**Enhancing community resilience to sudden cardiac arrest through regulation of Public Access AEDs: Balancing the regulatory burden and the public good**

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## Executive Summary

Sudden cardiac arrest (SCA) is an international health problem and a leading cause of death in Australia. It is a complex public health issue requiring a multi-faceted, well-coordinated, and standardised response that includes public access defibrillation. Australia, like many other countries around the world though, has no legislative mechanism that would regulate the acquisition and registration, maintenance, accessibility, and availability of AEDs.

The current discussion paper brings to attention this absence and, based on review of the published research, and examination of legislative efforts around the world, proffers the following principles to inform the development of a regulatory framework necessary to enhance community resilience to SCA:

A. **Legislation should be enacted** in Australia to regulate maintenance, registration, regulation, availability and accessibility of publicly accessible AEDs, and provide greater "Good Samaritan" certainty to those who employ an AED at SCA events.

B. **Legislation and accompanying regulation should be enacted at the national level** in order to promote a comprehensive, integrated programmatic approach to regulation of public access AEDs.

C. Legislation and accompanying regulation regarding publicly accessible AEDs should be **informed by the principles of the Building Code of Australia (BCA)**, as they relate to the location, installation, registration, and maintenance of fire extinguishers.

D. **Public access AED data should belong to the statutory ambulance service within a particular jurisdiction**, to ensure that data integrity is assured, and location and accessibility data are made generally available to the public for use in cases of sudden cardiac arrest.

E. **Accredited first aid courses should be adapted** to accommodate provision for the maintenance as well as use of AEDs.

## 1. Introduction

Sudden cardiac arrest (SCA) is an international health problem and a leading cause of death in Australia [1-3]. Researchers argue a core contributing factor to the number of deaths may be the absence of a well-coordinated, standardized response to SCA events, that includes bystander CPR and early defibrillation with automated external defibrillators (AEDs)[4]. A further absence in Australia, like many other countries around the world, is a legislative mechanism that would regulate the acquisition and registration, maintenance, accessibility and availability of AEDs[5].

The aim of this discussion paper is to bring to attention some of the barriers to widespread adoption of public access defibrillation in Australia, with the ambition of encouraging government, business, and members of the public generally, to engage in the development of the kind of coordinated response system necessary to enhance community resilience to SCA.

Commentary here builds on excellent review work undertaken by the George Institute for Global Health in NSW, which concludes there is sufficient evidence that publicly accessible defibrillators can improve SCA survival rates by a factor of 2-3[6]. In doing so, this paper proposes a regulatory framework that seeks to balance the burden on owners and operators of AEDs with the public good it is intended to promote, while providing for an authoritative "single source of truth" (SSOT)[7] regarding the location and operability of AEDs.

## 2. Sudden Cardiac Arrest: Scope of the Problem and Barriers to Solution

The global incidence of SCA is estimated at 100 per 100,000 population[3], approaching 8 million SCA events per annum. It is also a leading cause of death in Australia – more than 28,000 SCAs each year result in nearly 26,000 deaths, with a survival rate of less than 10%[3]. Despite considerable activity to identify factors associated with higher SCA survival rates, the survival rate remains stubbornly low.

Researchers argue that a core contributing factor to the number of deaths may be the absence of a well-coordinated, standardized response to SCA events. To achieve that effective care for cardiac arrest, they argue, requires a coordinated response across various groups, organizations and disciplines, including the public/bystanders, first responders, emergency medical services (EMSs) and health care facilities[4]. Bystander CPR and early defibrillation, using automated external defibrillators (AEDs), are recognised as central to this coordinated response, which is commonly referred to as the cardiac "chain of survival"[8].

Publicly accessible AEDs save lives [5, 9-10], and there is a great push in communities around the world to turn bystanders into first responders, by installing publicly accessible AEDs, and training people in their use. In Australia, for example, organisations such as St John Ambulance, the Australian Resuscitation Council and the Michael Hughes Foundation are actively placing AEDs into the community. The NSW Government is coming towards the end of a four-year funding program to provide 2,400 AEDs for community-based sporting clubs throughout the State, including regional and remote areas.

To be successful, however, AEDs need to be locatable and operable, when they're required. Locational data for publicly accessible AEDs are kept in registers, held by ambulance services for example, but their accuracy and accessibility is problematic. The location of the nearest AED is not available in real-time or may simply be wrong. Another complication is that, when the AEDs are located, they may not be operable, because of depleted batteries, or chest pads being past their use by date. In the US alone, for example, more than 1,100 cardiac arrest deaths over a 15-year period have been directly connected to the failure of AEDs, with battery and chest pad failure accounting for nearly 50% of those failures[11]. These problems with the location and operation of AEDs are complicated by significant barriers to giving the public access to defibrillation devices, including bystander knowledge, awareness, and willingness to use AEDs; training and medicolegal issues; and acquisition, maintenance, registration, regulation, availability and accessibility of AEDs[12].

The focus of this paper is on overcoming the barriers related to the maintenance, registration, regulation, availability and accessibility of AEDs. For example, although AEDs are considered a medical device by Australia's Therapeutic Goods Administration, there are no post-purchase regulatory or other requirements regarding the registration and maintenance of AEDs imposed by either State or Federal governments. Accordingly, there is no assurance that AEDs are locatable, accessible or in good working order when they are needed. Instead the approach appears to be one of "set and forget", reflecting an Australian attitude of "she'll be right, mate". Again, the solution is necessarily a multivariate one, addressing what is recognised to be a complex problem by way of a systematic/ programmatic approach[12]. One element of this multifaceted response is the approaches to legislation discussed in the next section.

## 3. Legislative Responses to the Regulation of AEDs

This section provides summaries and comparisons of the legislative frameworks that have been implemented in the USA and Europe, along with a presentation of the key elements of bills introduced into the UK Parliament that have yet to be passed into law. A more recent initiative, the private member's Bill introduced to the South Australian parliament early in 2020, rounds out the discussion.

### *(i) AED Legislation in the USA*

A systematic/programmatic approach has been adopted in the USA, including the majority of its 50 States and the District of Columbia, by introducing legislation that governs:

- administrative and operational requirements for AED programs (including maintenance, training, agency reporting and so on),
- liability protection for AED programs and those involved in the programs (Good Samaritan laws), and
- organisations required to have AEDs[13]

The AED Law Center presents a clear, authoritative analysis and explanations of AED laws for every US state, in plain English[13]. What it also does is highlight the significant variation in approaches adopted across the states.

The AED Law Center web site also provides an exceptional *evaluation* of the legislative requirements and is quick to note when those requirements are inconsistent or burdensome on the organisations responsible for AED programs[13]. For example, in New Mexico, New York and Oklahoma, organisations or individuals who acquire AEDs are required to notify appropriate authorities of the existence, location and type of any AEDs. In none of those states, however, do the laws identify which specific agencies are to be notified. Nor do they authorise or require a receiving agency to use the reported AED data for any particular purpose.

In the same way, many of the States demand that AED *acquirers* ensure that AED *users* activate Emergency Medical Services (EMSs) as soon as possible. The AED Law Center argues this places an unreasonable burden on AED acquirers. On the one hand, *acquirers* generally have no active control over AED *users* during SCA events. On the other hand, the EMS system can be activated reasonably and appropriately by another person nearby, freeing up the AED user to attend directly to the AED event.

Good Samaritan Laws

In the US, AED Good Samaritan laws protect individuals and/or organisations from having to pay damages resulting from ordinary mistakes (characterized as "negligence"), but the AED Law Center concludes that the degree of protection depends on how immunity laws are written. The Center argues that immunity laws must cover the *right* people for the *right* activities and the *right* levels of conduct to provide real immunity protection. It points to the structure of the following four key components as determining whether AED programs and the people who are part of them are beneficiaries of broad or limited immunity protection[13]:

- *Covered Participants*: Four categories of participants are identified – (1) AED acquirers and those responsible for AED program sites, (2) AED users (trained or untrained), (3) CPR/AED trainers, and (4) AED program medical directors (sometimes) Each of these are involved in AED programs. Broad immunity laws offer protection to all four groups, while other legislation limits the categories of participants protected.
- *Activities Protected*: AED programs engage in pre-event activities (e.g., assigning AED program personnel roles, buying and placing AEDs throughout an organization, establishing response time policies, properly maintaining equipment, and so on) as well as event-related activities (recognizing possible SCA, retrieving and using an AED in a timely and appropriate matter, etc). Broad immunity laws offer protection for all AED program activities, while others limit protection solely to AED use.
- *Conduct Protected*: In negligence lawsuits, actions are judged along a continuum of conduct, from non-negligent to negligent, grossly negligent, or worse. Broad immunity laws offer protection to AED program managers and those involved in AED responses while other laws do not.
- *Conditional Immunity Limitation*: Conditional immunity laws provide immunity protection only if AED programs and participants comply with some or all of administrative and/or operational requirements referred to earlier.

### *(ii) AED Legislation in Europe*

Noting that a number of countries are developing public defibrillator programmes in the context of widely differing legislative frameworks, and that a lack of clarity over the rules

regarding AED use could cause confusion in an emergency, the European Emergency Number Association (EENA) has recently released a report on the findings of its research with 22 countries (19 in the Europe Union and 3 outside the European Union) to document the legislation, rules and recommendations in each country[15]. Given the large variations between the *states* of the United States of America, it is perhaps unsurprising to read of the differences between *countries*, in the European Union and beyond, in regard to national AED legislation registration of AEDs, training requirements to use an AED, and mapping of public access AEDs.

An added level of complexity is that there is also variation between different regions in the same country. For example, in Spain, there are significant differences in the rules covering who can purchase and install an AED in public places, and who can use an AED in public places between the Principality of Asturias and the Regions of Galicia, Madrid and Valencia[16].

One of the interesting and instructive case studies for our purposes here is the Swedish AED Register, or SAEDREG[17]. Established in 2009 and managed by the Swedish CPR Council, the SAEDREG is a *non-compulsory* register of public AEDs in Sweden, containing information entered by AED owners on AED location and accessibility. To establish and maintain a high level of ongoing validity, AED owners are sent an automated reminder email every 6 months after initial registration, to verify all entered data, and only owner-verified AED data are displayed on the SAEDREG web page. By the end of 2013, SAEDREG only held data on 7078 AEDs or 36% of the AEDs sold in Sweden (based on figures from AED companies in Sweden[18]).

More positively though, a recent overview of the SAEDREG shows a two-fold increase of registered AEDs since 2013 (to 15,849 AEDs), with the largest group (45%) installed in offices and other workplaces[17]. As part of the review, a survey was sent to all 218 owners of AEDs in a region of Sweden. One of the survey's foci was on reasons for not registering the AED on SAEDREG. The main reasons proffered for not registering on SAEDREG were lack of awareness of the national AED registry and difficulties with the registration process itself.

Notwithstanding the significant increase in AED registrations on the SAEDREG system over the succeeding five years, it seems that voluntary registration may need to be replaced with another form of registration to gain as high a level of registration as possible. There is also a need to engage in awareness raising exercises and to make the registration process as straightforward as possible.

### *(iii) Proposed AED Legislation in the United Kingdom*

Noting the ties between Australia's legislative system and the UK's common law system, it is worth pointing out that, like Australia, there is currently no legislation in the UK which obliges certain businesses or premises to provide an AED, nor is it compulsory for employers to purchase AEDs to comply with the UK *Health and Safety (First-Aid)* Regulations 1981. There appears to be, however, a determination on the part of UK lawmakers to enact such requirements, with the aim of increasing rates of survival from cardiac arrest[18-20].

Maria Caulfield, the Conservative MP for Lewes in the UK, has twice introduced in the UK House of Commons a Bill for an Act to require the provision of defibrillators in education establishments, and in leisure, sports and certain other public facilities; to make provision for training persons to operate defibrillators; to make provision for funding the acquisition, installation, use and maintenance of defibrillators; and for connected purpose[18-20]. On both occasions, the Bills failed to complete their passage through Parliament before the end of the session, but the drafts of the legislation do provide a familiar framework within which Australian governments might consider ways forward in enhancing the Australian community's resilience to SCA. Unfortunately, at the time of writing this paper, the Bill does not appear on the UK "Bills before Parliament 2019-21" list.

While UK AED legislation remains a statement of good intent, one area where UK health agencies have led the world in providing a "best practice" response to SCA is in linking bystanders, responders and ambulance despatch services through the GoodSAM smartphone app. Discussion of this important public health initiative is taken up in the next section on locational data.

### *(iv) Proposed AED Legislation in South Australia*

Reference was made earlier in this discussion paper to the absence of Australian legislation to regulate AEDs. There has been an attempt recently to change this situation, however, with the introduction by a cross-bench MLC, the Hon Frank Pangallo, in the South Australian Parliament of the *Automated External Defibrillators (Public Access) Bill 2020*, which will require the installation and registration of Automated External Defibrillators in certain buildings, facilities and vehicles[21].

Capturing a broad range of public and commercial premises, the Bill would require the installation of one AED in buildings less than 1200m$^2$, one AED for each 1200m$^2$ in larger buildings, and on buses, trains and a variety of other public vehicles. The Bill also makes provisions for the establishment and maintenance of an AED register which is accessible via smartphone app, the development and implementation of an awareness strategy, and the development and implementation of an AED training strategy.

We commend Mr Pangallo for his efforts to address this important issue in the absence of a national approach to AED regulation. At the same time, we have some concerns regarding the spatial elements of his Bill's requirements, and address these concerns here. Other aspects of the Bill are considered against the range of legislative principles we elucidate later.

Research tells us that *time* is the most critical factor to SCA survival[6] and it is held that public access AED programs should enable lay responders to retrieve and use AEDs within three minutes of recognizing SCA[22]. Generally, two minutes of the AED response time are allocated to AED retrieval, so it is necessary to calculate the maximum potential AED coverage area that will allow an AED retrieval time of up to two minutes.

The key factors affecting AED retrieval time include distance from the SCA event to the AED and any intervening obstacles. On average, adults walking rapidly travel approximately 100

metres per minute, so a 100-metre radius is an appropriate measure for any calculation of AED coverage area. Using the familiar $\pi r^2$ (where r = 100m) coverage area per AED would be 34120$m^2$ or the size of 5 football fields. This coverage area would need to be reduced, however, to account for obstacles such as people, doors, hallways, stairs, elevators, escalators, physical barriers and obstructions, AED storage methods, and similar constraints that reduce the effective area an AED can cover within the two-minute AED retrieval time[22].

The calculated maximum AED coverage area of 34120$m^2$ is significantly greater than the 1200$m^2$ in the *Automated External Defibrillators (Public Access) Bill 2020*, the latter representing a radius of approximately 19 metres or 1/5$^{th}$ the radius deemed appropriate above (100 metres). In the circumstances, it is argued that the 1200$m^2$ requirement of the proposed legislation would impose a significant, and even unnecessary, burden on owners of designated buildings that would outweigh the public good that would be provided as a result.

On a related matter, noting the complex definition of what constitutes a "designated" or "prescribed" building, perhaps a more straightforward and familiar definition might be given by "any class of building requiring the provision of a sprinkler system or fire hose should also require the provision of one or more AEDs based upon a formula that takes Into account the total floorspace of the building and the number of storeys or floors and the number of inhabitants". The definition could be included in an amendment to the Building Code of Australia, while AEDs could then be located in close proximity to the sprinkler controls and fire hoses to give adequate and equal coverage.

## 4. Locational Data for Publicly Accessible AEDs: A "single source of truth"

A phrase that has appeared in Australia's public discourse in in the context of the 2019-2020 bushfires and the continuing CoViD-19 pandemic is the need for "a single source of truth"[23]. With all the conflicting "information" being promoted to the public by different sources, business and sustainability advisor, Sam Mostyn called for a single source of truth – one source of information that could be relied on by the public in terms of what was happening and what needed to be done to respond positively and responsibly to those events[23]. This is a term that could be usefully applied to the regulation of publicly accessible AEDs.

With that in mind, we draw attention to GoodSAM (Smartphone Activated Medics), a London, UK-based not-for-profit organisation that utilises a Cloud-based emergency alerting and dispatching platform, integrated with ambulance service dispatch systems, to trigger actions by a community of trained and trusted responders while the ambulance service is on route[24]. The GoodSAM system also has a built-in crowd-sourced defibrillator registry, recognised as the world's largest of its kind. Members of the GoodSAM community have mapped thousands of Public Access AEDs, by taking a picture of a fixed location AED (e.g. fixed to a wall) and uploading it through the GoodSAM App.

Importantly for our purposes here, the Good Samaritans at GoodSAM believe that AED data should belong to the statutory ambulance service and they share their data with their ambulance service partners[24]. For example, in the State of Victoria, Australia, GoodSAM is collaborating with Ambulance Victoria, the State Government's statutory

ambulance service, to build a community of responders and establish a registry of public access AEDs via the GoodSAM App[25]. GoodSAM's view, that the data regarding public access AEDs should belong to the statutory ambulance service within a particular jurisdiction, is one shared by the authors of this discussion paper.

One barrier to communicating the "truth" that is rarely examined in the research literature more generally is the question of cultural influences on bystander awareness, knowledge and willingness to use AEDs. In a multicultural country like Australia where, in 2016, there were over 300 separately identified languages spoken at home[26], this is a significant issue that needs to be addressed. Quite apart from the need to ensure that awareness-raising initiatives take account of key community languages, there are other aspects of culture to consider. For example, one report on conditions that facilitate CPR and AED use by bystanders noted that fear of liability has previously been identified as a barrier to performing CPR and suggested that fear of liability (including the presence or absence of "Good Samaritan" Laws) might play different roles in different cultures[27].

It may be useful in addressing the issue of cultural influences on bystanders to consider Australia's Good Samaritan laws against these criteria to determine a balanced approach to the needs and rights of those who suffer SCA events and those who intervene as "Good Samaritans".

## 5. Additional Considerations for an Australian Legislative Framework

*Regulation maintaining pace with Technological Developments*

An ongoing issue (partly due to the legislative processes in a federation) is the apparent lag between technological developments, community expectations and regulatory currency. The proposed regulatory framework provides an opportunity to government to stay ahead of the potential problems by providing a national direction for the management and monitoring of AEDs, in a similar way to that by which we manage and monitor safety systems such as fire extinguishers.

It also represents a most significant opportunity to contribute to the human, social and financial capital of the country, by reducing the Burden of Disease attributed to sudden cardiac arrest (SCA) and coronary heart disease; by enhancing community resilience to SCA, through better health policy and planning; and by the positive economic impact of improving SCA survival rates.

*Ease a potential burden on the Civil Judicial System using basic risk management principles*

With an increasing public awareness of the vital life-saving function that AEDS serve in the community will come the attendant demand for AEDs not only to be found in their allotted location but to be in good working order. The provision of a faulty or inoperative AED or the failure to locate an AED in its allotted location will lead to additional complex civil law suits taking up the time and resources of the Courts when the issue can be readily managed by using basic risk management principles in the way that Fire Extinguishers are managed, but in a more cost effective and timely manner.

*Facilitate consistent interpretation and decision*

With the potential for an increase in civil law suits regarding the failure to locate AEDs and/or the failure of AEDs to operate, it is likely that differing, even contrary, judgements may be delivered by the different jurisdictions in the Australian civil judicial system. National legislation that provides regulation for consistent management and monitoring of AEDs, will, in turn, provide a consistent base for decision making and judgement, and may assist in diverting claims from the civil judicial system and allow any such claims to be initially fully examined through administrative means, including by underwriters of public liability and professional indemnity insurance.

*An Opportunity for Australia to model Global Best Practice*

Against the current environment of major health and safety concerns impacting social and economic policy, which is being largely designed and implemented using a reactive methodology, the proposed regulatory framework to manage and monitor AEDs uniformly across Australia also provides the opportunity for Australia to again lead the world in the sensible management and monitoring of AEDs. This approach would meet community expectations in a way that no other major (U.S., U.K. or Europe) health system has been able to successfully harness, operating in a vacuum or in up to 50 different regulatory frameworks in a single country.

## 6. Principles for Future Regulation of AEDs in Australia: Balancing regulatory burden and the public good

It is not the intention of the authors to be prescriptive about the nature of legislation/ regulation of AEDs in Australia or in any other jurisdiction. Rather the aim is to arrive at a series of evidence-/logic-based principles that would inform the development and implementation of an appropriate legislative framework and associated public health policy to balance any regulatory burden with a greater contribution to the public good. On that basis, the following informing principles, with attendant rationales, are derived and proffered:

A. **Legislation should be enacted** in Australia to regulate maintenance, registration, regulation, availability and accessibility of publicly accessible AEDs, including but not exclusive to
    a. Public access AED location and installation
    b. AED Registration and Placement Reporting
    c. Maintenance of AEDs
    d. Training in the use and maintenance of AEDs
    e. Good Samaritan provisions regarding the use of AEDs

    Legislation is necessary to provide the systematic framework for an integrated program-based approach to enhancing community resilience to SCA.

B. **Legislation and accompanying regulation should be enacted at the national level** in order to promote a comprehensive, integrated programmatic approach to regulation of public access AEDs.

   That is not to say that the administration of the regulatory framework cannot be distributed throughout the constituent states or provinces. Indeed, this is the most common level at which emergency services (including emergency medical services) are most commonly situated.

C. Legislation and accompanying regulation regarding publicly accessible AEDs should be **informed by the principles of the Building Code of Australia (BCA)**, as they relate to the location, installation, registration, and maintenance of fire extinguishers.

   The BCA is well-established as a uniform set of technical provisions, designed to achieve nationally consistent minimum standards. It is also an evolving code, reflecting the continually changing nature of building and construction.

D. **Public access AED data should belong to the statutory ambulance service within a particular jurisdiction**, to ensure that data integrity is assured and location and accessibility data are made generally available to the public for use in cases of sudden cardiac arrest.

   This is the position promoted by GoodSAM and supported by the authors, on the principle of a "single source of truth" regarding the location and operability of public access AEDs.

E. **Accredited first aid courses should be adapted** to accommodate provision for the maintenance as well as use of AEDs.

   Part of the responsibility for accredited first-aiders is not only having knowledge of how to use an AED but also to ensure any AEDs for which they are responsible are properly maintained and in good working order when they are needed.

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