Counting the cost of AED failures: 1150 dead in 15 years, says US study

AEDs vital, but must be properly deployed

- Sudden cardiac arrest kills between 23,000 and 33,000 Australians each year, more than breast cancer, shootings and road crashes combined.¹ Australian and US research proves timely use of an Automated External Defibrillator (AED) could have saved a significant number of these lives.²
- Exactly how many lives might have been saved depends on the AEDs being readily available and in working order when they are needed. Unfortunately, there have been fatalities from malfunctioning or poorly deployed devices: US research has linked 1150 deaths to AED failures over 15 years.³
- The effective maintenance, positioning and routine testing of AEDs are vital to ensuring any device is ready to use
 in an emergency. Further, according to most manufacturers' instructions, defibrillators must be checked daily for
 operability. Yet, there is evidence from US and Australian research that they are not, and that some may not be
 accessed for years. Clearly, if defibrillators are not checked daily, there is a risk that they will not deliver the life-giving
 shock for which they are designed.
- According to US research, more than 21 per cent of nearly 386,000 defibrillators surveyed between 1996 and 2005 were made so defective by electrical, software and other problems that they could not defibrillate a victim when needed.⁴ In Australia, the number of deployed AEDs is not even known, let alone their level of reliability.
- Clearly, there is cause for concern and public awareness needs to be raised. Further, legislation is needed at the federal, and state/territory levels to regulate the deployment of reliable and accessible AEDs that are supported by adequate training. In this respect, Australian governments could emulate US legislation under which all federal buildings and facilities have to have AEDs;⁵ it is important, however, that we also learn from their mistakes.

Deployment Registry and Defibrillator Guidelines will save lives

- This position paper argues the case for the Automated External Defibrillator Deployment Registry (AEDDR) as a registering body for AEDs in Australia.
- The AEDDR is a non-legislative national policy body and voluntary accreditation scheme for the proper deployment of AEDs in workplaces and public spaces. Announced at an official launch in Canberra on 29 November 2012, it is a not-for-profit organisation which has been established to ensure that AEDs throughout Australia meet standards of safety, reliability, effective capability and ease of use. It will also ensure all AED-associated training is effective, of a high quality standard and delivered with sufficient regularity and efficiency so users in the workplace and elsewhere are enabled to confidently save lives.
- Funded through the sales of its guidelines and AED registrations, the AEDDR is independent of organisations and representative bodies associated with defibrillator resellers. US experience with the American Heart Association demonstrates that only an organisation that is commercially independent in this way can monitor a product while satisfactorily exercising its duty of care toward consumers.⁷
- Chair of the AEDDR Dr Graeme Peel argues this is what makes the AEDDR the only agency fit to monitor AEDs in Australian public spaces and workplaces:
 - "We support AEDs. We just need to make sure they work when they are needed."

Recent Case Histories

While there are numerous examples of AED failures and fatalities, a few are cited as illustrative:

 When 41-year-old Prem Sebastian had a cardiac arrest at Essendon Tennis Club during his regular weekly match in February this year, fellow players started CPR while others searched for the defibrillator. When found, the defibrillator battery was flat. Luckily, adjoining Aberfeldie Sports Club had a functioning unit, which they used to shock Mr Sebastian's heart back to normal rhythm. He survived.

Recent Case Histories (Cont)

- But 19-year-old Stephen Buckman wasn't so lucky. When he collapsed after a cardiac arrest during football training in 2010, a defibrillator couldn't be sourced for 22 minutes: too late to save him. Mr Buckman died.
- The following year in the US, Ralph Polanec collapsed at a Washington gym. Unfortunately, the gym's defibrillator didn't work: its batteries had been removed when they lost charge and were never replaced. Mr Polanec died. ¹⁰
- Earlier, in November 2007, Anna Malofly woke in her Pennsylvania home to find her husband Eugene shaking and unresponsive. She called 911, but saw her husband die as paramedics tried to save him after the defibrillator a policeman brought to the scene failed.

What can go wrong with AEDs?

- AEDs provide automated heart rhythm analysis, voice commands, and shock delivery.
- In the case of sudden cardiac arrest, the heart stops beating. An AED can shock the heart back to its normal rhythm, but every minute that passes without a heartbeat reduces the patient's chance of survival by 10 per cent. ¹²
- Clinical trials in the US have shown AEDs are safe and effective and may be used by individuals with as little as a sixth-grade education.¹³
- But many things can go wrong, evidenced by those 1150 deaths attributed to AED failures by US researchers. Nearly
 half of the AED failures reported to the US Food and Drug Administration (FDA) occurred while attempting to deliver
 a recommended shock and a significant portion of these failures were unanticipated device shutdowns. 14
- While AED failures are still relatively uncommon, the same researchers believe they are under-reported and, even when they are, reports are often so vague it is hard to tell what went wrong.
- Maintenance neglect is the chink in the armour of defibrillation programmes. Consequently, organisations intending to introduce AEDs should ensure they are effectively managed and checked daily for operability.

Deployment of AEDs in Australia

- There are an estimated 1.5 million AEDs deployed across the US: five for each of up to 350,000 cardiac arrest victims, ^{15,16} who need them each year. ¹⁷ The number deployed across Australia is unknown, ¹⁸ as there has been no method of registering them up until now.
- Most AEDs in the US are in public places and may spend many years on a wall gathering dust before they are required in an emergency. Most of these AEDs will reach the end of their five to 10-year life without ever being used, yet must remain charged and ready to operate at a moment's notice.
- Despite wide distribution of public AEDs in the US, Australia lags behind. Few organisations have deployed fully
 monitored and enclosed AEDs in the workplace. Prominent among those that have done so are: railways, major
 mining and construction groups, unions, international hotels, a major airline and a number of government workplaces.
- Outside of these organisations, the location of public access AEDs remains unknown, as does their state of readiness. The AEDDR aims to rectify this.

Why Register Defibrillators?

- The AEDDR aims to ensure Automated External Defibrillators are properly deployed and always working, which
 will save lives and avoid fatalities caused by missing or faulty devices. To achieve this, the AEDDR aims to register
 the location and operational status of AEDs, and to encourage the research and development of innovative ways to
 disseminate this information to rescuers.
- Few public agencies in the US, including 911 dispatch centres, keep a database of AED locations or systematically check to make sure available devices are in working order.
- While reliable data are scant, some experts have estimated AEDs are used to help fewer than five per cent of people collapsing from sudden cardiac arrest.
- A University of Pennsylvania crowd-sourcing project called MyHeartMap aimed to map the location of public access AEDs and better monitor them. Using a smartphone app, more than 300 teams and individuals spent eight weeks knocking on doors, photographing and recording the GPS coordinates of defibrillators wherever they found them. The resulting map pinpointed 1400 AEDs in 500 buildings. The aim now is to make the map available to 911 despatchers who could provide the location of the nearest AED to an emergency caller. ²⁰
- It is not sufficient simply to know where a device is, however. Through the work of the AEDDR, Australians will know the location of any device via a map, that the device is there and in working order, and that consent for its use has been obtained
- A trial Public Access Defibrillation (PAD) program in Australia sponsored by the Federal Department of Health and Ageing (2005-2008), resulted in the installation of 147 defibrillators for 98 public and private organisations. These included airports, train stations, tourist sites, schools, shopping centres, sporting stadiums and clubs. However, the responsibility for maintenance and regular inspections was not made clear, with the potential for the same defects in AEDs found in US studies. ²¹

Why Register Defibrillators? (Cont)

- AEDs in the US have been subject to numerous recalls for faults. One study of advisories to the FDA between 1996 and 2005 found 21.2 per cent of units distributed during the study period had to be recalled.
- In Australia, the likelihood of a defibrillator being defective without the application of remedial action remains problematic. The AEDDR is engaging the Therapeutic Goods Administration (TGA) to facilitate their processes in this regard. The TGA has been helpful in developing avenues of cooperation with AEDDR, and has agreed to review the AEDDR guidelines with a view to an ongoing dialogue and information exchange.
- The purpose of the AEDDR is to save lives, and its Committee is dedicated to having the AEDDR known and recognised as the trustworthy standard for outstanding excellence in Australia and the world. For more information go to www.aeddr.com

References

- 1 Estimates from Campbell Research & Consulting, An evaluation of the public access defibrillation (PAD) PAD demonstration: Final report, Canberra: Department of Health and Ageing, August 2008; National Health Priority Action Council. National service improvement framework for heart, stroke and vascular disease. Canberra: Department of Health and Ageing, 2006; NRMA Insurance, NRMA Insurance gets jump on saving lives in Townsville, Queensland: NRMA Insurance, 12 June 2003. Website at www.nrma.com.au/about-us/mediareleases/ 20030612-a.shtml. Accessed 28 May 2009; NRMA Insurance, St John and NRMA Insurance are real heartstarters, Queensland: NRMA Insurance, 12 Oct 2004. Website www.nrma.com.au/about-us/mediareleases/20041012-a.shtml Accessed 28 May 2009
- ² Dingsdag, D., Reliability, sustainability and effectiveness of automated external defibrillators deployed in workplaces and public areas, J Occup Health Safety Aust NZ 2009 25(5): 351:361
- ³ DeLuca, L., et al, Analysis of Automated External Defibrillator Device Failures Reported to the Food and Drug Administration, Annals of Emergency Medicine Volume 59, Issue 2, Pages 103-111, February 2012
- ⁴ Shah, JS and Maisel, WH. Recalls and safety alerts affecting automated external defibrillators, JAMA 2006, 296(6):655-660.
- ⁵ 31. United States Government, Cardiac Arrest Survival Act of 2000, 106th Congress, HR 2498. Washington DC: House of Representatives, 2000
- ⁶ For details of the launch of the AEDDR see http://aeddr.com/?p=317
- ⁷ See Stephanie Saul, 'Heart Group Backs Drug Made by Ally' New York Times January 24, 2008, retrieved 21 March 2012 at http://www.nytimes.com/2008/01/24/business/24heart.html?_r=1&
- ⁸ Brigid O'Connell, 'Game, set and life saved' Herald Sun Saturday March 2, p19
- 9 Ibid
- ¹⁰ Linda Carroll 'Bad batteries in defibrillators tied to cardiac deaths' NBC News.com, February 9, 2011, retrieved 21 March 2012 at http://www.nbcnews.com/id/44364504/ns/health-health care/
- ¹¹ Mark Harris 'The Shocking Truth About Defibrillators' IEEE Spectrum March 2012, retrieved 21 March 2013 at http://spectrum.ieee. org/biomedical/devices/the-shocking-truth-about-defibrillators/?utm_source=techalert&utm_medium=email&utm_campaign=030112
- 12 Dingsdag, op cit, p352
- 13 Shah and Maisel, op cit, p655
- **14** DeLuca et al, op cit, p104
- ¹⁵ Bio-Medicine, FDA safety alerts for automated external defibrillators occur frequently, JAMA and Archives Journals. 8 August 2006. Website at news.bio-medicine.org/medicine-news-3/FDA-safety-alerts-for-automatedexternal-defibrillators-occur-frequently-3573-1/Accessed 23 May 2009.
- ¹⁶ United States Government, Public Health Improvement Act, 106th Congress, Public Law 106-505. 114 Stat 2336. Washington DC: US Government, 13 November 2000.
- 17 Harris, op cit
- 18 Dingsdag, op cit, p352
- ¹⁹ Ron Winslow 'The Device That Saves Lives But Can Be Hard To Find' The Wall Street Journal 12 November 2012, retrieved 21 March 2012 at http://online.wsj.com/article_email/SB10001424127887324073504578115051054664668-IMyQjAxMTAyMDEwNTExNDUyWj. html?mod=wsj_valettop_email
- **20** Ibid
- 21 Dingsdag, op cit, p354
- 22 Shah and Maisel, op cit, p655