PUBLIC ACCESS DEFIBRILLATION (PAD)

A REVIEW OF THE LITERATURE and AUDIT

For the
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Commonwealth Department of Health and Ageing

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1.0 EXECUTIVE SUMMARY

Survival from out of hospital cardiac arrest in Australia remains poor with less than 10% of victims leaving hospital alive. Factors which have been identified as those influencing outcome include the underlying cardiac rhythm, the early initiation of Cardiopulmonary Resuscitation (CPR) and early defibrillation.

Time to defibrillation has been shown to be a key factor that influences survival which has been demonstrated in numerous studies. The non linear relationship is in the order of about a 23% reduction in survival per minute. Expressed in another way, this represents a reduction in survival of approximately 10% for every minute the patient is in cardiac arrest due to ventricular fibrillation (VF).

The use of Automated External Defibrillators (AEDs) by targeted responders saves lives. This has been demonstrated in a number of prospective observational studies. Recognising the importance, and considerable potential, for these strategies to effect health outcomes, the Commonwealth Department of Health and Aging convened a meeting with major stakeholders including the Australian Resuscitation Council, The Heart Foundation of Australia and St John Ambulance. Subsequent to this meeting the “Eclipse Statement” was developed and endorsed which outlines a set of principles in relation to PAD.

In order to address specific issues pertaining to PAD a review of the relevant literature was undertaken. Specific questions addressed in the review were:

1) What is the evidence for PAD.
There have been only two studies that have prospectively evaluated the efficacy or effectiveness of PAD. Both studies have demonstrated an improvement in survival to discharge from hospitals. Numerous other studies in which an AED is used as part of a first responder program have also shown marked improvement in survival. Accordingly, the evidence to date supports the premise the early defibrillation delivered within a PAD
mode improves survival following cardiac arrest occurring outside of hospital. (Level of Evidence: Level II)

2) What is the evidence on position of AEDs in the community
The vast majority, approximately 60% - 75% of cardiac arrests occur in the home. PAD will have no impact on these patients. About half of public places have more than one cardiac arrest within a three to five year period. Within each community where PAD is to be implemented, specific sites which have higher incidence of cardiac arrest should be identified to guide placement of AEDs. Airports, shopping centres, transit areas and sporting venues are likely to be associated with higher incidence of cardiac arrest. (Level of Evidence: Level IV)

3) What is the evidence supporting the use of AEDs by untrained persons and trained lay persons.
With increases in both AED technology and public advocacy for AEDs, the training required to use AEDs may now be less than initially considered appropriate. AEDs available within a PAD mode have been successfully used to treat patients in cardiac arrest. Training may shorten the time to defibrillation. AEDs can adequately and safely be used by the lay public with minimal or no training. (Level of Evidence: Level IV)

4) What are the risks associated with broad implementation of PAD.
Little information is available that outlines specific risks associated with the broad implementation of PAD. Implementation of PAD has been undertaken in the United Kingdom and within the context of a randomised community trial in the United States of America and Canada. There is no data available as to whether widespread PAD programs will improve survival following cardiac arrest. The experience of the initiative undertaken in the United Kingdom and trial data from the USA would suggest that implementation of broad based PAD programs are feasible and the risks manageable. (Level of Evidence: Level IV)
5) Other issues not covered above.

PAD would appear to be potentially a cost effective intervention however no formal cost benefit analysis has been undertaken in Australia. Such economic evaluation should be undertaken using Australian cost data as a matter of some urgency. (Level of Evidence: Level IV)

The findings of this review would suggest that PAD has the potential to improve the survival following cardiac arrest occurring out of hospital. There however remain several issues surrounding the PAD concept which would require further investigation, particularly in the Australian context.

The use of AEDs in the community is gaining increasing prominence in many countries throughout the world. The most developed and sophisticated AED initiative is being undertaken in the United Kingdom. A national strategy overseen by the Department of Health and funded by government ($5.3 million) has seen over 680 AEDs in 110 sites being available. With government support this initiative has realised considerable community involvement and support. Similar, but not as well advanced strategies for placing AEDs in the community, have been undertaken in Europe, the United States of America and Australia. Common themes associated with implementation of these AED programs have been funding support and the potential, real or perceived, fear of litigation.

Almost without exception, AED programs have been introduced within a “first responder” framework. That is, that there exists a systems approach with program oversight and that training lay persons to respond to cardiac arrest is seen as an integral part of overall strategy. While in some public places AEDs are placed allowing public access (eg airports and railway stations), the extent to which they are use by trained or untrained bystanders, rather than first responders remains generally unknown. As such, the true benefits of placing AEDs in public places, in a manner similar to “fire extinguishers”, remains generally unknown and the potential benefits unrealised.
From the audit is was apparent that the success of implementing an AED program was very dependent on understanding and addressing local issues. The program as implemented in the UK serves as a good model on which to base further developments in this area. It specifically addresses:

- Adopting a national approach to address a significant health issue.
- Program input from a clinical advisory group
- Funding.
- Government support.
- Community involvement.
- Integration with emergency medical services.
- Training.
- Data collection and program evaluation.

Australia has addressed some of these issues and clearly the potential exists for a nationally co-ordinated approach to significantly reduce the time to defibrillation. Thus improve the survival of those suffering cardiac arrest in the community.
2.0 BACKGROUND

Survival from out of hospital cardiac arrest in Australia remains poor with approximately less than 10% of victims leaving hospital alive. (1, 2) Factors which have been identified as those influencing outcome include the underlying cardiac rhythm, the early initiation of Cardiopulmonary Resuscitation (CPR) and early defibrillation. (3-7) It has been over three decades since the potential of closed chest CPR to improve outcome following cardiac arrest had been demonstrated. (8) Since then there has been great emphasis placed on training the general community in CPR in order to “save lives” following cardiac arrest.

The experience of patients suffering a cardiac arrest in hospital showed that underlying electrical rhythm of the heart causing the cardiac arrest was predominantly ventricular fibrillation (VF). This is readily correctable with the use of a defibrillator however this treatment was only available within hospitals. Pantridge recognised that the time to defibrillation was crucial and that cardiac arrest survival could be improved if defibrillation occurred at the scene. He subsequently trialled a pre-hospital defibrillation program which clearly demonstrated improved survival. (9) This became the forerunner to the widespread acceptance and use of defibrillators by ambulance staff to treat the victims of cardiac arrest.

In 1991, the American Heart Association issued a challenge to the manufacturers of defibrillators to produce a device that could be use by the lay public with minimal or no training. (10) The outcome being the development of Automated External Defibrillators (AEDs). AEDs have the ability to identify the underlying cardiac rhythm as to being either a “shockable” or “non shockable rhythm”. The specificity and sensitivity of the decision algorithm is 100%, that is it will never shock a non shockable rhythm, and approximately 98.5%, correctly identifying a shockable rhythm, respectively. (11, 12) As such the potential for these devices to be used within the community, and possibly by the public, was established.
As previously stated, the time to defibrillation has been shown to be a key factor that influences survival which has been demonstrated in numerous studies. The logarithmic relationship is in the order of about a 23% reduction in survival per minute. Expressed in another way, this represents a reduction in survival of approximately 10% for every minute the patient is in cardiac arrest due to VF.\(^{(1, 13, 14)}\) Thus the importance of early defibrillation is clearly established.

Recognising there was now a major opportunity to further improve survival following cardiac arrest within the community, attention began to focus on how the delivery of “early defibrillation” could be achieved. This has been advocated by all resuscitation councils worldwide.\(^{(12, 15, 16)}\) While numerous strategies were developed and trialled they can be categorised under the following headings.\(^{(17)}\)

- Emergency Medical Services: - Defibrillation by ambulance service personnel.
- First Responder: - Defibrillation by appropriately trained persons who have a duty to respond to medical emergency.
- Public Access Defibrillation (PAD): - Defibrillation by undertaken by anyone trained or untrained.

The use of AEDs by targeted responders saves lives. This has been demonstrated in a number of prospective observational studies.\(^{(18, 19)}\) Recognising the importance, and considerable potential, for these strategies to effect health outcomes, the Commonwealth Department of Health and Aging convened a meeting with major stakeholders including the Australian Resuscitation Council, The Heart Foundation of Australia and St John Ambulance. Subsequent to this meeting the “Eclipse Statement” was developed and endorsed which outlines a set of principles in relation to PAD. (Attachment 1)

The literature pertaining to the use of AEDs covers all of the broad implementation strategies outlined above. However it is the focus of this review to only examine the literature that relates specifically to “Public Access Defibrillation”.

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3.0 SCOPE OF THE REVIEW

The scope of this review is to examine the literature pertaining to PAD. Specifically it addresses the following questions:

1) What is the evidence for PAD.
2) What is the evidence on position of AEDs in the community.
3) What is the evidence supporting the use of AEDs by untrained persons and trained lay persons.
4) What are the risks associated with broad implementation of PAD.
5) Other issues not covered above.

For each of the above questions a “level of evidence” as recommended by the National Health and Medical Research Council (NHMRC) guidelines is provided.(20)

3.1 SEARCH STRATEGY

In undertaking this review the following literature databases were searched:

- MEDLINE
- EMBASE
- COCHRANE Database of Systematic Reviews
- COCHRANE Clinical Trials Register
- International Liaison Committee of Resuscitation (ILCOR) Literature Database

The following search terms were used, either as a MESH Heading or as text words.

- Public Access Defibrillation
- Shock Advisory Defibrillation
- Automated External Defibrillators
- AED
In order to increase the search yield no other limitations on the search strategy were placed. Only articles published in English were included in the review.

The literature search yielded at total 153 references. The abstracts of these were subsequently reviewed and of these only 12 were specific to PAD. A search of the secondary references relating these 12 PAD studies was also undertaken.

### 3.2 DEFINITIONS

For the purpose of this review the following definitions as recommended by the Australian Resuscitation (ARC) will be used.

**EARLY DEFIBRILLATION**

The provision of defibrillation within a short time after cardiac arrest.

**BASIC LIFE SUPPORT**

The preservation of life by the initial establishment of and/or maintenance of airway, breathing, circulation and related emergency care.

**Bystander**

A person who witnesses or comes across a victim who has collapsed or is injured.

**CARDIAC ARREST**

Cessation of the heart action.

**CARDIOPULMONARY RESUSCITATION**

The technique of compression of the heart and inflation of the lungs, used in an attempt to revive a person who has suffered a cardiac arrest.
DEFIBRILLATION
The application of a controlled electric shock to the victim’s chest in order to terminate a life threatening cardiac rhythm (ventricular fibrillation or pulseless ventricular tachycardia.)

DEFIBRILLATOR
A device which stores electric energy which can be discharged when required for the purpose of achieving the passage of an electric current through the heart in an attempt to achieve defibrillation. (It may be manual, semi-automatic or automatic in operation.)

FIRST RESPONDER
A person trained in basic and advanced first aid and use of a semiautomatic external defibrillator who is part of an organised medically controlled emergency response system.

HEALTH CARE PROFESSIONAL
A person who is a registered medical practitioner, registered nurse or qualified ambulance officer.

PUBLIC ACCESS DEFIBRILLATION
The provision of an automated external defibrillator (AED) for use by the public in treating cardiac arrest.

SEMI AUTOMATIC EXTERNAL DEFIBRILLATOR
(also referred to as a Shock Advisory Defibrillator)
An external defibrillator which analyses the electrical rhythm of the heart and charges automatically if a shockable rhythm (ventricular fibrillation or ventricular tachycardia) is recognised. It provides the operator with audible and/or visual prompts on actions required for safe delivery of an electrical shock.
4.0 LITERATURE REVIEW

4.1 What Is The Evidence For PAD

It has been stated that the theoretical basis by PAD should improve survival appears sound.(21) However all the benefits of “early defibrillation” have mostly been observed in systems implementing First Responder programs, not PAD. Notwithstanding this limitation there is some evidence which would support the premise of PAD improving survival.

Pell and co-workers undertook retrospective cohort study of cardiac arrest in Scotland. 15,189 arrests were analysed and survival statistically modelled based on location of arrest and the potential for an AED.(22) They identified that only 21% of arrests occurred in a location potentially suitable for PAD. Survival rates in PAD suitable locations in which an ambulance arrived within 3 minutes were compared to similar sites where ambulance response was more than 3 minutes. The less than 3 minute groups serving as a surrogate for an AED being available within a PAD framework. They determined only a minimal improvement of 0.2% would be achieved with a PAD strategy which could be realised, and exceeded, with increasing the existing first responder approach.

This paper relies on a number of assumptions being meet which may not reflect reality. In particular, the 3 minute ambulance arrival time which does not reflect the true time interval from when the patient is found collapsed to when defibrillation occurs. The time taken for bystanders to respond, make the call to the ambulance service and for the ambulance paramedics to reach patients side, not just arrive at scene, and commence resuscitation including defibrillation. As such this interval may actually be greater than 3 minutes and may actually explain the lack of observed improvement.

Caffery and colleagues have reported outcomes from a PAD program established at three Chicago airports (O’Hare, Midway and Meigs Field).(23) AEDs were placed within a 90
second walking distance throughout these airports. During the first two year period of the program, 21 persons had suffered a cardiac arrest, of which 18 were in ventricular fibrillation requiring defibrillation. Of these 11 (62%) were resuscitated to leave hospital alive and neurologically intact. All but one patient was alive one year later. While the program operated in PAD mode, that is AEDs were available for the lay public to use, 83% of the rescuers have either been trained in the use of an AED or were trained health care professionals, all of which acted as a “good Samaritan”.

Kuisma and colleagues prospectively studied compared sites where PAD was available with no PAD sites in Helsinki. This study was unable to show any benefit is survival as only 20 patients (7 PAD / 13 non PAD) were enrolled.(24)

Capucci and co-workers undertook a observational study following the placement of 39 AEDs in numerous locations in the Piacenza region of Italy.(25) This included high risk locations such as airports, non physician staffed ambulances, fire engines and police cars. 1285 volunteers were trained to use AEDs without additional training in CPR, and respond as part of a co-ordinated ambulance response. Overall survival to hospital discharge improved from 3.3% for the EMS group only compared with 10.5% (p=0.006) for the early defibrillation intervention. Neurological outcomes were also significantly better in the intervention group (2.4% vs 8.4%; p=0.009)

The improved outcomes observed in this group were all derived from those acting as mobile first responders within a EMS co-ordinated system. Where AEDs were placed in public places in a PAD mode, that is available for anyone to use, none were used.

To address the lack of any substantive trial evidence for PAD, a prospective randomised community based trial has been undertaken in the USA.(26) The trial design and rational have been reported.(27) In this study, 993 community units in 24 sites were randomised to a CPR only (control) or CPR / AED intervention. Study units included shopping centres, workplaces, community centres, entertainment complexes, hotels, transit lounges and residential complexes. The rescuers were all interested lay volunteers who agreed
they would respond to cardiac arrest within there units. Those with a traditional duty to respond such as Police and Fire officers, Paramedics, Nurses and Physicians were excluded from the study. The results of the trial have only been published in abstract form however indicate improved survival in the PAD group. Survival in the PAD vs control arms was 22% and 15% respectively (p=0.042). In absolute terms the number of survivors almost doubled (15 in the control vs 29 in the PAD group). The relative risk for this intervention being 2.0 (95% CI 1.07 to 3.77). The findings of this RCT demonstrate the potential for improved survival within the community setting with the addition of AEDs in a public access mode. This is the most convincing data to date.(26)

This is the only RCT of PAD yet to be undertaken. The methods were sound and randomisation appeared to be maintained. The results support the notion that large numbers of trained laypersons can effectively use AEDs and this in turn can have a positive influence on survival following cardiac arrest.

Summary:
There have been only two studies that have prospectively evaluated the efficacy or effectiveness of PAD. Both studies have demonstrated an improvement in survival to discharge from hospitals. Numerous other studies in which an AED is used as part of a first responder program have also shown marked improvement in survival.

Accordingly, the evidence to date supports the premise that early defibrillation delivered within a PAD mode improves survival following cardiac arrest occurring outside of hospital.

(Level of Evidence: Level II)
4.2 What Is The Evidence On Location Of AEDs In The Community

Numerous retrospective analyses have been conducted to identify the optimal location for the placement of AEDs within the consideration of a PAD program. Fedoruk and colleagues retrospectively reviewed the location of cardiac arrest in 2,142 events in Ontario, Canada.(28) There were 28 public locations identified of which 19 (68%) had two or more arrests at that location. They concluded that AEDs in public locations may have the potential to improve survival. Further, they considered understanding the local epidemiology of cardiac arrest was important in establishing PAD optimal outcomes.

A further retrospective analysis of cardiac arrest data conducted by Frank et al concluded that approximately 40% of cardiac arrests occurred in non residential locations.(29) Twenty seven non-residential locations had two or more arrests during the three year period of the study. This accounted for 50% of the total arrests occurring in non residential locations. The remainder were single isolated events.

Becker and colleagues retrospectively examined non residential site specific cardiac arrest incidence.(30) They reviewed 7815 arrests of which 16% were in public locations. During the 5 year period of the study, ten high risk public locations (cardiac arrest incidence >= 0.03 per year per site) were identified. These included;

- airports  7 per year
- gaols   1 per year
- shopping centres 0.6 per year
- public sports venue 0.4 per year
- industrial sites  0.4 per year
- golf course  0.1 per year
- shelter  0.1 per year
- ferries / trains  0.1 per year
- gymnasiums  0.08 per year
- community centres 0.03 per year.
The authors estimate that if AEDs had been available in the “high risk” locations between 8 and 32 lives could have been saved during the five year period. They further recommend that communities should identify the location specific cardiac arrest incidence in order to identify optimal placement of AEDs. The probability of AED use within a 10 year period ranged from 20.5% in government buildings to 99% in shopping malls and public places.(31)

The influence of population density has been investigated by Malcom.(32) Using retrospectively collected patient care record information for cardiac arrests in Georgia (USA), locations were divided into population densities of <100; 100-400; 400-1000 and >1000 persons per square mile. Their findings indicated an inverse relationship between population density and incidence of cardiac arrest. That is as population density increases the incidence of cardiac arrest decreased and visa versa. However, in high population density areas the incidence of cardiac arrest occurring outside of home was higher, thus increasing the potential benefit for PAD programs.

Location of cardiac arrest has not been well defined in Australia. Information from unpublished data in Perth, indicates that approximately 25% of cardiac arrests occur in non residential settings.

A number of jurisdictions have moved to have AEDs available for PAD. Of note has been the “Defibrillators in Public Places Initiative” of the National Health Service in the United Kingdom.(33) In this program AEDs are being located in various public places including airports, the London Underground, train stations and large public venues. There is currently no published data as to the epidemiology of arrests in the AED locations or subsequent outcomes.

Summary

The vast majority, approximately 60% - 75% of cardiac arrests occur in the home. Clearly PAD will have no impact on these patients. About half of public places have more than one cardiac arrest within a three to five year period.
Within each community where PAD is to be implemented, specific sites which have higher incidence of cardiac arrest should be identified to guide placement of AEDs. Airports, shopping centres, transit areas and sporting venues are likely to be associated with higher incidence of cardiac arrest.

(Level of Evidence: Level IV)
4.3 What Is The Evidence Supporting The Use Of AEDs By Untrained Persons And Trained Lay Persons

The Australian Resuscitation Council has included the use of AEDs as part of its basic life support flow chart. (Attachment 2). Such statement clearly identifies the importance of early defibrillation. There is consistent evidence that training non medical personnel including fire, police and security officers, to use AEDs is feasible, safe and effective in improving survival from cardiac arrest.(18, 19, 34) These have all been within a first responder program. In Australia, training of St John Ambulance volunteer first aiders to use AEDs has significantly improved survival at public gatherings. Melbourne Fire Service Officers have also been successfully trained as first responders.(35)

The extent to how much training, if any, is required to safe and effectively use an AED remains unproven. Numerous courses and instructional programs have been developed, both within Australia and internationally, and vary as to the duration and required competencies. Kern et al have suggested that with improved AED technology and widespread advocacy for AEDs in the community, training requirements for lay persons may be less than first anticipated.(21)

Grundy and colleagues compared time the performance of using an AED between 15 naïve six grade children (about 12 years old) with 22 trained ambulance staff.(36) None of the children had seen an AED. They used a simulated cardiac arrest scenario with time first shock as the key end point. While ambulance staff delivered the shock sooner (90 vs 67 seconds), they all safely and appropriately delivered the shock. Electrode placement was correct in all cases. This study, while recognising the limitations of simulated events and overall generalisability, would suggest that AEDs can be used effectively with minimal or no training.

This finding was further supported by a similar study conducted by Lawson.(37) In their study, children (mean age 9 years) with no training in the use of AEDs were exposed to a mock cardiac arrest scenario. Time to first shock was about 59 seconds. The children
were given instruction on AED use and re-tested. Time to first shock fell to 35.2 seconds. All children use the AED safely. This study illustrated untrained children can safely and effectively use an AED and with training, time to defibrillation can be shortened.

Eames and colleagues compared the use of three different types of AEDs on a manikin during a cardiac arrest scenario. (38) Twenty four untrained participants were tested to assess overall performance and safety of using differing types of AEDs. All participants were able to safely and appropriately use the AEDs and apply first shock within 75 and 153 seconds, depending on the AEDs. The authors concluded that training decreased the time to defibrillation however those with no training are able to effectively use the AED.

A survey of 2683 non residential locations which had an AED for at least one year was conducted by Jorgenson. (31) Defibrillation was done by minimally trained or untrained persons and the overall usage rate was 11.6% per year of all AEDS available. The probability of AED use within a 10 year period ranged from 20.5% in government buildings to 99% in shopping malls and public places.

In both the PAD trial AEDs were safely used by minimally trained volunteers with no duty to respond. (27) At Chicago airport the vast majority of defibrillations undertaken were by bystanders who had some training. Only 3 patients were defibrillated by lay persons with no training. All were safely defibrillated. (23)

A major consideration surrounding training relates to the safe use of AEDs. In each of the studies that evaluated the use of AEDs by both untrained and trained lay persons, all study participants were able to safely use the AED. (31, 36-38) No study published to-date has identified any adverse events to either the rescuer or the patient.

**Summary**

*With increases in both AED technology and public advocacy for AEDs, the training required to use AEDs may now be less than initially considered appropriate. AEDs*
available within a PAD mode have been successfully used to treat patients in cardiac arrest. Training may shorten the time to defibrillation. AEDs can adequately and safely be used by the lay public with minimal or no training.

(Level of Evidence: Level IV)
4.4 What Are The Risks Associated With Broad Implementation Of PAD.

Risks associated with PAD may be defined as risks to either the patient, rescuer or a third party. There is no published data as to the specific risks associated with the implementation of a PAD program. However, the broader issues of PAD implementation in the United Kingdom have been published.

The “Defibrillators in public places initiative” undertaken in the United Kingdom by the National Health Services outlines several important considerations with implementing PAD.(33) In their paper, Davies and colleagues outline a two phase approach. Phase one consisted of:

- Defining the legal status of lay persons using an AED.
- The purchase of defibrillators.
- Identify pilot sites
- Training and deployment.

Of particular note was the legal advice provided by the UK Department of Health. As there is no good Samaritan legislation, or any legal obligation on the lay person to go to the aid of another, legal liability must arise in common law. The likelihood of any action against the lay rescuer was negligible provided the rescuer acted in the best interests of the victim, in a reasonable fashion and similar to other lay persons of similar training and experience.

Phase two involved the national implementation of PAD. This consisted of:

- Identifying further PAD sites.
- Arranging training.
- Provide ongoing medical advice and expertise.
- Audit of the use of AEDs.

While the project included training of lay rescuers in the use of AEDs, the AED was placed in public locations accessible to anyone and as such, could be considered as PAD.
The strategy adopted in this project represents a considerable drive by the Department of Health in the UK to reduce the time to defibrillation, and potentially survival. The British Government allocated 2 million pounds to the project with approximately half of this amount being for the purchase of AEDs. Whilst the strategy has been widely implemented it is not without criticism. Pell argues that a widespread PAD program will have little effect on survival and the funds could be better spent on further enhancing the first responder program.(22) This belief is based on statistical modelling of retrospective cardiac arrest data and required a number of assumptions to be considered. As other studies appear to contradict these findings, it is questionable as to whether the model accurately predicts cardiac arrest survival associated with PAD programs.(23, 27)

The PAD trial conducted in the USA was informative as to some of the issues associated with PAD implementation. However these were within the context of a randomised community trial and may not reflect the situation outside such conditions.(27)

**Summary**

Little information is available that outlines specific risks associated with the broad implementation of PAD. Implementation of PAD has been undertaken in the United Kingdom and within the context of a randomised community trial in the United States of America and Canada. There is no data available as to whether widespread PAD programs will improve survival following cardiac arrest. The experience of the initiative undertaken in the United Kingdom and trial data from the USA would suggest that implementation of broad based PAD programs are feasible and the risks manageable. (Level of Evidence: Level IV)
4.5 Other Issues - Cost Benefits

Very few formal cost benefit analyses have been undertaken relating to the provision of PAD programs. Nichol compared the costs between standard emergency medical service (EMS) systems and PAD supplemented EMS systems.(39) PAD by lay responders had a median incremental cost of $US44,000 per additional quality adjusted life year. The authors noted that the findings were sensitive to cost changes and relative survival benefits. They concluded that although PAD was more expensive, it may be economically attractive but should be assessed in a randomised controlled trial. This is currently being done in the US PAD trial however findings are not yet available.

A number of other investigators have undertaken cost benefit analysis within their jurisdiction.(24, 40, 41) All of these studies indicate that PAD may be economically attractive. In particular, where response times are short and cardiac arrest frequent, PAD by targeted responders may represent good value for money.(40)

There are no published cost benefit analyses of PAD in Australia or the potential of these programs to delivered cost effective outcomes.

Summary

PAD would appear to be potentially a cost effective intervention however no formal cost benefit analysis has been undertaken in Australia. This would need to be undertaken using Australian cost data.

(Level of Evidence: Level IV)
5.0 AUDIT

In order to determine the extent to which PAD activities are being undertaken within the international context an audit of such was undertaken. Data for the audit were obtained from:

a) A request for information from members of the International Liaison Committee on Resuscitation. (ILCOR). This group represents all the international resuscitation councils including the American Heart Association and the European Resuscitation Council. The request was made by email.
b) An extensive search of resources available through the internet.
c) Other resources as identified by the respondents.

As with the literature review the focus of the audit was on truly PAD activities. It is recognised that other aspects of reducing time to defibrillation, including first responder programs, may play an integral part of the effectiveness of this overall strategy.

5.1 PAD in the United Kingdom

The UK is well advanced in developing a national approach to reducing time to defibrillation. This resulted from a deliberate decision to by British government to place defibrillators in public places. This initiative entitled “Defibrillators in Public Places” rose from a government policy to prevent premature death and recognised the evidence base for early defibrillation to improve survival following cardiac arrest. This was the first government led AED program in the world. This ambitious program has been well described in the literature.(33) In summary the program involved;

- Developing an administrative structure including advisory committee.
- Obtaining support from key stake holders including ambulance, community groups and health professions.
- Determining the legal status of the those using the equipment
- Procurement of the defibrillators
• Establish pilot sites including training.
• Ongoing and long term management of the program.

The initial government investment was 2 million pounds (AUD$5.3 million). The allocation to pilot sites was based on a number of considerations including local enthusiasm to be part of the initiative and the likelihood of use. Of particular note is that while defibrillators were place in public places, this was doing in the concept of a first responder program. That is trained responders would also be available to respond. For example the could be security officers, lay first aiders or transit police. The program was not designed to merely put defibrillators in public places but rather as part of an integrated response system.

The legal status of those using a defibrillator in this environment was also determined. The UK has no civil liabilities, good samaritan or similar legislation. As such, similar concerns pertaining to liability to those expressed within the Australian context were expressed. Legal opinion was that while action could be taken against someone using a defibrillator this would be highly unlikely and would only arise if the rescuers actions were unreasonable and negligent. This was an important consideration as introducing legislation to protect the rescuer would have delayed the project considerably. (33)

The project team consists of a full time project manager and 3 full time project officers. It is overseen by the Defibrillator advisory group chaired by Professor Douglas Chamberlain.

The project has maintained a high public profile. A bi-annual magazine is produced along with a website. (http://www.dh.gov.uk/PolicyAndGuidance/HealthAndSocialCareTopics/CoronaryHeartDisease/CoronaryPromotionProject/fs/en

Information relating to the program including successful outcomes in terms of individual survivors are published on this site.
As of April 2004, 681 AEDs had been placed in public places throughout England. This includes:

- London 294
- South East 87
- East England 60
- Yorkshire 48
- North East 26
- East Midlands 14
- South West 23
- West Midlands 39
- North West 90

Of those distributed in London, all have been placed in either train stations (including the underground) or airports. For example, London Heathrow terminal has 96 AEDs placed throughout the four terminals. These AEDs are located in 109 live sites.

As with the many of the deployed AEDs throughout England, they are useable in a true PAD mode. Personal communication from ILCOR respondents would indicate that use of these devices in public by bystanders essentially does not occur. It is also noted that the recommendations of the defibrillator advisory committee is that defibrillation should be carried out by lay people who have been appropriately trained.

The placement of these devices while managed by the Department of Health, are co-ordinated by local organisations to form partnerships in the process. In most cases this is the local ambulance authority or community response or services group. This includes organisations such as St John Ambulance and the British Red Cross. There is also strong overview and support from the Resuscitation Council of the UK (RCUK).

As part of the overall “defibrillator in public places” initiative the need to collect data on the effectiveness of the program in improving the survival of patients suffering a cardiac arrest outside of hospital was identified. Under the auspices of the RCUK a data
collection template has been developed. The rationale and details of this data tool has been published in the journal Resuscitation by Colquhoun and colleagues.(42) This aim of this report form is to have a nationally standardised and accepted collection tool to be completed when AEDs are used in order to monitor the outcomes of PAD programs.

In designing the form the authors considered the following requirements:(42)

- The form be no longer than one A4 page.
- No requirement to analyse “on board” memory chips.
- Data items are unambiguous and preferably categorical where possible.
- Free text data entry kept to absolute minimum.
- Outcome focused on status of the casualty at the scene.
- Useable by a wide range of responders.

A copy of this form is reproduced below.

The “defibrillator in public places initiative commenced February 2000. As yet detailed statistics on the number of survivors has not been published. Nevertheless, numerous accounts of lives saved, including high profile individuals such as Sir Ranulph Fiennes, have been documented in the bi annual newsletter of the National Defibrillator Program.

In summary, the UK initiative represents a strong government approach to addressing cardiac arrest survival. It is nationally co-ordinated and funded, clinically led, involves the local community, provides web based resources and feedback, establishing mechanisms for data collection and system evaluation.
# Resuscitation Council (UK)

## Event Report Form

**Date of incident**

(dd/mm/yyyy)

**Organisation responsible**

for the defibrillator

**Sex (♂)**

Male [ ]

Female [ ]

Unknown [ ]

**Age**

Years [ ]

Known [ ]

Estimated [ ]

Unknown [ ]

**Place of collapse**

Tick (♂) one box only:

- Airport [ ]
- Bus station [ ]
- Leisure centre / Gym [ ]
- Doctor’s surgery [ ]
- Exhibition / Conference [ ]
- Railway station [ ]
- Street [ ]
- Remote location [ ]
- Road Traffic Accident [ ]
- Other location [ ]
- Shopping centre [ ]
- Underground railway [ ]
- Sporting event [ ]
- Workplace [ ]

**Specific place or address of collapse**

(e.g. Luton Airport, Sports Centre, Penarth Road, Cardiff, etc.)

**Was the collapse witnessed? (♂)**

Yes [ ]

No [ ]

Unknown [ ]

**Was CPR started before**

the defibrillator arrived? (♂)

Yes [ ]

No [ ]

Unknown [ ]

**What was the delay between the victim**

collapsing and the start of CPR?

Minutes [ ]

Measured [ ]

Estimated [ ]

Unknown [ ]

**Time the event was notified to central ambulance control**

(where applicable)

Hours [ ]

Minutes [ ]

**Time delay between collapse and placing**

the electrodes on the victim’s chest

Minutes [ ]

Measured [ ]

Estimated [ ]

Unknown [ ]

**Was a shock given? (♂)**

Yes [ ]

No [ ]

Unknown [ ]

**If YES, what was the total number of shocks**

given before the ambulance arrived?

Shocks [ ]

**Did the victim have signs of circulation**

AFTER any shock was administered? (♂)

Yes [ ]

No [ ]

Unknown [ ]

**Did the victim start breathing or recover**

consciousness before the ambulance arrived? (♂)

Yes [ ]

No [ ]

Unknown [ ]

**Was the victim:**

Tick (♂) one box only

- Alive not transferred to hospital [ ]
- Recognised dead at the scene [ ]
- Transferred to hospital - no circulation [ ]
- Transferred to hospital - with circulation [ ]
- Transferred to hospital - CPR in progress [ ]

**Victim’s status after transfer to hospital:**

Tick (♂) one box only

- Dead on arrival [ ]
- Admitted, but did not survive to discharge [ ]
- Discharged alive [ ]

**Additional information**

**FOR OFFICE USE ONLY - PLEASE DO NOT COMPLETE THIS SECTION**

**Supplier**

- BHF [ ]
- DOH [ ]
- Other [ ]

**Outcome**

- Dead on arrival at hospital [ ]
- Died in hospital [ ]
- Recognised dead at scene [ ]
- Survived to discharge [ ]

**Region**

- England [ ]
- Northern Ireland [ ]
- Scotland [ ]
- Wales [ ]

**C. Data? (♂)**

Yes [ ]

No [ ]

Unknown [ ]

**Organisation:**

[ ]

**Event ref:**

[ ]

PLEASE SEND THE WHITE COPY AS SOON AS POSSIBLE TO:

The Resuscitation Council (UK), 6th Floor, Tavistock House North, Tavistock Square, London WC1H 9HR

BLUE COPY: Send to your department. GREEN COPY: Retain for your records


Fig. 1. AED event report form.

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5.2 PAD in Europe

A recent publication by Priori and colleagues outlines the use of AEDs in Europe. (43) This document represents the consensus views of the European Resuscitation Council and the European Cardiac Society and has led to the following recommendations (summarised):

AED programs within emergency medical services (EMS) should be a fundamental objective.

- Careful evidence based planning of AEDs programs outside of EMS is needed.
- Uniform legislation be enacted to allow first responders to use AEDs.
- Priority setting and integration of all aspects of AED programs.
- Local epidemiology and data should be used to inform AED programs.
- Co-ordinated and standardised dispatching systems to cardiac arrests.
- Identification of potential responders.
- Training of responders should include basic life support and AEDs.
- Data collection and analysis of outcomes of AED programs.
- Appropriate budgeting for AED programs to include all ongoing costs.

There are a number of AED programs currently underway in Europe. These are all first responder programs attached to existing emergency or medical aid services.

Luxembourg:
AED training initiated within fire service.

France:
AED training for first aid members of the French Red Cross (FRC). As of 2003, 700 AEDs had been placed with FRC first responders attending over 20 cardiac arrests per month. Ten victims had been documented to have attained return of spontaneous circulation during the first 18 months of the program. No data available in terms of survival to discharge.
Italy:
In 2001 legislation was passed allowing non medically trained health personnel and lay persons trained in CPR, and individually licensed by the local EMS, to use AEDs. Training programs have emphasised the use of AEDs however these devices can only be used by those who have been to at least one re-training sessions and certified by a government health instructor. No data is available as to the placement in public places of AEDs.

There is increasing activity relating to the use of AEDs in ether a first responder program or PAD format in other European countries including:
- Austria
- Denmark
- Belgium
- Finland
- Germany
- Iceland
- Netherlands
- Portugal
- Sweden.

In summary, the level of AED activity in Europe is varied. The recent ERC / ECS recommendations are supportive of the further development of AED programs within an evidence based framework. The recommendations also address basic issues, such as defibrillators on ambulances, which was achieved in Australia over a decade ago.
5.3 PAD in the USA

The use of AEDs in the USA has gained considerable momentum. There are numerous programs and have been tailored to meet local needs. The most comprehensive information regarding the use of AEDs in the USA is collated by the National Centre for Early Defibrillation (NCED). (http://www.early-defib.org/default.asp)

As described on their website the NCED is;
“…a not-for-profit information resource center based at the University of Pittsburgh. The mission of the National Center for Early Defibrillation is to foster optimal immediate care for victims of sudden cardiac arrest by providing leadership, expertise and information related to early defibrillation.”

The NCED provides excellent resource material on developing and conducting early defibrillation programs within a community setting. It covers issues of:

- Medical control (by state)
- Legislation and liability (by state)
- Obtaining funding
- Training
- Equipment
- Demonstration programs
- Limited outcome data
- Resources information including pre-done MEDLINE searches
- Research reports
- Position statements
- Links to state EMS organisations
- PAD trial

Of the programs outlined by the NCED all are typically first responders. That is they have placed AEDs in public locations and trained first responders to supplement the existing EMS systems.
While the placement of AEDs in a number of these programs allow for these devices to be used by trained and untrained bystanders outside the existing first responder concept, no data as to the occurrence of such use is available. The exception being the published experience of the PAD trial and O’Hare airport.(23, 27)

The issue of liability of using AEDs in the USA is interesting. Since the Cardiac Arrest Survival Bill was passed by the Clinton administration, the overall perception within the community is that the use of AEDs is a good thing. However, translation of this notion to workable legislation within each state has been a significant undertaking.

More specifically the NCED has stated:

*The purchase and use of AEDs occurs within a complex maze of federal and state laws and regulations. At the federal level, the U.S. Food and Drug Administration (FDA) oversees the manufacture of AEDs because they are medical devices. At the state level, various regulatory agencies oversee the use of AEDs. Both the FDA and state regulatory agencies determine who can use AEDs and how they may be used.*

(http://www.early-defib.org/03_06_02.html)

The Cardiac Arrest Survival Act requires guidelines to be developed for the placement of AEDs in federal buildings. Within these guidelines consideration must be given to:

- Training.
- Equipment maintenance including testing.
- Medical oversight of the program.
- Co-ordination with local EMS.

State laws within the USA are not consistent with wide variation as to who can use AEDs. These have been defined by user groups such as Paramedics, public safety officers (Police / Fire), targeted first responders and trained citizens. For example, in California anyone can use an AED provided they are trained and deemed competent and there is medical oversight. Whereas in Florida, the AED can be used by anyone for the
purpose of saving a life provided the rescuer is training in CPR and AED use.

While the number of AED programs are rapidly increasing in the USA, they are almost exclusively introduced under a first responder model. There is no data as to the extent to which those AEDs placed in a public place are used and accessed by trained or untrained bystanders, with the exception of O’Hare Airport in Chicago. It would be reasonable to speculate that the legal issues, real or perceived, would still be a significant barrier to AEDs being used in a true PAD mode.

The issue of data collection of AED events remains unresolved to a considerable degree. It would seem that in those places where a formal first responder program exists varying levels of data are collected at a local level, mostly by the EMS. There are no uniform data definitions or agreed data items. Furthermore, there are no national data repositories similar to the National Register of Cardiopulmonary Resuscitation sponsored by the American Heart Association.

In summary, the use of AEDs in the USA has been in a first responder mode. There would appear to be considerable government and community support with extensive web based resources available. Efforts have been made to address the legal issues however mostly require the person to be trained in CPR and the use of AEDs.
5.4 PAD in Australia

Like the USA, the implementation of AEDs into public places is gaining considerable momentum. This is mainly be driven and led by not for profit community service groups such as St John Ambulance and local ambulance services. Like many of the AED programs internationally, AED programs in Australia have all generally been established under a first responder concept. This includes community and workplace emergency response teams capable of using an AED.

The implementation of AEDs into public places has occurred in all states and territories of Australia to varying degrees. In Western Australia, there are some 25 sites at which an AED has been placed and this program has been co-ordinated by the ambulance service (St John Ambulance). Limited data is collected on events in which an AED is used. Recently, a AED was used on a cardiac arrest victim who collapsed at a gymnasium. Staff at the site had been trained as first responders and acted accordingly using their AED. The patient required 1 shock and was conscious and orientated on arrival to hospital. This is a typical scenario of numerous lives saved in Australia through first responder programs

The Western Australian Department of Health through its Critical Care Council has endorsed the principles outlined in the Eclipse Statement. This is outlined in Attachment 3. The Queensland Government through the Queensland Emergency Medical Systems has also published a statement on early access to defibrillation in Queensland. (Attachment 4)

Victoria has placed AEDs in a number of public locations including airports, casinos and sporting stadiums. In addition, Victoria has piloted and implemented a first responder system using the Melbourne Fire Service.(35) Similar AED programs to those described above occur elsewhere throughout Australia.

Almost without exception the implementation of AEDs in public places has been under a
first responder model rather than true PAD. Notwithstanding this, as there are no legislative restrictions on who is able to purchase AEDs, it is quite possible that more devices are in the community which do not fall under any formalised systems approach.

Community service groups, in particular St John Ambulance Australia and National Heart Foundation, have been instrumental in developing national approaches to placing AEDs in the community. Unlike the experience in the UK, this has been done with little or no government funding. Despite this the role out of AEDs continues to gain momentum with additional sites being included on a daily basis. Information pertaining to AED programs are provided on a number of websites including those belonging to St John Ambulance and the Victorian Centre for Early Defibrillation. (www.vced.org.au/)

Consistent issues that form barriers to the placement of AEDs in the community are those of legal liability and cost of the AEDs. Legislation encompassing civil liabilities and good Samaritans vary between states which further increases general concern with the placement and use of AEDs. This further hampers the development and adoption of a national strategy.

These issues have been clearly addressed in the UK initiative of having defibrillators in public places. Recognising that litigation remains a possibility strong leadership from the Department of Health nationally in supporting and funding, has been instrumental in allaying these concerns. The UK initiative serves as a good model for a national approach.(33)

As stated, AED programs introduced in Australia to date have been in a first responder mode. There are no data as to the extent to which AEDs are placed that allow use by bystanders first on the scene. It would be reasonable to conclude that this approach remain essentially untested with its effects unknown. A proposal supported by the Victorian Government to site AEDs in public access mode at a number of railway stations has yet to be finalised.
The use and benefits of AEDs in the home, where approximately 75% of cardiac arrests occur, remains unknown. This is being addressed through a multinational multicentre randomised trial of placing AEDs in the homes of high risk patients. (Home AED Trial) This is being co-ordinated in Australia by the National Heart Foundation.

Issues of data collection also remain unresolved. Where AED programs are linked within a system providing training and oversight, data is being collected at varying levels. Similar to the experience of the USA no uniform requirements for data collection or definitions exist for AED use in Australia. It may be of considerable benefit to closely examine the AEA data collection system and tool developed by the RCUK and published in the journal Resuscitation.(42)

In summary, the placement of AEDs in the Australian community has been driven by ambulance services and community organisations. Almost exclusively these have been implemented as part of a first responder system with little or no government funding. The use of AEDs by trained or untrained bystanders, while supported within the Eclipse Statement, remains generally unknown but may potentially improve outcome. There lacks a national strategy for data collection and analysis of outcomes.
6.0 References


ATTACHMENT ONE

The Eclipse Statement

The participants developed and refined a joint statement in the days following the workshop (see final statement – attached) and agreed that a small committee should be established to address issues such as legal protection and physical safety for users of the devices. The Commonwealth will circulate a draft report on the workshop in early 2003.

*The Eclipse statement in support of Public Access Defibrillation*

The participants at the Public Access Defibrillation Workshop (4 December 2002, Canberra) agree with the following principles:

There is evidence to support the access to and use of Automated External Defibrillation in the community.

Defibrillation should preferably be undertaken by trained lay people or health professionals. As trained personnel may not be available immediately, untrained bystanders should also have access to the use of public access defibrillators.

Public Access Defibrillation is a highly effective, low cost component in the treatment of sudden cardiac arrest when these devices are placed appropriately.

Public Access Defibrillation represents an important link in the Chain of Survival for a person experiencing a sudden cardiac arrest. Any initiative in this area should promote the other links in that chain.

Promotion of public access defibrillation should also aim to raise awareness of the broader issues around preventing unnecessary deaths from cardiac arrest.

Programs are needed to support the broader education of the Australian community in emergency response and cardiopulmonary resuscitation (CPR).

A national strategy, informed by the Australian Resuscitation Council (ARC) guidelines, should be developed as a matter of urgency.

The individuals and organisations represented at this workshop are prepared to work together in developing a strategy for implementing Public Access Defibrillation.

By coincidence, a total solar eclipse was observed in parts of Australia on the day of the Public Access Defibrillation Workshop - 4 December 2002. In the past, eclipses caused panic among those who misunderstood them. Compared to an eclipse, defibrillation can be even more life changing - indeed life saving - yet like eclipses we must overcome entrenched attitudes, for example the notion that only emergency personnel can resuscitate a person with cardiac arrest. By linking this workshop to the solar eclipse, we remind the community to overcome irrational fears and act in accordance with the evidence.
ATTACHMENT TWO

Basic Life Support Flow Chart
Australian Resuscitation Council
Basic Life Support Flow Chart

**COLLAPSE**
Check for Dangers
Assess Responsiveness
Call for Help

**CONSCIOUS**
Make comfortable
Observe: Airway
Breathing
Circulation

**UNCONSCIOUS**
Clear airway
Check for breathing

**BREATHING**
Stable recovery position
Observe: Airway
Breathing
Circulation

**NOT BREATHING**
Commence EAR
Check for signs of circulation

**SIGNS OF CIRCULATION**
Continue EAR

**NO SIGNS OF CIRCULATION**
Begin CPR
Attach SAED if available

Check for signs of circulation after one minute and then at least every two minutes.

**EAR** = Expired Air Resuscitation
**CPR** = Cardiopulmonary Resuscitation
**SAED** = Semi-Automatic External Defibrillator