diversity of approaches to UA/NSTEMI as evidenced by the survey results was reflected in the workshops.

The formulation of guidelines is a useful means of translating the results of clinical trials into routine practice, but ultimately, guideline implementation depends on the responses of individual physicians to the task force recommendations. We hope you find our discussions of the new UA/NSTEMI guidelines interesting and relevant to your own evaluation of these documents.

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 International Cardiology Forum*

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Appendix

The International Cardiology Forum

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