Public Access of Automated External Defibrillators.  
Fargo Cass Public Health AED Project of The Dakota Medical Foundation.

By

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Abstract

Sudden cardiac arrest (SCD) affects between 200,000 and 400,000 people in the U.S. each year. These statistics indicate that a very serious public health problem is present. The only effective treatment of these conditions is early (within a few minutes) application of defibrillation – an electric shock provided by a specialized device called a defibrillator. However, the presence of only a small number of qualified rescuers equipped with the defibrillator immediately available at the scene of cardiac arrest, significantly limits an effective intervention. To overcome this limitation a portable lifesaving machine was constructed, called an Automated External Defibrillator (AED). The American Heart Association estimates that nearly 20,000 lives can be saved each year through the use of AEDs.

In an effort to disseminate AEDs in communities across the United States and prepare the population for their use, Public Access Defibrillation programs were introduced – starting in 1990s. AEDs were utilized by many segments of the population including police, firefighters, airline crews, and even completely non-trained individuals. The results from several studies observing the effectiveness of the public access defibrillation programs have shown a significant improvement in the survival rate of individuals that suffer from cardiac arrests.

One of these Public Access Defibrillation programs that allocate AEDs to the community is based in Fargo, North Dakota, sponsored by the Dakota Medical Foundation, and coordinated through the Fargo Cass Public Health. Since its inception, the initiative has assisted local communities, by providing funding to place a total of 528 AEDs and associated training required
to operate the AED. Available information indicates that 23 lives have been saved through the use of AEDs from this Program.

In order to assist similar programs throughout the U.S., several state and federal regulations have been enacted – all of which encourage and regulate AEDs use, designate grants, and provide legal immunity for individuals providing emergency public defibrillation treatment.

The allocation of AEDs to locations with the highest risk of sudden cardiac death is the most cost effective method of their use. However placement of these devices in other locations with a smaller rate of SCD is fully justified and supportive due to the specific features of these given locations.

Another important aspect of a successful Public Access Defibrillation initiative is to have leaders and managers in place that provide both a visionary and competent view to the program itself.

The results of many research studies, coupled with the practical experience of the Fargo Cass Public Health AED Program, has shown that Public Access Defibrillation programs utilizing Automated External Defibrillators are critical elements of resuscitation efforts and significantly contribute to a more effective and cost efficient system of health care delivery.

**Introduction**

Sudden cardiac death (SCD) is responsible for approximately 5 to 15 percent of total mortality in industrialized nations and 20 percent of all deaths in the United States [1-3]. These statistics suggest that this is a very significant medical and public health problem [4]. The incidence of
Sudden cardiac death in the U.S. is estimated between 200,000 and 400,000 cases per year [5, 6].

Sudden cardiac death is defined as a natural and unanticipated death associated with the abrupt loss of consciousness less than one hour after the acute symptoms [7]. About two-thirds of sudden cardiac deaths occur outside of the hospital [8]. One study estimated that the occurrence of out-of-hospital cardiac arrest, attended by Emergency Medical Services, is in the range of 36/100,000 and 128/100,000 per year in different communities [9].

Due to this very significant epidemiologic data and the social and public implications associated with unexpected deaths, often people in productive age, the high costs for the economy (cardiovascular disease is estimated to have cost $368 billion in the United States in 2004) multiple strategies have been developed to prevent sudden cardiac death [10]. They include primary prevention such as public education about a heart healthy life style, screening to detect persons at risk, aggressive treatment of risk factors for coronary artery disease such as diabetes, hypertension, hyperlipidemia and smoking cessation. Among secondary preventive measures are implantable defibrillators or anti-arrhythmic medications to treat lethal ventricular arrhythmias.

The final tool in the SCD prevention arsenal is a community intervention strategy with increased public access to automated external defibrillators, public education on their use and basic cardiopulmonary resuscitation education [11].

The importance of electrical defibrillation in treating victims of cardiac arrest is the implication of ventricular tachycardia or ventricular fibrillation as the prevalent pathophysiological
mechanism – constituting up to 85 percent of SCD cases [12]. Survival from sudden cardiac arrest is low – less than 10 percent in the SCD due to any rhythm and 20 percent when the responsible pathophysiologic mechanism is ventricular fibrillation [2, 3, and 13]. The chance of survival decreases by 7 to 10 percent for every one minute delay in defibrillation. After ten minutes the likelihood of survival is bleak. When CPR is provided, the survival rate declines about 3 to 4 percent each minute [14, 15]. However, basic cardiopulmonary resuscitation only is very unlikely to reinstate normal heart rhythm. It is of utmost priority to provide electrical defibrillation as soon as possible, as it is the only effective method of restoring effective circulation to the brain and other vital organs. Even if the patient survives there is a very high risk of anoxic brain injury resulting in persistent vegetative state. Almost all survivors of cardiac arrest who, after this event had intact neurological function, had a ventricular tachycardia as an underlying cause treated which was with electrical defibrillation [16-21].

Despite an advanced system of Emergency Medical Services (EMS) in the United States, very often the time from EMS activation to their arrival is longer than anticipated to effectively treat cardiac arrest, especially in large metropolitan areas (vertical high buildings, heavy traffic, and spread suburbs) or rural communities. Responding to these challenges, the American Heart Association stimulated the development of a defibrillator that could be used in public settings by responders that have minimal training or are even untrained and could still provide earlier effective therapy.

The idea of electrical shock to bring back the native rhythm was first introduced in the 1940s with electrodes placed directly on the heart [22-24]. In the 1950s machines called defibrillators
were developed with the electrical therapy applied through the chest wall [24, 25]. These manual devices must be operated by a person trained in electrocardiogram (ECG) interpretation to recognize which situation requires defibrillation. This requirement of a trained defibrillator operator significantly reduces the availability of this therapy in public places. In order to overcome this barrier the new devices, called automated external defibrillators were constructed. They are able to analyze the victim’s cardiac rhythm and direct the operator when the shock should or should not be applied. Of note, there is a subset of defibrillators called automatic electrical defibrillators which have the capability of both recognizing and delivering the shock. Recently there has been very substantial progress in automated external defibrillators (AED) technology. Modern AEDs weigh between 2 and 4 kilograms (kg) and can cost less than $1000.00 [26]. Several studies showed their effectiveness and benefits (but also limitations) on their use in public access settings [27]. These devices may be operated effectively by non- or minimally trained person [28-32]. On the other hand some studies showed that AED use can be challenging for the layperson [33-35]. Different modes of learning were proposed to improve public AED use skills – face-to-face classes, video and web-based courses [36, 37]. AED operation skills are included in basic CPR classes.

This thesis reviews the results of the studies and current status of public access defibrillators in the United States, and to some extent in other countries. It also describes The Dakota Medical Foundation AED Initiative which provides automated external defibrillators to qualifying locations within the community and encourages the training of volunteers in CPR and AED use. On the basis of the literature review and the experience and results of The Dakota Medical Foundation project this thesis provides advice for AED use in similar type communities.
The Dakota Medical Foundation program is managed through Fargo Cass Public Health, the local public health unit in Fargo, North Dakota. The AED initiative covers Fargo, North Dakota and Moorhead, Minnesota and a radius of 125 miles around these two communities. The literature review and the analysis of the Fargo AED Initiative prove that widespread placement of automated external defibrillators and support for public access defibrillation is “the way to go”. These objectives can be accomplished by increasing federal and state legislation that mandates AED placement in public locations and also provides appropriate funding for such measures. Ultimately these measures can save lives of many otherwise potential pre-matured victims while significantly reducing health-care costs.

**AED concept and development of Public Access Defibrillation**

The first clinical use of an Automated External Defibrillator (AED) was done in 1979. The basic premise is to have accurate analysis of electrocardiograms recorded through defibrillation pads placed by minimally trained or untrained responders. International standards set up the requirements for AEDs to have a sensitivity of more than 90 percent for recognizing ventricular fibrillation and a specificity of at least 95 percent to exclude non-shockable rhythm (this level is comparable to the emergency ECG interpretation by the qualified human responder in the field)[38, 39].

The use of automated external defibrillators includes placement of two self-adhesive pads, in standardized positions, over the victim’s chest which detect rhythm and deliver shock. The energy of the electrical impulse is usually between 120 and 360 Joules, based on the stage of CPR or the waveform used (monophasic or biphasic). AEDs guide the rescuer by audio
commands such as to the placement of the patches, pressing the shock delivery button, and clearing of the victim prior to defibrillation and restarting CPR.

This first trial of AED use showed successful defibrillation from ventricular fibrillation (VF) to sinus rhythm in twenty one sudden cardiac arrest cases [40]. In 1990, the American Heart Association (AHA) established the “Future of CPR” Task Force, which recognized the importance of AEDs in public places:

“The placement of automated external defibrillators (AEDs) in the hands of large number of people trained in their use may be the key intervention to increase survival chances of out-of-hospital cardiac arrest patients... The widespread effectiveness and demonstrated safety for the AED have made it acceptable for nonprofessionals to effectively operate the device. Such persons must still be trained in CPR and use of defibrillators. In the near future, more creative use of AEDs by nonprofessionals may result in improved survival...Participants in the national conference recommended that (1) AEDs be widely available for appropriately trained people, (2) all fire-fighting units that perform CPR and first aid be equipped with and trained to operate AEDs, (3) AEDs be placed in gathering places of more than 10,000 people, and (4) legislation be enacted to allow all EMS personnel to perform early defibrillation”[41].

The concept of public AED use was later augmented through the American Heart Association’s creation of the “AED Task Force” and the addition of the Public Access Defibrillation (PAD) idea to the 1992 AHA Guidelines on CPR [41]. The 1992 Public Access Defibrillation conference was organized in Washington, D.C. Representatives of researchers, clinicians and the AED industry discussed and ultimately agreed on the importance of use and further development of AEDs
and PAD programs. The conference led to the AHA statement on Public Access Defibrillation published in 1995:

“Early bystander cardiopulmonary resuscitation (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. Automated external defibrillation is one of the most promising methods for achieving rapid defibrillation. In public access defibrillation, the technology of defibrillation and training in its use are accessible to the community. The AHA believes that this is the next step in strengthening the chain of survival. Public access defibrillation will involve considerable societal change and will succeed only through the strong efforts of the AHA and others with a commitment to improving emergency cardiac care” [42].

In 1997 there was a second Public Access Conference held at the international level [43]. During this conference the concept of “four levels” of responders was defined: Level 1 – traditional first-responder defibrillation (police, highway patrol, firefighters); Level 2 – non-traditional first-responder defibrillation (lifeguards, security personnel, airline flight attendants); Level 3 – citizen CPR defibrillation (laypeople but after AED training); and Level 4 – minimally trained witness defibrillation (untrained individuals who witness cardiac arrest).

Since their first use the AEDs have undergone significant technological improvements. Currently used devices are portable, small, easy to operate and safe. They have a highly sensitive and specific internal algorithm to detect “shockable” rhythm (ventricular tachycardia
or fibrillation) and differentiate it from conditions not requiring electrical defibrillation like supraventricular arrhythmias or artifacts, in which defibrillation could potentially be harmful.

To guide a lay responder Automated External Defibrillators have voice commands coupled with visual instruction system. Many of the new devices comply with the International Liaison Committee on Resuscitation and the American Heart Association guidelines for CPR [43].

**AED use by first responders**

The four levels of responder groups cited above were selected based on several research studies showing their usefulness and effectiveness. Because police officers are many times first at the scene when a cardiac arrest occurs, even before Emergency Medical Services, this group was targeted in several studies [44-47]. The studies showed a positive impact on cardiac arrest survival rates among patients treated with AEDs by police officers. In White’s study [44] conducted in Rochester, Minnesota from 1990 to 1995 84 patients received defibrillation with an AED. Of the thirty one (or 37%) patients that were initially treated with AED by police, 13 had return of normal circulation and all survived to discharge. In the Miami-Dade County Police AED Program 2400 police officers with AEDs were compared with paramedics and EMS. The survival to discharge was significantly higher in the Police AED Program versus Standard EMS program in the patients with shockable rhythm (17.2% versus 9.0%). In the group of patients with shockable plus non-shockable rhythm a higher survival rate was cited in the Police Program (7.6% versus 6.0%) [48].

Some of the studies revealed less promising results, mainly due to such factors as the efficiency of the control systems, distance traveled in rural areas, lack of medical responder habit,
problems with assuming role of a medical provider, varying medical direction, refresher trainings [49, 50].

A study conducted by Weaver evaluated results from automated external defibrillators used by firefighters [51]. Those results showed a 30% survival rate of sudden cardiac death treated initially by firefighters with CPR and AEDs compared with a 19% survival rate when firefighters used CPR only and defibrillation was provided at a later time by paramedics (odds ratio, 1.8; 95% CI, 1.1-2.9). The average time from call to defibrillation was 3.6 minutes in the firefighters AED-equipped group and 5.1 in the paramedics providing defibrillation group.

**AED allocation in public places**

Due to specific conditions, including emotionally and physically stressful situations, increasing risk of cardiac emergencies, and no access to regular medical services, passenger airplanes are an ideal target for Public Access Defibrillation and AED utilization. The first limited AED program, initiated by Quintas Airlines showed promising data. The results of this program were published in 1997 [52]. A larger American Airline program [53] recorded 36 cardiac arrests during the first two years of the program. Ventricular fibrillation was documented in 13 and presumed in 2 cases. 6 of 15 (40%) patients treated with defibrillation by trained flight attendants survived. This program results led to widespread placement and use of AEDs on passenger airplanes. The first airline to introduce such measures in 1997 was American Airlines. Subsequently, the US Federal Aviation Administration made AEDs mandatory on all United States domestic and international flights originating in the United States.
In addition the aviation industry also investigated the need for public defibrillation access in the airports, due to the high flow of people. The first initiative included O'Hare and Midway airports in Chicago and placed 59 AEDs throughout their terminals in glass-faced cabinets. They were accessible to the public with a retrieval time of less than 3 minutes. Airport security was also trained on AED use. In the first two years of the program 21 cardiac arrest cases occurred, 18 of them in the mechanism of ventricular fibrillation. Eleven patients were successfully defibrillated, and ten out of eleven survivors had no neurological deficits. Among the responders half had no previous training in the use of Automated External Defibrillators [54].

Other locations for effective public defibrillators, similar to the airports (high flow of the people, stressful situations) were casinos. In a program conducted by Valeunzela et al [55] security officers in U.S. casinos were trained to perform CPR and the use an AED. 148 cases of cardiac arrest occurred, with ventricular fibrillation present in 105 patients. The survival rate was 86% and the mean time from collapse to first shock was 4.4 minutes and from collapse to EMS arrival 9.8 minutes.

The results of the aforementioned studies proved the effective and safe use of Public Defibrillation and Automated External Defibrillators provided by trained lay-rescuers in locations with heavy high flow of people under stressful situations. However, such programs require consistent support, maintenance and continuous education of the responders. Those procedures imply additional costs – so it is very important to have very efficient distribution of AEDs.
Community and home AED placement

In more general public places the use and effectiveness of AEDs was also studied. The biggest, and the first randomized trial of AEDs use was the PAD (Public Access Defibrillation) study [56]. The study was conducted in 2002-2003 and sponsored by National Institute of Health. PAD was a multicenter study using 993 community units in 24 regions of the U.S. and Canada and prospective trial which involved 19,000 volunteer responders. In the study arm with CPR plus AED use 23% of cardiac arrests victims survived to hospital discharge compared to only a 14% survival rate in the CPR only arm. However the PAD study had some limitations - the choice of sites for AEDs placed had high number of people over 55 years of age, who are already at higher risk for cardiac arrest due to their age. In addition, there was an unexpected low rate of cardiac arrests in chosen locations. This led to difficulties in providing the recommendations for the optimal public sites for AED distribution. Another confounding factor was that all responders were trained in CPR and AED use, so it is not possible to apply the results to lay responders. Finally, the PAD trial showed very low Public Access Defibrillation success in residential areas. PAD results showed that home AED use survival rate was only 0.6%, compared with 29.9% survival after arrest in public place. With known data that 80% of out-of-hospital cardiac arrests occur at home [57, 58] this implicated a very strong need for further research.

This research was implemented in the Home AED Trial (HAT) [59]. This trial enrolled 7001 patients who suffered anterior wall myocardial infarction (high risk for decreased function of the left ventricle of the heart and associated ventricular tachycardia and fibrillation) but who
were not qualified to receive implantable cardiac defibrillators. These patients had an individual from their home trained in CPR and activation of Emergency Medical Services but half of the patients also received an in-home AED. The HAT study showed no significant difference in the survival rate with home AED use, but it is important to remember that the event of sudden cardiac death at home was significantly lower than expected – only 41% during this trial. The limited effectiveness of AEDs at home may be explained by the fact that many arrests are not witnessed (in contrary to busy public locations). On the other hand in situations when cardiac arrest was witnessed the HAT study confirmed a high rate of survival with AED use – 33%. The lack of survival improvement with AED at home in the HAT study most likely implicated that third party payers do not cover home AEDs. However, for patients with a higher risk of sudden cardiac death (long QT syndrome, arrhythmogenic right ventricle dysplasia, hypertrophic cardiomiopathy, patients after myocardial infarctions with significantly depressed left ventricle systolic function who refuse implantable defibrillator) home AEDs may be the right approach, especially if they live with people that are able to correctly perform defibrillation.

**AED use in the hospitals**

Sudden cardiac death certainly can occur among hospitalized patients, healthcare personnel and hospital visitors. In response to such events the hospital based response team is equipped with manual defibrillators and can provide full resuscitation according to Advanced Cardiac Life Support guidelines. However delayed defibrillation can happen due to many factors including location, time of activation and availability of trained rescuers along with other factors.
To increase the chances of survival from cardiac arrests in hospitals settings, trials with AED placed inside the hospital were performed.

The small studies of Friedman and Gombotz suggested that AED placed in certain clinical and non-clinical areas shortens the time to defibrillation [60, 61]. However the analysis of CPR from 253 U.S. and Canadian hospitals (data obtained from the National Registry of Cardiopulmonary Resuscitation) showed different results. The analysis reviewed 11,695 cases of SCA between 2000 and 2008, with 39 percent of them treated with the use of AED. For patients with ventricular tachycardia or ventricular fibrillation (so called shockable rhythms) there was no statistical difference in survival between AED and manual defibrillator use 38.4 versus 39.8 percent, adjusted RR 1.00, 95% CI 0.88 to 1.13). But more important were data showing that for patients who did not require defibrillation (the underlying rhythm at the time of starting CPR was asystoly or pulseless electrical activity) the survival rate was lower in the group treated with AED comparing to rescuer based ECG interpretation and decision about manual defibrillation (10.4 percent versus 15.4 percent, adjusted RR 0.74, 95% CI 0.65 to 0.83).

A possible explanation for the worse survival among the victims with non shockable rhythm treated with AED is the delayed beginning of other CPR measures such as rescue breathing or chest compressions while waiting for AED interpretation of the underlying rhythm – as it requires “hands off” the patient. In the case of manually operated defibrillators the “hands-off” is not always necessary, also the ECG rhythm interpretation by a skilled rescuer may be faster.

Thus the in hospital AED allocation remains unsettled and may depend on given hospital’s staffing, structural design, and patient profile [62, 63].
Automated External Defibrillators and Public Access Defibrillators Programs outside the USA

Public access defibrillation programs were studied not only in the United States but also in other countries, mainly in Western Europe.

In England in 1999, a program started with 700 AEDs placed in London [64]. The sites for AEDs placement were chosen from ambulance service data showing a high rate of cardiac arrest occurrence - airports, mainline railway stations, ferry terminals, underground railway stations, and bus stations. The majority of cardiac arrests were witnessed (177 out of 182). The recorded first rhythm was ventricular tachycardia or fibrillation in 82%, asystoly (8%), severe bradycardia (7%), and idioventricular rhythm. The survival rate was 29% among ventricular VF/VT patients and 25% overall. The results were similar to data from the USA studies described earlier.

In Piacenza, Italy, and the surrounding area in 2002, a project called Piacenza Progetto Vitto Vita (PPV) was performed [65]. Again, there was a significantly better survival (with no neurological dysfunction) rate in the group with AED use (35%) than in the traditional EMS group (15%).

In Finland, a community-based pilot study [66] was performed with AED placement in seven public locations. During the 3 year study there were 7 events of cardiac arrest in those places, but only 4 were in the ventricular fibrillation mechanism. In the control group (standard EMS approach) there were 13 patients, 6 of them in VF. In the AED group no patient was discharged
from the hospital. In the EMS group 4 were discharged. Due to very small numbers reliable interpretation of this study is impossible.

In the Netherlands the Amsterdam Resuscitation Study (ARREST) proved that the response time was shortest when police were activated [67]. In Australia, an early defibrillation program in two locations was conducted in 2002 [68]. In this study all responders were professionally trained ambulance officers and certified nurses, but in the first half of the study manual defibrillators were used. All 28 cases of cardiac arrest were due to ventricular fibrillation, and 20 patients (71%) were discharged.

There are also Public Access Defibrillation studies taking place in Brazil, on the use of AEDs in commercial aircrafts [69].

**Fargo Cass Public Health AED Project of the Dakota Medical Foundation**

Responding to the sound evidence about Public Access Defibrillation and the safety and efficacy of AEDs, the community of Fargo, North Dakota launched an initiative to place defibrillators in both Fargo and Moorhead, Minnesota. This program also extends to a radius of 125 miles around these two cities.

Beginning in 2001, Fargo Cass Public Health became the fiscal agent for the Dakota Medical Foundation Automated External Defibrillator Initiative, a program that places AEDs in qualifying locations throughout the previously identified region. This initiative is funded by an organization called the Dakota Medical Foundation. The Dakota Medical Foundation initially funded a community-based AED PAD (public access to defibrillation) program in 2000, through
North Dakota State University, a land-grant, research university located in Fargo, North Dakota. That initiative placed 30 AEDs with local middle and high schools and area colleges as well as with local and rural law enforcement. The community response to this initial program was so overwhelmingly supportive that Dakota Medical Foundation recognized a unique need in the Fargo-Moorhead community and beyond: strategic placement of AEDs with law enforcement and EMS groups as well as select public locations defined as having or serving a high-risk population.

An AED Steering Committee was developed in early 2001 and in June, 2001, an AED Program Coordinator was hired at Fargo Cass Public Health, through grant funds provided by Dakota Medical Foundation. Since the first AEDs were placed in 2000, a total of 528 defibrillators are now located throughout not only the Fargo, North Dakota and Moorhead, Minnesota communities, but also within a 125-mile radius outside of these two cities.

Initial funding from the AED Initiative supported not only placement of defibrillators, but also CPR & AED training and certification. Through the course of the AED Initiative, more than 1,500 people have been trained and certified in both CPR and AED use.

The AED Program Coordinator has developed and implemented a tracking system to capture data on AED usage rates and ultimately, the number of ‘saves’. For the AED Initiative, the term ‘save’ indicates a situation where an AED was connected to the patient and subsequently delivered one or more shocks, restoring the hearts’ natural rhythm. Due to health information privacy laws, information on the status of the patient can no longer be gathered after they have been transported to a local healthcare facility. Information gathered since the AED Initiative
began indicates that 23 lives have been saved through use of AEDs distributed with this program.

### AEDs Placed by Year

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<th>Year</th>
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<td>2000</td>
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Total 528

The AED Initiative only awards AED placement to non-profit groups and organizations. Priority is given to law enforcement, fire and ambulance services. A selected number of AEDs are reserved in each grant cycle for public placement, through a 50% cost matching program. This means that a public location (church, community center, and the like) can submit a letter of
request to receive a machine but they must provide approximately 50% of the purchase price of
the device and Dakota Medical Foundation will provide the remaining 50%. In addition,
beginning with the 2009-2010 grant cycles, AEDs were only considered for placement in
communities with a population of less than 15,000 people. That allowed for a more rural focus
on AED placement, given that EMS response times in Fargo-Moorhead are typically 3-5
minutes. The qualifying criteria for rural matching and first responder AED program were
developed by AED Steering Committee and become available in conjunction with a new grant
award to Fargo Cass Public Health (Appendix 1).

Analyzing the placement of AEDs through the AED initiative, one can see that most of the
defibrillators are given to small rural communities where the overall incidence of sudden
cardiac death is low. Most of the studies concerning Public AED use did not address such
locations. However the geography and demography of North Dakota and Minnesota (and
several States with similar population and geography in the U.S.) mandates such placement as
necessary to provide basic health safety for inhabitants of small rural communities.

**Cost-effectiveness of public defibrillation programs and AEDs**

Analyzing the cost-effectiveness ratio of an AED in a given location requires that several factors
need to be considered: (1) the risk of cardiac death occurrence, (2) the EMS response time, and
(3) the demographics and patients population. In order to start immediate CPR and AED use
cardiac arrest must be witnessed and a rescuer able to use public defibrillator must be present.
From the whole population perspective it would seem reasonable to locate multiple AEDs
widely throughout all communities and popularize AED training to a broad group of volunteers.
However cost issues and factors presented above make it more reasonable to target selected locations – where the chance for successful AED use is maximized. The American Heart association recognizes at least one cardiac arrest every two years as a threshold for a reasonable AED location [70]. Conversely to this recommendation AED are allocated in many public places not reaching the AHA threshold. The study from King County, Washington conducted by Becker from 1990 to 1994 public sites with potential cardiac arrests events were stratified into 23 categories. Ten locations categories were estimated in the study to have “high” incidence of sudden cardiac death (but only three of them met the criteria set by the AHA – the international airport, county jail, and a large shopping mall). There were total 172 such sites and 276 AEDs were placed in the “high” risk locations. During the study period 134 cardiac arrests occurred in those locations, 80 (60%) of them due to ventricular fibrillation with the benefit of AED deployment. The survival rate from those incidences was estimated between 10 and 40 percent. Based on the data from the study investigators concluded that between and 8 and 32 lives were probably saved due to public AED use. But the rest of documented cardiac arrests (347) occurred in places without AED. That means that additional 70,000 AEDs would have to be allocated [57]. Based on results from King’s County and other studies (previously discussed PAD and HAT trials) one can see that it is very difficult to define an ideal targets for public defibrillators.

It is true that the benefits of using public defibrillators are relatively easy to state but is more difficult to estimate the real gain in terms of extra life for resuscitated cardiac arrest survivors, in addition discounted by disability. Cram and colleagues estimated that using AED in public places meeting the AHA requirements for the cardiac arrest occurrence, each AED would cost
$30,000.00 per each quality-adjusted life-year (QALY) gained compared to EMS response alone. The AEDs would be even less effective in places of lower cardiac arrest incidence (community and primary care centers, hotels) – the cost is estimated to be more than $200,000.00 per QALY. [71]

Statistical models however only attempt to provide certain estimates but the potential error in those calculations is very significant and the final decision about AED access in the community should also include the financial resources of the community or a whole nation or country. [72]

Every community starting Public Access Defibrillations program must decide which places in the given community have a higher risk of cardiac death occurrence. The only general guideline could be to choose places where cardiac arrests are most likely to occur and the EMS arrival can take more than 5 minutes. In large metropolitan areas such places may be selected as defined by the AHA or King’s County study criteria, in smaller communities with more rural demography pattern these may be churches, shopping centers, city halls, fitness centers, schools. The Fargo Cass AED initiative is an example of such an approach optimally utilizing resources allotted for AEDs and rescuer training.

Legal regulations on public AEDs use

At present there are no standardized criteria for obligatory AED placement. Several state and federal regulations mandate AED availability in certain public use facilities like schools, offices, airports, etc [73, 74].

Congress Acts on AED: [75]
The Aviation Medical Assistance Act, Public Law 105-170, was the first federal law addressing the positive use of AEDs, signed April 24, 1998 by President Clinton. It declares air carriers and individuals “shall not be liable for damages” in attempting to obtain or provide assistance on airplanes. It directs the FAA Administrator to “evaluate regulations” and decide about future required use of AEDs on passenger aircraft and in airports.

On November 13, 2000 President Clinton signed the federal “Cardiac Arrest Survival Act:, in H.R 2498, now Public Law 106-505, regarding the placement of AEDs in federal buildings and providing civil immunity for authorized users. If a Good Samaritan, building owner, or renter acts in good faith to purchase or use an AED to save a life, this law will provide protection from unfair lawsuits. It appropriates $25,000,000 for fiscal years 2001 through 2003 for local grants to purchase AEDs. The federal bill does not preempt state laws on immunity.

In May 2002 President Bush signed into law the Community Access to Emergency Devices Act (Community AED Act) within H.R. 3448 of the Public Health Security and Bioterrorism Response Act. The President signed the bill on June 12, 2002 as Public Law 107-188. The provisions authorize $30 million in federal grants in year one of the five-year measure. The grants, to be made available to applying states and localities would be used for the purchase and placement of AEDs in public places where cardiac arrests are likely to occur. Grant funds would also be used to train first responders to administer immediate life-saving care, including AED use and CPR. The bill also encourages private companies to purchase AEDs and to train employees in CPR and emergency defibrillation.
Similar legal regulations were behind the nationwide public access defibrillation program in Japan [76]. At the state level in the last six years State Legislators have become more active in regard to AED and public defibrillation.[75] There were several new bills enacted – mainly concentrating on one the following: (1) Establishing legislative intent that an AED may be used by any person for the purpose of saving the life of another person in cardiac arrest; (2) Encouraging or requiring training in the use of AED devices by potential users; (3) Requiring AED devices to be maintained and tested to manufacturer’s standards; (3) Creating a registry of the location of all such defibrillators, or notification of a local emergency medical authority; (4) Allowing a “Good Samaritan” exemption from liability for any individual who renders emergency treatment with a defibrillator; and (5) Authorizing a state agency to establish more detailed requirements for training and registration.

There are a few examples of the recent State Laws:

In 2003, Utah updated its AED law by establishing a statewide registry; while Virginia updated laws by deleting the requirements for registration. Alabama, Alaska, Colorado, Connecticut, Indiana, Kansas, Nebraska, Nevada, Tennessee and Texas also changed or expanded their AED laws.

In 2004, AED laws were changed or expanded in Connecticut, Florida, Hawaii, Idaho, Illinois, Louisiana, Maine, Michigan, Missouri, New York, Ohio, Oklahoma and Rhode Island. The Illinois law (H.4232) requires every physical fitness facility to have at least one AED on premises.

In 2005-06, Maryland added a requirement that every high school and school-sponsored athletic events have an AED available. California required health clubs to have at least one AED.
Florida authorized state and local police vehicles to carry an AED. Indiana and Virginia repealed filing and training requirements. New York required places of public assembly to maintain an AED. Oregon updated Good Samaritan protection for trained AED providers, employers, property-owners and sponsoring agencies. Arizona, Colorado, Florida, Illinois, Maryland, Massachusetts, Nebraska, New Jersey, Pennsylvania, and Wisconsin also enacted AED laws.

In 2007, Texas added a requirement for AEDs not approved for over-the-counter sales.

In 2008, laws were enacted in Georgia, Idaho, Illinois, Indiana, Iowa, Massachusetts, New Hampshire, New York, South Carolina, Tennessee, West Virginia, Wisconsin and the District of Columbia.

In 2009, Illinois added dentist offices; Kansas and North Carolina expanded access by allowing “any person” to use an AED.

In 2010, recently Arizona, Idaho, Maryland, Missouri and Oregon enacted laws to assure that program facilitators, individuals, businesses and entities that place AEDs are afforded appropriate immunity. Maryland and Missouri’s new laws also guarantee protections to lay rescuers who in “good faith” use an AED when working to save someone from sudden cardiac arrest. Iowa and Wisconsin require all high schools students to be offered life-saving CPR training. Arkansas secured $300,000.00 to fund a Medical Emergency Response Planning in Schools program to assure that the AEDs are placed appropriately and school staff is trained properly.
As in every aspect of life a very important part is a legal safety. In regard to AED, the law and legal requirements not only regulate the technical standards of defibrillators and mandate public defibrillators in certain locations, but also provide protection, from lawsuits, to rescuers. A very important document is, cited previously, the Cardiac Arrest Survival Act, signed by President Clinton on November 13, 2000. This act, now Public Law 106-505, in addition to requiring federal buildings to place an AED also provides civil immunity to rescuers using public defibrillators. State legislatures, in all 50 States have also, passed similar acts granting limited immunity for AED use [74].

It is important to keep in mind that the legal duty of AED presence and proper personnel training may be required from certain groups or businesses such as airlines, cab companies, passenger railroads and cruise ship operators, and hotel/motel operators [77].

**Continuous education and up-to-date standards**

Besides supplying public defibrillators a very important part of increasing sudden cardiac death survival is overall basic and advanced CPR knowledge and skills. This is outlined in several publications on CPR and public AED use. [77-80] General information on public AED use is available on several websites [Appendix 2]. This information helps to disseminate the idea and knowledge of early defibrillation among many potential lay rescuers. The Fargo project follows these guidelines by providing support for AED placement and requiring CPR training. The best example of the importance of CPR and AED courses to the broad public is the study by Gundy comparing the naive sixth grade children with trained professionals in the use of an automated
external defibrillator. The children performed very well, and in some cases even better than the professionals [81].

The very recent study from the Netherlands investigated attitudes and understanding about AEDs among the public. It was a cross-sectional survey of 1018 adults, from 38 countries, traveling through the Central Railway Station in Amsterdam, the Netherlands. Participants were asked open-ended questions about AEDs. Answering the question about what to do first when approaching a victim of cardiac arrest, only 6% of responders mentioned defibrillator or AED. Responding to further questions only 64% knew what a defibrillator is used for, and 43% knew that defibrillators were available for public access. Asked about willingness to use AED only 47% said they would be willing to use one [82]. The above mentioned study shows how much more needs to be done for public education and more effective AED utilization

Staying up to date in the field of cardiac resuscitation requires following CPR guidelines, as published periodically in new versions by the American Heart Association, not only by the lay and trained rescuers but also manufacturers of the medical equipment. An example of the AHA postulated change to CPR and AED and its introduction by the industry is the requirements for the AED program to deliver a one-shock protocol and have voice prompts. The newest edition of the Advanced Cardiovascular Life Support Manual, published in 2010 contains the whole section on Public AED use [83].

**Essentials of a Quality Public Access Defibrillation Program**

During the process of starting an AED allocation program it is very important to apply several Public Health management and leadership rules, including: (1) Establishing an AED task force;
(2) Reviewing laws, regulations and advisories; (3) Conducting a needs assessment; (4) Cultivating and creating public awareness; (5) Estimating program costs; (6) Seeking funding; (7) Establishing medical oversight; (8) Selecting the appropriate device; (9) Conducting training; and (10) Developing an adequate response plan [84]. The Dakota Medical Foundation AED Initiative fully meets all of these criteria in its AED allocation Program.

At the receiving end, businesses, groups or locations with AEDs also bear several responsibilities, namely: (1) Establishing program leadership; (2) Reviewing laws and regulations; (3) Conducting a site assessment; (4) Developing an adequate response plan; (5) Developing a program budget; (6) Selecting the appropriate device; (7) Conducting training; (8) Device installation; (9) Providing awareness and education; and (10) Providing continuous evaluation [84]. The Dakota Medical Foundation AED qualifying criteria, as set by the AED Steering Committee, guides local communities in this regard [Appendix 1].

For every Public Health program to be effective and successful it is crucial to have strong and competent leaders at its helm. The leader of such an initiative must be someone who is passionate and dedicated to the program, preferably a person already in a leadership position within the organization. Such a devoted leader, not only assures that the resources and tasks are correctly assigned, but also motivates other team members to be adequate contributors on the team [84].

Generally, the most accepted characteristics, that a visionary leader displays, is the ability to have a broad general knowledge on the organization at hand, the capacity to look into the future (also known as visioning), the aptitude to maintain an element of respect for the past,
the possession of both fortitude and flexibility - which are both necessary to transform vision into action. In addition, a visionary leader must have the talent to work well with others and to accept someone else as a leader if necessary. Another very important aspect of public health leadership is an inherent commitment to the community and its values, while at the same time the distinct ability to keep the delicate balance between social justice and public health agenda. At the very least, public health leaders must be able to fulfil their mission of “society’s interest in assuring the conditions in which people can be healthy.” This task can be accomplished by performing the core functions of public health: assessment, policy development and assurance [85]. One must also keep in mind that leadership is not only attributed to a single individual; rather, leadership also encompasses a certain skill set and competencies associated with that set of skills. With regards to public health practice, these skills include analytical and assessment competencies, policy and program competencies, communication competencies, cultural competencies, community practice competencies, management and leadership competencies. [86]

All of the aforementioned leadership ideas can also be applied to the development and maintenance of a quality public access defibrillator program as well. Medical directorship, for example, provides an individual with the ability to oversee medical aspects of AED use, such as prescription for chosen AED, checklists for expiration dates, battery-life status, and equipment requirements. Another equally important person that ensures the success of the AED initiative is the program coordinator. The coordinator handles most of the work in terms of coordination, administrative functions, and providing advice and needs assessment for local communities. At the community level, a designated person, often called an on-site coordinator, is necessary in
order to be responsible for the AED and Standard Operating Guidelines. The on-site coordinator also serves as a liaison between the community and the program coordinator. The Standard Operating Guidelines also serve as another important element of the Public Access Defibrillation program. This instruction manual binds together all of the elements of the AED program. The Standard Operating Guidelines serve as an outline for both the program coordinator and the on-site coordinator [84].

Finally, another critical element of the AED program is the process of incident follow up. Records of the event, including the date and time, location, CPR timing, AED use time, any problems associated with the AED itself, EMS notification, and any other important information should be available to the appropriate medical personnel. The information stored in the AED memory should be downloaded and forwarded as soon as possible to the medical facility in order to ensure its availability for provider that is responsible for taking care of the patient. The same information should also be sent to the program coordinator and medical director, as they will use for quality assurance purposes and to provide feedback to the community site [87].

**Summary**

Sudden cardiac arrest (SCD) affects between 200,000 and 400,000 people in the U.S. every year. These statistics indicate that a very serious public health problem is present. Survival rate is low, usually estimated at less than 10% for cases occurring outside the hospital. The underlying pathophysiologic cardiac disturbance in the majority of cases is ventricular tachycardia or ventricular fibrillation. The only effective treatment of these conditions is early (within few
minutes) application of defibrillation – an electric shock provided by a specialized device called a defibrillator. Initially only manually operated defibrillators were used – which require a qualified rescuer to analyze ECG rhythm, make a decision about the need for defibrillation (not all cases of SCD are treated this way) and then apply the shock. Only a small number of qualified rescuers equipped with the defibrillator are immediately available at the scene when an instance of cardiac arrest occurs, which significantly limits an effective intervention. To overcome this limitation a portable lifesaving machine was constructed, called the Automated External Defibrillator (AED). AEDs can analyze cardiac rhythms and prompt the rescuer (even untrained or minimally trained rescuers) on how to assess whether a shock is indicated and how to apply it. The American Heart Association estimates that approximately 20,000 lives can be saved each year through the use of AEDs.

Public access Defibrillation programs were introduced in an effort to disseminate AEDs in communities across the United States and prepare the population for their effective use. The utilization of AEDs in such programs was undertaken by police, firefighters, airline crew, even completely untrained individuals. Several studies have shown that AED use by this portion of the population has led to a significant improvement in the survival rates of the individuals that suffer from cardiac arrests.

One Public Access Defibrillation program is based in the community of Fargo, North Dakota, provided through the Dakota Medical Foundation. The Program, coordinated through Fargo Cass Public Health, started operating in 2001. Since that time, the program assisted local communities with the appropriate funding for a total of 528 portable AEDs and associated
training provided. Available information indicates that 23 lives have been saved through the use of AEDs from this Program.

To assist similar programs throughout the U.S. several state and federal regulations have been enacted – which encourage and regulate AEDs use, designate grants and provide legal immunity for individuals providing emergency public defibrillation treatment.

Over time, it has been proven that the allocation of AEDs to places with the highest risk of sudden cardiac death, such as casinos, large shopping centers and international airports is the most cost effective method. However placement of these devices in other locations (of smaller SCD incidence) is fully justified and supportive due to the specific features of given locations. More specifically, airplanes have no access to regular emergency medical help and small rural communities frequently experience long waiting time for EMS arrival.

A very important aspect of a Public Access Defibrillation initiative is visionary and competent leadership and management. In order to facilitate success for such an initiative a few key positions are required, namely medical director, program coordinator and on-site coordinators.

The results of many research studies and the practical experience of the Fargo Cass Public Health AED Program show that Public Access Defibrillation programs utilizing Automated External Defibrillators are critical element of resuscitation efforts and significantly contribute to a more effective and cost efficient health care delivery system.

Appendix 1:

Application Information for Criteria, Deadline and Guidelines
I. **Qualifying Criteria**
Below is a list of criteria developed by the AED Initiative Steering Committee to determine placement of AEDs through the “Rural AED Match Initiative.”

1. Interested party must present a non-profit status.
2. Interested party must be located within 75 miles from Fargo, ND and/or Moorhead, MN. **Population must be less than 15,000.**
3. Interested party must agree to uphold the financial commitments as they pertain to the Matching Funds program. The financial commitments include but are not limited to: 1) Payment in the amount of **$827.50 per AED.** [50% of the purchase price] 2) Battery and patch replacement and 3) Future volunteer CPR & AED certification.
4. Interested party must agree to present match payment for AEDs within 60 days of award notice from AED Initiative Steering Committee. Failure to agree to and comply with this stipulation will result in forfeiture of the AED.
5. Interested party must agree to place AED in a geographic location so that EMS response time is within fifteen (15) minutes.
6. Interested party must present evidence of easy access to the AED and that any victim can be reached in three (3) minutes.
7. Interested party must provide information on AEDs already placed in their community with the following groups: law enforcement, fire, ambulance, first responders, quick response units, schools, churches, etc. Evidence of AED placement will not disqualify applicant. Rather, this information will be used to aid the AED Steering Committee in determining the best possible placement for these resources.
8. The community or population served needs to be defined as high-risk. A high-risk site would have a majority of the population served age 50 or over. Additional factors to consider would be previous cardiac arrest events, smoke-free status, etc.
9. Interested party must present evidence of volunteers who are both willing to receive CPR & AED training and able to respond to a cardiac emergency, if needed.

II. **Application Deadline**
Applications must be received by **February 9, 2010.** Applications may be sent two ways:

1. Via e-mail to: hscott@cityoffargo.com
2. Regular mail to: Fargo Cass Public Health, Attn: Holly Scott, 401 3rd Avenue North, Fargo, ND 58102

III. **Application Guidelines**
Applications may be submitted in a letter format, including all outlined items above. Additional items to include may be schedules of events or classes held at your location or any additional information deemed necessary and helpful in the selection process.

**Contact Information:** Holly Scott, AED Coordinator, 701-241-8576.

**2010 Rural First Responder AED Initiative:**
Application Information for Criteria, Deadline and Guidelines

IV. Qualifying Criteria
Below is a list of criteria developed by the AED Initiative Steering Committee to determine placement of AEDs through the “Rural First Responder AED Initiative.”

10. Interested party must present a non-profit status.
11. Interested party must be located within 75 miles from Fargo, ND and/or Moorhead, MN. Population must be less than 15,000.
12. Interested party must agree to uphold the financial commitments as they pertain to the Matching Funds program. The financial commitments include but are not limited to battery and patch replacement and future volunteer CPR & AED certification.
13. Interested party must agree to place AED in a geographic location so that EMS response time is within fifteen (15) minutes.
14. Interested party must present evidence of easy access to the AED and that any victim can be reached in three (3) minutes.
15. Interested party must provide information on AEDs already placed in their community with the following groups: law enforcement, fire, ambulance, first responders, quick response units, schools, churches, etc. Evidence of AED placement will not disqualify applicant. Rather, this information will be used to aid the AED Steering Committee in determining the best possible placement for these resources.
16. The community or population served needs to be defined as high-risk. A high-risk site would have a majority of the population served age 50 or over. Additional factors to consider would be previous cardiac arrest events, smoke-free status, etc.
17. Interested party must present evidence of volunteers who are both willing to receive CPR & AED training and able to respond to a cardiac emergency, if needed.

V. Application Deadline
Applications must be received by February 9, 2010. Applications may be sent two ways:
3. Via e-mail to: hscott@cityoffargo.com
4. Regular mail to: Fargo Cass Public Health, Attn: Holly Scott, 401 3rd Avenue North, Fargo, ND 58102

VI. Application Guidelines
Applications may be submitted in a letter format, including all outlined items above. Additional items to include may be schedules of events or classes held at your location or any additional information deemed necessary and helpful in the selection process.

VII. Contact Information: Holly Scott, AED Coordinator, 701-241-8576
Appendix 2:

www.ILSF.com (Initial Life Support Foundation)

www.medicfirstaid.com (Medic First Aid)

www.aedusa.com (AED USA)

www.emsaonline.com (Emergency Medical Authority EMSA)

www.paracademy.com (CyberCME)

www.early-defib.org (National Center for Early Defibrillation)

www.americanheart.org (American Heart Association)

www.aedemeddirect.co (AED Med Direct, Inc)

www.nscl.org/progrsams/health.aed.htm (State-by-state policy analysis)

www.americanheart.org/statepolicy (Model AED legislation, AED Policy Toolkit)

http://www.americanheart.org/presenter.jhtml?identifier=3011859#training (AED programs Q&A)

http://www.americanheart.org/presenter.jhtml?identifier=3027304 (AED program implementation resources)

www.learncpr.org (Learn CPR)

www.learnAED (Learn AED)

www.survivecardiacarrest.org (Survive cardiac Arrest)
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