

An Evaluation of Technologies for Identifying Acute Cardiac Ischemia in the Emergency Department: Executive Summary of a National Heart Attack Alert Program Working Group Report

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INTRODUCTION AND METHODS

As the most common cause of death in this country, acute myocardial infarction (AMI) has deservedly been the subject of substantial efforts of clinicians, scientists, government and other agencies, and the public in efforts to reduce its devastating impact. Although very significant progress continues to be made, the National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health (NIH) recognized the need for a concerted and coordinated effort to reduce mortality and morbidity in this country from AMI and in 1991 initiated the National Heart Attack Alert Program (NHAAP). This ongoing effort, bringing together scientists, clinicians, and NHLBI staff, with the active participation and leadership of a coordinating committee that includes representatives of 40 professional organizations, has commissioned a number of working groups to review and make recommendations for physicians and other health care providers about issues related to the rapid recognition and response to patients with symptoms and signs of AMI. Recognizing the central and growing role of diagnostic technologies for AMI and for acute cardiac ischemia (ACI) in general (including both unstable angina pectoris [UAP] and AMI) in emergency settings, which represent patients' entry points into the health care system, in 1994 the NHAAP Working Group on Evaluation of Technologies for Identifying Acute Cardiac Ischemia in the Emergency Department was formed to assess the utility of diagnostic technologies for ACI/AMI in the ED. This report summarizes the Working Group's assessment of the diagnostic performance and impact on care

of those technologies. The charge by the NHAAP to the Working Group was to use ACI, rather than AMI, as the diagnostic outcome of interest in the ED. This reflects the fact that identifying only AMI would miss a large number of ED patients at significant and immediate cardiac risk.

The technologies reviewed address the diagnosis of ACI (ie, both AMI and UAP) because this is the condition that must be identified in the treatment of patients with AMI and potential AMI. The review included all such technologies directed at the *diagnosis* of ACI in the ED; methods primarily directed at prognostic or risk stratification of such patients were not included. In this context, to aid the medical community in the use and further evaluation of diagnostic technologies for ACI, this report by the Working Group (1) comprehensively reviews the important technologies for identifying ACI in the ED setting available at the time of this writing and (2) describes the extent to which there are data for each technology that demonstrate its accuracy and effectiveness in actual use in the ED setting. The Working Group was selected to provide expertise in the areas of cardiology, emergency medicine, general internal medicine, family practice, and nursing, as well as in the specific disciplines of metaanalysis and health services research.

WORKING GROUP PROCESS AND METHODS

To accomplish this review, a formal process of review and evaluation of the scientific literature related to these technologies was undertaken, based on Medline and related electronic literature searches and supplemented by the panelists' knowledge of the literature and ongoing research. All relevant English-language literature on each technology was reviewed, summarized, analyzed, and reported on independently by three panel members in a process analogous to an NIH Study Section.

For each technology, studies were formally evaluated and then rated. The *quality of evidence* provided by the relevant studies was rated as A, B, C, or NK, as follows: A, prospective controlled clinical studies of high quality (eg, large multicenter trials with concurrent controls); B, substantial

clinical studies; C, limited studies or evidence (eg, case studies, small clinical studies); and NK, not known (eg, expert opinion or case reports only).

On the basis of compiled initial reviews and a consensus process, the panel rated each technology (in addition to the quality ratings described above) for its primary purpose using two distinct metrics: (1) *diagnostic performance*, the accuracy of the technology, measured by sensitivity, specificity, or receiver-operating characteristic curve, for ACI; and (2) *clinical impact*, its demonstrated impact on diagnosis, triage, treatment, or outcome (eg, mortality) when used by clinicians in actual practice.

The *diagnostic performance* of the test and the magnitude of its demonstrated *clinical impact* were rated as +++, very accurate/large clinical impact; ++, moderately accurate/medium impact; +, modestly accurate/small impact; NK, not known; NE, not effective.

As indicated, in assigning these ratings, each technology was evaluated on the basis of its performance of its *primary* diagnostic purpose of general ED detection (G), early detection (E), and detection in specific subgroup (S). These designations are noted in Table 1 (see p 10).

The Working Group's conclusions and ratings for each reviewed diagnostic technology follow. The ratings of the Working Group reflect its estimation of the accuracy or impact of the test in actual practice in the ED. These assessments incorporate the quality of the literature, the magnitude or effect of size of the reported findings, and considerations of generalizability and feasibility. These ratings take into consideration the text of the reviews but also include a weighting of the evidence by the Working Group. Therefore the text and the ratings, although linked, are sometimes not entirely concordant. Full reviews and evaluations of each technology appear in the main body of this report. The key for interpreting the ratings tables is as follows. The quality-of-evidence rating system comprises A, high-quality clinical studies; B, substantial clinical studies; C, limited studies; NK, not known; and NE, not effective. The diagnostic performance and clinical impact rating system comprises +++, very accurate/large clinical impact; ++, moderately accurate/

Table 2.

Working Group ratings of standard ECG.

ED Diagnostic Performance		ED Clinical Impact	
Quality of Evidence	Accuracy	Quality of Evidence	Impact
A	++	Standard of care	Standard of care

Table 3.

Working Group ratings of prehospital ECG.

ED Diagnostic Performance		ED Clinical Impact	
Quality of Evidence	Accuracy	Quality of Evidence	Impact
A	++	B	+

medium impact; +, modestly accurate/small impact; NK, not known; and NE, not effective.

STANDARD ECG

The ECG represents a safe, readily available, and inexpensive technology for assessing patients with acute chest pain and is central to its evaluation. However, the ECG suffers from imperfect sensitivity and specificity for ACI. When interpreted using liberal criteria, the ECG operates with relatively high (but not perfect) sensitivity for AMI, at the cost of low specificity. Conversely, when interpreted using stringent criteria for AMI, sensitivity drops to levels around 50% or below.

The ECG depends on a trained interpreter; less experienced ED interpreters appear to operate at lower positive predictive values than trained interpreters. Additionally, the interpreter frequently cannot tell whether ischemic electrocardiographic changes are new or old because previous tracings are not available or changes such as bundle-branch blocks obscure possible new changes. The ECG's yield is greater during active chest pain, and sensitivity may increase.

In spite of these shortcomings, the standard ECG functions as an integral component of the evaluation of patients with acute chest pain and should continue to be incorporated in strategies that incorporate other clinical characteristics such as historical and physical examination parameters. The ECG is not a perfectly sensitive test, and it should always be considered a supplement to, rather than a substitute for, physician judgment. The Working Group recommends the ECG continue to be considered the standard of care in the evaluation of chest pain in the ED patient.

The results of the Working Group's final ratings of the quality of evidence evaluating this technology and of its ED diagnostic performance and clinical impact are depicted in Table 2.

PREHOSPITAL ECG

Table 4.
Working Group ratings of continuous 12-lead ECG.

ED Diagnostic Performance		ED Clinical Impact	
Quality of Evidence	Accuracy	Quality of Evidence	Impact
NK	NK	NK	NK

Studies to date demonstrate that prehospital 12-lead ECG technology is feasible and clinically practical and probably could be implemented in most established urban paramedic systems. *Prehospital identification* of thrombolysis candidates through the use of prehospital 12-lead electrocardiography has been shown in almost every study to significantly reduce hospital-based time to treatment. This time savings is perceived as beneficial but has not, by itself, demonstrated a reduction in mortality. *Prehospital treatment* with thrombolytic therapy may result in a significant mortality reduction if the time savings is in the area of 1 hour or more. Parallel controlled randomized prospective studies are required to further analyze the cost-benefit issues, additional uses, and ultimate role of prehospital 12-lead electrocardiography.

The results of the Working Group's final ratings of the quality of evidence evaluating this technology and of its ED diagnostic performance and clinical impact are detailed in Table 3.

CONTINUOUS 12-LEAD ECG

There have been no well-designed large randomized prospective ED or CCU studies evaluating this technology. Cost-benefit analysis of this technology has not been accomplished. Although ED ST-segment monitoring holds the potential to detect silent myocardial ischemia and infarction, reduce missed ischemic diagnoses, and provide the earliest evidence for coronary occlusion in patients presenting with preinfarction angina, larger prospective studies are required to make this assessment.

The results of the Working Group's final ratings of the quality of evidence evaluating this technology and of its ED diagnostic performance and clinical impact are shown in Table 4.

Table 5.
Working Group ratings of nonstandard ECG leads and body-surface mapping.

	ED Diagnostic Performance		ED Clinical Impact	
	Quality of Evidence	Accuracy	Quality of Evidence	Impact
Nonstandard ECG leads	C	+	NK	NK
Body-surface mapping	NK	NK	NK	NK

NONSTANDARD ECG LEADS AND BODY-SURFACE MAPPING

Sampling right ventricular leads is clinically practical, uses the universally available 12-lead ECG, and appears to increase the sensitivity and specificity for detection of right ventricular infarction (a strong, independent predictor of major complications and in-hospital mortality in patients with inferior AMI). Such leads have the potential to improve severity classification of AMIs, help refine the process of risk-benefit assessment for emergency interventions, possibly provide an indication for thrombolytic treatment, and avoid nitrate-induced hypotension in patients with right ventricular infarction. Sampling posterior leads may also improve the sensitivity of the ECG for posterior AMI. Larger prospective studies applied in a variety of EDs with a broader range of admitted and discharged chest pain patients are required to determine the risks and benefits of this technology. If sensitivity and specificity are comparable to the standard 12-lead ECG, then studies to assess clinical impact in the ED would be warranted.

Body-surface mapping is a valuable research tool requiring specialized equipment for acquisition and specialized software for processing the information. This is not currently practical for ED patient assessment. However, the improved sensitivity and specificity suggested by preliminary efficacy-type trials indicate that this approach may eventually contribute to the ED diagnosis of ACI.

The results of the Working Group's final ratings of the quality of evidence evaluating these technologies and of their ED diagnostic performance and clinical impact are detailed in Table 5.

ECG EXERCISE STRESS TEST

Currently there are limited data on the impact of ECG exercise stress testing in the ED. Where the risk of coronary artery disease is low to moderate, the expedited ECG stress test may offer the benefit of an expedited workup and may reduce hospital admissions for chest pain. Observation status, where the patient is observed pending definitive test-

ing, may offer a similar benefit. However, ECG exercise stress testing in the ED cannot be recommended in the absence of additional data demonstrating safety and effectiveness.

The results of the Working Group's final ratings of the quality of evidence evaluating this technology and of its ED diagnostic performance and clinical impact are shown in Table 6.

ORIGINAL ACI PREDICTIVE INSTRUMENT

The original ACI predictive instrument uses readily available clinical and ECG data to compute a probability of ACI. Its diagnostic performance and clinical impact have been well demonstrated in large prospective clinical trials^{1,2}, which have shown it to be safe and effective in improving ED triage of patients with possible ACI in a wide range of hospitals. Although appropriate for general clinical use, it has not been widely adopted in EDs, possibly because of the need for a hand-held calculator to compute the probability of ACI.

In the near future, the original ACI predictive instrument probably will be superseded by the ACI-TIPI (time-insensitive predictive instrument), which may have a similar impact on ED care, with the advantages of computerization and its applicability to retrospective review of care.

The results of the Working Group's final ratings of the quality of evidence evaluating this technology and of its ED diagnostic performance and clinical impact are shown in Table 7.

ACUTE CARDIAC ISCHEMIA TIME INSENSITIVE PREDICTIVE INSTRUMENT (ACI-TIPI)

The ACI-TIPI, like the original ACI predictive instrument, provides the ED physician with the 0% to 100% probability that a given patient truly has ACI to supplement the ED triage decision. Its diagnostic performance has been tested in large studies that included ED^{3,4} and EMS⁵ patients and has been demonstrated to be diagnostically equivalent to the earlier version³, except for a slightly higher sensitivity for AMI. Thus, clinical use should be comparable to the

Table 6.
Working Group ratings of ECG exercise stress test.

ED Diagnostic Performance		ED Clinical Impact	
Quality of Evidence	Accuracy	Quality of Evidence	Impact
C	+	C	NK-NE

Table 7.
Working Group ratings of original ACI predictive instrument.

ED Diagnostic Performance		ED Clinical Impact	
Quality of Evidence	Accuracy	Quality of Evidence	Impact
A	+++	A	+++

original ACI predictive instrument³, with two advantages for clinical use. First, its incorporation into the conventional computerized electrocardiograph allows direct measurement of details of the ECG waveform without the need for physician interpretation, with automatic printing of the ACI probability on the ECG header. Second, its “time insensitivity” makes it valid for retrospective review and assessment of care, as well as for real-time ED clinical care.

Two published early trials have shown impact on the speed and accuracy of ED triage.^{4,6} Although published only in abstract form, the trial of clinical impact on ED triage decisionmaking of a 10,689-patient multicenter controlled clinical trial should provide definitive information regarding the impact of the ACI-TIPI. However, because results of abstracts were not considered in arriving at the Working Group’s ratings, at this writing, the quality of evidence warrants a C rating and clinical impact a + until rerating once the trial’s results are fully published.

The overall results of the Working Group’s final ratings of the quality of evidence evaluating this technology and of its ED diagnostic performance and clinical impact are detailed in Table 8.

GOLDMAN CHEST PAIN PROTOCOL

The Goldman computer-based chest pain protocol was developed with the use of a sound methodology. The fact that it was validated in a large population that included two university and four community hospitals, with at least two of the hospitals having racially diverse populations, supports its potential utility in a diverse patient population. As the protocol currently stands, its greatest potential benefit would likely be in improving physicians’ specificity for AMI and avoidance of triage to the CCU, with attendant cost savings. However, this impact has not been demonstrated in a controlled clinical trial of its use. The only published trial of its impact on care suggests that when it is provided to physicians, there is no impact on care and no change in resource utilization.⁷

Table 8.
Working Group ratings of ACI-TIPI.

ED Diagnostic Performance		ED Clinical Impact	
Quality of Evidence	Accuracy	Quality of Evidence	Impact
A	+++	C*	+*

*Abstract and pending reports are not included in the ratings.

Given that UAP may be as important as the possibility of AMI with regard to clinical and cost implications, the fact that non-AMI ACI is not addressed by the Goldman protocol is a significant limitation. Moreover, because non-chest pain presentations of ACI (or AMI) are not considered by the protocol, the protocol may well not be applicable for general identification of ACI among all ED patients with symptoms consistent with ACI. Again, its exact clinical value in current practice settings remains to be demonstrated in interventional clinical trials.

The results of the Working Group’s final ratings of the quality of evidence evaluating this technology and of its ED diagnostic performance and clinical impact are listed in Table 9.

OTHER COMPUTER-BASED DECISION AIDS

These computer-based decision aids provide examples of a variety of ways to identify patients for CCU admission but have a number of major limitations, especially that they predict AMI rather than ACI and have not yet been demonstrated to be safe and effective in actual use. In addition, there are some concerns about the generalizability and transportability of some of their input variables and, for the neural network model of Baxt⁸, concerns about the “black box” and lack of publication of the model to allow testing by others.

Although each of these models has some promise, including very encouraging performance in their preliminary studies, at this point, none can be considered ready for clinical use.

The results of the Working Group’s final ratings of the quality of evidence evaluating these technologies and of their ED diagnostic performance and clinical impact are detailed in Table 10.

Table 9.
Working Group ratings of Goldman chest pain protocol.

ED Diagnostic Performance		ED Clinical Impact	
Quality of Evidence	Accuracy	Quality of Evidence	Impact
A	For AMI: +++ For UAP: NE	B	NK-NE

CREATINE KINASE

Creatine kinase (CK) and CK isoenzyme–cardiac muscle subunit (CK-MB) measurements are traditionally obtained early in the ED course of a patient admitted to the hospital for suspected AMI or ACI. The utility of the assay in the ED as a one-time test is limited because levels do not significantly increase until 4 to 6 hours after the onset of AMI. Mass measurements of CK-MB, compared with the older activity analysis, have improved sensitivity and specificity. Improved sensitivity may also be achieved with CK-MB subforms, and these may be more useful in making the diagnosis of AMI in the ED for patients who present early after the onset of symptoms. This is also achieved by the repeated measurements of CK-MB in the ED or the hospital. However, and importantly, CK and CK-MB do not identify patients with UAP, who comprise about half of all patients with ACI.

Despite improvements in the diagnostic performance and practicality of CK and CK-MB assays, there is no controlled clinical impact trial showing that these tests are effective for decisions to send a patient home or to the appropriate level of care of admission for patients with suspected ACI, either as one-time or serial tests. A prospective intervention study, with follow-up of all (including nonadmitted) patients, of the effect of serial CK and CK-MB on patient outcomes is needed before a strategy incorporating CK-MB into medical decisionmaking can be fully evaluated or recommended.

The results of the Working Group’s final ratings of the quality of evidence evaluating this technology and of its ED diagnostic performance and clinical impact are detailed in Table 11.

OTHER BIOCHEMICAL TESTS

Myoglobin, an early marker of AMI, and the cardiac troponins T and I, which are specific for myocyte damage and are late markers, hold promise to improve the identification of patients with AMI and minor myocardial injury. However, the use of new biochemical markers in the ED as a routine measure to improve either the initial triage or ther-

apy of patients with AMI is currently unproven. Although this information may be useful in those hospitals attempting to triage patients between ED holding areas and inpatient beds, the value of their approach needs further bolstering by additional data from carefully controlled studies.

Ultimately, serum protein testing may likely include a panel of multiple markers, which provide a spectrum of information regarding the time of AMI onset. An early sensitive marker such as myoglobin, when combined with CK-MB and troponin-T (increased in the presence of AMI), could provide the clinician with critical information necessary to make decisions in the emergency setting.

The results of the Working Group’s final ratings of the quality of evidence evaluating these technologies and of their ED diagnostic performance and clinical impact are detailed in Table 12.

ECHOCARDIOGRAM

Although echocardiography in the ED showed initial promise, it is labor-intensive and insensitive for distinguishing new from old ischemia. Its use in the absence of chest pain appears to be more accurate in a single study with low numbers for unclear reasons. It can be recommended as an adjunctive test if readily available during atypical chest pain; there are insufficient data demonstrating that it can effectively triage patients in large clinical settings.

Echocardiography is a generally accurate technique, but in the ED setting, when looking for ACI, it still has a false-negative rate that precludes discharging all patients with a negative echo. For the purpose of ruling in or ruling out AMI, echocardiography cannot be done accurately by ED personnel. During hours when expert technicians and interpreters are readily available, echocardiography might improve the accuracy of diagnosis and might thereby lead to a reduction in unnecessary admissions and costs. Beyond the diagnosis of ACI, for those with AMI, additional poten-

Table 10. Working Group ratings of other computer-based decision aids.

ED Diagnostic Performance		ED Clinical Impact	
Quality of Evidence	Accuracy	Quality of Evidence	Impact
B	+	NK	NK

Table 11. Working Group ratings of CK.

	ED Diagnostic Performance		ED Clinical Impact	
	Quality of Evidence	Accuracy	Quality of Evidence	Impact
Single test	A	For AMI: + For UAP: NE	NK	NK
Multiple tests over time	A	For AMI: +++ For UAP: NE	NK	NK

tially useful clinical information about complications and hemodynamic status (ejection fraction, pulmonary artery pressure) would also become known, possibly leading to improvements in management and prognosis. Study results that suggest alternative diagnoses that need acute care would also be potentially beneficial.

However, overall, the available investigations to date suggest that even in a *selected* ED population, echocardiography may be reasonably specific but not clearly sufficiently sensitive for either ACI or AMI for this tool to be recommended for ED use. Its role for the overall ED population is even less clear and cannot be recommended without much more information about which patients for whom it should be considered, its diagnostic performance in the usual ED setting, and its safety and effectiveness in this setting when tested in a controlled interventional clinical trial.

The results of the Working Group's final ratings of the quality of evidence evaluating this technology and of its ED diagnostic performance and clinical impact are shown in Table 13.

THALLIUM SCANNING

The use of radionuclide imaging for the diagnosis of ACI/AMI in the ED should be restricted to specialized and limited situations in which the clinical triad of history, ECG changes, and enzymatic/laboratory measurements is not available or is unreliable. Such imaging may be helpful, for example, in patients with equivocal chest pain histories and nondiagnostic ECG findings. Thallium-201 is an excellent perfusion tracer, but the available data indicate relatively poor diagnostic accuracy in the setting of AMI or UAP, with a particularly low specificity. There are also difficulties with isotope availability and tracer redistribution (necessitating imaging within 15 to 20 minutes of injection). Hence thallium-201 does not appear to be an ideal agent for use in the ED management of patients with chest pain.

Table 12.
Working Group ratings of other biochemical tests.

	ED Diagnostic Performance		ED Clinical Impact	
	Quality of Evidence	Accuracy	Quality of Evidence	Impact
Troponin-T and troponin-I	B	For AMI: ++ For UAP: NE	NK	NK
Myoglobin	B	For AMI: + For UAP: NE	NK	NK

The results of the Working Group's final ratings of the quality of evidence evaluating this technology and of its ED diagnostic performance and clinical impact are detailed in Table 14.

SESTAMIBI AND OTHER TECHNETIUM-99m PERFUSION AGENTS

The use of radionuclide imaging for the diagnosis of ACI/AMI in the ED should be restricted to specific and limited conditions in which the clinical triad of history, ECG changes, and enzymatic/laboratory measurements is not available or is unreliable. Such imaging may be helpful, for example, in patients with equivocal chest pain histories and nondiagnostic ECG findings. The applicability of this imaging modality depends primarily on logistical issues. Technetium-99m-sestamibi (^{99m}Tc-sestamibi) is an excellent perfusion tracer, with advantageous physical characteristics compared with thallium-201. Its availability, excellent imaging properties, and stable tracer distribution with time make it a practical agent for ED use. Although large-scale trials are lacking, the available data (in relatively small numbers of patients) indicate that ^{99m}Tc-sestamibi is a promising agent for use in the ED evaluation of selected patients with chest pain. Its use to date has been limited to a handful of centers that have studied patients who were judged to be at relatively high risk of having ACI, particularly those having chest pain at the time of the study. It is unclear whether the technique will be of value as a screening test in lower risk ED patients without ongoing chest pain or when used by less experienced interpreters. However, until more evidence is available, it cannot yet be recommended at this stage for general use.

The results of the Working Group's final ratings of the quality of evidence evaluating this technology and of its ED diagnostic performance and clinical impact are shown in Table 14.

Table 13.
Working Group ratings of echocardiogram.

ED Diagnostic Performance		ED Clinical Impact	
Quality of Evidence	Accuracy	Quality of Evidence	Impact
B	+	NK	NK

CONCLUSIONS AND RECOMMENDATIONS

Summary of clinical recommendations based on demonstrated diagnostic performance and clinical impact Recommendations regarding the use of a technology should be based on both ED diagnostic performance and clinical impact data obtained in high-quality or substantial studies. Of the various diagnostic technologies evaluated in the 14 sections, however, only five met this highly desirable standard of evaluation.

The original ACI predictive instrument was found to be excellent for diagnostic performance (+++) and substantial clinical impact (+++) in a high-quality prospective multicenter trial (A) for both forms of ACI (UAP and AMI). Its accuracy and demonstrated improvement in ED triage make it possible to recommend it for general use in the ED evaluation and triage of patients with symptoms suggestive of ACI. Its main drawback has been that its use requires a programmed calculator or chart, which has been an obstacle to its widespread use. This may be overcome by its successor, the ACI-TIPI, which is incorporated into and reported as part of the header printout on a standard 12-lead ECG.

The second diagnostic technology on which there are studies of both diagnostic performance and clinical impact is the ACI-TIPI, although the largest clinical trial of impact is available only in abstract form. It has comparable diagnostic performance (+++) to the original ACI predictive instrument based on multicenter prospective studies (A), and the ECG-based ACI-TIPI has ease of use. On the basis of published clinical trials but not including the results of a large prospective trial published to date only in abstract form, its quality of evidence is a C, and clinical impact rating is a +. More definitive recommendations regarding its general use await the full publication of the results of the multicenter trial.

The prehospital ECG was found to have good (++) diagnostic performance on the basis of evidence from high-quality prospective studies (A). However, this technology was judged to have a small clinical impact (+) on the basis of substantial clinical studies (B). It was the impression of the

Table 14.
Working Group ratings of thallium scanning.

ED Diagnostic Performance		ED Clinical Impact	
Quality of Evidence	Accuracy	Quality of Evidence	Impact
C	NK-NE	NK	NK-NE

Working Group, on the basis of these results, that although this technology has promise, it will probably be realized in areas with long EMS transport times. Thus, until more evidence is obtained, its general use cannot be recommended.

The fourth technology for which data are available on both its ED diagnostic performance and clinical impact is the Goldman chest pain protocol. An important caveat, however, is that this protocol was designed only for AMI detection and not the more general detection of ACI in the form of UAP. Its diagnostic performance for AMI has been demonstrated to be excellent (+++) in multicenter high-quality studies (B). However, in a high-quality prospective study (B), it has not had a demonstrable impact on clinical care (NK/NE), and thus, at this point, its general use cannot be recommended.

The final diagnostic technology, the ECG exercise stress test, a different extension of the standard ECG, has also been evaluated to some extent in the ED. Its diagnostic performance for coronary artery disease in this setting has been only modest. Given this, and that its actual impact on triage has received only limited testing, its routine ED use cannot be recommended.

Summary of clinical recommendations based on demonstrated diagnostic performance but without data on clinical impact For all but five of the technologies reviewed above there was some published evidence of diagnostic performance but no studies of actual clinical impact (ie, evidence grades were NK for clinical impact). The Working Group strongly advises that, with the exception of the standard 12-lead ECG (see immediately below), diagnostic performance alone is an insufficient basis for recommendation for general use. This is from the long experience of numerous examples of technologies that have excellent or good diagnostic performance but negligible or even negative clinical impact when tested under conditions of actual use.^{7,9-11}

The standard 12-lead ECG has been shown in many studies to have very good, although not perfect, diagnostic performance in the ED. However, despite its key role in the diagnosis of ACI in the ED it has not been demonstrated to

Table 15.
Working Group ratings of sestamibi and other technetium-99m perfusion agents.

ED Diagnostic Performance		ED Clinical Impact	
Quality of Evidence	Accuracy	Quality of Evidence	Impact
C	+++	NK	NK

have impact on care in the ED setting other than its central role in other technologies such as the ACI predictive instruments described above. In fact, given that the ECG is part of standard ED evaluation, in the view of the Working Group, a trial to demonstrate its impact would be neither necessary nor ethical. Indeed, the 12-lead ECG should be part of the very initial evaluation of any ED or EMS patient with symptoms suggestive of ACI.

Although they have not as of yet been demonstrated to actually improve clinical care in the ED, *blood biochemical tests of myocardial necrosis, particularly CK*, including a variety of assay types and protocols, have undergone prospective testing of their diagnostic performance for the detection of AMI. Available data suggest that the use of a *single CK-MB* test yields performance insufficient for use in ED triage but that the use of *multiple CK-MB* tests over several or more hours has very good diagnostic performance for AMI. Although less complete, the data for *troponin* also suggest that performance of a single test is not satisfactory. The use of multiple tests over time may improve diagnostic performance. The one other biochemical test that has undergone considerable testing is *myoglobin*, but its performance has not yet defined its exact role as an early marker of AMI. Finally, neither myoglobin nor CK detect UAP, which raises the possibility of missing this form of ACI if triage is dependent on such tests. This is one of the reasons that in the absence of prospective trials of the impact of this technology on ED triage (level of admission or discharge), these tests cannot yet be recommended for general ED triage use at this time, although they are very useful for in-hospital care.

Echocardiography, well studied in other settings, has undergone several studies in the ED, which have generally shown modest diagnostic performance for initial ED evaluation. Given this, and that its actual impact on ED care has not been evaluated, this technology cannot be recommended for general ED use at this time.

Radionuclide imaging, although generally used in non-ED settings, has undergone some study of diagnostic performance in the ED. *Thallium scanning* is less appropriate for ED use than sestamibi, has not been evaluated in ED use, and cannot be recommended. *Sestamibi and other technetium-99m perfusion agents* have been studied in the ED setting, and although the overall diagnostic performance of sestamibi has been promising, it has not been sufficiently tested to recommend its general ED use. Whether sestamibi will be found to be more helpful when evaluated for special subgroups, and when tested for its actual impact on care, remains to be seen. At this point, its general ED use cannot be recommended.

As an extension of the standard ECG, *nonstandard ECG leads* have undergone some limited testing in the ED for detecting ACI, and another prospective trial was just completed. The quality (C) of published data at this point does not provide sufficient evidence of diagnostic utility. This may be altered by the just-finished trial. In addition, its impact on care has not been tested, and thus nonstandard ECG leads cannot yet be recommended for general use.

Although reported in several case studies in EDs or suggested in a preliminary way in discussions of work done in other settings such as the CCU, *continuous ECG* and *body-surface mapping* have not been tested as to their diagnostic performance in general ED use or for their impact on ED care, and these cannot be recommended for general use at this time.

RECOMMENDATIONS FOR RESEARCH

Although the primary purpose of this report is to provide clinical recommendations, Table 1 (see p 10) makes it clear that there is currently a great lack of research results related to the diagnostic performance and especially the clinical impact of these most important technologies for the emergency evaluation of the most common cause of death in our country. Further diagnostic trials addressing both their accuracy and impact are critical to the NHAAP mission to improve rapidity and effectiveness of care for emergency cardiac patients. Additionally, the evaluation of diagnostic approaches integrating multiple technologies (such as panels of different biochemical markers) or of multiple modalities (such as combining ECG, imaging, and biochemical tests) is needed. In doing this, it will be important to understand the incremental contribution of each modality. In this context, further investigation is needed of the potential utility of computer-based decision aids and analytic programs for integrating and presenting different forms of information.

With more than 6 million patients yearly in this country presenting to the ED with chest pain or analogous symptoms^{1,12}, with the care of those unnecessarily admitted to cardiac care costing on the order of \$3 billion a year¹³, and approximately 20,000 ED patients being inappropriately sent home each year^{14,15}, there is little question that such studies of ways to improve diagnostic and triage performance would be an excellent investment financially and would substantially improve medical care. The Working Group strongly recommends that such studies be supported far more than has been the case to date.

Table 1.
Summary Working Group ratings of diagnostic technologies for ACI for ED use.

Technology	Primary Diagnostic Use	ED Diagnostic Performance		Demonstrated ED Clinical Impact	
		Quality of Evidence	Accuracy (max = +++)	Quality of Evidence	Impact (max = +++)
Standard electrocardiogram (ECG)	G	A	++	Standard of Care	Standard of Care
Original ACI predictive instrument	G	A	+++	A	+++
ACI-TIPI (time-insensitive predictive instrument)	G	A	+++	C*	+
Prehospital ECG	E	A	++	B	+
Goldman chest pain protocol	G	A	For AMI: +++ For UAP: NE	B	NK-NE
Creatine kinase, multiple tests over time	S	A	For AMI: +++ For UAP: NE	NK	NK
Sestamibi	S	C	+++	NK	NK
Creatine kinase, single test	S	A	For AMI: + For UAP: NE	NK	NK
ECG exercise stress test	S	C	+	C	NK-NE
Echocardiogram	S	B	+	NK	NK
Other computer-based decision aids	G	B	+	NK	NK
Troponin-T and troponin-I	S	B	For AMI: ++ For UAP: NE	NK	NK
Myoglobin	S	B	For AMI: + For UAP: NE	NK	NK
Nonstandard ECG leads	S	C	+	NK	NK
Thallium scanning	S	C	NK-NE	NK	NK-NE
Body surface mapping	S	NK	NK	NK	NK
Continuous 12-lead ECG	S	NK	NK	NK	NK

Key:
 AMI = acute myocardial infarction
 UAP = unstable angina pectoris
 G = general detection of ACI
 E = early detection
 S = detection in subgroup

Diagnostic Rating:
 A = high-quality clinical studies
 B = substantial clinical studies
 C = limited studies
 NK = not known
 NE = not effective

Clinical Impact Rating:
 +++ = very accurate/large clinical impact
 ++ = moderately accurate/medium impact
 + = modestly accurate/small impact
 NK = not known
 NE = not effective
 * = abstract and pending reports are not included in the ratings

NOTE: The technologies are listed in order of the Working Group's ratings of diagnostic accuracy and demonstrated clinical impact, and alphabetically among equivalent ratings, with the exception of standard ECG, which is considered to be a standard of care.

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American College of Occupational and Environmental
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American College of Physicians
American College of Preventive Medicine
American Heart Association
American Hospital Association
American Medical Association
American Nurses' Association, Incorporated
American Pharmaceutical Association
American Public Health Association
American Red Cross
Association of Black Cardiologists
Centers for Disease Control and Prevention
Department of Defense, Health Affairs
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Emergency Nurses Association
Federal Emergency Management Agency
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International Association of Emergency Medical
Technicians
National Association of Emergency Medical Technicians
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Society of General Internal Medicine