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RE: House Committee on Health, hearing schedule, February 1, 2008, ~~8:00~~ A.M., Conference Rm. 329 Representative Josh Green, M.D., Chair & Representative John Mizuno, Vice Chair

RE: Testimony ~~in~~ <u>Strong Support</u> of HB 2063, Relating to wireless electrocardiogram data transmission.

Chair Green, Vice Chair Mizuno, and members of the Committee on Health.

Thank you for the opportunity to submit testimony in strong support of HB2063, which would create a pilot project to implement wireless electrocardiogram data transmission. My name is Paul C. Ho, and I am the Chief of Cardiology at Kaiser Permanente Hawaii.

Two years ago I appeared before this committee in support of Hawaii's smoke-free law. At that time I testified that as a Cardiologist I can only treat one patient at a time, and that passing the smoke-free would save more lives than I could in one year.

On January 9, 2008, I appeared before this committee to report on the significant drop in heart attacks that we were seeing at Kaiser Hospital, almost 25% since passage of the smoke-free law. Today I am here testify how we can even save more lives by providing our ambulances with wireless EKG transmission capability.

When an individual has heart attack or AMI **(an acute myocardial infarction) "TIME IS MUSCLE".** This phase applies to artery-opening therapy. There are on two recommended procedures:

- Clot-busting medication (thrombolytics) or "Door to Needle Time"
- Balloon Angioplasty or "Door to Balloon Time"

In hospitals equipped with Cath Lab (Cardiac Catheterization Laboratory), primary angioplasty is preferred, and the ACC/AHA recommended Door-Balloon time is 90 minutes or less. Otherwise, the clot-busting medication is the only option and the recommended Door-Needle time is 30 minutes.

Procedurally what happens on Oahu is this;

1. The heart attack occurs
2. The EMS responds
3. Patient is evaluated by EMT's
4. Transport to Hospital
5. Arrive at Hospital ER (ER doc evaluation & 1st ECG 10 minutes.
6. Cardiologist contacted & Cath Lab personnel to come into hospital (30 minutes)

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While the Cardiologist and staff are driving to the hospital, the patient is acting having a heart attack in the Emergency Department (ED).

With wireless electrocardiogram data transmission, the Cardiologist and staff are notified of the heart attack while the patient is still at home. The Cardiologist and staff will begin their commute to the hospital while the patient is being transport by the ambulance. Often they arrive at the same time in the ED; the time saved is 30 minutes – 30 minutes of the patient's active heart attack. This will save lives! This will save suffering and cost of medical care for those who survive a prolonged heart attack!

The American College of Cardiology (ACC)'s current guidelines specifically address the responsibilities EMS has in the early diagnosis of AMI. The guidelines strongly encourage active EMS involvement and urge advanced providers to perform and evaluate ECG's of chest pain patients suspected of STEMI.

As I noted earlier **"TIME IS MUSCLE".** It is essential for EMS providers to perform ECG's in the field and to transmit them to the receiving hospital. Prehospital ECG's are easily performed in about 2 minutes, do not significantly delay transport and case save a considerable amount of time once a patient arrives at the receiving Facility.

In closing I would say, I don't think that there is anybody in this room on either side of the table that would dispute that saving time will save lives.

I will be happy to answer any questions that your may have.

Attachments: I have attached to my testimony a 2006 study from North Carolina showing the positive impact of ECG transmissions, as well as a brochure of what the system of "Field-to-Hospital" ECG transmission may look like.

Sincerely yours,
Paul C. Ho, MD, FACC, FSCAI
Chief, Division of Cardiology
Hawaii Region Kaiser Permanente

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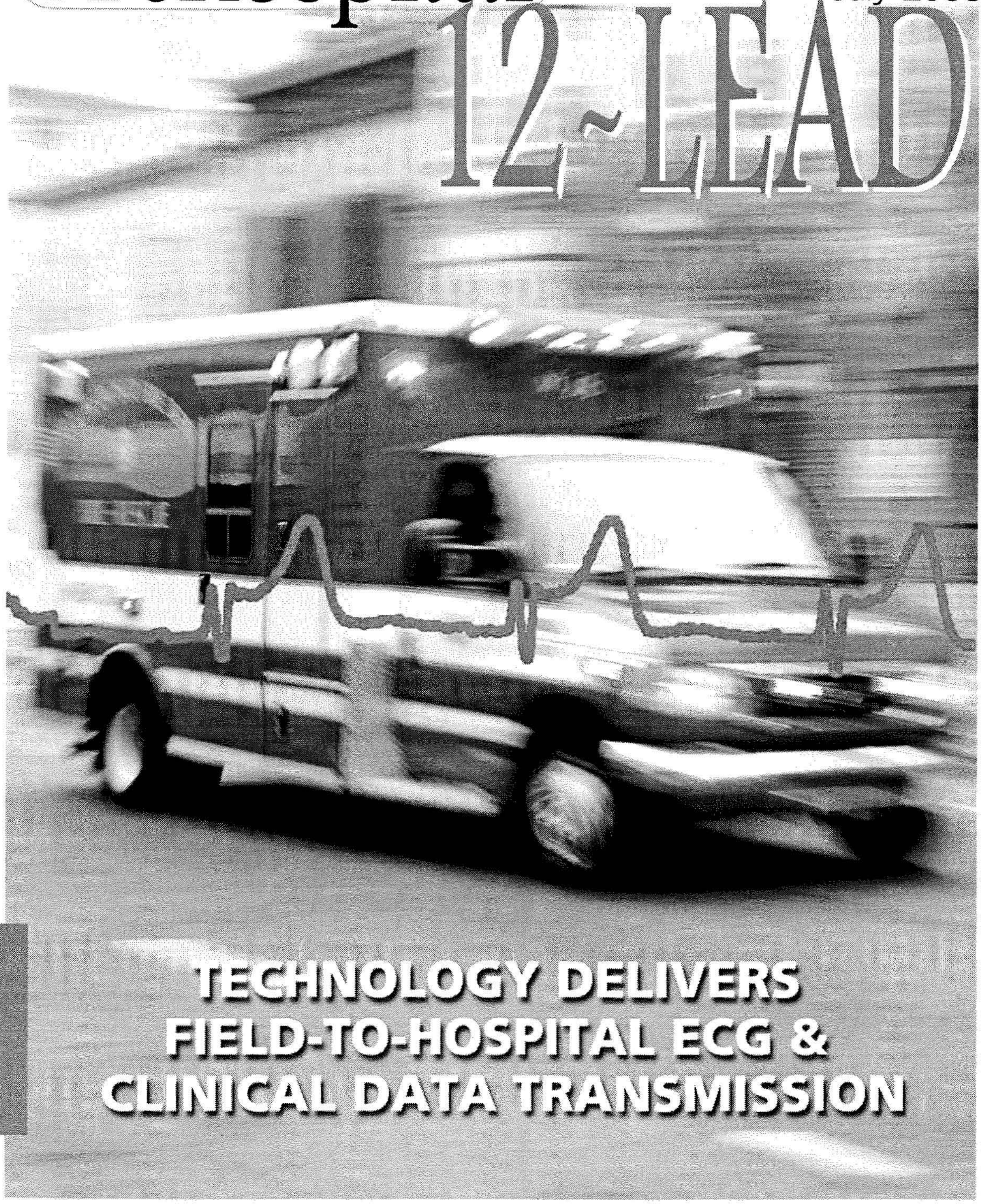
Prehospital 12-LEAD

July 2006



TECHNOLOGY DELIVERS FIELD-TO-HOSPITAL ECG & CLINICAL DATA TRANSMISSION

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Prehospital 12~LEAD

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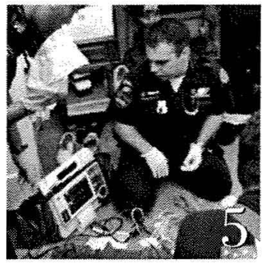
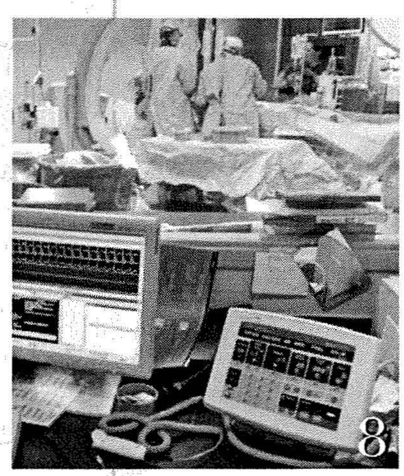
Technology Delivers Field-to-Hospital ECG & Clinical Data Transmission



Importance of ECGs



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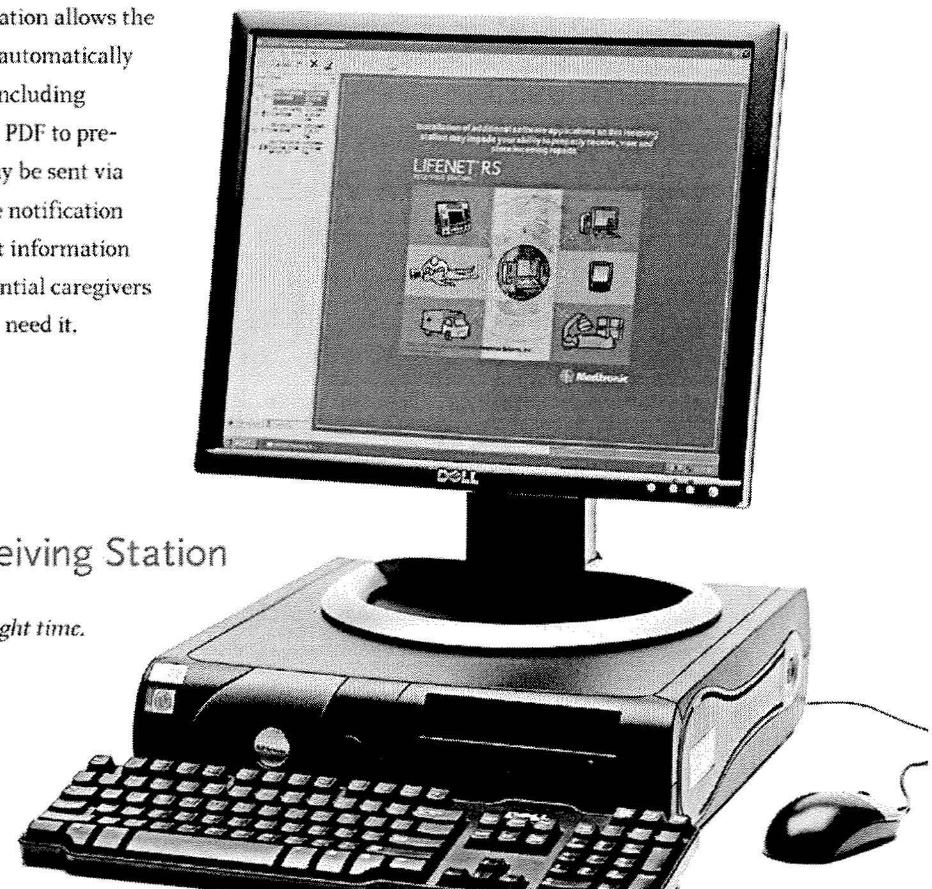

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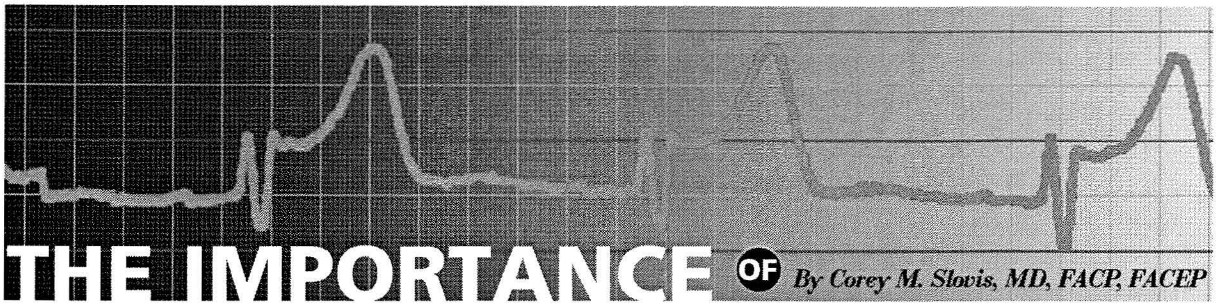


THE IMPORTANCE OF PREHOSPITAL ECGs

By Corey M. Slovis, MD, FACP, FACEP

The early diagnosis and treatment of acute myocardial infarction (AMI) is a primary responsibility of all emergency care providers. There is no question that "time is muscle" as it applies to providing artery-opening therapy.

The key to providing rapid definitive therapy in AMI is the rapid identification of ST elevation myocardial infarction (STEMI). Similarly, a patient with unstable angina who presents dynamic or changing ST segments requires more aggressive therapy that will likely include early admission to the cardiac catheterization lab.

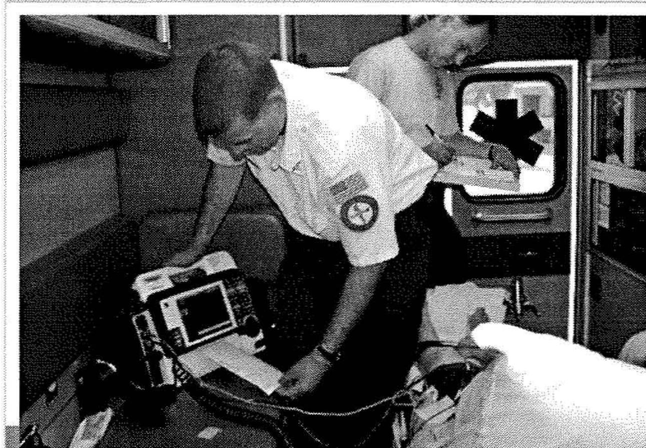
Because STEMI, non-ST elevation AMI and unstable angina are part of the same disease continuum, the term *acute coronary syndrome* (ACS) is often used to refer to these entities.

EMS providers now have the opportunity—some might say duty—to help rapidly identify patients with ACS. The American Heart Association's and American College of Cardiology's current guidelines specifically address the responsibilities EMS has in the early diagnosis of AMI.[1] The guidelines strongly encourage active EMS involvement and urge advanced providers to perform and evaluate ECGs routinely on chest pain patients suspected of STEMI.[1]

Many think we have only three ways to definitively diagnose AMIs by ECG: 1) ST elevation of 1 mm or more in two or more contiguous leads; 2) reciprocal ST depression; and 3) Q waves.

There are, however, a total of five ways. The two additional ways are: 4) changes compared with an old ECG; and 5) changes seen from one new ECG to the next.

Paramedics can play a key role in diagnosing ACS and be an integral part of the chest pain center team. To do so requires that all patients at risk for ACS get a 12-lead ECG performed in the field.



Prehospital 12-lead ECGs decrease time to lytic therapy by 25–36 minutes, a critical factor in saving heart muscle.

Most EMS systems that perform a 12-lead will transmit it to the hospital and/or provide a pre-arrival alert to the receiving emergency department (ED) if ischemic or diagnostic ECG changes are noted.

Multiple studies have shown that high-quality prehospital ECGs can be performed very rapidly and rarely add significant on-scene time.[2-6] With short training periods, paramedics should be able to complete a 12-lead in less than two minutes.

Optimally, paramedics should be able to recognize the classic AMI patterns of an anterior (including anterior septal and anterior lateral), inferior and lateral AMI. However, it doesn't require an ECG expert to perform an ECG and either bring it to the hospital or, preferentially, transmit it.

Most prehospital monitor/defibrillators that perform 12-lead ECGs also provide a computerized ECG interpretation. Although neither paramedics nor physicians should entirely depend on a computerized ECG's accuracy, a monitor/defibrillator diagnosis of STEMI should alert a paramedic to a patient with a dramatically increased likelihood of STEMI. Such computerized readings should result in an immediate prehospital alert to the receiving hospital.

The impact on STEMI

EMS agencies that don't perform 12-lead ECGs often don't appreciate the potential impact 12-leads can have on a patient's care and ultimate outcome. Numerous studies have shown that prehospital 12-lead ECGs can significantly decrease the time to definitive therapy for patients with AMI.

Two recent meta-analyses showed that prehospital ECGs decrease time to lytic therapy by 25–36 minutes.[2,3] Time for angioplasty is also significantly decreased.[6]

Similarly, some EMS agencies divert to a "heart hospital" that has an angioplasty suite readily available when a patient's prehospital ECG shows a STEMI. Studies have shown that patients who get a prehospital 12-lead ECG are more likely to get lytic therapy or PCI and have a significantly better likelihood of surviving their AMI.[6]

Only a small percentage of patients who have a prehospital 12-lead ECG will have a classic STEMI-pattern ECG. A study done years ago in Seattle demonstrated that about 4% of patients with presumed cardiac chest pain had an acute AMI on ECG.[7] However, diagnosing an AMI in the field is not the only reason to switch from doing single-lead or three-lead ECG monitoring to performing a 12-lead ECG.

An important reason to take one to two minutes of extra time in the field to perform a prehospital 12-lead ECG is to provide

continued from page 5

the ED with a comparison to previously performed ECGs and to also provide them with a tracing to compare with the ECG that will be performed within minutes after the patient's ED arrival.

A recent, very provocative study of 192 patients reviewed prehospital ECGs and continuous ECG monitoring.[8] In this study, 23 of the patients were admitted for ACS. In five of the 23 (22%) admitted patients, the prehospital ECGs showed ischemia that was not present on arrival at the ED.[7]

This finding is highly significant because the patients' lack of ischemia on their ED ECG would have suggested their chest pain might be non-cardiac or at least not an emergency. However, knowing that these patients had prehospital ECGs that showed different ST and T wave changes, it was much more likely that the patients would receive aggressive ED interventions and urgent cardiac catheterization.

Another reason some systems have delayed prehospital 12-lead ECGs is the mistaken perception that EMS providers cannot accurately read a multilevel ECG. Investigators in Boston compared the 12-lead ECG reading abilities of paramedics, ED physicians and cardiologists.[9] In this study, highly trained paramedics were equally as good as both the ED physicians and the cardiologists in correctly identifying AMI patterns.

Table 1: 10 Reasons to Perform a Prehospital ECG

1. Does not significantly delay transport.
2. Takes only one or two minutes to perform.
3. Quality is increasingly high.
4. Allows early diagnosis of AMI.
5. Can be used to identify patients for prehospital lytic therapy.
6. Allows a pre-alert to the hospital for a STEMI patient.
7. Gives the cath lab personnel time to prepare.
8. Provides the ED with a ECG to compare to past ECGs and to the one performed on ED arrival.
9. Improves patient outcomes.
10. Makes EMS an integral part of the chest pain team.

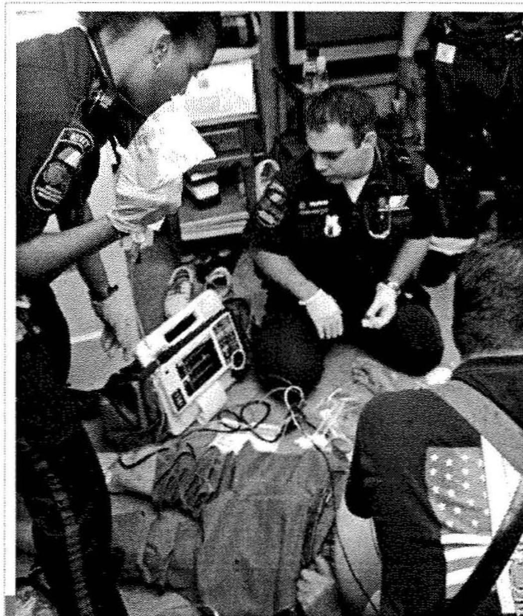


PHOTO CRAIG JACKSON

Prehospital ECGs provide the ED with an early version of the patient's pattern for comparison with later ECGs.

Summary

Prehospital 12-lead ECGs improve patient outcomes and help save lives. Table 1 (above) lists 10 reasons why every EMS agency should implement a prehospital ECG program.

In short, it's essential for all advanced EMS providers to perform 12-lead ECGs in the field and to transmit them to the receiving hospital. Prehospital ECGs are easily performed in about two minutes, do not significantly delay transport and can save a considerable amount of time for definitive care once the patient arrives at the receiving facility.

Corey M. Slovis, MD, FACP, FACEP, is professor and chair of the Department of Emergency Medicine at Vanderbilt University Medical Center, Nashville, Tenn., and serves as the medical director for Nashville Fire Department. Slovis is also a member of the JEMS *editorial board. Throughout the 1980s, he served as medical director for the Grady Hospital EMS program and as the fire surgeon for the city of Atlanta.*

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PREHOSPITAL ECGs & AMI RESEARCH

Studies every EMS system should review before revising their protocols

By David G. Strauss, BA, EMT-I, & Galen S. Wagner, MD

In the past five years, literature on myocardial infarction and the transmission of prehospital ECGs has revealed improved patient outcomes due to a reduction in time to treatment. The following notable articles discuss paramedic diagnosis of STEMI, the effectiveness of transmission of prehospital ECGs, cardiologist readings on handheld computers, and associated patient outcomes.

Paramedic Diagnosis of STEMI

Conclusion: Paramedics had 50% sensitivity in diagnosing STEMI on the prehospital ECG.

Reference: Sejersten M, Young D, Clemmenson P, et al: "Comparison of the ability of paramedics with that of cardiologists in diagnosing ST-segment elevation acute myocardial infarction in patients with acute chest pain." *American Journal of Cardiology*. 90(9):995–998, 2002.

Transmission of Prehospital ECGs to the ED

Conclusion: Transmission of the ECG from the ambulance to the emergency department produced a 27% time reduction (109 to 80 minutes) in time to reperfusion. However, a 10-year follow-up study showed that maintenance of the same system failed to achieve further reduction in time.

References: Wall T, Albright J, Livingston B, et al: "Prehospital ECG transmission speeds reperfusion for patients with acute myocardial infarction." *North Carolina Medical Journal*. 61(2):104–108, 2000.

Vaught C, Young DR, Bell SJ, et al: "The failure of years of experience with electrocardiographic transmission from paramedics to the hospital emergency department to reduce the delay from door to primary coronary intervention below the 90-minute threshold during acute myocardial infarction." *Journal of Electrocardiology*. 39(2):136-141, 2006.

Transmission of ECG from Ambulance to a Cardiologist

Conclusion: Transmission of the ECG from the ambulance to a cardiologist's handheld computer reduced the door-to-balloon time by 50% (101 to 50 min).

References: Campbell PT, Patterson J, Cromer D, et al: "Prehospital triage of acute myocardial infarction: Wireless transmission of electrocardiograms to the on-call cardiologist via a handheld computer." *Journal of Electrocardiology*. 38(4):300–309, 2005.

Adams GL, Campbell P, Adams J, et al: "Prehospital Wireless Transmission of Electrocardiograms to a Cardiologist via Handheld Device for Patients with Acute Myocardial Infarction; the Timely Intervention in Myocardial Emergency, North East Experience (TIME-NE)." *Journal of the American College of Cardiology*. 47(4) 383A, 2006.

Cardiologist Diagnosis of STEMI on a Handheld Computer

Conclusion: Cardiologists made similar decisions about initiation of reperfusion therapy when viewing an ECG on paper or on a handheld liquid crystal display (LCD).

Reference: Leibrandt PN, Bell SJ, Savona MR, et al: "Validation of cardiologists' decisions to initiate reperfusion therapy for acute myocardial infarction with electrocardiograms viewed on liquid crystal displays of cellular telephones." *American Heart Journal*. 140(5):747–752, 2000.

Improved Outcomes with Reduced Time to Thrombolytic Therapy

Conclusion: The reduction in infarct size after thrombolytic therapy was achieved by shortened time to reperfusion either in the ambulance or in the hospital.

Reference: Weaver WD, Cerqueira M, Hallstrom AP, et al: "Prehospital-initiated vs. hospital-initiated thrombolytic therapy. The Myocardial Infarction Triage and Intervention Trial." *Journal of the American Medical Association (JAMA)*. 270(10):1211–1216, 1993.

Conclusion: Prehospital therapy reduced the time to thrombolytics by two hours, which produced a 50% reduction in one-year mortality.

Reference: Rawles J: "Halving of mortality at 1 year by domiciliary thrombolysis in the Grampian Region Early Anisteplase Trial (GREAT)." *Journal of the American College of Cardiology*. 23(1):1–5, 1994.

Improved Outcomes with Reduced Time to Percutaneous Coronary Intervention (PCI)

Conclusion: Every 30 minutes of delay to PCI results in an 8% increase in one-year mortality.

Reference: De Luca G, Suryapranata H, Ottervanger JP, et al: "Time delay to treatment and mortality in primary angioplasty for acute myocardial infarction: Every minute of delay counts. *Circulation*. 109(10):1223–1225, 2004.

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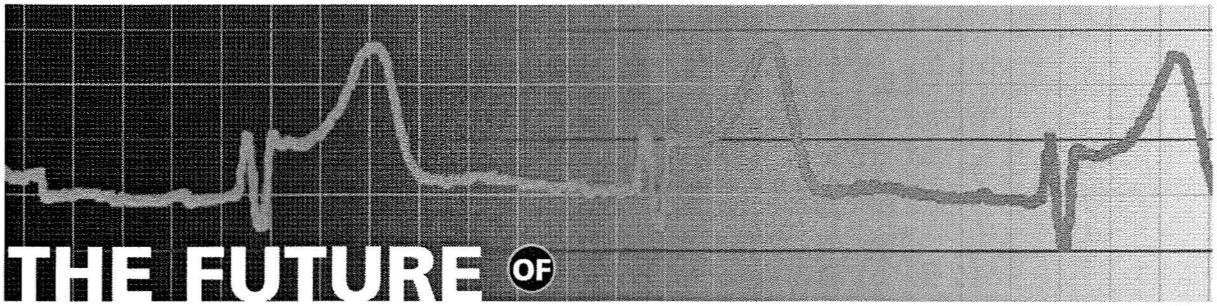

THE FUTURE OF STEMI RESPONSE

Implementing field-to-cardiologist ECG transmission to accelerate reperfusion in acute MI

By Jonathan A. Lipton, MD; David G. Strauss BA, EMT-I; Dwayne Young, BS, REMTP; Maria Sejersten, MD; Charles Maynard, PhD; Creighton Vaught, MD; Debra Versteeg, BS; Denise Munsey, RN; James L. Albright, BA, MSA, REMTP; Paul N. Leibrandt, BA; Samuel Bell, MS; Samuel Jacubowitz, MD; Thomas Wall, MD; & Galen Wagner, MD

Medic 6 arrives at the home of a 68-year-old male with chest pain. After conducting a complete assessment, obtaining a 12-lead ECG and starting initial interventions, the crew sends the 12-lead directly from their monitor to the PDA (personal digital assistant) of a cardiologist. The physician hears the device's alert tone, checks the PDA and evaluates the ECG in real time.

The cardiologist evaluates the patient's ECG to determine if it meets criteria for emergency reperfusion therapy in the facility's cardiac catheterization (cath) lab. It does, so he advises the crew to bypass the emergency department (ED) and proceed directly to the cath lab where he and his team will meet the patient.

The crew acknowledges the cardiologist's orders and then notifies the ED. The patient arrives at the hospital 12 minutes later and within another seven minutes is under the care of the specialized catheterization team.

Sound far-fetched? It's not. Technology has begun to make this scenario happen in EMS systems throughout the world. This article describes the protocol the authors are using to study this clinically important and innovative technology.

Background

An estimated 2 million annual hospital discharges in the United States are for acute coronary syndromes, and one-third of these patients have ST-elevation myocardial infarction (STEMI).[1] The underlying cause of STEMI is typically an acute occlusion of a coronary artery (e.g., thrombosis).

The rapid identification of STEMI should be of highest priority to EMS crews because reperfusion treatments (e.g., thrombolytic medications or mechanical intervention in the cath lab) can save cardiac muscle and potentially even the patient's life if treatment is administered rapidly.[2-5] To reduce the time from onset of acute thrombosis to reperfusion therapy, clinicians have employed numerous strategies, including patient educational initiatives,[6-8] specific acute myocardial infarction (MI) protocol development for EDs,[9-15] prehospital ECG transmission from EMS vehicles to EDs[16-19] and prehospital thrombolysis.[20-25]

Cellular transmission of ECGs to receiving hospitals has been in use by EMS systems since 1987.[26] In the TIME 1 (Timely Intervention in Myocardial Emergency 1) trial in Guilford County, N.C., Wall et al documented a 27% time reduction (109 to 80 minutes) from hospital arrival to percutaneous coronary intervention (PCI) by implementing prehospital ECG transmission to the ED.[19] However, a follow-up study revealed that the initial decrease in door-to-balloon time was not sustained over a 10-year period.[27]

These results stimulated the discussion of whether door-to-balloon times could be consistently reduced for patients with clearly abnormal ECGs by increasing direct communication between paramedics and cardiologists. Such a system would involve paramedics evaluating 12-lead ECGs for ST-elevation and directly contacting the cardiologist when STEMI was present. (*Note:* A study found that the true-positive rate of STEMI diagnosis by paramedics is high in patients presenting without confounding factors, e.g., prior MI, poor-quality ECG, bundle branch block, left ventricular hypertrophy and pacemaker, but decreases when the ECG has confounding factors.[28])

ECG transmission directly from a prehospital ECG monitor to a handheld digital device has only recently become an option.[29] This system can now provide parallel ECG transmission to the ED and an on-call cardiologist for patients with both symptoms and ST-segment changes that most strongly suggest an MI.

Testing of this technology has been performed in both Europe and the United States.[30,31] The hypothesis of these studies is that the time to reperfusion therapy will be reduced when the assigned cardiologist has immediate access to a 12-lead ECG and other patient data directly from paramedics in the field. It's further hypothesized that earlier treatment will result in increased myocardial salvage as estimated by previously validated ECG scoring techniques described below.[32-35]

Technical aspects

In the studies referenced, paramedics obtain a 12-lead ECG for patients experiencing symptoms suggestive of acute coronary syndrome. If a probable STEMI is indicated by at least 1 mm ST elevation in two or more contiguous leads, the ECG is transmit-

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ted from the ambulance to a central computer at the EMS headquarters or a hospital, using a cellular connection or digital wireless network.[36] The ECG can be transmitted to a fax machine at the ED, a receiving station or a PDA. Systems with a receiving station can forward the ECG to a cath lab or other location.

Notification can also be sent to an on-call cardiologist's PDA. The small, handheld device alerts the physician of an incoming ECG. Using proprietary software, the cardiologist can download the ECG from the central computer and view it on the PDA screen. The software provides a view of the six limb leads, the six precordial leads and a more detailed zoom view of each individual lead. If the cellular connection to the PDA fails, the ECG is faxed to the hospital ED. The fax system is maintained as a back-up to the electronic transfer system. In addition, the ECGs are stored on the central computer, which facilitates their use for computing the predicted final MI size.

Figure 1: Evolution of the Timely Intervention In Myocardial Emergency (TIME) Studies

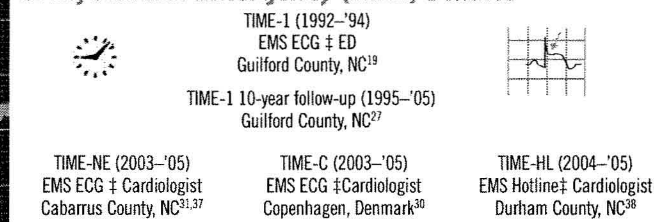


FIGURE LEGEND

TIME = Timely Intervention in Myocardial Emergency

TIME-NE = Study at NorthEast Medical Center, Cabarrus County, NC

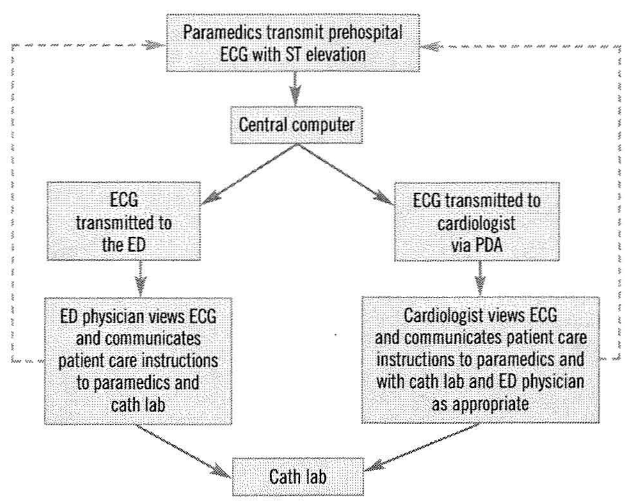
TIME-C = Study in Copenhagen, Denmark

TIME-HL = Study of a EMS-to-Cardiologist "Hotline"system in Durham, NC

TIME-MC-1 = Multi-Center study at 12 sites

TIME-MC-2 = Multi-Center study at 3 sites

Figure 2: Prehospital ECG Transmission & Communication Protocol



Results

The method described was developed by investigators at Guilford County (N.C.) and Duke Clinical Research Institute in response to an absence of sustained reduction in time to reperfusion for STEMI patients.[27] This ECG transfer method has been implemented in TIME studies in both Copenhagen, Denmark (TIME-C), and Cabarrus County, N.C. (TIME-NE), and is now the basis for multi-center TIME studies of two commercial prehospital ECG manufacturers (Figure 1).[30,37]

In addition, a study in Durham, N.C. (TIME-HL) has shown a significant decrease in door-to-balloon time when paramedics called the coronary care unit directly to activate the cath lab using a dedicated "hotline."[38] This intervention did not involve ECG transmission and relied solely on paramedic recognition of STEMI.

The ideal environment for implementation

A community interested in implementing this technology must have a well-organized EMS system and hospital health system that provides primary coronary intervention and/or IV thrombolytic therapy on a 24-hour basis. Both EMS and the health system must have resources for collecting patient data into a computerized database. A relationship must be established with a study coordination center capable of designing the ECG transfer protocol, managing the data and determining the study outcomes. The cellular network must support messaging/paging services, as well as data and voice transmission services.

EMS involvement: Paramedics involved in remote transmission programs must be well-educated in the interpretation, recording and transmission of 12-lead ECGs, as well as in the advanced patient treatment associated with cardiac chest pain.[28] The ambulances must be equipped to transmit the ECG via cellular or wireless technology.

An EMS research coordinator should be appointed to ensure the education of the paramedics and be responsible for testing, introducing, and maintaining the necessary technology. The coordinator would be responsible for monitoring and ensuring the correct functioning of the ECG transmission system and EMS data collection after the technology has been implemented.

Participating hospital involvement: Participating hospitals must provide reperfusion therapy on a 24-hour basis using thrombolytic therapy or PCI. Protocols must be established regarding the responsibilities of the paramedics, ED physicians and cardiologists. A research coordinator within the hospital must be appointed and given responsibility for obtaining data on patients with reperfusion therapy.

Study coordination center: A study coordination center should oversee the study progress, determining the requirements of each of the participants before the technology can be implemented in the community. The center must be experienced in coordinating clinical research studies and the testing of new technologies, and have facilities to maintain and analyze patient data in a study database and experts to analyze the ECGs.

A study coordinator establishes a system for data collection and analysis from the different sources and for direct communication between the participants. The coordinator appoints a Data Safety and Monitoring Board (DSMB) to approve the study design and monitor patient safety.[39]

Communications flow

In our system, paramedics transmit an ECG for patients meeting STEMI criteria to a cardiologist's handheld digital device on a 24-hour basis. The cardiologist receives and views the ECG, and contacts the paramedic by phone. Assuming primary medical control, the cardiologist decides what emergency treatment is indicated and discusses the plan with the paramedic.

The paramedic then establishes contact with the ED charge nurse, providing information regarding the cardiologist's decision of treatment and transport site. Depending on local EMS capability and treatment protocols, the paramedic initiates field thrombolytics, transports the patient directly to the cath laboratory for PCI or transports the patient to the hospital ED, either for thrombolytic therapy or to hold until the cath lab is ready (Figure 2, p. 9).

A protocol is followed for the patient to bypass the ED when the cath lab is operational, and a shortened admission protocol is followed when it's not operational so the patient can be transported to the cath lab as soon as it's available. If the patient will be transported directly to the cath lab, the cardiologist will notify the cath lab nurse directly. The cardiologist then meets the patient at the arrival site—the ED or the cath lab.

Figure 3: Key Data Elements to be Recorded

Technical & Procedural Data to Monitor Reliability	**From EMS/paramedic:** • Time of prehospital ECG transmission • Transmission information • Communication with cardiologist and ED **From cardiologist carrying receiving device:** • Notification of ECG received • Ability to view ECG • Treatment decision • Communication with paramedic and cath lab **From ECG recorder:** • Prehospital ECG
Information from Paramedics	**Dates & times of:** • Symptom onset • EMS arrival on scene • ECG recording • Hospital arrival **Patient baseline characteristics** • Date of birth, sex, race, etc. **Clinical data** • Chest pain characteristics • Risk factors • Medical history • Success of transmission • Communication and treatment decision
Patient Care Information from Hospital	**Dates and times of:** • Hospital admission (arrival at ED, arrival at cath lab) • Treatment (administration of thrombolytics or start of PCI) • Hospital discharge **Patient baseline characteristics** (for matching with EMS data) **Clinical data:** • Pre-treatment assessment • Treatment • Post-treatment assessment • Complications and survival

Data collection & analysis

To safely introduce this technology and monitor the ongoing study, it's essential to have a well-functioning data collection system. The study coordination center gathers the information (Figure 3). Reports from these computerized databases provide information on patient flow and study progress. This database can then be queried for quality control and outcome research.

An ECG analyst calculates myocardial salvage by analyzing and comparing the transmitted and hospital discharge recordings.[32, 33, 40-42] Automated ECG analysis programs facilitate this process by providing the required digital measurements.

The analysis includes demographic data, medical history, presenting patient characteristics, diagnosis and procedure utilization, delay and treatment time intervals, and hospital outcomes. Thus, patients with and without ECGs transmitted to the cardiologist can be compared.

Lessons learned

Before making the decision to implement this technology, control data on current time to treatment and transportation should be collected from the community regarding the patient population. In addition, the paramedics should be sufficiently trained in 12-lead ECG acquisition and diagnosing STEMI.

Technology: There are various methods of transmitting the ECG to a cellular device; there are also different types of devices. When making a choice between the technology options one should consider the availability, dependability (especially software reliability) and capability of the cellular devices.

Transmission methods: To view a transmitted ECG on a cellular device as an electronic file requires specially designed software. Commercially available software and technology can also fax the ECG via a cellular device, although the quality of the ECG when displayed on the device needs to be verified.[43,44]

Factors that should be evaluated are the image resolution, size and the number of leads that can be displayed on the cellular device at one time. The current technology is capable of displaying and transmitting ECGs but often has too many software issues to be sufficiently dependable.

Data entry & collection: Data should be entered as it becomes available, and appropriate edit checks should be applied. Separate databases can be used to analyze the ECGs and to track the transmissions. Establishing a central database that stores all patient data appears to be the most efficient setup. Because the number of study patients at a single site is limited, standardization of the data elements would be valuable for facilitating multi-center data analysis, providing stronger results.

Communication: The number of participating sites and organizations involved necessitates a structured feedback plan. Feedback from weekly visits of the study coordinator to the study sites and regular conference calls should be presented to all study participants in a newsletter.

An institutional review board (IRB) should monitor the study results and, if called for, terminate the study. A list of responsibilities for solving specific problems should also be established, and the study coordinator should refer to this list to gather information and set up conference calls to resolve any issues.

Conclusion

Based on our results, we recommend the implementation of this system be done in three phases:

Phase one: After developing an initial plan, the technology to be used is chosen and, if necessary, clinically tested. This applies to the treatment possibilities as well. Existing data from the community is evaluated.

Phase two: The communication lines and protocols are finalized and tested together with the technology. At the same time, data collection is started. Patient safety is ensured via an established backup system and a Data Safety and Monitoring Board that approves the study protocol. Final adjustments, based on testing results, are made to the technology and protocols.

Phase three: The technology is applied, allowing the cardiologists to make prehospital treatment decisions. The IRB

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monitors patient safety and study progress. The data are analyzed and compared with other communities.

Implementing this advanced technology requires a long-term commitment from all participants. Technology will always be changing, so clear communication protocols must form a framework for introduction of newer technologies.

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APPLYING NOT JUST IMPLEMENTING A 12-LEAD PROGRAM

By Teresa McCallion

Determining the success of a 12-lead ECG program is easy. Does it lead to advance notification of the receiving facility, speed diagnosis and shorten the time to reperfusion? *The bottom line:* Does it reduce damage to the heart muscle and save lives?

Early identification of an ST-segment elevation myocardial infarction (STEMI) and the speedy activation of the hospital's cath lab have been proven to dramatically reduce wait time for patients who need cardiac catheterization. However, despite compelling clinical studies, many 12-lead programs have floundered. The primary culprit is often a lack of cooperation between EMS and the medical community.

The American College of Cardiology and the American Heart Association recommend that patients suffering from an acute myocardial infarction (AMI) and presenting with STEMI receive cardiac catheterization to open their arteries within 90 minutes of arriving at the hospital. However, less than 40% of patients who receive percutaneous coronary intervention (PCI) are treated within the 90-minute window.[1] The problem is that many hospitals are reluctant to activate a catheterization team at a cost of thousands of dollars based on the recommendation of paramedics, even when a 12-lead ECG has been transmitted from the field.

Beyond simply transmitting 12-lead ECG data to a hospital, successful programs require a systematic approach. Paramedics and cardiologists must work together to identify STEMI in patients with chest pain in a prehospital setting. Once identified, precious time is saved by circumventing the emergency department (ED) and taking the patient directly to the cath lab. According to a number of studies, the potential reduction in door-to-reperfusion therapy for patients who are expedited to the cath lab ranges from 10 to 60 minutes.

Directing patients to the most appropriate hospital is also crucial to their survival. Currently, 33% of STEMI patients do not receive any reperfusion therapy, partly because the receiving hospital does ***not*** have the capability. To date, less than 25% of U.S. hospitals perform primary PCI.[2] Even among cardiac care facilities, few cath labs are staffed 24 hours a day. The AHA suggests that if even half of these patients were able to undergo primary PCI, an estimated 2,640 lives would be saved annually.[3]

The AHA feels so strongly that prehospital 12-lead ECG programs can successfully reduce time to reperfusion therapy that the programs are a *Class I* recommendation for urban and suburban EMS systems, according to the 2005 Guidelines for CPR and ECC. (*Note:* Class I is the strongest recommendation that the AHA gives; it's reserved for those procedures, treatments, diagnostic tests or assessments that have been proven to provide the greatest benefit with the least risk.)

PHOTO KEVIN LINK

When a prehospital 12-lead ECG is sent in advance of hospital arrival, precious time can be saved by circumventing the ED when indicated.

The technology

Transmitting an ECG from one location to another isn't new. In 1905, Willem Einthoven—the first person to use the term *electrocardiogram*—sent an ECG of a healthy male from the hospital to his laboratory nearly a mile away via telephone cables. Almost 100 years later, researchers updated the process, demonstrating the feasibility of wireless transmission of 12-lead ECGs to handheld computers. Within the past year, a number of studies have shown that transmitting 12-lead ECGs from the field to a cardiologist's PDA significantly reduced the time from onset of chest pain to reperfusion.

Fax transmissions of ECGs have been around since the 1970s. The primary complaint, however, is that the resolution is often not of diagnostic quality, especially if the fax is re-sent to a secondary location.

Today, four manufacturers of prehospital defibrillator/monitors—Medtronic, Philips Medical Systems, Welch Allyn Medical Products and ZOLL Medical Corp.—offer the latest in wireless transmission solutions. And General Devices has developed a product line that acts as a communication reception and distribution center, receiving ECG and other vital sign transmissions from Medtronic, Philips or ZOLL devices and forwarding them to other locations.

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Transmission devices include cell phones, field radios, standard telephones and PDAs. The signal is sent to the hospital via cellular towers, landlines, microwave links, or the newest wireless Internet connections, which are faster and more reliable.

Depending on the defibrillator, patient data is not limited to an ECG. Some units can relay a variety of patient statistics, automatically updating them as the need arises. If configured properly, some defibrillators, such as Medtronic's LIFEPAK 12 defibrillator/monitor series, can continuously monitor the patient, automatically sending another 12-lead ECG if changes in ST elevations occur.

One of the most popular technological advancements for wireless transmissions is Bluetooth technology. It allows the defibrillator to send a signal wirelessly from the monitor to a cell phone or PDA, eliminating at least one cable for paramedics. The signal is viable up to 100 meters (approximately 325 feet) between the defibrillator and cell phone when the phone has been configured to "bond" with the defibrillator.

All transmissions—however they are sent—arrive and are decoded by a computer-based transfer or receiving station. Typically located at the hospital, the computer station can redirect the ECG to a cardiologist's PDA, cath lab computer or fax.

The computer stations offer archival capabilities, allowing cardiologists the luxury of reviewing previous and serial ECGs. "Fifty percent of heart patients who walk through the door have been treated at the hospital for a coronary issue," says Ian Rowlandson, chief engineer of diagnostic cardiology at GE Healthcare. It gives cardiologists a unique opportunity to compare past ECG readings. ECGs can also be archived for quality assurance and data collection purposes. Some of these 12-lead computer stations can also forward ECGs to the cardiology department's diagnostic ECG databases, such as TraceMasterVue and GE MUSE.

The cost of instituting a 12-lead program is relatively inexpensive and depends on the size of the EMS system. Medic units may need upgraded defibrillators, and a computer station with specialized software must be centrally located to receive the transmissions. Other hardware includes conventional cell phones, PDAs and a printer. No special modifications are required for cell phones or PDAs, although program-specific software is needed.

Some defibrillators are also able to utilize a broadband router in the ambulance and avoid the need for either a phone or PDA. This is becoming more common, especially in larger EMS systems that are seeking to lower the cost of transmission by leveraging access to a shared network.

Keys to a successful program

Those who have lived through the implementation of a 12-lead program say one of the biggest challenges is creating a healthy level of cooperation between their EMS agency and the receiving hospitals. Resistance can come from both sides. Demoralized paramedics may not feel particularly motivated to cooperate with a hospital staff that has been less than supportive of a collegial relationship with EMS providers in the past. The hospital staff may not have a clear understanding or appreciation of the paramedics' skills.

At least initially, systems implementing a 12-lead ECG program can also expect some of their paramedics to view the transmission of patient data as a step back to the "Johnny and Roy" days of "Mother may I?" telemetry.

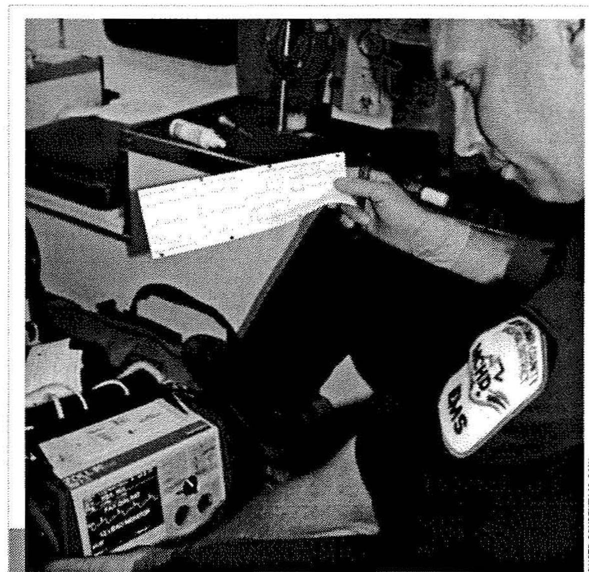


PHOTO COURTNEY McCAIN

By identifying STEMI patients in the field and tramitting ECGs, paramedics can help shorten the time to definite care.

To help both parties better understand each other's roles, some successful systems start by walking EMS providers and hospital staff through the entire continuum of care from the scene to the cath lab.

Beyond attitudes, the most common obstacles are turf and money. EMS must purchase the necessary equipment with no hope of reimbursement for this service. It's a concern expressed by more than one manufacturer.

Many systems find that establishing the right team members to participate in the project is critical to the success of the program. They suggest identifying all of the key stakeholders from the medical control physician to the cardiologists, emergency physicians and nurses. Don't forget the unit secretaries. Chances are, they're the ones who'll be in charge of the computer stations.

Buy-in isn't the only reason for team building. Everyone must be included when the processes are developed. EMS protocols must seamlessly integrate with the emergency department's chest pain protocols. Forget one step along the way, and even the finest set of protocols will be derailed.

As with all technology, wireless transmissions periodically experience glitches. Cell phone coverage can be spotty, and overcoming the fear of new technology can be challenging. Systems must have a plan B protocol in place for cath lab activation in the event of transmission problems.

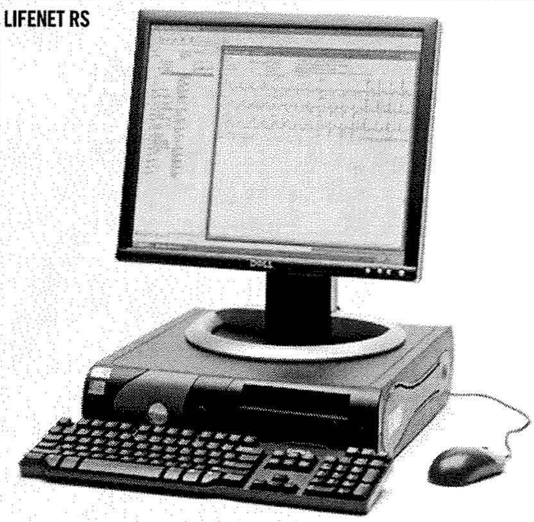
Crucial to all successful programs is an ongoing commitment to training. Often, systems bring in an expert for initial training, but may forget that it's equally important to provide regular reviews so skills don't fade. A multi-discipline oversight committee that provides feedback to the rest of the team is essential to identify areas of improvement and maintain quality control.

Benefits

EMS systems that have successfully implemented a 12-lead program report several benefits, not the least of which is an improved relationship with personnel at the receiving hospital. One EMS system says that as a result of the program, a mutual respect and confidence between paramedics and physicians exists where it did not before.

Some studies found that as the public became aware of the program, more patients experiencing chest pain were calling 9-1-1 rather than driving themselves to the hospital.[4]

LIFENET RS



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Company Description

Medtronic is a global manufacturer of medical technology. Earl E. Bakken and Palmer J. Hermundslie founded the company April 29, 1949, in Minneapolis, and Medtronic's headquarters remains there, with regional headquarters in Switzerland, Japan and elsewhere. In 1998, Medtronic acquired Physio-Control, renaming it Medtronic Emergency Response Systems. Located in Redmond, Wash., Medtronic ERS develops, manufactures, sells and services LIFEPAK manual defibrillator/monitors and AEDs.

Products

- LIFENET BLUE
- LIFENET RS (Receiving Station)

Product Description

LIFENET BLUE is an enhancement to the LIFEPAK 12 defibrillator/monitor. With the touch of a button, BLUE enables you to wirelessly download patient data from a Bluetooth-enabled LIFEPAK 12 to a PC tablet running LIFENET EMS ePCR. If the 12-lead ECG needs to be sent to the hospital, it's wirelessly transmitted to a Bluetooth-equipped cell/mobile phone and then to the LIFENET RS at the hospital. The LIFENET RS is designed to redirect the 12-lead ECG report to a number of predetermined PDAs, computer e-mail, cardiology management systems, faxes or other LIFENET RS systems.

The technology, introduced in 2004, uses a tiny, built-in Bluetooth microtransmitterinstalled in the LIFEPAK 12 to communicate data between the defibrillator and phone up to 30 meters away without cables. No additional data transmission software is required.

This product, which is an upgrade to an existing device, is a small card that can be added to the existing LIFEPAK 12. Because the device requires a minimum of 4 MB memory, older systems including the defibrillator and the PC tablet may need to be upgraded to make them compatible.

The types of patient data sent include a Trend Summary Report that contains patient information, vital sign values and trending graph; a Vital Signs Summary Report, with patient information, event and vital sign logs; and a Snapshot Report that includes patient information and eight seconds of waveform data captured at the time of transmission.

The LIFENET RS is a receiving station that works in conjunction with the LIFEPAK 12 defibrillator, receiving and generating diagnostic quality 12-lead ECG reports from the field to the hospital. Patient data is sent to the LIFENET RS (usually located in the emergency department) from a LIFEPAK 12 defibrillator in the field via landline, cellular or satellite phone.

An automatic audible and visual alarm alerts the staff to an incoming 12-lead ECG report, a Vital Signs Summary report and other reports.

The LIFENET RS can be configured to automatically export 12-lead ECG reports as a fax or PDF to predetermined sites. PDF files are sent as an e-mail attachment along with an alternate notification text message. The e-mail messages can be received on a computer or PDA.

Requirements

- Bluetooth accessory for the LIFEPAK 12 defibrillator.
- Bluetooth adapter for PC tablet (may require an upgrade for older systems).
- LIFENET BLUE supports applications running on 2000 and XP Windows operating systems.

LIFENET RS Receiving Station System Features

- Dell computer system with new generation design.
- Dell 19-inch flat panel monitor.
- Dell laser printer.

Optional Features

To interface with other systems, the LIFENET system can auto-export and auto-forward patient information from the LIFENET RS to GEMS MUSE and Infinity MegaCare systems. (This requires network connection between the receiving station and cardiology management system. In addition, it requires purchase of additional software interface from the GEMS MUSE or Infinity MegaCare system to the LIFENET RS Receiving Station.)

The patient privacy filter removes identifiable patient information (e.g., name or address) when exporting records to predetermined destinations. Other security enhancements include a function that allows only specified users into the system and an administrator to configure settings.

Multiple languages are available, including English, French, Spanish, German, Swedish, Italian, Danish, Norwegian and Dutch.

An annual service contract provides software and hardware service support.

System Requirements

For the LIFENET RS Receiving Station:

- Two analog phone lines.
- Three power receptacles.
- GEMS MUSE option requires network connection, MUSE Version 5C or higher and software interface to the LIFENET RS Receiving Station.
- Infinity MEGACARE option requires network connection and software interface to the LIFENET RS Receiving Station.
- E-mail features require network connection and external e-mail account.

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CASE STUDY: St. Mary's Health Care System, Athens, Ga.

The 12-lead program at St. Mary's Health Care System in Athens, Ga., celebrates its first anniversary this month. Last July, the extensive planning culminated in a vision to shave time from MI recognition to time of treatment.

Subodh K. Agrawal, MD, medical director of St. Mary's cath lab, initiated the program. "He's our cardiac visionary," says David Bailey, director cardiovascular, critical care, medicine and respiratory at St. Mary's Hospital.

Bailey brought in John Sartain, St. Mary's manager of EMS, to help identify vendors and determine the protocols. Chief Information Officer Kerry Vaughn co-chaired the Remote EKG Planning team with Bailey and was instrumental in working through the information systems (IS) questions and discussions.

Communication was the foundation of St. Mary's program. Early on, a presentation explaining the program was made to all of the staff cardiologists. When St. Mary's was ready to implement the program, they invited the entire staff, city officials and the media to a live demonstration.

To help inform the citizens about the program, St. Mary's developed a television and print advertising campaign centering on the identification of cardiac symptoms and the need to call 9-1-1. As a result, says Bailey, "we noticed dramatic growth for the entire cardiac program."

The program uses cell phones to simultaneously transmit the ECG data to St. Mary's ED and a cardiologist's PDA. Bailey says the hospital is one of the first in the country with this type of set-up.

Only St. Mary's Emergency Center has the receiving station. If a patient is transferred to another facility via EMS, the ED faxes the 12-lead ECG to the facility receiving the patient.

During the planning process, the biggest hurdle was security. "That slowed us down by about six to eight weeks," he says. An attorney who specializes in privacy issues reviewed the plan that involved using the patient's age and initials on the transmission. Once the transmission arrives at the hospital, it is assigned a number. When the ambulance arrives at the hospital, the emergency crew hands a printed ECG strip to the physician to verify the identity of the patient.

Quality assurance is especially important to Bailey. The EMS division and a special products technician each conducts a daily audit.

Sartain admits that the physicians weren't the only ones who were skeptical at first. "Once it started going," he says, "I haven't had any concerns since. We've had very good success, getting patients to the cath lab in less than 10 minutes."

News of the program's success is spreading. "Several outlying hospitals and EMS agencies have expressed interest in having St. Mary's assist in expanding their cardiac care capabilities," Bailey says.

CASE STUDY: North Shore-Long Island Jewish Health System, Center for EMS, New York

In a large, busy system, such as the Center for Emergency Medical Services (CEMS) for the North Shore–Long Island Jewish (LIJ) Health System, obtaining patient information is necessary in order to route patients to one of its 15 hospitals.

"I wholeheartedly endorse this," CEMS Director of Operations Alan Schwalberg says of the 12-lead ECG program.

CEMS uses a single receiving station to direct a 12-lead ECG and other diagnostic signs to any one of the hospitals in the North Shore LIJ system. Emergency crews transmit 12-leads, vital signs, SpO_2 and other patient data. A fax is sent immediately upon receipt at the computer station. As the data are being received, a second modem is relaying it to a cardiologist.

"You can get the whole snapshot of what's going on with the patient," Schwalberg says.

Paramedics work in cooperation with the cath labs at North Shore University Hospital and Long Island Jewish Medical Center. Physicians and paramedics discuss the course of treatment before the patient arrives at the hospital. Schwalberg says the paramedics recognize the physician's input as a valuable tool that affords them another set of eyes. Two years after the program was launched, paramedics regularly bypass the ED to go straight to the cath lab when appropriate.

CEMS serves as an EMS provider for 5.2 million people within a 2,200-square-mile area in New York City, and Nassau and Suffolk counties. Instituting the program for one of the largest hospital-based ambulance services in the United States required significant coordination.

"We started small-scale to work out the kinks, then went systemwide," Schwalberg says.

CEMS plans to adapt and enhance the program as new technology is introduced. It's considering adding Bluetooth capability, but because all the divisions must switch at the same time, it's neither easy nor inexpensive.

Overall, Schwalberg is pleased with the results. "It has cut down time to treatment," he says. "At the end of the day, it's proven to be a simple device."

CASE STUDY: Tampa Fire & Rescue, Tampa, Fla.

Last summer, Tampa Fire and Rescue moved its entire system from interpretive three-lead ECG defibrillators to 12-lead models. At the same time, it instituted a 12-lead ECG program with four area hospitals.

"It was quite a project to take on," Rescue Division Chief Nick LoCicero says. As the department's quality assurance officer, LoCicero oversaw the entire process.

Technological issues, not skills or education, presented the biggest roadblock to smooth implementation LoCicero says. "The main issues were small, but they will derail you," he says. Something as simple remembering to activate Bluetooth can cause confusion.

He suggests fostering a good working relationship with the IT (information technology) personnel.

Because of the shift from three- to 12-lead, Tampa did not retrofit any defibrillators, but instead purchased all new devices for each transport unit and ALS engine. Tampa Fire used grant money to help supplement the program budget, and the city of Tampa provided additional funding.

Implementation of the program didn't cost the hospitals a dime, says LoCicero. Each hospital simply provided an e-mail address for the Tampa crews to send the ECG data via a PDA. The data arrives at the computer station as an e-mail with a PDF (portable document format) attachment. An alarm alerts the staff to an incoming transmission. Once at the hospital, the data can be forwarded like any other e-mail to other locations, including to a cardiologist.

Typically, LoCicero says, the file is printed and delivered to the ED physician, who validates the STEMI. Copies of the PDF are automatically sent to Tampa's quality assurance office.

LoCicero found the ease of acceptance was somewhat

HeartStart MRx with Bluetooth capability and optional 56K Bluetooth modem

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Company Description

Royal Philips Electronics of the Netherlands is one of the world's biggest electronics companies and Europe's largest, with sales of $37.7 billion in 2005. Subsidiary Philips Medical Systems is the single largest Philips business in the United States, employing approximately 30,000 people worldwide. It maintains sales and service organizations in 63 countries and runs manufacturing operations in the Netherlands, Germany, Finland, Israel and the United States.

A recent study conducted by Frost & Sullivan determined that Philips is the world market share leader for automated external defibrillators in both prehospital and hospital/alternative medical settings.

Products

- HeartStart MRx monitor/defibrillator
- HeartStart 12-Lead Transfer Station

Product Description

Philips Medical introduced Bluetooth 12-lead ECG transmission as an option for its HeartStart MRx monitor/defibrillator in November 2005. This time-critical transmission feature involves the enabling of the MRx and the installation of the HeartStart 12-lead Transfer Station software on one or more computers (to act as a post office or hub).

The HeartStart 12-Lead Transfer Station is designed to automatically or manually send 12-lead reports to one or more printers or fax machines or to a TraceMaster ECG Management System. Adding Bluetooth capability to a HeartStart MRx allows it to wirelessly network to a cell phone for dialing up the Internet. Transmission takes place digitally over the Internet to the 12-Lead Transfer Station.

For customers who want to use landline transmission as a back up for spotty or non-existent cell phone coverage, Philips offers an external 56K Bluetooth modem. This system establishes a dial-up connection from the MRx device to the Internet to the 12-Lead Transfer Station for ultimate delivery to the ED.

Once the data arrives at the hospital, the 12-lead report can be forwarded into TraceMasterVue and/or GE Muse (via the Osborne Box) diagnostic databases in cardiology.

Some customers have also used the 12-Lead Transfer Station in conjunction with third party rendering software, which converts the 12-lead ECG report into a jpg or PDF and automatically e-mails the file to an on-call cardiologist's PDA.

Cost

The cost to add 12-lead transmission to the MRx is $2,000. The 12-Lead Transfer Station software is $1,100, and it runs on a $1,500 personal computer.

Tech Support is included in the purchase price. Set-up of the computer and software is relatively easy. However, a third party called Compucom offers a turnkey package that includes the 12-Lead Transfer Station Computer and installation consulting for $5,000.

Optional Features

- E-mail notification, including 12-lead ECG report available via third parties.

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dependent. "The younger people—the Game Boy generation—jumped right on it," he says.

Tampa Fire and Rescue has been using PDAs on rescue units for patient care reporting since 2003. Once the 12-lead program was in place, the PDAs small screen size became an issue. This summer, the department plans to begin using tablet-size personal computers to resolve those concerns.

From start to finish, LoCicero says implementation of the 12-lead program and STEMI program took about two years.

"We did what we set out to accomplish, and we were successful," he says. "We are providing a much better level of care to the citizens we serve."

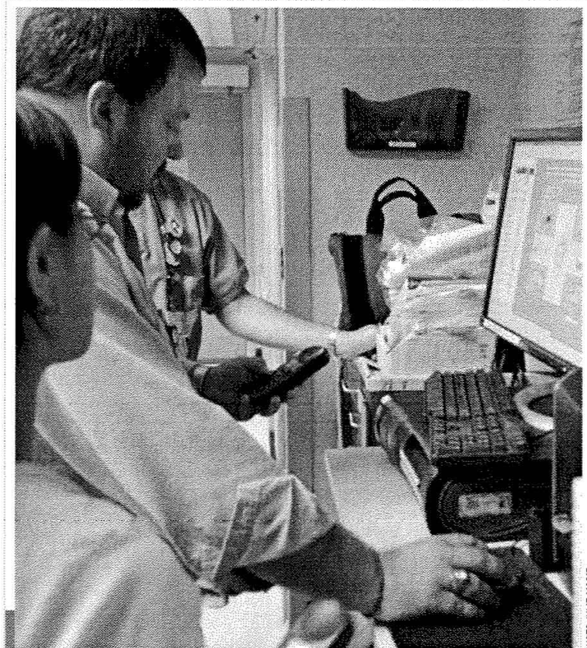


PHOTO JULIE MACIE

ECG data sent from an ambulance can be forwarded from the receiving unit at the hospital to a cardiologist's PDA and the cath lab.

CASE STUDY: MedicWest Ambulance, Las Vegas

It's eight months into the development of the 12-lead program at MedicWest in Las Vegas, and the system is nearly ready to send its first transmission, says VP of Operations Brian Rogers. The process is slow, but Rogers says, "When you are dealing with cardiologists and interventionists, you want it to go smoothly."

Cardiac patients represent a large portion of MedicWest's call volume. Serving the cities of Las Vegas and North Las Vegas plus all of Clark County, the third-party EMS system sees an average of 20–25 cardiac-related patients per day.

Instead of equipping each defibrillator with wireless connectivity, MedicWest opted to wire the paramedic units to be "hot spots" for wireless transmission through Internet-enabled cell phones at a cost of $1,000 per unit.

Wireless Internet service means that the paramedics don't have to worry about dropped calls during data transmissions. Connectivity is maintained through one cellular card on each unit instead of per defibrillator/monitor. Monthly service fees for the Internet connection are approximately $80 per unit.

Although MedicWest has an IT person on staff to handle technology issues, Rogers says this system is less complicated for the paramedics to manage during an emergency. "I believe the fewer steps the paramedic has to take for transmission to occur will make it a more positive process," he says.

Operations Administrator Ron Tucker says MedicWest already plans to expand the data transmitted to include a code summary. The company will launch a public awareness campaign once the program is firmly in place to remind residents to call 9-1-1.

Rogers says that beyond the technology, instituting a 12-lead program requires a paradigm change for some. "Bypassing the ED is a whole new mindset for people," he notes. The change is not so much in how prehospital providers provide care, but rather a wholesale change for hospitals. Making that change requires input at all levels from all participants. Rogers says he now sits on the local cardiac quality care board. As a result, MedicWest has a much closer working relationship with the hospitals.

CASE STUDY: Cabarrus County (N.C.) EMS

In 2003, Cabarrus County EMS, working with Northeast Medical Center (NEMC) in North Concord, N.C., was one of the first systems in the United States to transmit digital wireless 12-lead ECGs directly to a cardiologist's PDA. The project, called the North Carolina Acute Coronary Response EKG Study (NC CARES), was part of a collaboration with Duke University in Durham, N.C., and funded by a grant through the Duke Endowment Program.

The study documented a reduction of "door-to-dilation time" from a median pre-study time of 93 minutes to 33 minutes. Since then, Cabarrus County EMS and NEMC have improved on that time, posting a personal best of 17 minutes in the past six months.

As an original member of the project, NEMC EMS Nurse Liaison Paula Fox believes the improvements in "door-to-dilation time" are due to experience. "People are getting more efficient," she says.

The process starts when paramedics identify a cardiac patient with an ST elevation in at least two contiguous leads. They digitally transmit a 12-lead ECG via cell phone to a designated PC, located in the hospital ED. On receipt of the transmission, a secretary forwards the ECG to the cardiologist, simultaneously paging them. If appropriate, the cardiologist activates the cath lab team and directs the paramedics to take the patient directly to the cath lab, bypassing the ED.

Once the paramedics arrive at the cath lab, they assist the hospital staff in preparing the patient for the procedure.

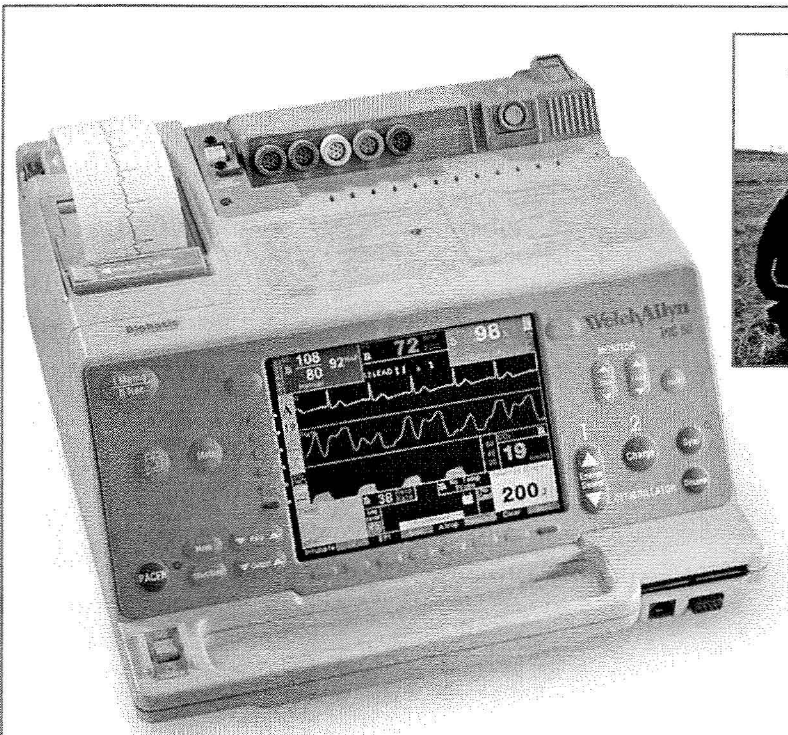
According to Fox, the cardiologists supported the program because they had not been comfortable with the previous system of sending ECG transmissions to a fax machine. The diagnostic quality of the fax was poor, they said. In addition, it was impossible to tell from the fax if a transmission had been dropped and then picked up again.

New wireless technology has also improved transmission times. Transmissions that used to take two to three minutes have been cut to a mere four to six seconds.

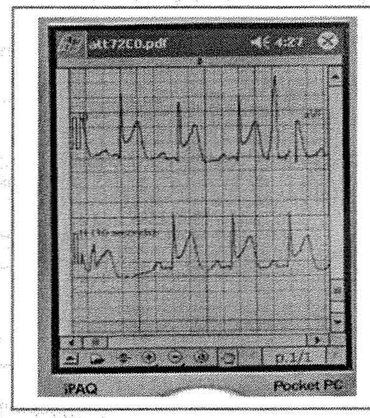
Marrying wireless and cellular technology was not easy. "A lot of things you didn't think were going to be a big deal, were a big deal," she says. Initially the wireless carriers refused to participate because of liability concerns, for instance.

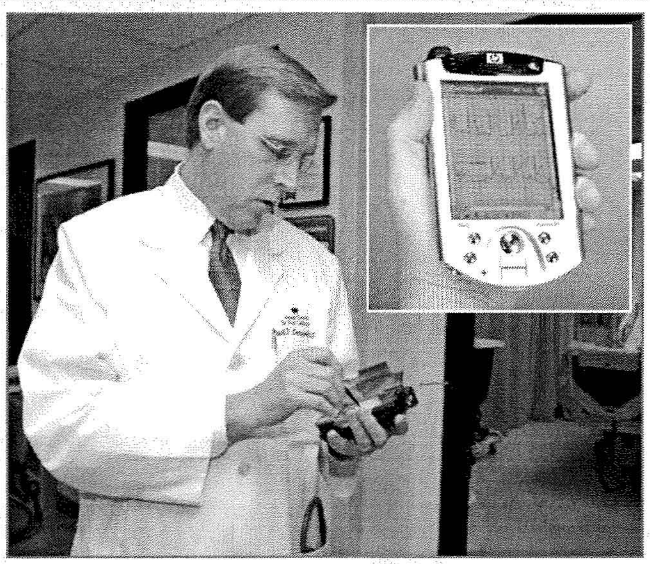
Although cell coverage is spotty in some parts of the county, especially in the more rural areas, Fox says they have not run into problems with dropped calls during transmissions. The paramedics know where those areas are, and simply wait until they are back in the coverage area.

Even if it's clear to the paramedics that the patient is a



PIC 50 monitor/defibrillator with SmartLink Wireless System





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Company Description

Welch Allyn Inc. was founded in 1915 and today is a leading manufacturer of medical diagnostic and therapeutic devices, cardiac defibrillators, patient monitoring systems and miniature precision lamps. Headquartered in Skaneateles Falls, N.Y., Welch Allyn employs more than 2,100 people and has numerous manufacturing, sales and distribution facilities located throughout the world.

Products

- Welch Allyn PIC 50 Monitor/Defibrillator with Communication Option.
- SmartLink Wireless System.

Product Description

The SmartLink Wireless system—an option for the PIC 50 monitor/defibrillator—is one of the fastest 12-lead transmission systems available, which reduces retransmissions and delays in patient transport. It transmits diagnostic 12-lead ECG data through a handheld Web-enabled PDA via a high-speed wireless Internet connection directly to a hospital PC. The 12-lead data is automatically redirected to individual clinicians to be viewed on the physician's Web-enabled PDA or hospital PC.

The system automatically notifies selected personnel via e-mail, text messages and pager when a new transmission has been received. Clinicians can use this diagnostic-quality ECG data to make a diagnosis immediately, speeding the treatment of patients when they arrive at the hospital.

The SmartLink Wireless System includes software for both the PDAs and the hospital PC, and receives data directly from Web-enable PDAs with the proper connections. The PDAs, PC and wireless services are purchased separately from the Welch Allyn SmartLink Wireless system.

Cost

The SmartLink Wireless System for PIC50 12-Lead Monitor/Defibrillator is $1,295. The SmartLink Wireless Transmission Server Software (includes software for hospital server and e-sync software for PDA) is $9,995.

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PHOTO JULIE MACIE

WakeMed EMS paramedics now diagnose STEMI and transmit the ECG to facilitate rapid transport to the interventional cardiology suite, reducing door-to-needle time by 50% since April 2006.

candidate for dilation, the cardiologists are the ones who must make the decision to activate the cath lab. Fox explains that contributing factors, such as the availability of the cardiologist or cath team, require the physician's approval. "The ultimate goal is to go to the cath lab," Fox says. "But it still needs to be the cardiologist's call."

Fox claims the biggest challenge is to get people to call 9-1-1. More than 80% of cardiac patients drive themselves to the hospital instead of calling 9-1-1. To help educate the public, the hospital used part of the grant money to develop a video in both English and Spanish to illustrate how the system works. The video is shown to church groups, community service clubs and senior centers and has run on local cable access channels.

"We want people to know that it's not a bother," Fox says. "It's here. We want you to use it."

Technology advances

The process of collecting prehospital ECGs has already affected the technology. Studies show that ECGs from a prehospital patient look different because they're being seen so much earlier. As a result, algorithm areas, such as the contour of the ST segment, have had to be updated. For example, the ST segment of a patient in the early stages of cardiac event is concave, not convex, requiring new rules to detect an AMI.

"Cath labs are getting more aggressive," GE engineer Ian Rowlandson says. So expect new technology to identify acute coronary syndromes beyond STEMI, such as right ventricular infarction and acute ischemia, he says.

Outside the U.S., a Swedish company, Ortivus, has equipped almost 1,000 ambulances in Europe with its combined EMS telemedicine and information management system, MobiMed. The system transmits ECGs, other vitals and electron paramagnetic resonance (ePR) information in real time to various receivers. Ortivus has been selected to participate in one of the clusters in the National Health Services Connecting for Health Program in England, providing the MobiMed online ePR functionality for all ambulances—approximately 800—in that cluster. The project, designed to integrate health-care systems nationwide, is said to be the largest health-care IT project in the world.

The Ortivus product transfers patient data from the field. In the near future, however, the company says paramedics will also be able to download patient data directly to the paramedic unit from a central database or, for instance, a hospital ePR.

One concern faced by 12-lead ECG programs is the integration of technology from a number of manufacturers. New Jersey-based General Devices has developed a group of products that allow a single computer station to receive transmissions from defibrillators manufactured by Medtronic, ZOLL and, most recently, Philips. This solution provides an added level of cooperation between hospitals and the different EMS agencies that serve their community. The ability of one system to operate with many types of field devices eliminates the need to provide a separate computer station for each manufacturer's defibrillator. General Devices' Rosetta-Lt enables 12-lead ECGs and other patient information generated by the Medtronic, ZOLL or Philips defibrillator to be sent quickly and easily via two-way radio or cell phone to the General Devices CAREpoint EMS workstation or Rosetta-Rx Receiver.

Medtronic has begun working on ways to streamline the data collection process. The company envisions a centralized, Web-based facility that is available to all EMS systems, eliminating the need for computer stations at each individual hospital. Banks of servers could provide secure, reliable high-speed transmissions. "Servers have more processing power and are better protected," says John Giaever, product development director for Medtronic. Such a facility would have the advantage of tying together different types of patient information beyond 12-lead ECGs in a reliable, secure environment. "Our goal is not to store patient data," Giaever says.

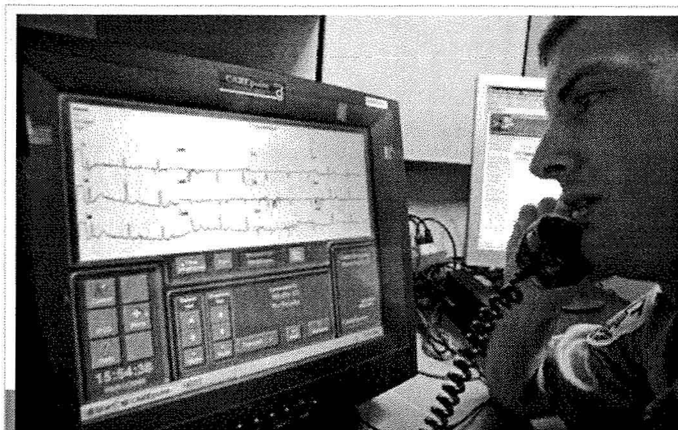

PHOTO MARK C. IDE

The CAREpoint EMS Workstation from General Devices integrates radio, cellular, landline, intranet, Internet and most standard ED software. It's the first and only multi-function workstation specifically designed for EMS.

In Eastern Pennsylvania, MEDCOM, a regional advanced medical communications system that serves 144 EMS agencies, 16 hospitals and three trauma centers, is implementing a system to centrally transfer data and ECGs to the region's hospitals.

MEDCOM, the brainchild of *JEMS* Editor-in-Chief A.J. Heightman when he was the region's EMS director, is staffed 24/7 and routes units to the most appropriate hospital in the system for medical command or radio reports via UHF and microwave technology. The center, which is funded by the participating agencies, also manages all hospital diversions.

MEDCOM is ideally set to serve as a hub for 12-lead ECG transmissions. According to current MEDCOM Executive Director Everitt Binns, PhD, the center will launch a 12-lead ECG wireless transmission program in November after MEDCOM moves into a new headquarters location.

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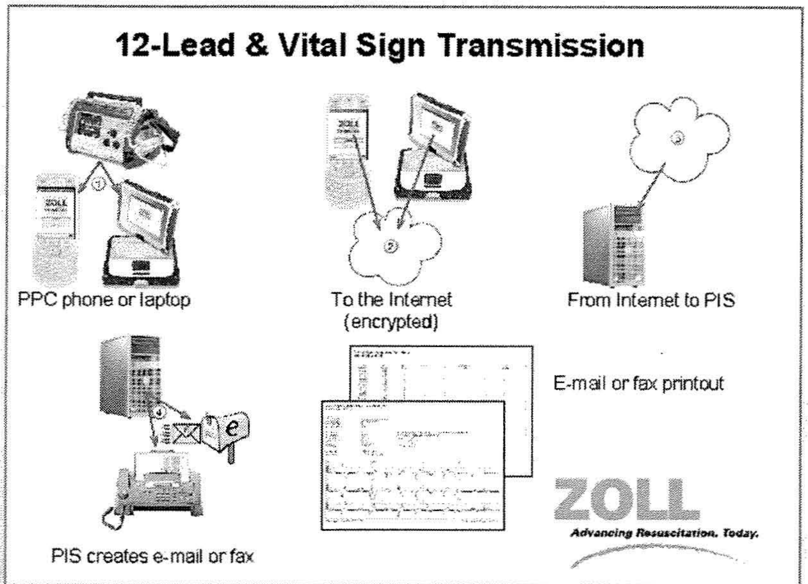

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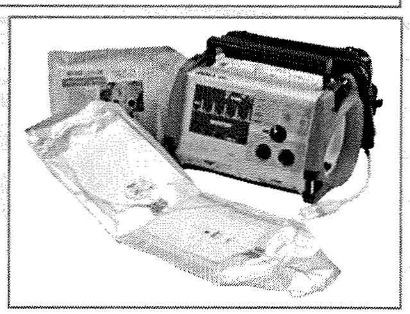

Company Description

Since 1983, ZOLL Medical Corp. has been developing technologies that help advance the practice of resuscitation. ZOLL also designs and markets software that automates the documentation and management of both clinical and non-clinical information. The company has direct operations, distributor networks and business partners in more than 140 countries including the United States, Canada, Latin America, Europe, the Middle East, Asia and Australia.

Products

- M Series/E Series Wireless Bluetooth option to ZOLL Data Relay Service.
- M Series/E Series Bluetooth Activation Kit to fax machine and GE MUSE and MAC 5000.

Product Descriptions

The M Series and E Series are available with Bluetooth, which enables the transmission of 12-lead and vital trend reports to a PDA to the hospital. Using Bluetooth technology, the data is transmitted to a mobile computing device (e.g., laptop or PDA), which then transmits the data via preconfigured, autodial cell phone or landline numbers to a Bluetooth-enabled cell phone. Cellular technology transmits captured 12-lead ECG and vital trends from a Bluetooth-enabled cell phone to the ZOLL Data Relay Service, which forwards the data to the local hospital's fax or e-mail.

The ECG data can also be redirected to another location, such as a cardiologist's e-mail, which can be accessed via a PC or PDA.

In addition, another option is the Bluetooth Pod Activation Kit, which is a cost-effective option for a customer to send 12-lead ECG reports direct to a fax machine or to the GE MUSE system at the hospital. This small attachment to the M Series or E Series communicates with a Bluetooth cell phone.

Requirements

- Bluetooth option on the E or M Series defibrillator.
- Bluetooth-enabled PC or phone PDA.

For the ZOLL Data Relay Service Software

- RescueNet CodeReview Enterprise Edition software.
- Pentium 2 or higher PC.
- Internet or dial-up connection.

Bluetooth Pod Activation Kit Requirements

- Activation Kit.
- Bluetooth-enabled cell phone.

GE MUSE Direct Connection Requirements

MUSE option on the M and E Series is approximately $900. Customers can use version 4B or higher MUSE. No other components needed. In addition, the customer can also send the 12-lead ECG directly to the GE MAC 5000 cardiograph, which can also act as a receiving station.

Cost

The cost for the Bluetooth option on the M or E Series is approximately $600. The required software, which can run on most computers, is approximately $2,500.

Keep in mind that this system does not require purchase of a dedicated receiving station. However, EMS agencies should factor in the cost of the PDA, phone or laptop, and the costs to send the data via cellular transmission. Other deployment/installation costs may also apply.

The Bluetooth Pod, which can transmit directly from the M Series or the E Series to a standard fax machine or the GE MUSE system, costs approximately $800. EMS customers must also factor in cell phone and carrier costs.

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At WakeMed (Raleigh, N.C.), prehospital ECGs are received and forwarded to the cath lab. The system's door-to-needle time is under 45 minutes.

The center will use its existing UHF and microwave connections, which Binns believes is the best technology, especially during a disaster. He says microwave is usually the last communication conduit to go down when the power goes out, because microwave towers are backed up by generators.

With a strong working relationship between EMS and the medical community already in place, Binns doesn't see that as a problem when implementing a 12-lead ECG program.

"Because we have MEDCOM, we have 16 hospitals that are already working with each other," Binns says. "That doesn't mean they don't compete with each other, but it's a nice partnership between ALS and the ERs."

Dwayne Young, Emergency Services Manager, Planning and Research, for Guilford County EMS in North Carolina, has seen a number of changes since he helped launch one of the first prehospital 12-lead ECG programs in the United States in 1994. Today, Guilford County EMS transmits 4,000–5,000 ECGs per year. "We are a huge cardiac community," he says.

Back in the '90s, the only defibrillator with 12-lead capability was a Marquette 1500. Young appreciates that the current defibrillators can transmit, store, manage and share data with and without cables. He is looking forward to future products that are able to send a transmission to multiple locations, including a cardiologist's PDA, without being routed through a separate server or computer station.

But the real change is in the level of trust that has developed between physicians and paramedics. "The evolution of the profession has exceeded the evolution of the technology," he says.

Summary

Only about 5% of patients with chest pain are candidates for cardiac catheterization. Although that number may sound low, it means that as many as 500,000 Americans could be treated for a STEMI in the course of the year. It is these patients who are prime candidates to be saved by rapid, lifesaving treatment.

Simply having a 12-lead defibrillator in and of itself doesn't constitute a program. And transmitting 12-lead ECGs from the field is just one step toward improving the odds for cardiac patient. Successful 12-lead ECG programs use technology as a tool to create a seamless continuity of care between the prehospital and the hospital environments.

As advances in the wireless transmission of 12-lead ECGs in a prehospital setting turn paramedic units into rolling EDs, the goal of every program should be to become part of an integrated system of patient care.

Teresa McCallion is a freelance public-safety writer living in Bonney Lake, Wash. Contact her at t_mccallion@hotmail.com.

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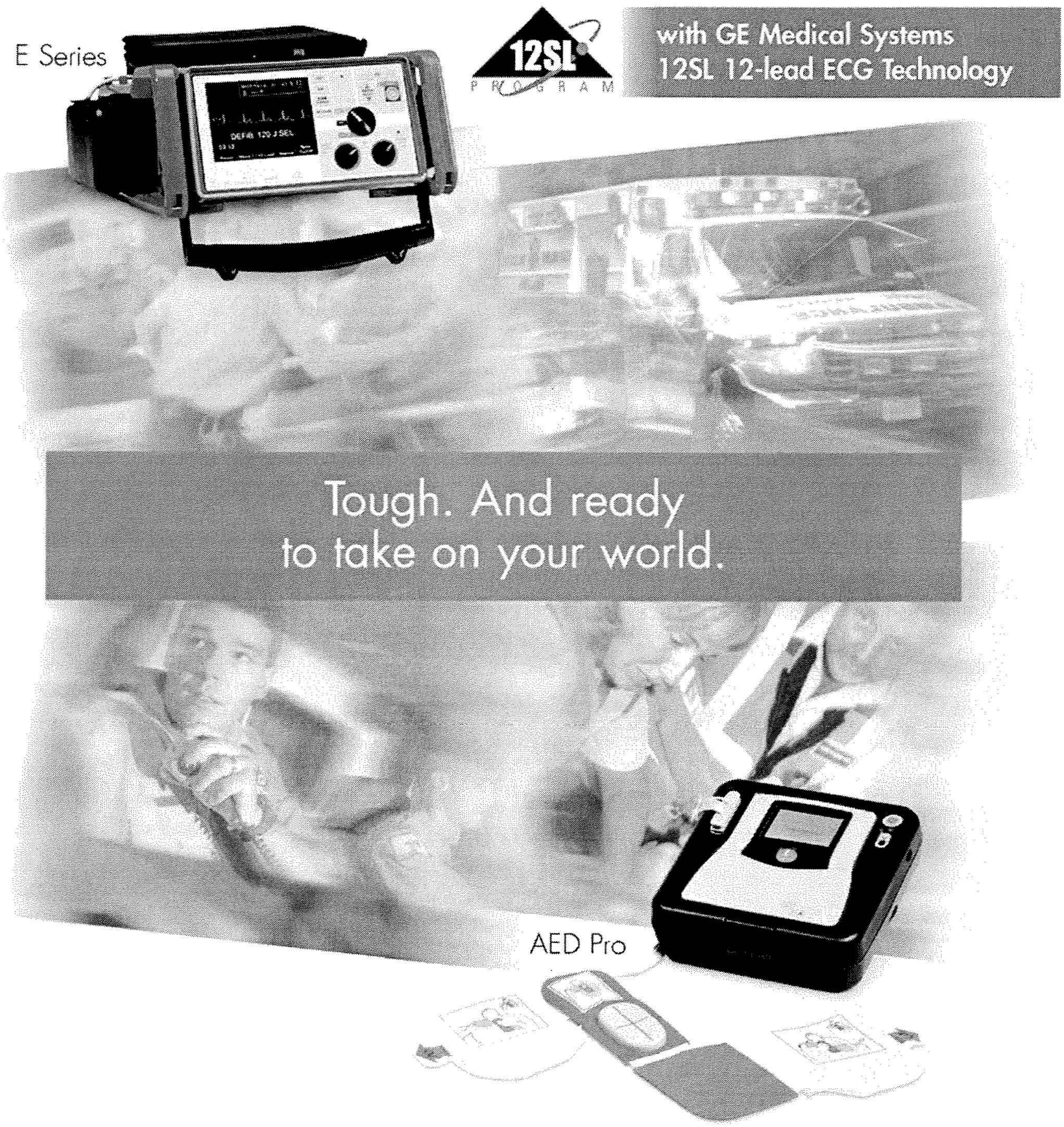

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George Massengale
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Email to: Committee on Health, HLTtestimony@Capitol.hawaii.gov

RE: House Committee on Health, hearing schedule, February 4, 2008, 9:30 A.M., Conference Rm. 329

Representative Josh Green, M.D., Chair & Representative John Mizuno, Vice Chair

RE: HB 2063, Relating to Emergency Medical Services

TESTIMONY IN STRONG SUPPORT

Chair Green, Vice Chair Mizuno, and members of the Committee on Health. I'm here this morning as an individual to offer my testimony in strong support for HB2063. In 1999, I suffered a heart attack which subsequently resulted in a quadruple heart bypass. No doubt I could be a potential consumer of wireless transmission of electrocardiogram data. Also, for the record Dr. Paul Ho is my cardiologist.

I met Paul 3 years ago, when he became involved in with the Coalition for a Tobacco-Free Hawaii's effort to pass our smoke-free law. About two years ago, after being chastised by Paul for putting on weight, he shared with me the concept of wireless transmission of EKG data to cut down on the time it took for individuals to receive appropriate treatment, whether an emergency angioplasty or clot blocking medication. In any case I certainly do understand "time is of the essence" and our current system of not transmitting EKG early or calling a cardiologist until after one has reached the ER is not efficient.

I am also honored that Paul asked for my assistance in making wireless transmission of EKG data a reality. Early on I shared with him my understanding of the legislative process—which I still don't fully understand myself. However, I do understand that proposed bills that a revenue neutral or have an identifiable existing funding stream have a much better chance of gaining passage. I will limit the remainder of my testimony on this issue.

Two years ago, I also had the privilege of working on passing Act 316, the cigarette tax measure to fund the Hawaii Cancer Research Center, and other critical health related programs including emergency medical services. Beginning **September 30, 2007, the Emergency medical services special fund began receiving 0.25 cents on each cigarette sold, although no one has the exact number on how much revenue the 0.25 cents will generate for the period ending October 1, 2008, my estimate is approximately $2 to 2.5 million.** I would suggest that the monies for this pilot come from this revenue stream. Although, I don't know what the exact cost would be for this pilot program, mostly equipment, I would think the cost would be minimal.

In closing I would say that this is a good bill, it will save additional lives, on Oahu for now, and hopefully this pilot program will become statewide. In early January this committee had a legislative briefing of the impact of Hawaii's smoke-free law. Preliminary data presented at that briefing strongly suggested that there has been a substantial drop in heart attack admissions and deaths in Hawaii because of the smoke-free law. Reducing the time it takes to evaluate a MI patient in an emergency situation, can only result in lowering the death rate further.

Thank you for the opportunity to testify before you this morning.

Respectfully,
George Massengale, JD