

**Medical Requirements
For the

Personal Heart Attack System
for the
NATIONAL HEART ATTACK ALERT PROGRAM**
Response to NLM-00NHAAP/VMS

**Johns Hopkins Medical Institutions
and the
Johns Hopkins University Applied Physics Laboratory**

Thomas Aversano, M.D.
Principal Investigator

I. Introduction

This document summarizes the medical requirements for the proposed Patient-Initiated Emergency Response System (PIERS). These medical requirements determine the system requirements specified in the System Requirements document. There is no repetition of information contained in these documents except where required to ensure clarity.

II. Purpose and Medical Functions of the Proposed System

The PIERS is designed to work in two clinical modes: Mode 2 and Mode 3 (a separate non-clinical test mode is described as Mode 1). Mode 3 involves non-scheduled, emergency use; Mode 2 involves scheduled, non-emergency use. All PIERS modes are described in detail in the Technical Proposal and the System Requirements document.

Mode 3:

Mode 3 is the primary operating mode of the PIERS. It is a non-scheduled, emergency operating mode.

The primary purpose of the PIERS is to minimize the delay between the onset of a patient's symptoms of acute myocardial ischemia and presentation for treatment. This corresponds to a reduction in stage 1 delay, as defined by the NHAAP. While use of the 911 system for patients with actual AMI may be preferable to PIERS in the ideal world, the very impetus for this particular RFP comes from the recognition that patients continue to arrive for therapy more than 2 hours after the onset of their ACS.

In addition, stage 2 and stage 3 delays will be reduced and care improved by PIERS for Emergency Medical System (EMS) and Emergency Room (ER) healthcare providers, respectively. This clinical function is possible by providing EMS and ER healthcare providers with access to the patient's historical and electrocardiographic data and, in many circumstances, his preliminary PIERS diagnosis. These data will shorten the time for EMS to pick up and transport the patient (stage 2) and allow ER healthcare personnel to be ready for the patient they are about to receive (stage 3). This latter function, while important for patients who are treated medically (e.g. thrombolytic therapy) is still more important in centers using primary percutaneous coronary intervention (PCI) to treat AMI, since availability of the catheterization laboratory and staff can be determined and required staff recruited prior to the patient's arrival.

While neither a primary nor a secondary goal or function of PIERS, as PIERS evolves it is possible that the number of unnecessary visits to the ER may be reduced.

Mode 2:

Mode 2 is a secondary, scheduled, non-emergent, monitoring mode for chronic coronary artery disease.

A secondary function of PIERS is a monitoring function, suitable for assessing a patient's cardiac status during the chronic stages of his coronary artery disease. Monitoring in the chronic phase of coronary artery disease may reduce the number of patients who progress to AMI by detecting changes in the pattern of angina early. In addition, when PIERS patients issue a Mode 3 call, a record of recent Mode 2 reports may facilitate diagnosis and disposition.

III. Background

Despite the well-recognized and well-documented benefits of early treatment for acute coronary syndromes (ACS), particularly acute myocardial infarction (AMI), there continues to be significant delay between the onset of a patient's ischemia symptoms and presentation to an ER for therapy. Of the 1.1 million AMI's that occur, nearly one-third will die before reaching the ER. The average time from the onset of symptoms to presentation continues to be two or more hours.

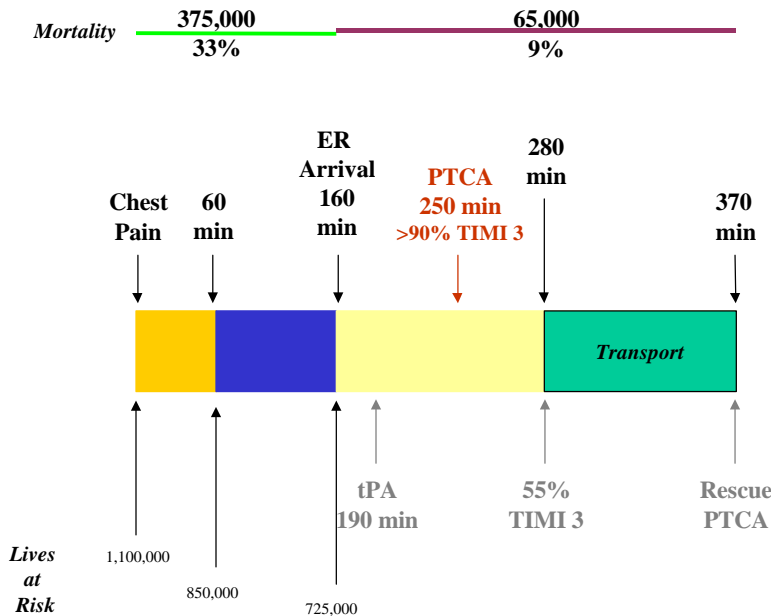


Figure 1 Typical time line for AMI.

The bottom line for ACS is relief of ischemia and for AMI this is effected by reperfusion.

In Figure 1, above, a typical time-line for patients with AMI is depicted. The “golden hour” after the onset of chest pain usually occurs outside the hospital and as many as 250,000 patients will die in this time this year. Still, on average, patients will delay an average of more than 2 hours before coming to the hospital: by then, more than 300,000 will die this year. After arrival, assuming medical therapy is chosen, tPA will be

administered at about 190 minutes into the ACS and by 280 minutes, only about 50-60% will have achieved TIMI 3 flow (flow associated with the best reduction in mortality). If medical therapy fails, then rescue PCI is often attempted, engendering additional delay in reperfusion.

If primary PCI is performed instead of medical therapy, reperfusion will occur at about 250 minutes into the ACS, although TIMI 3 flow rates achieved will be greater than 90%. This trade off appears, from literature published to-date, to favor PCI over medical therapy, at least for short-term outcomes.

The benefit of thrombolytic therapy over placebo is about 30 lives saved per thousand treated patients (about 21,750 lives saved in the US per year over placebo); and the benefit of PCI over thrombolytic therapy is another 20 to 30 lives saved per thousand treated patients (or about 43,500 lives saved in the US per year over placebo). These reductions amount to 30% reductions in mortality (tPA vs placebo and PCI vs tPA). What is clear from Figure 1 is that most lives are lost before medical attention is sought. A 12% reduction in mortality in the pre-hospital period will save as many lives as PCI over placebo in the hospital period (43,500 per year in the US).

Educational efforts (e.g. REACT Trial) are one way to reduce this delay. Results of this trial will be announced in JAMA on July 5, 2000.

The current Phase II proposal takes an approach complementary to that of REACT. In addition to patient and physician education, new technology is applied to the problem of treatment delay for ACS. Again, it is important to emphasize that this technology application does not supercede education, but is rather a supplement or complement to it.

The PIERS consists of a Personal Patient Module (PPM), System Server and Cardiac Teleconsultant linked together in a simple, reliable and robust way. Additional PIERS clients are EMS and ER healthcare workers and the patient's personal physician. At least two private companies, both in Israel, have developed commercial systems similar to PIERS, in which patients carry a device capable of acquiring and transmitting a current ECG to a central server. Both have a web presence (<http://www.aerotel.com>; <http://www.shahal.co.il/>). In the Shahal case, patients subscribe to this service and pay a monthly fee. The company maintains a database of the patients medical history, baseline ECG, prior calls, etc. When the patient calls, the patient's disposition is decided by trained staff at the company. In some instances, the patient is triaged to the ER. For emergency calls, one of these systems, Shahal claims an average time between the onset of ACS symptoms to ER arrival of 44 minutes, a dramatic improvement over the current situation.

PIERS is similar to Shahal in overall concept, but there are critical differences. First, irrespective of its final form, PIERS is part of an overall EMS system design, not a separate entity. Thus, even if all elements of PIERS are part of a private business, PIERS will be integrated into and regulated by the local EMS. Second, PIERS will affect not

only stage 1 delays, but also stage 2 and stage 3: thus, linking patient information and Cardiac Teleconsultant decisions to EMS and ER healthcare providers is an important feature of PIERS. Third, PIERS prospectively measures patient outcomes and system errors in order not only to manage quality and error, but to progressively improve Cardiac Teleconsultant algorithms for diagnosis and stratification and, perhaps, evolve toward increasing automation. And finally, PIERS has other operating modes which allow for chronic, ongoing monitoring of the patient's cardiac status and transmission of this data to the patient's personal physician for review.

IV. Medical Requirements

Overall *medical* requirements of PIERS:

1. PIERS must not be a *cause* of delay in stage 1 – *primum, non nocere*
2. PIERS must reduce the time between ACS symptom onset and presentation for therapy
3. PIERS must store accurate, easily updateable clinical and electrocardiographic information (i.e. past medical history, cardiac risk factors, baseline ECG) in a form the patient can have easily available at all times. The Personal Patient Module (PPM) and electrode patch must be extremely small, easily carried by the patient when away from home and easy to use; cabling must be simple and minimal
4. PIERS must reliably and reproducibly acquire and store current 12-lead ECG
5. PIERS must transmit historical and electrocardiographic information simply, reliably and confidentially
6. PIERS must correctly interpret the patient's current medical condition at the time of a call (Mode 3)
7. PIERS must define an appropriate disposition of the patient at the time of a call (Mode 3)
8. PIERS must be available 24 hours per day, 7 days per week, 365 days per year and be fail-safe for Mode 3 operation

PIERS must measure patient outcomes for quality assurance, error detection and system evolution. Medical Requirements of individual PIERS components:

1. Patient's Personal Module: Training in the use of the PPM is required for the patient and for a significant other (e.g. husband or wife). Training will require direct interaction between PIERS staff or PIERS-trained personal physician staff and the patient. Training must emphasize (1) using 911 as a first-line mechanism, (2) typical symptoms of myocardial ischemia, (3) importance of early detection and presentation, (4) use of the PIERS, and (5) guidance to training adjuncts such as PIERS literature, videos and internet training programs.
 - a. ECG component of the PPM: A critical feature of PIERS is the ability to easily and reliably obtain a patient-initiated standard 12-lead ECG. The lead system employed will importantly influence the ability of a patient, particularly in critical situations, to obtain a usable ECG tracing. The lead system must be simple to use,

- easily and reproducibly placed in the proper position on the chest and limbs, have a minimum of wires and connections that need to be made, and be easy and unobtrusive to carry.
- b. Patient's Personal Module (PPM): The module must very small. Ideally, it is the size of a credit card, but a pager-sized device would also be reasonable. It must be capable of storing baseline ECG, past medical history, including cardiac risk factors, and current medications. It must be easily updateable by the physician caring for the patient and/or PIERS personnel.
 - c. Telephone: In an emergency (Mode 3) situation the patient must be localizable and be able to speak directly with a Cardiac Teleconsultant. Using the telephone to link the patient with the System Server during a Mode 3 event allows both of these critical features. The patient must be localizable in order to dispatch EMS (particularly in the setting of definite AMI in which EMS is dispatched without preceding human intervention). The patient must be capable of reliable and clear communication with a Cardiac Teleconsultant; the telephone provides such capability.
2. System Server: The System Server provides several functions, detailed in the Systems Requirements document. From a medical point-of-view, the System Server must reliably receive transmitted data from the PPM, interpret the data, particularly the baseline and current ECG comparison, looking for clear evidence of AMI or acute ischemia, automatically determining patient location and dispatching EMS to such a patient immediately, routing the patient's information to a Cardiac Teleconsultant and connecting the patient by voice with the Cardiac Teleconsultant.
 - a. Algorithms: Automated interpretation algorithms that compare baseline and current ECG are critical elements of the PIERS. A well-validated, FDA-approved interpretation algorithm will be part of the System Server and will come from GE/Marquette, partners in PIERS development. The algorithm is excellent at detecting acute myocardial infarction and significant ($> 1\text{mm}$) ST segment shifts – electrocardiographic features which would prompt immediate EMS dispatch. The algorithm results will serve a decision support function for Cardiac Teleconsultants receiving patient information both for patients who clearly have ACS and those whose diagnosis is not clear.
 - b. Information routing: Information (historical and electrocardiographic) must be routed to the Cardiac Teleconsultant for review by the System Server and voice link established between the patient and the Cardiac Teleconsultant. In addition, this information should be available to EMS and receiving ER personnel. This latter requirement will assist stage 2 and stage 3 healthcare providers and potentially reduce delay in application of appropriate therapy. Finally, this information should be available to the patient's personal physician.

3. Cardiac Teleconsultant: In Mode 3, the Cardiac Teleconsultant will always be connected with the patient, whether EMS is automatically dispatched by the System Server for definite ACS or not. The Cardiac Teleconsultant will work from established algorithms (question-answer schemes) to define the patient's problem and an appropriate disposition. Initially, these algorithms will err on the side of seeking immediate medical attention for many, if not most, callers. As the Cardiac Teleconsultant algorithms are refined, based on measured outcomes and development of ACS predictive instruments, it is possible fewer unnecessary ER visits will result. The Cardiac Teleconsultant may also initiate basic therapy (e.g. aspirin), prior to EMS arrival.
 - a. Cardiac Teleconsultant algorithms: The Cardiac Teleconsultant will communicate with the patient. His interaction with the patient will be supported by emergency algorithms. Algorithms, such as emergency dispatch algorithms, may be used as models of the Cardiac Teleconsultant's algorithm. Questions are asked in specific sequence and various responses will trigger particular results. Ultimately, these algorithms should allow stratification of patients in terms of risk and result in an appropriate disposition. Examples of the principles upon which such algorithms are based include:
 - i. *all* patients connecting via a Mode 3 event will be required to seek medical attention within some time frame
 - ii. patients with definite ACS or AMI will have EMS dispatched by the System Server without prior Cardiac Teleconsultant intervention
 - iii. patients with unstable angina (no change in current ECG from baseline, no current chest pain, but anginal chest discomfort coming on at rest or minimal exertion) will have EMS dispatched by Cardiac Teleconsultant for transport to ER
 - iv. patients with worsening angina (no change in current ECG from baseline, no current chest pain, no rest angina, but increase in the frequency or duration of angina or reduction in activity leading to angina) will be advised to see physician within 6 hours. Cardiac Teleconsultant will arrange for patient visit. If not possible, then patient will come to ER
 - v. patient with suspected non-coronary life-threatening condition (dissecting aortic aneurysm, pulmonary embolus, myocardial trauma) will have EMS dispatched immediately for transport to ER
 - vi. patients with suspected non-cardiac, non-life-threatening conditions (GERD, etc) will be asked to see their physician within 24-72 hours. Cardiac Teleconsultant will make an appointment for the patient.

For all patients, the PIERS will communicate the patient's clinical data (transmitted historical and electrocardiographic information) plus response to Cardiac Teleconsultant algorithm questions and the Cardiac Teleconsultant's diagnosis (as far as possible) and

disposition to the patient's physician. This same information should be available to EMS and receiving ER healthcare providers for patients sent directly to the ER via EMS.

4. Outcomes Measures: An important aspect of the PIERS project is measurement of actual patient outcomes and detection and management of error. Outcomes of interest include time between symptom onset and presentation for care, death, incidence of myocardial infarction, peak CPK level, length of stay, direct medical costs, and other medical, quality of life and economic outcomes. Errors of interest include delays in seeking treatment among PIERS patients (for any reason) or incorrect diagnosis or disposition.
 - a. Outcomes Measures: Patient outcomes must be measured prospectively to define the quality of care.
 - b. Error Detection: Error in acute medical settings is common. Most errors do not result in significant adverse events. However, in the right setting, an error with little consequence in another situation might be devastating. Error detection is important to the monitoring and improvement of any complex system. Methods to detect errors aggressively and prospectively will be important parts of PIERS. Error may occur at any point in the process including PPM, System Server, Cardiac Teleconsultant or information routing.
 - c. Algorithm Evolution: Outcomes data and error detection may be used to refine System Server and Cardiac Teleconsultant algorithms to improve quality and minimize future error. Furthermore, over time, additional diagnoses other than definite acute myocardial infarction might be made by the System Server prior to Cardiac Teleconsultant intervention. Greater automation of the decision making process will increase speed, potentially reduce error, reduce cost and at a minimum improve the decision support ultimately provided to the Cardiac Teleconsultant.

Public Access to PIERS:

An implementation of PIERS in the general population remains of great interest and will be the subject of much thought and planning. As a future development, PIERS or a PIERS-like device can be made available in high-population density sites such as sports arenas, office complexes, shopping malls, airports, and apartment buildings. Trained responders at those locations could obtain an on-site ECG for transmission to the System Server and gain access to the PIERS system. The development and deployment of such an implementation needs extensive, careful planning, particularly since certain critical elements of PIERS (baseline ECG and stored medical history) cannot be part of the data set reviewed Teleconsultants.

PIERS in the General Population

PIERS is defined for use in high-risk patients. This is appropriate since nearly half of the 1.1 million AMI's occurring this year will occur in patients who have had prior myocardial infarctions. Nevertheless, more than half of the 1.1 million AMI patients have never had a cardiac event in the past.

Public access to a PPM-like module is possible at certain locations where trained responders might be located. For example, in pharmacies, office buildings, sports arenas, airports, shopping malls and other high-density facilities. It would seem preferable, however, as always, to use the current 911 system in this setting. To the extent that it is not used, however, a public PIERS might be a useful adjunct. We will continue to search for ways to make PIERS available to the general public in a form that may be usable without formal training and without participation of a trained responder.

PIERS is an integral part of a regional EMS. As such, PIERS can serve EMS during a response to a call to a public place or a home. For example, EMS could send current and past historical information and the current ECG to the PIERS monitoring center for expert, on-line advice and interpretation from the Cardiac Teleconsultant. This feedback could be useful to both EMS and receiving ER health care providers, both improving the quality of care and reducing Stage II and Stage III delay.