ESC-ERC Recommendations for the Use of Automated External Defibrillators (AEDs) in Europe

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Supplement 1

1. Strategies for community defibrillation with AEDs

In order to meet the goal of rapid access to defibrillation it is important that the right strategy is designed in order to achieve the best compromise between the widespread distribution of Automated External Defibrillators (AEDs) and economical feasibility. AED programmes may be designed within the EMS thus involving professional responders who are employed to provide aid for medical emergencies. AED programmes may also be targeted to individuals acting outside the Emergency Medical Service (EMS). The individuals acting in each environment may differ depending on their country of origin: for example the police force and the fire fighters may fall under different categories (within EMS and outside EMS) because the role of the two professional categories is not uniform in all countries.

It is highly recommended that the most suitable model should be identified for each specific environment: data collected from local ambulances providing the incidence of sudden cardiac death and their location may help tailor the most suitable system for each environment.

1.1. AED programmes within the EMS

Defibrillation programmes within the EMS were the first to be implemented based on the evidence that first on scene rescue teams provided Cardiopulmonary Resuscitation (CPR) to cardiac arrest victims but they were either not capable or not allowed to defibrillate.

The early studies demonstrating that defibrillation performed by first arriving basic rescue personnel is feasible and that it saves lives even when still conducted with manual defibrillators (1-3). With the introduction of the AEDs (4,5) several projects were initiated in many European countries even if legal barriers had to be removed before defibrillation could be performed by non medically trained individuals. Although the ILCOR International 2000 resuscitation guidelines recommend that a defibrillator (casu quo an AED) and properly trained personnel should be placed in every vehicle that may transport a patient at risk of cardiac arrest, there are still areas in Europe where this goal has not been achieved. There are several reasons for the delay in the implementation of these recommendations including lack of financial resources, legal constraints and also reluctance to accept a novel approach to resuscitation.

1.2. AED programmes outside the EMS

We have identified three main strategies for the implementation of defibrillation programmes outside the EMS and designed to decrease time from collapse to defibrillation: (1) community programmes, (2) onsite programmes, (3) home programmes.

Is it currently unclear which strategy is most cost-effective, because all three strategies have different and often opposite characteristics (Table I).

Location: It is well known that most victims of out-of-hospital cardiac arrest collapse at home (6). Ideally these victims are defibrillated by a system of home responders (the fastest strategy), or by a system of community responders (a slower strategy). The strategy of home defibrillation is not new but it has never been thoroughly evaluated and needs further investigation. In contrast, on-site programmes will only reach a fraction of the total number of cardiac arrest victims.

Time intervals: "*Community responders*" use dispatched volunteer rescuers, which per definition are not present at the time of collapse and therefore more time will pass before they arrive at the victim's side. *On site schemes* have the potential to dramatically reduce the time between collapse and defibrillation, on condition that the collapse is witnessed and that on site responders are alerted immediately. If the on-site defibrillator is accessible to the general public, an occasional bystander can use the AED before the arrival of the on-site responders (bystander defibrillation). *Home responders* may provide immediate defibrillation, but psychological barriers may delay treatment.

Training level: *Community responder schemes* require training of volunteers with a duty to respond. In *on-site schemes*, defibrillation is performed by an on-site responder or even a bystander. The latter may gradually become very important because more data are published that even untrained occasional rescuers may successfully use current generation AEDs.

It is highly recommended that careful examination of epidemiological data on cardiac arrests precedes the initiation of AED deployment projects. However, several studies have shown that cardiac arrests do not occur in geographical clusters but rather dispersedly (7). Moreover studies predicting survival benefit after implementation of on-site or community responder schemes have been criticized because they may not reliably simulate reality and therefore underestimate potential benefits. The problem is that the time of collapse is often unknown in cardiac arrest registries; therefore, the potential reduction in time from collapse to defibrillation with on-site defibrillation cannot be reliably calculated.

The most suitable model should be identified for each specific environment: data collected from local ambulances providing the incidence of sudden cardiac death and their location may help tailor the most suitable system for each environment. Analysis of the literature is a very important step (8,9) in order to collect basic information on the clinical and economical efficacy of the different strategies for the use of AEDs in the community. One limitation of this exercise is given by the inconsistencies in the definitions and the reporting of outcome that hamper the possibility of comparing results: it is recommended that in the future the use of common standards is adopted to facilitate the integration of data from different studies (10,11).

2. Critical appraisal of the literature on the use of AEDs

The need for out of hospital defibrillation and the concept of training non-medical personnel to defibrillate were initially elaborated in the late sixties when several groups concurred to the development of this concept (12). Among others, the Irish Heart Foundation performed a pivotal work that was initiated in 1967 (13): two private ambulances in Dublin were equipped with defibrillators and the ambulance staff was trained to use them. Over a three and a half-year period 20 patients who suffered a cardiac arrest were successfully defibrillated by ambulance staff. A little later in Europe (1,2,14) and the United States (5,15) successful studies were performed that demonstrated the feasibility of the approach. In the early eighties AEDs became available and prompted a rapid development in the fields: the first reported clinical use of an AED was published as early as 1982 by Jaggarao et al (4,16)

Since these pioneering times, early defibrillation with AEDs has been evaluated in a number of different environmental settings, including hospitals, local urban communities, airplanes, casinos, and private homes. They have used different types of “shock providers” including non-trained or minimally trained subjects (fire-fighters, flights attendances, police officers and security guards) (5,17-25). The majority of trials concur to document the value of this approach including a recent, large scale study, that added important information on long term outcome and quality of life of individuals resuscitated from cardiac arrest demonstrating that after discharge from hospital, cardiac arrest survivors have similar survival rate and quality of life similar to that of an age-matched population (26). In the following sections and in tables IIA and IIB we will review some of the published data concerning the use of AEDs in different settings. We do not intend to review all studies but to provide an overview of the status of development of the field and the different approaches used to improve survival form cardiac arrest in the community.

2.1 AED programmes within the EMS

Defibrillation programmes within the EMS were the first to be implemented based on the evidence that rescue teams provided CPR to cardiac arrest victims but they were either not capable or not allowed to defibrillate.

The early studies that demonstrated that defibrillation performed by first arriving basic rescue personnel is feasible and saved lives were still conducted with manual defibrillators (1-3). With the introduction of the AEDs (4,5) several projects were initiated and based on the positive outcome of AED programmes initiated in many European countries, even if in some countries (e.g. in France and Italy) legal barriers had to be removed before defibrillation could be performed by non medically trained individuals. Although the ILCOR International 2000 resuscitation guidelines recommend that an AED and properly trained personnel should be placed in every vehicle that may transport a patient at risk of cardiac arrest, there are still areas in Europe where this goal has not yet been achieved. There are several reasons for the delay in the implementation of these recommendations including lack of financial resources, legal constraints and also reluctance to accept a novel approach to resuscitation.

In- hospital programmes

The vast majority of cardiac arrests occur in the out-of-hospital setting and this may be the reason why early in-hospital defibrillation has been less extensively investigated (25). However, especially in larger hospitals where high risk subjects are likely to be present, the time to defibrillation may be inadequate if the patient has to be reached by an emergency team before receiving the first shock. For these reasons it seems reasonable to advocate deployment of AEDs at various locations within hospitals (wards, hospital lobbies, cafeterias, parking lots) and training of all medical and non-medical personnel working within the hospital to defibrillate and perform CPR. When assessing the need for AED programmes within the hospital it is appropriate to consider also that delayed access to defibrillation in the hospital setting may have medico-legal implications. Unfortunately at present large studies evaluating the survival benefit of deployment of AEDs in hospitals are not yet available. Preliminary data on survival before and after the implementation of an in-hospital early defibrillation program (AED deployment and staff training), showed an improvement of survival to discharge (27). Thus, strengthening the in-hospital chain of survival with rapid defibrillation by first responders using AEDs seems to be a crucial goal. Automated external defibrillation training should be incorporated into BLS programmes for all hospital personnel expected to respond to a patient with cardiac arrest (28).

2.2 AED programmes outside the EMS

Community programmes

The development of reliable arrhythmia detection algorithms and user friendly devices, as well as devices equipped with voice-messages that can guide the user to follow resuscitation guidelines has promoted the development of defibrillation programmes based on the involvement of minimally trained or even untrained rescuers (bystander defibrillation).

The initial programmes on the use of AEDs outside the EMS involved community responders such as police officers and fire-fighters (5,20,24,29). More recently data have become available from studies based on on-site schemes in which AEDs have been placed in strategic locations such as airports (30,31) and casinos (25) – or a hybrid approach with on-site AED locations plus involvement of community responders.

Several studies suggest that a tiered response system (e.g. with police officers using AEDs to support the traditional EMS) increases survival rates even if it reduces the time-to shock only by one or two minutes (21), however this is not consistently confirmed by other studies (32). Overall survival rates in the various studies vary from <3% to >50% and time to shock is remarkably different among studies, ranging approximately from 2 to 11 minutes. Best survival rates are usually obtained among those patients in whom the restoration of spontaneous circulation is obtained by defibrillation only without requiring ALS (20,21).

On-site programmes

In seeking a reduction of time from onset of ventricular fibrillation to defibrillation, deployment of AEDs in public places is very attractive. Two large-scale observational studies involving airlines have been carried out, one involving the deployment of AEDs both on board of larger international flights and in major airport terminals (33) and the second in which the experience was restricted to airplanes only (31). Both studies reported remarkable results for treatment of witnessed VF with >55% survival, and confirmed that time-to-shock is a major determinant of success. However, the studies also revealed a high incidence of unwitnessed cardiac arrests and non-shockable rhythms (33) (tables II A and II B).

The survival rate from witnessed and unwitnessed cardiac arrests was also evaluated in an observational study performed in casinos (25). Among subjects in whom VF was the initial recorded rhythm there was an overall 53% survival to hospital discharge, but survival was 74% for those patients who had a witnessed event and received the first shock ≤ 3 minutes from collapse. The program in Chicago O'Hare airport is another extremely interesting on-site programme that provided encouraging short and long-term results (30).

Home programmes

The vast majority of out of hospital cardiac arrests occur at home (6,34), prompting the need for a careful assessment of the possible positive impact of AED deployment at the patient's home. Several categories of patients could potentially benefit from in-home AEDs e.g. high risk post AMI patients when an ICD is not indicated (35) or not available, patients enlisted for heart transplant and patients/families with inherited arrhythmogenic diseases.

Initial experiences with home use of AEDs in small groups of patients showed no benefit (36), while more recently Snyder et al. (37) provided more encouraging data. Among 8 patients treated by AED shocks, 6 patients (75%) survived.

These data support the concept that AED deployment at home or offices may save lives, but further confirmations are still needed to prove or dismiss this hypothesis.

Psychological issues are among the major concerns for a large deployment of AEDs at home for the high-risk individuals. Indeed, at least some of the published evidences show that failure to apply BLS by family members or other lay bystanders may be due to the anxiety feelings related to the personal performance (38).

3. Cost-effectiveness

Few clinical studies have been specifically designed to address this issue (39) and at the present time only rough estimates of cost may be drawn. In the OPALS study a cost of 46,900 US$ per life saved for establishing the early defibrillation program and 2,400 US$ per life saved annually for maintaining the programme was calculated (40). In the study by Capucci et al., costs were 270,000 US$ to acquire 39 AEDs and train 1285 volunteers over a period of 22 months of observation in a medium sized community (41).

Forrer et al. retrospectively estimated the cost effectiveness of a 7-year police programme in four suburban communities (42). The estimated cost per life saved as a result of decreasing time to first shock with the P-AED program was 70,342 USD with the estimated cost/year of life saved of 16,060 US$.

Cost-effectiveness of early defibrillation in public places was evaluated by Groeneveld et al. who analyzed by simulations the costs associated with airlines programmes (43). This study carried out differential cost-effectiveness analysis for a strategy of full deployment on all aircrafts as well as strategies of partial deployment only on larger aircrafts. The data analysis showed that adding AEDs on passenger aircrafts with more than 200 passengers would cost 35,300 US$ per quality-adjusted life-year (QALY) gained. On aircrafts with capacities between 100 and 200 persons it would cost an additional 40,800 US$ per added QALY, and full deployment on all passenger **aircrafts** would cost 94,700 US$ per QALY. The conclusion of that study were that the cost-effectiveness of placing AEDs on commercial aircraft compares favourably with the cost-effectiveness of widely accepted medical interventions but this was more evident with deployment on large planes.

Nichols et al. provided additional data by performing metanalysis of published clinical trials. (44,45). Public access defibrillation by community responders was associated with a median cost of 44,000 US$ per additional quality-adjusted life year (QALY), while programmes involving the police force had a cost of 27,000 US$ per QALY. In casinos (45), standard EMS was associated with a median cost of 24,800 US$ per cardiac arrest, and early defibrillation by security guards was associated with an incremental cost of median 14,100 US$, per additional QALY. Cost of AED programmes may vary significantly according to deployment locations: in airports early defibrillation by lay responders was associated with incremental cost of 55,200 US$ per QALY while in health clubs gyms costs were 4,759,200 US$ (45).

Table I: *Strategies for early defibrillation outside the Emergency Medical System*

	Community responder	On site responder (including bystander defibrillation)	Home responder
Location of victim	All areas, including home	Public or private areas, excluding home	Home
Training level	High	Moderate (to untrained for bystander defibrillation)	Moderate
Number of reachable victims	High	Limited	Low (relatives only)
Number of AEDs needed	Moderate	High	One per home
Time interval collapse-defibrillation	Reduction is limited	Potentially very short	Very short

TABLE IIA: trials on AED in the community

Year	Source	Design	n. of pt	Survival	Time to shock	Other
1988	(17)	FF standard BLS (first shock by paramedics) vs. FF+ AED	1287	44/228 (19%) vs 84/276 (30%)		Odd Ratio. for better survival when FF used AED: 1.8 (95%CI 1.1-2.9)
1986	(46)	AED Vs Manual Def (18 small communities)	205 CA	Non significant as hospital admissions and discharges	AED: 1.56min vs Manual: 2.77min P<0.001	Higher VF conversion rate for AED: 97% vs 70% (p<0.01)
1987	(47)	EMS+ manual def Vs EMS + AED	116 (M) 158 (AED)	54% admission - 28% discharge vs 52% admission - 23% discharge NS	1.1 min vs 2.0 min p<0.05	47 manual even if AED assigned
1984	(18)	EMT + Paramedics Standard BLS Vs BLS+AED	179 CA randomized	18% vs 38% P<0.05	NA	Similar findings (19% vs 42%) for time to arrival > 4min.
1988	(48)	AED to shock Vs AED only record no shock	14 communities 4000-36000 people	6/36 (17%) vs 1/27 (4%)		Higher survival if using 911 system→ thus not only early def is important
1995	(49)	Meta-analysis with 10 studies		9.2% increase in survival with EAD.		

1995	(19)	Meta-analysis with 7 studies		Risk of mortality 0.95 with AED P=0.0003		
1986	(5)	FF Vs Paramedics	260 pt with CA –118 with VF –91(77%) received shock	21/91 (23%) were in SR at paramedic arrival 56 (62%) admitted 30(33%) survived		FF arrived 5 mins earlier than PRM
1984	(50)	AED FR (who arrived first) Vs Standard BLS (until PRM arrived)		87 CA /82% survival vs 370 CA /27% survival only BLS P<0.02	FF could deliver defibrillation 5 minutes earlier than PRM	Survival benefit when PRM arrival >9mins Neurologic recover better for AED (18/36, 39% vs 49/204, 24% -p<0.02
1998	(20)	Police-AED Vs Paramedics	Rochester-Minnesota 70745 inhabitants 7 years observation	131 patients with VF 58 (44%) shocks by police 16(28%) ROSC→all survived; 42pts ACLS→ 7(17%) survived 73(56%) shocks by EMS 20(27%) ROSC→19 survived; 53pts ACLS→11(21%) survived No significant differences	ROSC pts: 5.5min (2.0-7.9) ACLS pts: 6.7min (2.8-13.2) P<0.001 Survivors: 5.6 (2-6.9) Non-survivors: 6.9m (2.8-13.2) P<0.001	115 pts. non shockable Time to shock significantly influence outcome Even small differences in the order of one minute may be crucial
1996	(51)	FR (who arrived first) Police Vs EMS (paramedics)	All a-traumatic CA 1990-1995 in 76865 citizens community. 84 pts. shocked	31/84 (37%) by police 13/31 only def→all survived 18/31 def+ACLS→5 survived 53/84 (63%) by EMS 15/53 only def→14 survived 38/53 def+ACLS→9 survived No survival differences	5.8min survivors vs 6.4min non survivors p=0.020	**survival after shock**: 27/28 (96%) ROSC vs 14/56 (25%) non ROSC p<0.001 time-to-shock and ROSC were the determinants of survival.

1994	(21)	Assessment of time to shock vs survival for 911 calls when police arrived first	City with a population of 70,745	44 pts with FV 14 treated by police: 7/14→ROCS 7/14→ROCS+ACLS Survival increased from 26% to 58% when shocked by police	ROSC : 4.9±1.3min Vs Non ROSC: 6.1±0.7 min P=0.035	Small differences in time to shock significantly affect outcome
1998	(22)	Assessment of police Delivered def. with AED Control vs prospective phase only EMS EMS vs police in the prospective phase	Prospective study with historical control 7 suburban communities where police usually arrived first vs EMS	Control phase: 183 resuscitations, 80(44%)VF Prospective phase: 283 resuscitations, 127(45%)VF survival: 26% (12/46) when police first vs 3% (1/29) – p=0.01	Control phase: 11.8±4.7 min Prospective phase : 8.7±3.7min	Police use of AEDs decreased time to defibrillation and was an independent predictor of survival to hospital discharge
1993	(29)	FF with AED vs pre-FF	>445,000 inhabitants (1,136 km2)/one year observation	297 out of hospital CA	Pre: 11.96 min vs Post: 8.50min p<0.001	
1993	(23)	Impact of adding FF to EMS Bystanders CPR FF+AED EMS paramedics	610,337 people, 39 months observation	879 treated 431 (49%) found in VF Bystander CPR in 12% of pt Survival at admission: AED+CPR 32% vs CPR 34% - NS Survival at discharge: AED+CPR 14% vs CPR 10% - NS	FF were 2.5 minutes faster than paramedics	Early defibrillation alone cannot overcome low community rates of bystander CPR. Careful attention to every link in the "chain of survival" is needed

2002	(41)	Early def outside EMS vs EMS: Lay volunteers; FF; police; Public Assistance (PA) 12 fixed AED locations + 15 police and FF + 12 PA veichles	173114 inhabitants 1 AED/4438 inhabitants 22 months observation	354 CA (73% witnessed) PA 143 (40.4%) EMS 211 (59.6%) ROSC: 19/143 vs 15/211 NS Survival: 15/143(10.5%) vs 7/211(3.3%) p=0.006 Neurologically intact: 12/143(8.4%) vs 5/211 (2.4%) p=0.009	Call-to-arrival time: 4.8±1.2min vs 6.2±2.3 p<0.05	Shockable rhythms: 23.8% vs 16.6% p=0.055
2002	(24)	Police-AED vs EMS(FF)- AED Vs Historical controls	1181612 inhabitants	Police first in 237/420 (56%) EMS first in 138/420 (33%) Simultaneous 11% Survival et discharge: (shockable rhythms) Police AED 17.2% vs EMS 9% P=0.047	Control EMS 7.64±3.66min EMS: 7.56±3.6 Police : 6.16±4.27* P<0.001 vs control EMS *NS vs EMS	Shockable rhythm: Police:163 (39%) EMS 122 (38%)
1999	(40)	Implementation of a rapid defibrillation program with a target of <8 minutes call-to shock time Comparison with phase I (pre optimization)	19 communities. 2.7 millions inhabitants	Survival at discharge: 3.9% vs 5.2% (phase I) p= 0.03	Percent of cases meeting the 8-minute response time: 76.7%→92.5% p<0.001	**Estimated charges** USD 46900 per life saved/year for implementation and USD 2400 for maintaining the program

Table IIB. AEDs in public places

Year	Source	Design	n. of pt	Survival	Time to shock	Other
2002	(30)	Two-years prospective evaluation of fixed AED location in O'Hare, Midway and Meig Filed airports. 70 AED were placed in highly visible locations. AEDs were 60-90 seconds of brisk walking apart.	Approximately 100 millions of passengers/years	AEDs were used in 26 cases 4 pts. Were defibrillated by flight attendant (with their own device) 1 pt was defibrillated by paramedics True FV was present in 18 patients. 7 → deaths 11→ ROSC Long term (one year) survival 56%	No direct assessment but lung term survival (one year) was 67% among pts. Who were defibrillated within 5 minutes from dispatch.	All survived patients also had CPR. Untrained individuals may safely perform cardio-version using AED. COSTS 3000 UDS per pt 7000 USD per life/saved
2000	(31)	Observational study of the use of AED on a major US airline company. From June 1997 to July 1999 all flights carried an AED	An AED was present on 627,956 flights carrying 70,801,874 passengers	AEDs were used on 200 subjects 185 ECG available 145→SR; Bradycardic arrest (agonal rhythm)→13 pt; VF→14pts. 15 pts were shocked (two no ECG) 40% (6pts) survived at discharge	Not tested	AED usage: 1/3288 flights. Events (both defib. Or death): 1/21654 flights Estimate worldwide usage: 2975 times for 452CA saving 93 lives.

1997	(33)	AED in the major Australian Terminals + on international Quantas flights.	65 months observation time on 203,191 flights, approx. 31 millions passengers	27 SCD on planes+19 in terminals. Planes: 16/27 witnessed; 7asystole; 6 FV→5 resuscitated **Terminals**: all witnessed; 17FV→16 effective 4/17 long term survival (24%)	Not tested	High incidence of unwitnessed arrests; on planes: 11→total asystolic CA; 10 idiovent. rhythm At terminal: 1 asystole; 1 idiovent rhytm Estimate of 1000 SCD/year on planes
2000	(25)	Prospective evaluation of AED in fixed location in casino (goal of <3min from collapse to cardio-version) Training of 1350 security officers as first responders.	Prospective collection of 148 cases of cardiac arrest in a 32 months observation time in 32 casinos	148 cardiac arrest→105 VF (71%);17 EM dissociation; 26 asystole 56pt (53% of VF pts) survived to discharge	For 90 witnessed FV 2.9±2.8min to CPR 3.5±2.9min to pad positioning 4.4±2.9min to first shock 9.8±4.3min to paramedics arrival	74% survival if shock <3min vs 49% if>3min. p=0.02

Abbreviations for table IIA and B

ACLS = Advanced Cardiac Life Support

BLS = Basic Life Support

CA = Cardiac Arrest

CPR = Cardio-Pulmonary Resuscitation

EM = Electromechanical Dissociation

EMS = Emergency Medical System

EMT = Emergency Medical Technician

FF = Fire Figthers

FR = First Responders

NS= Non statistically Significant

SR = Sinus Rhythm

VF = Ventricular Fibrillation

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