

3. Literature Review and Desktop Research

In this chapter, CR&C provides an overview of recent literature relating to the effective and appropriate use of AEDs under PAD and first-responder programs. Literature was sourced from both Australia and overseas.

In 2004, Associate Professor Ian Jacobs conducted a similar review for the Department (Jacobs 2004). CR&C has adopted the structure used in this review, and has ‘updated’ the findings with evidence that was made available after 2004. In addition, CR&C has provided additional information about alternative models for delivering AED/PAD programs, drawing evidence from the UK and the US.

3.1 The evidence for PAD

3.1.1 Findings from the 2004 review

The 2004 Jacobs review identified a number of sources of evidence for the effectiveness of PAD in increasing survival rates for people who suffer cardiac arrest in public places. Studies cited came to the following conclusions.

- A study of a PAD program in American airports concluded that 21 persons had suffered an arrest during the two-year project period, of which 62% were successfully resuscitated using an AED.
- An Italian study compared the use of PAD to traditional EMS treatment for cardiac arrest, a higher survival rate was shown for people treated by volunteers trained to use AEDs compared with EMS services.
- Only one sizeable randomised control trial was reported (the studies described above were non-controlled observational studies). This American study randomised sites into two groups: one set of sites was provided with CPR training alone (control group), the other with CPR training *and* training in the use of AEDs (intervention group). The study demonstrated a higher (almost double) survival rate for the intervention group compared with the control group.

However, the 2004 review was quick to point out that the object of these studies was not *Public Access Defibrillation* in its truest sense. The programs in question were generally based on a ‘first responder’ that centred on trained personnel operating the device, rather than the lay public.

Based on these considerations, the 2004 review concluded that:

The evidence to date supports the premise that early defibrillation delivered within a PAD mode improves survival following cardiac arrest occurring outside of hospital (Jacobs 2004, p.14).

3.1.2 Update: evidence published since 2004

In 2004 (shortly after the submission of the original literature review to the Department), Culley et al. published a cohort study of the impact of a PAD program on cardiac survival rates in Seattle and Washington, America (Culley 2004). The study compared survival rates for out-of-hospital cardiac arrests for those treated with an AED vs. those treated with traditional EMS. Culley concluded that PAD was involved in a small proportion of successful resuscitations for out-of-hospital cardiac arrests. The proportion of successful cardiac arrests was noted to increase over time as the implementation of the program progressed. Compared with traditional EMS, Culley concludes:

Survival rate was 50% in cases treated by PAD AED, a figure considerably better than most EMS systems (p. 1861)

A literature review by Clare (2006)¹⁵ also concluded that there was some evidence for the efficacy of PAD programs. Following the examination of 22 studies of PAD and related programs, the review concluded that PAD programs had a small but noticeable improvement in survival rates for people who suffered sudden cardiac arrest in public places. However, the paper noted that many of the studies in question incorporated bystander Cardiopulmonary Resuscitation (CPR) training as part of their interventions. The presence of people with CPR training was reported to exert a far greater effect over survival rate compared with PAD alone. The paper concluded:

Finally the effect of level one PAD programmes is partially dependent on the provision of bystander CPR (CPR by a member of the public with no duty to respond) as physiologically CPR maintains the shockable cardiac arrest rhythm by perfusing the heart and preventing degradation into asystole (p. 1061).

3.2 PAD locations

3.2.1 Findings from the 2004 review

The 2004 review examined a number of studies of PAD programs that emphasised the importance of strategic placement of AEDs to maximise utility. From an epidemiological perspective based on Australian and overseas research, the review states:

- Approximately 40% of cardiac arrests occur in non-residential locations (based on overseas findings), the estimate for Australia is somewhat lower at 25%;
- The five most common locations for out-of-home cardiac arrests are airports, gaols, shopping centres, sports venues and industrial sites;
- Between 5 and 32 lives *could have* been saved if AEDs had been placed in these high-risk locations during the five year period covered by the study (no AEDs were present at the time that that study was conducted);
- There is an inverse relationship between population density and the overall incidence of cardiac arrests – that is, the more dense the population in a given area, the lower the incidence of cardiac arrest. However, this relationship is reversed for out-of-home cardiac arrests – the higher the population density, the greater the incidence of out-of-home cardiac arrests.

The review concludes:

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 (Jacobs 2004, p.16).

3.2.2 Update: evidence published since 2004

Reed et al. (2006) published a study that examined epidemiological data to determine the optimal location and number of AEDs for PAD and related programs. Reed concluded that the greatest rates of treatable cardiac arrests occurred in fitness centres and golf courses. However, the greatest survival rates from cardiac arrest were noted for different locations: recreational complexes, public transportation facilities and fitness centres. The difference between incidence and survival was attributed to the rate of volunteer presence and intervention.

¹⁵ Conducted separately from the 2004 review for the Department

3.3 Implementation: recruitment, training and implementation issues

3.3.1 Findings from the 2004 review

The 2004 review considered the effective and appropriate use of AEDs in the hands of trained and untrained lay-people, as opposed to professional members of EMS who may also administer AEDs or other forms of resuscitation. Based on examination of a number of local and overseas studies, the review stated:

- Advancements in the technology used in AEDs reduce the training requirements for lay-people;
- Lay-people and even very young children are able to effectively and safely use an AED, however the time taken to administer the required shock is longer for this group compared with trained professionals; and
- While untrained people can safely and effectively use AEDs, the vast majority of AED activations are still performed by trained people.

The review also stated that the quantity of training required to optimally use an AED remains unproven.

The review concluded:

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 (Jacobs 2004, p.20).

3.3.2 Update: evidence published since 2004

The importance of AED training of both staff and volunteers is widely acknowledged as a vital component of any PAD program. However, Reigal et. al. (2006) note that skills imparted as part of training programs are not maintained indefinitely. Reigal conducted an observational follow-up study of 19,320 staff and volunteers who had taken part in AED and CPR training programs in America. Reigal estimated that 91% of the study participants had maintained the required skills and knowledge to operate AEDs five months after initial training. This proportion fell to 84% seventeen months after initial training. Retention of required skill and knowledge were noted to be higher for AED operation compared with other interventions such as CPR. Successful retraining of those who had not retained the required skills was reported to take only ten minutes.

Richardson et. al. (2005) published a descriptive study of a trial of a PAD program in America and Canada. The program in question was community-based, and used training of staff in public places as well as volunteers in the use of AEDs and CPR techniques. The paper describes a number of issues similar to the Australian experience, and notes a range of barriers to the successful implementation including difficulties in the identification of suitable sites for implementation; difficulty in recruiting businesses and individuals to take part in the program and fear of litigation as a result of participation. The key driving factor behind successful implementation was reported to be the involvement of a key decision maker at the ground level. Despite these challenges, the paper concluded that:

These data indicate that implementation of community-based lay responder programs is feasible in many types of facilities, although these programs require substantial resources and commitment, and many barriers to implementation of effective PAD programs exist (p. 668).

3.4 Risks

3.4.1 Findings from the 2004 review

The 2004 review identified a number of risks associated with the provision of AEDs in PAD programs. The primary risk identified was legal in nature.

A study of a PAD program in the UK identified the possibility of threats of legal action for lay-people who use AEDs. In UK law at the time, no protection was provided for lay-people such as ‘Good Samaritan’ legislation. However, the risk of legal action was seen to be minimal.

The review concluded:

Little information is available that outlines specific risks associated with the broad implementation of PAD ... 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 (Jacobs 2004, P.22).

3.4.2 Update: evidence published since 2004

AEDs are noted for their safety and reliability, particularly with advancements in technology in the past years.

However, as with any complex electronic device, AEDs can be prone to error and failure. In an American study, Shah et al. (2006) examined AED recalls and safety alerts to estimate the rate of failure and malfunctions for AEDs. The study included 775,539 AEDs sold between 1996 and 2006. Key findings of the study included the following:

- Actual malfunctions and failures of AEDs were reported to be very low, the risk of failure was estimated to be less than 1%;
- The number of recalls of AEDs was far higher at 21%. Recalls were most commonly done as a result of known hardware weaknesses. Errors due to software were less common;
- The study identified 370 instances of fatal AED device malfunctions.

Despite these known issues with AEDs, the paper concluded that:

... the total number of malfunctions is small compared with the number of lives saved (p. 658).

A study published in Austria cites a risk associated with AEDs that may be relevant to the Australian context. Schlimp et. al. (2004) suggested that interference from high-voltage power-lines may affect the functioning of AEDs. Schlimp noted that AEDs operated near such power-lines were at an increased risk of failure due to the high electrical charge interfering with the devices’ ability to detect and analyse rhythms prior to shock. This interference was reported to have the potential to cause substantial harm to patients. The study concludes:

The proper function of AEDs needs to be reconsidered to guarantee patients’ safety near high-voltage power lines (P. 595)

It should be noted that the high-voltage power line system in Austria may differ to that in Australia, and the results of this study can not necessarily be applied in the Australian context.

3.5 Cost benefits

3.5.1 Findings from the 2004 review

The 2004 review identified few studies that examined the cost effectiveness or cost benefits of PAD programs. An American study that was included in the Jacobs review concluded that PAD programs

may be ‘economically attractive’ despite the fact that they are more expensive than traditional EMS response mechanisms. No Australian data was available at the time of the review.

The review concluded:

PAD would appear to be potentially a cost effective intervention however no formal cost benefit analysis has been undertaken in Australia (Jacobs 2004, P.23).

3.5.2 Update: evidence published since 2004

No studies regarding the cost benefits of PAD or AED that were published since 2004 could be identified for this updated review.

3.6 Other models in other countries

3.6.1 Findings from the 2004 review

The 2004 review examined a PAD program that was being delivered in the UK. The program:

- Developed an administrative structure including advisory committee;
- Obtained support from key stakeholders including ambulance, community groups and health professions;
- Determined the legal status of the those using the equipment;
- Procured defibrillators;
- Established pilot sites including training; and
- Administered long-term management of the program.

These activities were funded under the National Health Service, the UK equivalent of the Department of Health and Ageing.

A number of challenges were reported for the program including defining the legal status of lay-people who use AEDs, generating the enthusiasm and interest in the program and developing data collection mechanisms for evaluation. The progress of the program was reported to the public via a series of six-monthly bulletins.

The review concluded:

... 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 (Jacobs 2004, P.27).

3.6.2 Update: The UK experience

A number of developments have been noted in the UK approach since the 2004 review. The review extensively cites a paper by Davies (2002) which describes in detail the introduction of the PAD program in the UK. In the concluding sections of the paper, Davies looks to the future and suggests:

The Department of Health may not be the best place for the longer-term administration of the project however because operational activities such as this are not a key part of Department of Health work (p. 19).

A review of the program’s website in 2008 has suggested that indeed the Department of Health in the UK has divested much of its role in the program to other organisations such as ambulance trusts and charitable organisations, thus completing the ‘evolution’ of the UK model.

Early stages of the UK model

The PAD Program’s website describes the early stages of the program:



In July 1999, the White Paper, Saving Lives: Our Healthier Nation announced the Government's intention to invest £1 million in installing AEDs in busy public places. A further £1 million was then committed to training people employed at the site in their use and in basic life support. (Department of Health 2008).

At this time, the program was entirely funded by the Department of Health who also provided governance and oversight of training and installation via a series of committees and panels of experts. In the coming years, this model was maintained as further funds were allocated and the implementation of AEDs under the program became more wide-spread.

The program was the object of much scrutiny from both the academic and health sectors, with many papers published on the process of implementation and outcomes arising from the use of AEDs.

The early stages of the implementation of the UK model appeared to be successful. The program's website clearly states the extent to which AEDs have been taken up by the community, and the benefits that have arisen from AED usage.

700 AEDs have been placed at 110 locations across England and more than 6,000 volunteers have been trained in Basic Life Support skills. Current evidence suggests that 74 lives have been saved as a direct result of the work of the programme¹⁶ (Department of Health 2008).

The UK Model today

Today, the way in which the model is implemented and governed in the UK is quite different to that described above. Described as the shift to 'Phase 2' of the program, key developments include the following.

- As of February 2005, the program became a 'Core NHS activity', which meant that ambulance trusts at a local level are now charged with all training and re-training of volunteers. Local ambulance trusts were also given responsibility for who would then receive a publicly funded AED (Department of Health National Defibrillator Programme 2005). This function had initially been provided by the 'defibrillator advisory committee' formed by the Department of Health (Davies 2002). According to the program's website:

In the current and final stage of the programme Ambulance Trusts across England have been invited to identify areas in their regions that would most benefit from the installation of AEDs and apply accordingly. Thirty-one trusts will now receive a share of the next 2,300 AEDs for their areas as well as a Community Defibrillation Officer to oversee and coordinate the necessary installation, training and management of these AEDs (Department of Health 2008).

Responsibility for the existing 400 sites established for the first phase of the program was also devolved to the local ambulance trusts.

- Funding for this second batch of AEDs was, however, not provided by a Department of Health budget measure. In 2003, six million pounds was provided directly to the British Heart Foundation via an allocation from the 'Big Lottery Fund' (BLF). The BLF:

... gives out millions of pounds from the National Lottery to good causes. Our money goes to community groups and to projects that improve health, education and the environment (Big Lottery Fund 2008)

A review of the Department of Health website suggests that the Department is no longer directly funding the purchase of AEDs.

¹⁶ CR&C has used the UK spelling of 'programme' in this section as it is reported in UK publications. Elsewhere, the Australian spelling of 'program' is used.

As such, it would appear that while the Department of Health still plays some role in the administration of the program, day-to-day management and funding mechanisms have been shifted to not-for profit and peak body organisations.

Despite these changes, the UK program remains a centralised, relatively uniform and publicly funded model with many similarities to Australia.

3.6.3 Update: In stark contrast, the American experience

In contrast to the UK approach, the US does not have *one* funding or legislative model for AEDs. Rather, America has 50 funding/legislative models, one per state.

Historically, AEDs first entered the legislative arena in 1998, when the then President Clinton signed the *Aviation Medical Assistance Act* that stated that “airlines and individuals shall not be liable for damages” in attempting to obtain or provide assistance in the use of AEDs on aeroplanes”. This legislation was later expanded by Clinton in 2000 when he signed the *Cardiac Survival Act* providing civil immunity to authorised users of AEDs in public places. Additionally, this act also made provision of US\$25,000,000 over two years for the appropriation of AEDs. Further legislative change occurred in 2002 when the then President Bush signed the *Community Access to Emergency Devices (Community AED Act)*, a sub-section of the *Public Health Security and Bioterrorism Act* (obtaining funding under the banner of terrorism was common at that time). The Act provided for a further US\$30,000,000 in funding for the purchase of AEDs, and training of staff and volunteers in their use (National Conference of State Legislatures 2008).

AED and PAD programs appear to be still very much on the American agenda. The advocacy group *The American Heart Foundation* plays a strong role in advocating for ongoing funding and is very vocal in its views in a range of publicity campaigns. In 2007, the Foundation published a series statements urging the federal government to release almost US\$45 million, that had allegedly been promised in 2004 (American Heart Association 2007).

Between 1995 and 2000, all states introduced laws and regulations relating in some way to AEDs. Since 2000 many states have gone on to re-examine these pieces of legislation to facilitate the purchase of AEDs, and the implementation of AED and PAD-based programs. However, the introduction, funding and implementation of these pieces of legislation have been far from consistent from state to state (Aufderheide 2006).

The table on the following pages provides a summary of the way in which the 50 different states have legislated, funded and implemented AED and PAD-related programs.¹⁷

States have used a mix of approaches to roll out PAD programs, some using federal funding, some introducing legislation mandating the use of AEDs, others providing incentives to organisations to purchase and register AEDs. While all states have taken some action in this regard, some states have done very little. The table on the following page provides seven key pieces of information for each state:

- Whether legislation had been introduced that provided any form of protection for lay people to use AEDs (such as Good Samaritan legislation);
- Whether immunity from legal action had been provided to trained and authorised users of AEDs;
- Whether federal funding had been appropriated for the purchase of AEDs and training of operators, and the amount of that funding where known;

¹⁷ This table is based on summary information provided by the American National Conference of State Legislatures. A full review of specific legislation from each of the 50 states is beyond the scope of this review. Some of the information provided by this organisation is incomplete and is noted as such in the text.

- Whether non-binding resolutions had been passed that *encouraged* organisations to take part in AED programs, but not *mandating* participation;
- Whether changes had been made to legislation about training and liability requirements since 1998 (when AED legislation was introduced at the federal level);
- Whether legislation had been passed that mandated the purchase and maintenance of AEDs for certain businesses; and
- Comments on the types of legislative change and funding arrangements implemented by each state.

Considering the states overall, the following can be concluded:

- Almost all states (96%) have implemented some form of legislation that gives limited protection to lay-people using AEDs;
- Almost all (90%) have introduced legislation that gives total immunity to people trained in AED use in the conduct of resuscitation using the device;
- One third (30%) of states had received some form of federal funding of amounts between \$100,000 and \$3,300,000. Funding was obtained from a variety of sources, not all of which are relevant to the Australian context:
 - Directly via the budget measures described above (states tended to re-badge the budget measure using their own program names such as ‘First State – First Shock!’);
 - A small number of states obtained funding via a tobacco settlement fund;
 - One state established a ‘donation partnership’ with the American Heart Foundation that co-ordinated donations for the purchase of AEDs;
 - One state appropriated a small amount of funding (\$100,000) but required organisations to make an in-kind contribution of 50% for the purchase of AEDs; and
 - One state facilitated the bulk purchase of AEDs at a discounted rate for distribution to schools.
- One fifth (18%) of the states passed non-binding resolutions with requests for actions such as the identification of suitable sites and liaison with AED manufacturers by state health departments, or generally encouraging (but not mandating) the installation of AEDs in selected businesses;
- Two thirds (61%) of the states made recent legislative changes that provided some form of protection for either trained or untrained users of AEDs. The general pattern for these changes was two-fold: An initial revision to legislation that provided some form of immunity to trained users, followed by a second revision that broadened this protection (though often in a lesser form) to untrained users;
- Three quarters (27%) of states introduced legislation that mandated the purchase and maintenance of AEDs in specified organisations. The most commonly mandated organisations were schools (typically public schools) ‘fitness studios’ and sporting venues. It was not clear whether funding was provided to these organisations following the legislation change;
- Three quarters of the states introduced specific regulation that mandated the registration of AEDs, either with the state health authority or emergency services (based on additional information obtained from the American Heart Association 2008). However, one state took the unusual action of *removing* the requirement to register AEDs, presumably in an effort to reduce administrative burden.

3.7 Desktop research – cost analysis

CR&C reviewed financial data for the PAD Demonstration that was current for the 2006 and 2007 calendar years. Estimates of the efficiency of the Program were made based on reported program and administrative costs, and unit costs were calculated based on the number of lives saved, the number of activations and the number of host organisations. In summary:

- **The total funded amount for the program was \$869,563** (excluding GST) for the 2006 to 2008 period. This total funding allocation includes an additional budget allowance of \$200,000 in 2007. In 2007, \$589,425 (48%) of this allocation had been expended.
- **The PAD Demonstration appears to be operating efficiently.** Overall, 14% of expenditure was allocated to program administration. The remaining 86% was allocated to program costs. This allocation of program/administration costs is within an acceptable range.

Program costs included the purchase and installation of AEDs, provision of training and the production of posters. Administrative costs included travel and expenses for management meetings and costs associated with setting up a home office. One assumption was made in this analysis: 20% of all salary costs were assumed to be administrative costs and the remaining 80% assumed to be program-related.
- **The PAD Demonstration has achieved a number of tangible outputs and outcomes**, most notably the recruitment of nearly 100 sites, the installation of nearly 150 AEDs and ultimately the saving of seven lives. Based on expended costs to December 2007, unit costs associated with these outcomes include:
 - **Cost per site: \$6,015** (98 sites);
 - **Cost per AED: \$4,010** (147 units, with multiple units installed at some sites);
 - **Cost per activation: \$29,471** (20 activations); and
 - **Cost per life saved: \$84,204** (seven lives saved, not all activations result in a saved life).

It can be reasonably assumed that these unit costs will decrease as single AEDs are used multiple times at their respective sites.

These calculations are based on data obtained from the PAD Demonstration project. The unit costs were estimated by dividing the total number of sites, AEDs, activations and lives saved by the total expenditure of the project to date. The program and administrative costs were calculated by dividing program costs (AEDs, training etc) and administrative costs (salaries, on-costs etc) by the total expenditure of the project to date.

These calculations may provide a rough estimate of expected costs should the program be expanded to incorporate a greater number of sites/AEDs, and the cost of the ultimate intended outcome of the program: successful resuscitations of people suffering cardiac arrest in public places.

Comparative data for alternative means of resuscitation (e.g., emergency response services) were not available for this evaluation. The Department may wish to consider such a comparative analysis for future research and evaluation.