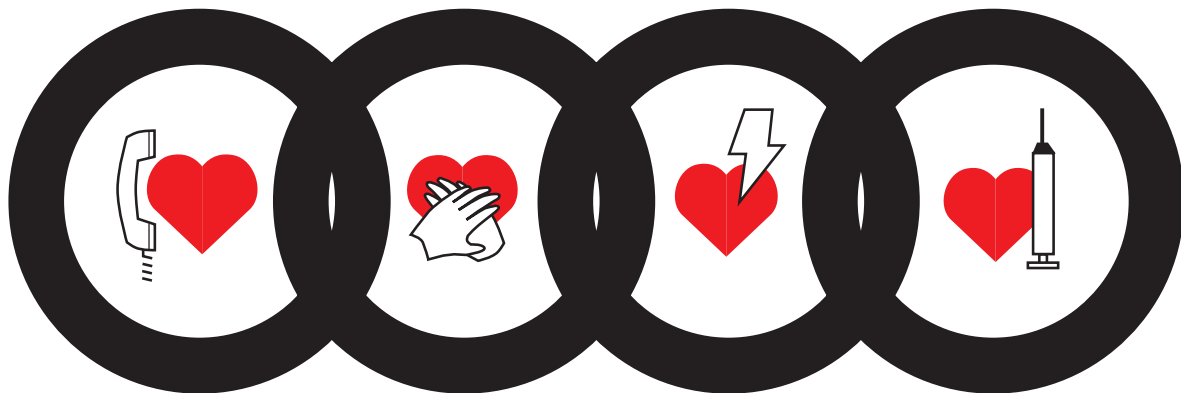




Medtronic
PHYSIO-CONTROL

LIFEPAK® 500
automated external defibrillator

Program Planning and Implementation Guide—EMS



Timely defibrillation is the only effective therapy currently available for cardiac arrest caused by ventricular fibrillation. In June of 1995, the American Heart Association (AHA) Board of Directors approved the following position of the Task Force on Automatic External Defibrillation.

Early bystander CPR and rapid defibrillation are the two major contributors to survival of adult victims of sudden cardiac arrest. The AHA supports efforts to provide prompt defibrillation to victims of cardiac arrest. Automatic external defibrillation is one of the most promising methods for achieving rapid defibrillation.¹

There are many facets in the development of a successful early defibrillation program. Some of the most important factors to consider are: legal issues, financial concerns, data collection, gaining support for the program and program development.

I. Legal Issues

Every EMS system must be sensitive to the legal issues related to their activities. Since local laws, regulations and court decisions vary, it is recommended that specific issues relating to the initiation of an early defibrillation program be reviewed by legal counsel. Proper documentation of initial training, continuing education training, field performance, quality assurance measures and routine equipment checks help to reduce the exposure to litigation.²

Medical directors of early defibrillation programs assume medical control and take responsibility for the performance of emergency care providers. Most medical directors who agree to oversee an EMS program insist upon some type of liability insurance protection.

As with any other medical intervention, a certain level of care establishes the standard by which other systems may be compared. Early defibrillation is becoming the expected standard of care, therefore, it is possible that an EMS system or community could be liable for negligently failing to provide defibrillation.

II. Financial Concerns

One of the biggest obstacles to the initiation of any program is the ability to secure adequate funding. Many factors will influence this process including: the economic vitality of the community, type of funding mechanisms already in place (taxes, public, private, etc.), size of the organization, funds for equipment, existing relationship between the EMS agency and its funding resource (public relations), and the overall perceived priority of the request.

Justification

There is overwhelming evidence that early defibrillation programs save lives. In the United States at least 250,000 people die each year from cardiac arrest. If survival rates from sudden cardiac arrest were increased from 5 percent to 20 percent, up to 40,000 more lives could be saved each year. This is accomplished by strengthening the Chain of Survival at every step, including early defibrillation.³ Many EMS systems have financed defibrillation programs solely on emotional arguments.

If properly informed, it is difficult for a council person or budget committee member to vote against saving human lives. Using population demographics, call volumes for cardiac arrests, and cost of equipment, a projected "cost per life saved" figure can be calculated and compared to other traditional medical procedures.⁴ The benefit/cost ratio is usually very favorable.

Fundraising

Although funding is always an issue for EMS systems, it should not be a deterrent to creating an early defibrillation program. Sources of funding to be considered include:

- *Municipal grants*
Check with city, county and state governmental agencies for funds dedicated to EMS programs.
- *Local corporations and industries*
Send a well-written request to the person in charge of corporate grants describing benefits to the organization and community.
- *Local hospitals and civic organizations*
Rotary, Elks, Eagles, Lions Club, hospital guilds are all active in donations to the community. Many of their members would directly benefit from the enhanced service.
- *Private foundations*
Your public library may be able to help you to determine which specific foundations might be the most appropriate to contact regarding funding.
- *Traditional methods*
Successful fundraising activities used in the past have included bake sales, car washes and pancake breakfasts.

Be creative and persistent—it may require more than one source or proposal to secure adequate funding.

Maintenance and Replacement Costs

When securing initial program start-up funds, be certain to budget for ongoing expenses. These typically include the following:

- *Device maintenance or service agreement*
This is usually arranged with the defibrillator vendor.
- *Disposable items*
Included in this category are disposable defibrillation electrodes.
- *AED replacement cost*
A five year amortized fund can be established to pay for future units.
- *Battery replacement*
Sealed lead-acid batteries used in the LIFEPAK 500 AED have a useful life of about two years; they are rechargeable and have about a 60 shock capacity with each full charge. Lithium batteries for the 500 are essentially maintenance free with a five year shelf life and up to 300 shock capacity.
- *Training costs*
Personnel and instructor reimbursement will be ongoing costs. Training equipment includes rhythm simulator or test load, CPR manikin, training electrodes and LIFEPAK 500T AED Training System.

- *Data retrieval system*

Consider the need for computer, modem, printer and software. Medtronic Physio-Control offers a full range of data management software products.

It may be necessary to initiate your program in phases in order to distribute some of the costs over time, especially in larger systems.

III. Data Collection

The ability to collect and manage data is a vital part of any EMS system, regardless of size. However, information management becomes even more complex in large systems where there are multiple sites inputting data, different types of AEDs, and where there are specific data needs for conducting medical research.

Information management systems can provide the data required to optimize system performance and are essential in the quality control and improvement process. Additionally, information management can contribute significantly to training, system administration and maintenance record keeping.

Modern defibrillators automatically generate a substantial amount of useful data. Device data, serial number, date, times, message prompts, shocks, ECG information, and scene audio may be downloaded into a personal computer for analysis or printed out for review.

Many EMS systems combine defibrillator generated data with other manually entered information that typically includes:

- Age and gender of victim
- Location of arrest
- Time from collapse to call
- Time to initiation of CPR
- Presence of family or bystander CPR
- Time from collapse to shock
- Response times
- Crew member identification
- Victim outcome

The benefits of a properly designed and implemented information management system include:

- Timely feedback on individual performance
- Long-term evaluation of system performance and trends (quantify program success)
- Flexible/customized reporting (isolate or combine data elements)
- Data entry efficiency (avoids multiple data entry processes)
- Justification of budget/program expenditures
- Research (manage large volumes of data more efficiently)
- Create professional appearing reports

There are numerous hardware and software packages available to help you implement an effective information management system. The planning and design steps vary depending on the size of the EMS system, the available technology, and the amount of information to be managed. The ultimate goal, however, is to assist EMS personnel in improving survival rates from cardiac arrest.

IV. Gaining Support for Your Program

Another important determinant of a successful program is the support of program decision-makers, the public and service providers.

Begin by educating yourself on the incidence of cardiac arrest, the chain of survival, laws regulating early defibrillation, costs of equipment, training issues and any other important information that supports the concept of early defibrillation. Next, consider the following activities:

- *Gain public support*
Educate the community through press releases, letters to the editor, radio talk shows; speak to civic organizations, promote the concept of early defibrillation during public CPR classes.
- *Find potential advocates willing to help promote early defibrillation*
This includes local hospitals, physicians and nurses, members of state and local health care associations and committees, legislators, community leaders, police, fire and ambulance associations, Red Cross and AHA members.
- *Identify decision-makers who will support legislation for early defibrillation*
Consider administrators, commissioners, council members, mayors, state and local EMS directors, state health commissioner, legislators and health committee members.
- *Generate enthusiasm among emergency personnel*
Demonstrate the potential for improved survival rates; increased pride, responsibility and job satisfaction; the ease of use, reliability, performance and safety of equipment; and the minimal increase in training required.

Keep in mind that while developing an early defibrillation program, you have the opportunity to promote the entire range of EMS services that your agency provides.

V. Program Development

The primary goal of developing an early defibrillation program is to improve survival from sudden cardiac arrest due to ventricular fibrillation. Although the focus is on early defibrillation, it must be recognized that all links in the chain of survival must be equally strong to obtain the best resuscitation rates.

The steps necessary to meet this goal must include the following:

- Evaluate the existing EMS delivery system to predict the potential benefit from defibrillator placement.
- Identify/appoint a medical director to oversee the development and organization of the program and authorize the use of AEDs.
- Create standing orders for the use of AEDs by response personnel.
- Develop a training program to initially certify response personnel using qualified instructors.
- Provide consistent continuing education training scheduled on a regular basis.
- Monitor program effectiveness and field performance for quality assurance.
- Maintain fully operational equipment in accordance with the manufacturer's recommendations.

Evaluation of the Existing System

Before implementing an early defibrillation program, it is important to evaluate the existing EMS system to identify components which could impede its success. To achieve maximum success, a strong chain of survival must exist.³ Adding early defibrillation may only slightly improve survival rates if existing links in the chain are weak. A victim is more likely to survive when:

- The community knows how and when to access the EMS system
- Cardiac arrest is witnessed and reported
- Early bystander CPR is initiated
- Emergency medical response is quick and can provide early defibrillation
- Advanced life support is provided early

The following can help ensure that your community will benefit most from an early defibrillation program:

- Evaluate public education programs aimed at early recognition and reporting of medical emergencies to a 9-1-1 dispatch center. Without early dispatch, early access is not possible and an early defibrillation program is not likely to succeed in improving survival rates.
- Ensure public CPR training exists and is targeted at populations most likely to witness a cardiac arrest.
- Evaluate staffing and location of first response apparatus (e.g., police, fire and ambulance). The ability to provide rapid response to persons at risk for cardiac arrest with properly trained and equipped personnel must exist.
- Determine if advanced cardiac life support is available to stabilize victims who have been successfully defibrillated. The use of a tiered response system or location of medical facilities that provide ALS services should be considered.
- Evaluate existing cardiac arrest data. Statistical models may be used to predict your community's overall survival rate by adjusting the times to the critical interventions of CPR, defibrillation and advanced care.⁴

Medical Direction, Standing Orders and Authorization

Medical control is key to the success of an early defibrillation program. The medical director will determine the acceptability of the program to the medical community and the quality of care delivered to victims. Although many medical directors have a background in emergency medicine, MDs with a strong interest and knowledge of EMS and early defibrillation can also serve well. Other desired characteristics include motivation, energy, the ability to commit ample time to the program, hard work, honesty and sincerity. It is recommended physician directors undergo advanced life support training and be exposed to the American Heart Association's early defibrillation training program.⁵

The authorizing physician takes responsibility for the performance of the emergency care providers, assuring all aspects of care are performed correctly. The medical director's responsibilities may also include:

- Establishment of standing orders and protocols
- Approval of initial training and continuing education training curriculum
- Case review of field events
- Establishment of mechanisms for quality assurance

The medical director issues standing orders which allow first responding personnel to perform specified tasks (i.e. defibrillation) in the absence of direct contact with a physician. Good standing orders detail the sequence of activities to be accomplished. They also allow latitude for judgment under unusual circumstances as long as overall program goals and objectives are met.⁶

A certification process should be approved which establishes proficiency requirements in the operation of the defibrillator and the ability to follow standing orders. This is accomplished through written and practical skill evaluations.

Upon successful completion of the program's initial AED training, certified responders should receive formal authorization from the medical director to perform defibrillation. The standing orders should specify the circumstances under which defibrillation may be performed and the procedures that responders must follow. It must be clear that these personnel are granted permission to perform defibrillation only under the authority of the medical director's license.

Training

The American Heart Association has recommended that "all BLS personnel professionally responsible to respond to people in cardiac arrest must be trained in, equipped with, and permitted to operate a defibrillator."⁷ "The goal of early defibrillation is now defined specifically as a collapse-to-first shock interval of 3 minutes or less in hospital and 5 minutes or less out of hospital."⁷

The ability to train all levels of first response personnel in the use of AEDs is now feasible due to the intrinsic simplicity of the device. Operation of the LIFEPAK 500 AED requires only a few simple steps (power on, attach device to victim, analyze rhythm, deliver the shock). Learning standing orders and following treatment protocols present the biggest challenge for a training program.

Components of a successful training program include:

- *Instructor training requirements*
The medical program director or designee should provide initial certification for instructors. In large programs, annual instructor workshops improve program consistency and overall quality.
- *Initial training requirements*
This is usually a four hour course of didactic and practical training that emphasizes hands-on skill practice.
- *Continuing education (CE) training*
CE is the foundation for ensuring personnel have the skills to successfully manage a cardiac arrest resuscitation and is essential to maintaining a quality program. Quarterly reviews of the psychomotor skills involved with AED operation in simulated scenarios using a CPR manikin, rhythm simulator, bag valve mask and defibrillator will promote skill proficiency. For some personnel, this may be their only opportunity to use a defibrillator since their initial training session. Both instructor-led and computer-based simulation training have been shown to maintain skill levels in experienced EMT-D trained personnel.⁸

- *Field event documentation*

There are several methods to document field performance. Voice and ECG recording of incidents allow close medical control and legal documentation.⁶ A written incident report by the defibrillator operator should also be generated whenever the unit is used on a victim, whether or not a shock was delivered. Internal digital storage of ECG and voice data facilitates data review and collection, statistics, medical research and system performance monitoring.

- *Quality assurance*

This requires establishment of a system's performance goals, review and feedback. The medical program director or designee should review all cardiac arrest field events. A quality assurance/performance report should be returned to the response team and their training coordinator. Assessment of overall performance and areas needing improvement or training should be noted. Performance trends, protocol review and changes may originate here and can be managed at quarterly review sessions.

- *Record keeping and training documentation*

Records should be maintained for initial training, instructor training, continuing education training, equipment checks and maintenance and field events. Methods should be in place to forward the records to the overall program administrating agency in a timely manner.

Equipment and Maintenance

To help ensure a state of equipment readiness, routine visual inspection (as recommended by the manufacturer) should be performed and documented on a checklist appropriate to the device.

Since depleted batteries are the most common cause of defibrillator failures, a battery maintenance and replacement program based on manufacturer's recommendations should be implemented. Defibrillator clocks should be checked regularly and synchronized with the agency's dispatch center. An accessory equipment inventory (e.g., defibrillation electrodes, batteries, etc.) should be established and maintained.

Routine equipment checks incorporating reviews of protocols and procedures should be encouraged to improve long term skill maintenance and field performance.

Although there are many steps involved in creating and maintaining a successful AED program, the rewards are great and the results can significantly benefit the health and welfare of the community.

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