Point-of-Care Testing for Cardiac Biomarkers in the ED: A Blueprint for Implementation

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Dear Colleagues,

In this EMCREG-International newsletter, we would like to provide for you the evidence basis, and a "blueprint," for implementing point-of-care (POC) laboratory testing in your emergency department. In particular, cardiac biomarkers such as myoglobin, CK-MB, troponin and brain natriuretic peptide (BNP) are integral for clinical decision-making in the emergency setting. Risk stratification for acute coronary syndrome (ACS) patients can be performed with POC testing. Identification of high-risk ACS patients for disposition to the coronary care unit or the cardiac catheterization laboratory, as well as to provide guideline-based anti-thrombotic and anti-platelet therapy, can be facilitated with POC testing. Typically, time savings of an hour or more can be realized with POC testing compared to sending the test to a central laboratory for analysis.

The development of a POC testing program will require collaboration between emergency physicians and cardiologists, laboratorians, and hospital administrators. As the individual POC tests often cost more than the batch run central laboratory assays, determining the cost effectiveness of POC testing requires an understanding of how faster results can decrease time to disposition from the emergency department and speed the delivery of guideline-based therapies to patients with ACS. By decreasing the length of stay of patients with possible ACS in the ED, patient satisfaction and provider satisfaction (physician and nurse) can also be improved.

Through this monograph, we hope to provide you with the information you need to bring this new technology to your practice. As always, EMCREG-International hopes to provide you with unbiased, balanced information on this important topic to improve the care of your patients.

Sincerely,

W. Brian Gibler, MD and Andra L. Blomkalns, MD

Peer Review: Richard M. Nowak, MD, Henry Ford Hospital, Detroit, MI

OBJECTIVES:
To discuss the multiple factors present in the current emergency department (ED) environment responsible for the growth of point-of-care (POC) testing for cardiac biomarkers
To describe the hospital administrator, laboratorian, and clinician stakeholders involved with evaluation, implementation and maintenance of a successful POC testing program for cardiac biomarkers in the ED
To describe recent POC testing trials for cardiac biomarkers in the ED
To describe the strengths and limitations of POC testing in the ED environment

Emergency Department Environment

Multiple factors in the emergency department (ED) care environment have influenced the growth of point-of-care (POC) testing in the United States. In 2006, approximately 115,000,000 patients will visit EDs in the United States and over 5.2 million of these individuals will have possible acute coronary syndrome (ACS) requiring complex evaluations by the emergency physician including physical examination, electrocardiography, and cardiac biomarker testing. This large number of patients with potentially life-threatening ACS require diagnostic work-ups in EDs that are “overcrowded” due to the substantial variety of illnesses and injuries that can stress emergency human and material resources, and inundate hospital in-patient beds. To improve risk stratification and optimize use of in-patient beds for patients at significant risk for ACS and its complications, routine inpatient stays for chest pain have now been replaced by evaluations in the ED or adjacent chest pain observation unit. Patient expectations for emergency diagnosis of potentially life-threatening conditions such as ACS include not only high quality accurate and knowledgeable care by the emergency physician, but also treatment that is efficient and rapid. Additionally, there has been a significant increase in time dependent therapies for patients with ACS. Patient demands for efficient care and the development and implementation of evidence-based approaches to therapy such as the 2002 ACC/AHA Unstable Angina/Non-ST-segment Elevation Myocardial Infarction Guidelines have increased the need for rapid testing for cardiac biomarkers through a reduction in laboratory test turn-around-time (TAT).
Point-of-care testing is a response to process challenges in the central laboratory that is responsible for an ever-increasing number of sophisticated diagnostic tests for a variety of different conditions throughout the hospital. Central laboratory processing of blood samples from the ED includes the delivery of the blood specimen, centrifugation and clot extraction if serum testing is required, and up to 20 minutes of assay time for the large automated immunoassay analyzers. Prior to this laboratory “analytical time”, the pre-analytical time in the ED includes writing the order for blood work, drawing the sample by the nurse or patient care technician, correctly labeling the test tube for laboratory identification and laboratory information system processing, and either walking the sample to the lab from the ED or pneumatic tube transfer. For patients in the ED that receive serial cardiac biomarker sampling for evaluation of possible ACS, demands for a rapid return of laboratory information return to the clinician have clearly increased. These demands from the ED have translated to increased volume of testing and the need to “turnaround” cardiac biomarker blood tests quickly from the central laboratory of the hospital. Point-of-care testing has proved effective for multiple disease processes in addition to ACS. For patients with heart failure, B-type natriuretic peptide (BNP) has a remarkable ability to risk stratify patients with heart failure presenting to the ED, identifying patients likely to have complications. In patients with possible toxic ingestions, POC testing for toxic substances can decrease the time required for diagnosis in the emergency setting. For patients with possible hypoglycemia, POC testing for blood glucose has been a mainstay for the last decade.

The results of cardiac biomarker tests such as myoglobin, creatine kinase-MB (CK-MB) and troponin are critical for risk stratification, initiating anti-platelet and anti-thrombotic therapy, admission decisions, and for patients without evidence of myocardial necrosis or ischemia, providing the impetus for release from the ED to home. As previously noted, consensus guidelines published by the American College of Cardiology and the American Heart Association for the diagnosis and treatment of non-ST-segment elevation ACS recommend that cardiac markers should be made available to the clinician within 30–60 minutes from the time of ED presentation.3 As many EDs and central laboratories are unable to meet this recommendation using traditional processes through the laboratory, POC testing has to be considered as an operational necessity for evaluating these patients.

POC Cardiac Marker Assay Performance

The most commonly used markers in cardiac risk stratification are CKMB, cardiac troponin I or T (Tn), brain natriuretic peptide (BNP) and myoglobin. Other markers such as high-sensitivity CRP (hsCRP), myeloperoxidase, and D-dimer are also available.4-11

The measurement of the cardiac troponins is the major focus for POC testing in patients presenting with potential ACS to the ED as this cardiac biomarker has substantial research basis to support its use in risk stratification for these patients. In a trial of 248 total patients using a POC test for TnI, Apple and colleagues evaluated the antibody specificity, detection limit, imprecision, linearity, assay specificity, sample type stability, interferences and reference limit determination. The detection limit for the POC assay was found to be 0.02 ng/L with a 99th percentile reference limit of 0.08 ng/L. This study demonstrated that the POC assay accurately detected TnI and was appropriate for use in a bedside environment for the evaluation and risk assessment of patients with possible ACS.12

In the Chest Pain Evaluation by Creatine Kinase-MB, Myoglobin, and Troponin I (CHECKMATE) trial, “time to positivity” between POC testing and central laboratory were compared in the risk
stratification of non-ST-segment elevation chest pain patients by Newby and colleagues. The primary outcome of this trial was the relation of marker status to 30-day death and myocardial infarction. Three markers strategies were compared: (1) POC myoglobin, CKMB, and TnI, (2) POC CKMB and TnI, and (3) local laboratory. This study found that time to positivity was decreased in both POC marker strategies (2.5 hours and 2.8 hours, respectively) when compared to the local central laboratory (3.4 hours). Outcome data of 30-day death or infarction showed that POC marker strategies better identified patients at risk for adverse outcomes than the local central laboratory (positive 18.8% and 21.9% versus 13.6%). The authors concluded that POC multimarker determination provided faster and better risk stratification for this patient population.\(^{13}\)

In another evaluation by Wu et al, CK-MB and TnI whole blood POC assays were evaluated in a multi-center trial in 185 patients suspected of ACS compared to 180 healthy subjects.\(^{14}\) Clinical sensitivity and specificity for acute myocardial infarction (AMI) were determined using the redefined guidelines from the ESC/ACC.\(^{15}\) The authors concluded that for 39 AMI and 67 non-AMI patients, the clinical sensitivity, specificity, and diagnostic efficiency of the POC tests were similar to the predicate assays and this bedside testing was an acceptable alternative to automated central laboratory instruments. Total imprecision ranged from 7.2% to 11.4% for TnI over the range of 0.22 to 5 ng/mL and 4.8% to 8.6% for CKMB at 7, 14, and 25 ng/mL.\(^{15}\)

In another trial conducted by McCord et al evaluating 817 consecutive ED patients presenting with symptoms consistent with ACS, serial determinations of myoglobin, TnI, and CKMB at 0, 1.5, 3, and 9 hours were obtained using POC testing. Sensitivity and negative predictive value were compared for both the multimarker POC approach and the central laboratory strategy. This study found that sensitivity and negative predictive value for myoglobin and TnI by 90 minutes after patient presentation was 96.9% and 99.6%, respectively. CKMB measurements did not add to this evaluation. Additionally, laboratory result reporting was on average 57 minutes faster with the POC assay.\(^{16}\)

Renal failure patients also represent a particularly challenging population for cardiac biomarker assessment. False positive tests complicate the assessment and diagnosis in this high-risk group. Point-of-care testing has been successfully evaluated in these patients as well. Using the same patient population as the previously mentioned study by McCullough et al, patients were divided into five groups based on their renal function. Two independent cardiologists determined the diagnosis of AMI. Troponin I was found to be the most consistent cardiac biomarker across all patient groups without significant false positive results.\(^{17}\)

In a study by Hollander et al of patients presenting to the ED with potential ACS, the addition of BNP to the standard myocardial necrosis markers TnI, CK-MB, and myoglobin, improved detection of adverse cardiovascular outcomes observed when the cardiac biomarkers were obtained on ED arrival. The sensitivity for detecting a 30 day adverse outcome was 63% (95% CI 53-73%), specificity was 65% (95% CI 61-70%), negative predictive value 93% (95% CI 90-96%) and positive predictive value 20% (95% CI 14-26%). Using a mathematical model for integrating the results of the four cardiac biomarkers myoglobin, CK-MB, TnI, and BNP, called the multimarker index (MMX) improved the performance for detection of AMI on the initial sample compared to using the individual results of the same four cardiac biomarkers with the usual test thresholds. Table 1 shows the Area Under the Curve (AUC) for the MMX relative to the individual cardiac biomarkers at the time of ED presentation.\(^{18,19}\) If the reader wishes to have more information regarding the actual commercial assays used in these cited studies, please read the original references for each trial.

**Table 1:** Comparison of area under the curve (AUC) for the multimarker index relative to individual markers at the time of ED presentation. Greater areas under the curve represent greater diagnostic accuracy.

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Economic Assessment of Point-of-Care Testing

As medicine is under constant scrutiny to provide quality medical care with reduced costs, implementation of additional laboratory services will understandably be called into question. Is POC testing cost effective? This question is central for all parties involved with implementation of such a program. Benefits of POC testing generally fall into the major categories of consumer demand, medical care, as well as time and resource management. The ultimate goal clearly is high quality, cost-effective, and efficient health care.

Benefits of POC testing generally fall into the major categories of consumer demand, medical care, as well as time and resource management. The ultimate goal is clearly high quality, cost-effective, and efficient health care. Both physicians and patients demand rapid cardiac biomarker results provided by POC testing. Physicians understandably want accessible and rapid results for the diagnosis and care of their patients. Patients and their insurers want rapid and accurate diagnosis and treatment for their conditions which is cost-effective. In a world where internet, fast food, instant replay, e-mail, digital audio, cell phones, and pagers have become routine – does it not seem reasonable that laboratory results in acute care environments would return faster today than 10 years ago? At least from the patient’s perspective, the immediate return of medical information has become an expectation and a source of dissatisfaction if a delay in diagnosis occurs.

For time sensitive high morbidity medical conditions that are frequently encountered in the ED, rapid and improved turn-around time (TAT) for laboratory tests intuitively translates into improved medical care. If POC testing can improve the ability to diagnose efficiently, more effectively utilize medical treatment, improve pharmaceutical consumption, and decrease lengths of stay in the ED, the OR, the ICU, and the hospital, and improve resource utilization, then certainly an economic benefit has to be realized. These inter-related parameters, however, can be extremely difficult to quantify. Just as in the implementation of any new intervention, the ultimate test for POC testing will be to determine its effect on these outcomes. Showing improvement of outcomes is difficult but will be imperative in the ultimate judgment of POC testing.

Most notably, the cost/benefit analysis is not as basic as simply comparing the cost of the lab result in the POC and central laboratory environments. This has traditionally been called “cost-centered analysis”. Labor and reagent costs are not the only considerations. The focus of POC testing should be medical care and systems costs, not the very isolated cost of the test itself. The viewpoint of a global evaluation of the entire cost of a health care episode with an outcomes-oriented approach is imperative. Even with the efforts of trying to find an answer to this question, very little is understood regarding what POC testing actually accomplishes in terms of benefits and outcomes.

In one evaluation, Blick used cardiac biomarkers myoglobin, CK-MB, TnI, and BNP determined by a POC platform compared to central laboratory testing. Improvements in clinical outcome, operations, and economic benefits were realized when efficient protocols for ACS and heart failure were combined with ED POC testing. Length of stay (LOS) in the ED was reduced from approximately 15 hours to 8 hours for evaluation of patients with possible non-ST-segment elevation AMI. Combining 0 and 2 hour POC testing in an ED chest pain unit, the time to discharge of patients was reduced from 3.6 to 2.3 hours. For inpatient heart failure patients, length of stay was reduced from 5.2 to 3.2 days, saving approximately $1,000 per patient.20

Another study by Apple et al noted substantial decrease in charges associated with POC testing using cardiac biomarkers. In this trial using POC TnI, a trend for substantial reduction in patient charges was seen when 271 patients in the central laboratory evaluation portion of the trial were compared to 274 patients evaluated using POC TnI testing. These decreased charges were noted in room, pharmacy, laboratory, non-cardiac procedures, and cardiac procedures.21
The Time Issue

Decreased TAT is the central issue in POC testing. Lee-Lewandrowski et al showed an 84.5% reduction in TAT using a qualitative POC TnI assay which translated into a LOS reduction from 386 to 338 minutes.\(^{22}\) Likewise, Caragher et al, showed a TAT reduction of 55% compared to the central lab using the quantitative POC assays for TnI, CKMB, and myoglobin.\(^{23}\) Point-of-care assays can perform tests faster. While it is intuitive that a test performed at the bedside in 10 minutes would take less time than a test that has traditionally required 60 minutes, these studies illustrate that TAT can be decreased (with POC testing) in the acute patient setting due to the significant impact of minimizing pre-analytical preparation of the specimen and central laboratory handling.

In a pilot trial conducted at two tertiary care institutions comparing POC testing for TnI to an historical central lab-based approach, POC testing substantially reduced the collection time for the blood specimen to test results obtained by the emergency physician by 51% for 3759 patients in the historical central laboratory control group and 3626 patients in the trial group for the busy community hospital and 60% for the major urban teaching hospital. Point-of-care testing used a multiple test approach with myoglobin, CK-MB, TnI and BNP for patients with chest pain, shortness of breath and possible ACS (Figure 1). This reduction of TAT resulted in a substantial decrease in LOS for both patients receiving a single marker draw, often subsequently discharged from the ED, and also for admitted patients (Figures 2 and 3).\(^{24}\)

Does this decrease in laboratory TAT matter? The analysis of POC testing is only as robust as the clinical assumption that fast diagnosis and treatment is better for patients. From numerous studies we know that early intervention and medical treatment is beneficial for patients with non-ST-segment elevation ACS.\(^{2,3,25}\) A reduction in ED LOS is also a critical factor for potential implementation of a POC system. Singer et al. demonstrated a reduced ED length of stay of 68 minutes for potential ACS patients after implementation of a POC cardiac marker system.\(^{26}\) The success and benefits of POC testing clearly require that action be taken on the results obtained (Figure 4).

Figure 1: Collection time to test results in patients presenting with chest pain, shortness of breath or acute coronary syndrome.
Figure 2: Emergency department length-of-stay for patients presenting with chest pain, shortness of breath or acute coronary syndrome with one set of markers drawn.

Figure 3: Emergency department length-of-stay for admitted patients presenting with chest pain, shortness of breath or acute coronary syndrome and one set of markers drawn.
Stakeholders Required for Implementing POC Testing in the ED

To successfully implement POC testing in the ED, it is essential to recognize and involve the various stakeholders for cardiac biomarker testing from the beginning. Multiple viewpoints have recently been published which describe aspects of the implementation process for POC testing.\textsuperscript{27,32} The stakeholders from an institution should meet and discuss the available publications on POC testing which will include information from the Emergency Medicine, Cardiology, Laboratory Medicine, and Hospital Administration literature such as provided in this Newsletter. A meeting of these individuals from a variety of disciplines will allow a consensus to be developed for moving forward and an understanding of the possible impediments to successful implementation of POC testing.

Emergency Physicians and Cardiologists

Typically the emergency physician first recognizes that a more expeditious TAT for cardiac biomarkers is necessary for patients in the ED. Based on the 2002 ACC/AHA Guidelines for non-ST-segment elevation ACS, cardiologists also are willing to support this initiative. It is important for the clinicians to emphasize the necessity for improving TAT to decrease the time required for diagnosis of myocardial necrosis which can reduce time for both admission and discharge disposition decisions. In addition, a positive troponin result indicates patients at high risk for ischemic complications which drives the use of anti-thrombotic therapy such as low molecular heparin and bivalirudin as well as anti-platelet agents including clopidogrel and glycoprotein IIb/IIIa inhibitors. In addition, at many institutions, a positive troponin level will serve as evidence for the need to admit a patient to an intensive care unit versus a step-down unit or monitored bed.

Laboratorians

Clinical chemists and pathologists should be integrally involved in the evaluation and implementation of POC for the emergency setting. It is usually necessary for these specialists to provide a baseline evaluation of the POC test to be used in the ED. Often, a pilot trial will provide the necessary TAT and test result data required to analyze the practicality of a POC program. Suggested measures to evaluate a pilot trial’s outcome include TAT, test assay accuracy (sensitivity, specificity, positive and negative predictive value), costs for care including admitted patients and patients released from the ED, and care outcomes including time to admission, time to release, time to receiving therapy in the ED, time to the cardiac catheterization laboratory, and also clinical outcomes such as revascularization, repeat myocardial infarction in-hospital, and death. It should be recognized and anticipated that true clinical outcome differences (revascularization, repeat

Figure 4. Model for Point-of-Care Testing

"POC testing has value only if caregivers take action on the result."
myocardial infarction in-hospital, and death) will be difficult to achieve in comparing POC testing to standard central laboratory testing due to the small number of patients in each group. Time data and cost calculations, however, should be very important in demonstrating differences despite small numbers of patients.

Pre-POC test TATs should be calculated and then compared to post-POC test TATs to establish the difference between these two approaches. After implementation of POC testing as a standard approach, monitoring these data will continuously improve the process of cardiac biomarker testing in an ED. All laboratory testing within the hospital requires compliance with the Clinical Laboratory Improvement Amendment (CLIA) of 1988 which provides standards of quality to ensure accuracy of the results. Point-of-care tests are compared by laboratorians to the central laboratory version of the same cardiac biomarker assay to ensure that the assays provide the accurate test result information needed to make clinical decisions appropriately. In addition, POC tests currently being marketed are sufficiently straightforward such that individuals such as nurses and patient care assistants, not highly trained laboratory technicians, can perform the assays and achieve high quality accurate results. The laboratory’s involvement in routine checks of the POC equipment and assays, as well as routine checks of test accuracy as well as proper patient identification are essential. In addition, laboratorians should require an electronic connection between the POC device in the ED and the laboratory information system (LIS). Not only does this ensure that POC test results performed in the ED become part of the medical record for patient care purposes, appropriate billing for these important tests can be performed. The acceptance of POC test results are also improved when results are available from the electronic medical record as all other central laboratory results are provided. An excellent relationship with strong collaboration between the clinicians and laboratorians is therefore essential for implementation of a POC program in a particular hospital setting.

**Hospital Administrators**

Usually POC tests are, per unit, more expensive than tests run on “batch” central laboratory analyzers. Hospital administrators should therefore be involved in this POC implementation process from the beginning, including financial officers from the hospital, to demonstrate validity of cost savings and process improvement. Clinical effectiveness and six sigma process experts can help design the hospital pilot trial and subsequent long term implementation of POC testing in a fashion which maximizes the beneficial effects of the program to minimize costs and maximize efficiency. It is helpful for hospital administrators to feel comfortable with the cost savings achieved globally in their hospital despite the fact that an individual POC test may be 3-4 times more expensive than the central laboratory mass analyzer version of the test. In absolute terms, however, the cost of the individual POC test usually is minimal in comparison to the costs of significant disposition decisions such as admission to a step-down bed or monitored bed versus an intensive care bed, or improving ED throughput which decreases ED walk-outs.

**Strengths and Limitations**

It is important to note that POC testing supplements testing from the central laboratory. Some environments benefit more and are more conducive to POC testing. While the need for more rapid results is clear, the already burdened ED environment is challenging for non-laboratory personnel such as nurses or patient care assistants required to perform rapid and high quality tests. Ideally, the hospital laboratorian will be supportive of the POC testing initiative at an institution and provide expertise on the technical evaluation of the POC assay compared to the currently used central laboratory assay as well as help with implementation and analysis of the new bedside laboratory tests performed in the ED. These individuals are specially trained in quality control and assurance for laboratory testing and can assist in the complex implementation of POC systems (Table 2). From previous studies, it is clear that POC assays for cardiac biomarkers are effective in the emergency setting for evaluating ACS. The ACC and AHA recommend the cardiac specific troponins for the triage and treatment of patients with potential ACS. As even the most minor of elevations of troponin portend increased risk, how accurate does a POC test have to be to be useful clinically? Trials such as TACTICS TIMI-18 have shown that patients with troponin levels above the 99th cutoff percentile but below the 10% CV value are at increased risk.33 Other studies and reviews have documented the value of POC testing for cardiac biomarkers in the emergency setting and for risk stratification.34-40 It is important for emergency physicians to understand the limitations of POC testing and make informed decisions based on the quality of the individual test platforms. Collaboration with laboratorian colleagues can help in this critical process of determining the optimal POC test system.
Table 2. Anatomy of a Successful POC Program

- Equipment management (purchase, maintenance)
- Testing procedures
- Notification of results and integration in medical record
- Monitoring of quality
- Training and proficiency testing of personnel
- Accreditation and regulatory requirements
- Integration of results into a central accessible computer laboratory information system

SUMMARY

The successful implementation of a blueprint for POC testing in the ED requires collaboration of emergency physicians and cardiologists, laboratorians, and hospital administrators within a hospital. Studies demonstrating improvement in TAT, patient outcomes, and overall health care cost savings suggest that POC testing can optimize the care of patients in the ED. Satisfaction of patients and their physicians will also be optimized by increasing the efficiency of this evaluation. Evidence of improved outcomes, total cost savings, and assay standardization using POC testing will undoubtedly add to our ability as emergency physicians to provide the best care for our patients.

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REFERENCES


32. Sluss PM. Cardiac markers: current technologies for their measurement at points of care. Point of Care 2006;5:38-46.


CME Post Test

After you have read the monograph, carefully record your answers by circling the appropriate letter for each question. (Please circle answers below)

1) Factors which have increased the growth of point-of-care (POC) testing for cardiac biomarkers in the United States include all of the following except:
   a) Large volume of patients presenting to emergency departments each year causing “overcrowding”.
   c) The low cost of the POC test compared to the central laboratory assay.
   d) Decreased complexity of performing the POC test compared to using an assay performed on a central laboratory analyzer.

2) Cardiac biomarkers which are commonly used for POC testing in the emergency department include all of the following except:
   a) Myosin heavy chain
   b) Myoglobin
   c) CK-MB
   d) Troponin
   e) BNP (brain natriuretic peptide)

3) POC testing for cardiac biomarkers in the emergency department can be used for risk stratification and to identify patients with ACS for treatment with anti-thrombotic and anti-platelet agents
   a) True
   b) False

4) From the laboratory perspective, usual turn-around time (TAT) for cardiac biomarker testing includes pre-analytical time which occurs in the emergency department and the actual analysis of the specimen and reporting of the results back to the emergency physician.
   a) True
   b) False

5) Stakeholders for the implementation of a POC testing program in an emergency department should include:
   a) Laboratorians
   b) Clinicians
   c) Hospital administrators
   d) All of the above

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