Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Health technology assessment (HTA) of public access defibrillation

Draft for public consultation

23 September 2014

About the Health Information and Quality Authority

The Health Information and Quality Authority (the Authority or HIQA) is the independent Authority established to drive continuous improvement in Ireland's health and personal social care services, monitor the safety and quality of these services and promote person-centred care for the benefit of the public.

The Authority's mandate to date extends across the quality and safety of the public, private (within its social care function) and voluntary sectors. Reporting to the Minister for Health and the Minister for Children and Youth Affairs, the Health Information and Quality Authority has statutory responsibility for:

- **Setting Standards for Health and Social Services** – Developing person-centred standards, based on evidence and best international practice, for those health and social care services in Ireland that by law are required to be regulated by the Authority.
- **Social Services Inspectorate** – Registering and inspecting residential centres for dependent people and inspecting children detention schools, foster care services and child protection services.
- **Monitoring Healthcare Quality and Safety** – Monitoring the quality and safety of health and personal social care services and investigating as necessary serious concerns about the health and welfare of people who use these services.
- **Health Technology Assessment** – Ensuring the best outcome for people who use our health services and best use of resources by evaluating the clinical and cost-effectiveness of drugs, equipment, diagnostic techniques and health promotion activities.
- **Health Information** – Advising on the efficient and secure collection and sharing of health information, evaluating information resources and publishing information about the delivery and performance of Ireland's health and social care services.

Executive summary

I. Background

On 25 July 2013, the then Minister for Health, Dr James Reilly, requested that the Health Information and Quality Authority (the Authority) undertake a health technology assessment (HTA) of a public access defibrillation programme. This was with the aim of informing decision making on matters related to the Public Health (Availability of Defibrillators) Bill 2013.

The Bill lists the types of premises and venues that will be required to install and maintain automated external defibrillators (AEDs). Among the designated places specifically identified in the Bill are hospitals, places of worship, hospitality and entertainment venues, sports clubs, transport stations, retail premises and public buildings. When combined, this represents a total of over 43,000 premises throughout Ireland. The Bill imposes an obligation on the owners of these premises to install a defibrillator, ensure that it is maintained and available for use, display signs about its location and how to use it, and provide training to employees.

II. Terms of Reference

The Terms of Reference for this evaluation are:

- To review the clinical evidence on the effectiveness and safety of public access defibrillation programmes for out-of-hospital cardiac arrest and identify the main factors associated with effective implementation of such programmes.
- To review and summarise Irish data on the epidemiology of out-of-hospital cardiac arrest, the existing availability of automatic external defibrillators, and relevant initiatives in the management of sudden cardiac arrest and the configuration of emergency medical services.
- To review the international cost-effectiveness literature on public access defibrillation.
- To estimate the clinical benefits, cost-effectiveness, resource implications and budget impact of potential public access defibrillation programme configurations in Ireland.
- To consider any wider implications that the technology may have for patients, the general public or the healthcare system.
- Based on this assessment, to advise on the optimal configuration of an Irish public access defibrillation programme.

III. Methodology

This HTA was conducted using the general principles of HTA and employing the processes and practices used by the Authority in such projects.

In summary:

- The Terms of Reference of the HTA were agreed between the Authority and the Department of Health.
- An Expert Advisory Group (EAG) was established. An evaluation team was appointed comprising internal Authority staff. Dr Deirdre Madden, Faculty of Law, University College Cork, prepared the ethical and legal analysis. The Health Intelligence Unit in the Health Service Executive (HSE), assisted with the analysis of out-of-hospital cardiac arrest incidence data used in the economic model.
- A systematic review of the evidence was carried out to summarise the available evidence on the effectiveness and safety of public access defibrillation programmes.
- Irish epidemiological data was reviewed along with relevant international literature on out-of-hospital cardiac arrest. A review of the configuration of emergency medical services was also carried out, along with an analysis of the available data on the number of automatic external defibrillators (AEDs) currently available in public locations in Ireland.
- An economic evaluation was performed to estimate the cost-effectiveness of a number of alternative public access defibrillation programme configurations. These included the programme outlined in the proposed legislation as well as five other programmes that restricted AED placement to building types with a higher incidence of out-of-hospital cardiac arrest. A budget impact analysis was also performed, which estimated total costs for each of these public access defibrillation configurations over five years. Data to support the economic evaluation were obtained from the literature, the Out-of-Hospital Cardiac Arrest Register and other Irish databases and expert opinion. Endorsement of all inputs was sought from the EAG.
- A review of the wider implications of a national public access defibrillation programme for out-of-hospital cardiac arrest patients, citizens and the health service was conducted. This included an analysis of the likely impact on the delivery of health services, as well as the ethical, legal and social implications of public access defibrillation.

IV. Technology description

Cardiac arrest is a sudden loss of heart function due to a malfunction of the electrical system of the heart. Malfunction is usually caused by abnormal, or irregular, heart rhythms (called arrhythmias) which lead to inefficient pumping of blood to the brain, organs and tissues. Death occurs within minutes after the heart stops. A cardiac arrest may be reversed by timely cardiopulmonary resuscitation (CPR) and use of a defibrillator for certain shockable arrhythmias to restore a normal heart beat. The key factors influencing survival in out-of-hospital cardiac arrest are time to CPR initiation, time to defibrillation and the initial cardiac rhythm.

An automated external defibrillator (AED) is a small, portable device that analyses the heart rhythm of a person who has experienced a cardiac arrest and delivers an electric shock through the chest wall if it detects a rhythm that can respond to defibrillation. The electrical current momentarily stuns the heart, stopping the abnormal rhythm and helping the heart resume normal electrical activity.

Public access defibrillation programmes are designed to improve survival from out-of-hospital cardiac arrest by reducing the time to defibrillation. They increase the availability of AEDs, so that those who experience an out-of-hospital cardiac arrest can be defibrillated by non-emergency medical services' personnel prior to the arrival of an ambulance.

A number of different approaches to implementing public access defibrillation programmes have been described in the literature. These can be broadly separated into three groups:

1. Programmes that involve the provision of static AEDs in public buildings and communal areas that are designed to be used opportunistically by anyone who witnesses an out-of-hospital cardiac arrest (similar to the programme outlined in the Bill).
2. Equipping uniformed first responders, such as the police or fire service, with AEDs and simultaneously dispatching them, along with emergency medical services, to suspected out-of-hospital cardiac arrest events.
3. Community first responder groups run by volunteers that provide AEDs to members who respond to any out-of-hospital cardiac arrest events that occur in the area. These community first responder groups may or may not be linked to emergency medical services' dispatch systems, allowing ambulance dispatch centres to notify them when a suspected cardiac arrest occurs in the area.

V. Epidemiology and service configuration

The main source of epidemiology data for out-of-hospital cardiac arrest in Ireland is the national Out-of-Hospital Cardiac Arrest Register. This indicates that the incidence of emergency medical services-attended out-of-hospital cardiac arrest in Ireland is approximately 39.1 per 100,000 persons, equivalent to 1,800 cases per annum. The mean age of out-of-hospital cardiac arrest patients is 69 years and 67% are male. Seventy six percent of out-of-hospital cardiac arrests in Ireland occur in the home or in residential institutions. In 2012, the survival from emergency medical services-attended out-of-hospital cardiac arrest in Ireland was 5.2%, which is slightly lower than the international average. Although survival from out-of-hospital cardiac arrest is poor, neurological outcomes and long-term survival tend to be good for those who survive to hospital discharge, with approximately 80% of those who survive to discharge in Ireland achieving pre-arrest function and 50% surviving to 10 years.

An estimated 24% of the Irish population have had cardiopulmonary resuscitation (CPR) training in the last five years, and at present 45% of emergency-medical-services-attended out-of-hospital cardiac arrests receive bystander CPR prior to the arrival of the emergency medical services. Survival for those who receive bystander CPR plus defibrillation is 13.4%, compared with 5.5% for bystander CPR only and 4.0% for emergency medical services resuscitation.

Ireland has a dispersed population with a median emergency medical services response time of 11 minutes for out-of-hospital cardiac arrest incidents, indicating a reliance on bystander intervention to improve survival in cases of out-of-hospital cardiac arrest. Ireland also has approximately 100 community first responder groups that are linked to the emergency medical services. Linkage implies that that the community first responder group is integrated into the national ambulance system, and that the volunteers have undergone appropriate training. It also suggests that the group is appropriately equipped for emergencies, and that emergency calls are directed to the community first responder group from the ambulance control centre. These volunteer community first responder groups operate at a local level and as yet are not centrally coordinated, although plans are in place to establish a national cardiac first responder body.

Over the past number of years AEDs have been voluntarily installed in a wide range of places throughout the country. As no national register of AEDs exists at present, there is a high degree of uncertainty regarding the number and location of these AEDs. The Authority estimates that there are between 8,000 to 10,000 functional AEDs located around the country, equivalent to approximately 185 AEDs per 100,000 population. This figure is similar to that achieved by countries that have instigated public access defibrillation programmes. The implementation of the Public Health (Availability of Defibrillators) Bill 2013 would require the provision of an estimated additional 38,419 AEDs at designated places, resulting in an overall coverage of 1,030 AEDs per 100,000 inhabitants.

VI. Clinical effectiveness

A systematic review of the literature identified 15 relevant studies. Of these, only one examined the provision of static AEDs in public locations as a stand-alone intervention. Eight studies involved police or fire-fighter first responder programmes and six examined the effect of a combined intervention involving more than one method of providing rapid defibrillation.

The study on the provision of static AEDs in public places reported a doubling in the absolute numbers of out-of-hospital cardiac arrest survivors in the treatment group. When survival to hospital discharge was analysed as a rate based on all out-of-hospital cardiac arrests of cardiac causes where resuscitation was attempted, this increase was not statistically significant, which means that there is a chance that the observed effect could be explained by normal variation. The mean estimate of effect for public AED provision favoured this intervention over routine emergency medical services care (mean increase of 9% in survival to hospital discharge). Statistically significant increases in survival to hospital admission and neurologically intact survival were also reported.

No included study comparing fire-fighter or police first responder programmes with standard emergency medical services care demonstrated a statistically significant beneficial effect on survival to hospital discharge. The pooled mean estimate of effect for both fire-fighter and police first responders favoured these interventions over routine emergency medical services care (mean increase of 1% and 2%, respectively in survival to hospital discharge). No analytic studies involving public access defibrillation in paediatric populations were identified, so the effect of the intervention in this group is unknown.

No major safety concerns were identified in relation to public access defibrillation programmes. Among the adverse events associated with these interventions are increased emotional stress in responders, AED battery failure and devices being placed in inaccessible locations.

In keeping with the proposed legislation, the comparators considered in this HTA were limited to public access defibrillation programmes involving static AED provision, ranging from the comprehensive programme described in the Bill to a more targeted scheme involving only those locations with the highest incidence of out-of-hospital cardiac arrest, rather than those involving uniformed or community first responders.

As noted, the key factors influencing survival in out-of-hospital cardiac arrest are time to CPR initiation, time to defibrillation and the initial cardiac rhythm. Case-series analyses of international population-based registry data identified a positive association between survival and the implementation of public access defibrillation programmes. This type of data can have good external validity, which means the results can be generalised to other situations and to other places, but they are prone to bias and cannot reliably estimate the effect of interventions.

There is widespread international support for the introduction of public access defibrillation programmes among voluntary groups and professional associations. Measures to promote the effectiveness of public access defibrillation programmes include media campaigns to increase public awareness, directed placement of AEDs, training of lay volunteers, centralised AED registration and increasing accessibility of AEDs outside of business hours and at weekends.

VII. Economic evaluation

A review of the evidence on the cost-effectiveness of public access defibrillation identified a number of previous economic analyses on this topic. However, the available literature is not sufficient to reliably estimate the cost-effectiveness of an Irish programme, or to compare the likely consequences of different public access defibrillation programme configurations. There were also major differences between the studies identified in the systematic review of clinical effectiveness and a prospective national public access defibrillation programme that precluded the direct application of these results in an Irish setting. Therefore the expected impact of public access defibrillation in Ireland was modelled using:

- Irish data on the incidence of out-of-hospital cardiac arrest
- the number and location of designated places under different public access defibrillation configurations
- out-of-hospital cardiac arrest outcomes by type of first response (emergency medical services, bystander CPR and bystander defibrillation).

This was combined with data on the costs associated with public access defibrillation implementation and out-of-hospital cardiac arrest treatment to compare the cost-effectiveness of different public access defibrillation programmes with the existing situation and each other.

The public access defibrillation programme outlined in the Public Health (Availability of Defibrillators) Bill involves AED deployment in over 43,000 designated places, including hospitals, places of worship, hospitality and entertainment venues, sports clubs, transport stations, retail premises and public buildings. The Authority modelled the programme outlined in the Bill as well as five other potential public access defibrillation configurations and compared these with the existing situation (that is, voluntary placement in a diverse range of locations) and with each other. These comparators represent scaled-back versions of the Bill based on a reduced number of designated building types where AEDs would need to be provided. The number of designated places in these comparators ranged from 3,300 to 23,000. The base case comparator to which each of the modelled public access defibrillation strategies was compared includes the voluntary deployment of approximately 4,500 existing AEDs in places identified as designated places under the proposed legislation. Therefore, a number of high-incidence locations already have AEDs available and this analysis examines the incremental effect of implementing each strategy over and above that of the current situation. However, there is considerable uncertainty about the number and location of existing AEDs in Ireland and the current proportion of out-of-hospital cardiac arrest patients who have an AED applied by bystanders prior to the arrival of emergency medical services.

The analysis modelled a one-year cohort of out-of-hospital cardiac arrest patients to life expectancy and was conducted from a societal perspective, so it included costs that fall on the health system as well as the wider public and private sectors. It also included productivity costs associated with out-of-hospital cardiac arrest morbidity and mortality. Given the nature of public access defibrillation and the degree to which costs, particularly for the procurement and maintenance of devices, are spread across society, taking a narrower perspective would not provide a true reflection of the overall cost-effectiveness and budget impact of the intervention.

Based on the results of this analysis, public access defibrillation is expected to result in an average of between two and 11 additional out-of-hospital cardiac arrest patients surviving to hospital discharge annually, depending on which programme is implemented. However, none of the programmes would be considered cost-effective using conventional willingness to pay thresholds (€45,000 per quality-adjusted life year [QALY]). The model of public access defibrillation outlined in the proposed legislation is associated with the highest gains in survival (11 additional lives saved annually) and with the highest costs (€106 million over five years).

As expected, targeted public access defibrillation (PAD) programmes that involve AED deployment in building types with the highest out-of-hospital cardiac arrest incidence are the most cost-effective, with the most scaled down option (PAD15%) having the lowest incremental cost-effectiveness ratio (ICER) (€95,000 per QALY). As the intervention is expanded to include more building types with a relatively lower out-of-hospital cardiac arrest incidence, the ICERs increase significantly (that is, the programmes become less cost-effective). The ICER for the programme outlined in the Bill compared to the next best option (PAD55%) is in excess of €800,000 per

QALY whilst the average cost-effectiveness ratio (ACER) comparing legislation to the base-case is €298,000/QALY.

Results of the budget impact analysis over a five-year time horizon were disaggregated to show the cost implications for the health service, the overall public sector and the private sector. Implementation of a public access defibrillation programme is associated with total incremental costs over five years ranging from €1 million to €2.5 million for the health service, €2.5 million to €20.8 million for the public sector (including health) and €3.3 million to €85 million for the private sector, depending on which public access defibrillation programme is implemented. The majority of these additional costs relate to the procurement of AEDs and would be incurred in the first year of the programme.

A summary of the results of the economic evaluation are provided below:

Public access defibrillation (PAD) programme	Number of additional AEDs required	Increase in annual survival to discharge [n(%)]	Incremental cost-effectiveness ratio (ICER) (€/QALY)	Total incremental budget impact over five years (€)		
				Health service	Public sector (excluding health)	Private sector
PAD15%	1,900	2 (1.8)	95,000	€1.0M	€1.5M	€3.3M
PAD20%	3,100	2 (1.8)	Dominated	€1.1M	€3.5M	€4.6M
PAD25%	6,800	5 (4.6)	166,000	€1.5M	€3.5M	€14.4M
PAD45%	15,300	8 (7.4)	211,000	€2.0M	€17.7M	€24.4M
PAD55%	19,600	9 (8.3)	364,000	€2.2M	€15.6M	€37.1M
Legislation	38,400	11 (10.0)	806,000	€2.5M	€18.3M	€85.0M

Note: M = million.

A scenario analysis was carried out to examine the potential impact of any future changes in the cost of AEDs. This found that a 60% reduction in cost would reduce the ICER for the most cost-effective option (PAD15%) to €70,000 per QALY. A second scenario analysis examined the potential impact of increased utilisation of AEDs as a result of increased public awareness and an emergency-medical-services-linked AED register that could be used to direct callers to the nearest available AED in the event of a suspected out-of-hospital cardiac arrest.

This analysis found that AED utilisation for out-of-hospital cardiac arrests in public and residential areas that occur within 200 metres of a device would need to increase by over 20% for the PAD15% ICER to approach a threshold of €45,000 per QALY. If it was assumed that any increase would mainly apply to out-of-hospital cardiac arrests in public locations (with no change in residential rates), then an increase in AED utilisation in excess of 45% would be required for the public access defibrillation15% ICER to approach a threshold of €45,000 per QALY. However, there is no evidence to suggest that such an increase is plausible in the context of an Irish public access defibrillation programme.

There are some important limitations with regard to the data that were used in this analysis that need to be considered when interpreting the results. The number of out-of-hospital cardiac arrest events that occur within 200 metres of an AED in each of the comparators is based on the single year of national data currently available from the Out-of-Hospital Cardiac Arrest Register. The use of multiple years of data would provide greater certainty on the incidence of out-of-hospital cardiac arrest in different building types. There is also considerable uncertainty in relation to the location of existing AEDs and discriminating between Out-of-Hospital Cardiac Arrest Register cases that received AED intervention from a bystander as opposed to those who may have been treated by a community first responder or general practitioner (GP).

In this analysis, the Authority used the best available data to estimate each of these parameters and applied wide bounds on the range of possible values. A sensitivity analysis was used to investigate the impact of this uncertainty. This found that although the ICER values changed as a result of fixing each parameter at its upper and lower bound, these changes were not large enough to affect the ordering of the public access defibrillation programmes and did not decrease any of the ICERs to a level that would be considered cost-effective using conventional willingness-to-pay thresholds. Therefore, although there is a high degree of uncertainty for some important parameters, this is unlikely to affect the overall results in regard to the cost-effectiveness of different public access defibrillation programmes compared with the base case and each other.

In keeping with the proposed legislation, the Authority modelled deployment of AEDs based on building type. It is possible that a more efficient distribution of AEDs may be possible using a deployment rule based on location-specific out-of-hospital-cardiac-arrest incidence. Recommendations from the American Heart Association (AHA) and the European Resuscitation Council (ERC) advise that AEDs be located in places with an annual probability of an out-of-hospital cardiac arrest of 20% (one every five years) and 50% (one every two years), respectively. This would allow for differences in out-of-hospital cardiac arrest incidence within building groups to be taken into account, if, say, a subset of sporting venues were associated with a higher out-of-hospital cardiac arrest incidence. Developing clear rules for the widespread implementation of such a system would pose challenges, however, and would require additional data on out-of-hospital cardiac arrest incidence, beyond the single year of Out-of-Hospital Cardiac Arrest Register national data currently available.

VIII. Organisational and social implications

The introduction of a national public access defibrillation programme is not expected to have a major impact on the organisation of health services. Annual out-of-hospital cardiac arrest incidence would not be affected and the expected number of additional survivors per year would be relatively small in the context of overall service provision. The placement of AEDs in public locations is well accepted in society, as evidenced by the high numbers of AEDs already in place throughout the country, and such interventions have received widespread support from patient organisations and professional bodies.

There are, however, many important issues that remain to be decided prior to the implementation of a national public access defibrillation programme. These include deciding:

- how quality assurance and compliance will be achieved
- how the programme can maximise the accessibility of AEDs outside of normal working hours and at weekends
- how ongoing performance evaluation will be carried out
- how to ensure that adequate communication and support structures are provided to set up and maintain a national network of publicly accessible AEDs.

Another important factor is the creation of a centralised, emergency-medical-services-linked register of publicly accessible AEDs, which could be used by emergency medical services dispatchers to direct callers to the nearest AED. A recommendation contained in the 2006 report of the Task Force on Sudden Cardiac Death(1) to set up such a register in Ireland has not yet been implemented.(2) Previous efforts to register AEDs have encountered significant obstacles in identifying the location and functional status of existing AEDs and maintaining the participation of designated places to update this information on an ongoing basis.(3) The challenges in implementing a national register should not be underestimated and adequate planning and resources will be required for this to be successfully achieved. The availability of a national AED register, combined with additional years of national data on out-of-hospital cardiac arrest incidence from the Out-of-Hospital Cardiac Arrest Register, will be vital in the evaluation of a public access defibrillation programme and in informing decision making about potential changes that are required to increase the clinical and cost-effectiveness of any prospective programme.

IX. Ethical and legal implications

The assessment also examined relevant ethical and legal considerations associated with this type of public health intervention. The issue of informed consent is an important consideration in public access defibrillation, since the out-of-hospital cardiac arrest patient is unconscious at the time of arrest. If the victim's wishes are not evident, it would generally be considered reasonable for a rescuer or bystander to intervene to defibrillate the victim on the basis of implied consent and the doctrine of necessity. There is no statutory obligation imposed on any person to use the defibrillator, but if they do so, the Civil Law (Miscellaneous Provisions) Act 2011 provides that a Good Samaritan who intervenes to provide assistance, including resuscitation, will not be liable in negligence for any act done in an emergency unless it was done in bad faith or with gross negligence. The exemption from liability in the 2011 Act does not apply where the person owes a duty of care to assist the victim, for example, in the context of a doctor-patient relationship.

The imposition of public health obligations on private citizens is also a matter for consideration because the duty to safeguard public health is generally imposed on the State rather than private citizens. However, there are precedents for such obligations in the smoking ban, health and safety statutory duties and other public health initiatives which impose compliance and financial obligations on occupiers of public premises. The proposed Public Health (Availability of Defibrillators) Bill provides an exemption – to the owner of a designated place where a defibrillator is made available – from civil liability for any harm or damage as long as they have acted in good faith. The exemption will not apply where the person has acted with gross negligence, failed to properly maintain the defibrillator or where the premises is a healthcare facility.

X. Conclusions

Public access defibrillation has the potential to further improve survival from out-of-hospital cardiac arrest in Ireland. However, given the existing high rate of diffusion of AEDs in Ireland and the large numbers of the population already trained in CPR, coupled with uncertainty regarding where cardiac arrests will occur and low out-of-hospital cardiac arrest survival rates, a large number of additional AEDs are required in Ireland to increase the number of people who survive to hospital discharge.

Public access defibrillation is expected to result in an average of between two and 11 additional out-of-hospital cardiac arrest patients surviving to discharge annually depending on which programme is implemented. Budget impact analysis indicates that the total incremental cost of implementing public access defibrillation over a five-year time horizon ranges from €1 million to €2.5 million for the health service,

€2.5 million to €20.8 million for the public sector (including health) and €3.3 million to €85 million for the private sector, depending on which public access defibrillation programme is implemented. The majority of these costs would be incurred in the first year of the programme. The model of public access defibrillation outlined in the proposed legislation is associated with highest gains in survival and with the highest costs.

Ireland already has a high level of diffusion of AEDs on a voluntary basis, however, this system is not standardised, coordinated or linked to emergency medical services. Based on current data, none of the public access defibrillation programmes evaluated would be considered cost-effective using conventional willingness to pay thresholds. However, significantly increased utilisation of AEDs as a result of a national emergency-medical-services-linked AED register and increased public awareness could render public access defibrillation programmes more cost-effective. However, there is no evidence to suggest that the required increase in utilisation is achievable. It is possible that a more cost-effective distribution of AEDs could be achieved using a deployment rule based on location-specific incidence rather than building type. Multiple years of data from out-of-hospital cardiac arrests over and above the single year national data currently available would be required to increase certainty around the identity of such high-incidence locations.

If a public access defibrillation programme is introduced in Ireland, it should be considered in conjunction with measures to increase the utilisation of publicly accessible AEDs, such as increased public awareness, CPR/AED training and an emergency-medical-services-linked AED register. Any prospective programme should start by targeting the mandatory deployment of AEDs to locations with the highest incidence of out-of-hospital cardiac arrest. A process of performance evaluation and research should be incorporated from the outset to guide ongoing tailoring of the programme to maximise efficiency.

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Acknowledgements

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Particular thanks are due to the Expert Advisory Group (EAG), and the individuals and organisations listed below who provided advice.

The membership of the EAG was as follows:

- Ms Sandra Barnes, Assistant Principal Officer, Department of Health
- Mr Derek Barton, Consultant in Emergency Medicine, St Vincent's University Hospital nominated by the National Clinical Programme for Emergency Medicine and the Irish Association for Emergency Medicine
- Dr Angie Brown, Medical Director, Irish Heart Foundation and nominated by the Irish Cardiac Society
- Mr Brendan Cavanagh, Programme Manager, Health Service Executive (HSE) Acute Coronary Syndrome Programme
- Dr Michael Colquhoun, Chair of BLS/AED Sub-Committee, Resuscitation Council (UK)
- Professor Kieran Daly, Consultant Cardiologist, University Hospital Galway and Clinical Lead, National Clinical Programme for Acute Coronary Syndrome
- Dr John Devlin, Deputy Chief Medical Officer, Department of Health
- Mr John Fitzgerald, Vice-Chairman of the Wicklow First Responders and nominated by the Pre-Hospital Emergency Care Council (PHECC)
- Dr Patricia Harrington, Head of Assessment, Health Technology Assessment Directorate, Health Information and Quality Authority
- Dr Deirdre Madden, Senior Lecturer, Faculty of Law, University College Cork
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- Dr Cathal O'Donnell, Medical Director, National Ambulance Service, Health Service Executive
- Dr Máirín Ryan (Chair), Director of Health Technology Assessment, Health Information and Quality Authority

- Ms Catherine Sheridan, Training Site Coordinator, Croí, West of Ireland Cardiac Foundation
- Ms Brigid Sinnott, Basic Life Support Coordinator, Irish Heart Foundation
- Dr Conor Teljeur, Senior Mathematician/Statistician, Health Technology Assessment Directorate, Health Information and Quality Authority
- Dr Deirdre Ward, Consultant Cardiologist, The Adelaide and Meath Hospital, Dublin Incorporating the National Children's Hospital and Director, Centre for Cardiovascular Risk in Younger Persons (CRYP)
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Organisations and individuals that provided information or analysis, in writing or through meetings, included:

Mr Gearóid Oman and Mr Des Kelly, National Ambulance Service

Dr Coilín Ó hAiseadha, Health Intelligence, HSE

Dr Siobhán Jennings, HSE

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Members of the Evaluation Team:

Members of the Authority's Evaluation Team included: Patrick Moran, Dr Conor Teljeur, Dr Linda Murphy, Michelle O'Neill, Dr Patricia Harrington and Dr Máirín Ryan.

The ethical and legal analysis was written by Dr Deirdre Madden, Faculty of Law, University College Cork.

Conflicts of Interest

None reported.

List of abbreviations that appear in this report

AED	Automated external defibrillator
AHA	American Heart Association
BIA	Budget impact analysis
BLS	Basic life support
CEAC	Cost-effectiveness acceptability curve
CI	Confidence interval
CPC	Cerebral performance category
CPR	Cardiopulmonary resuscitation
DoH	Department of Health
DRG	Diagnosis related group
EMS	Emergency medical services
ERC	European Resuscitation Council
EVPI	Expected value of perfect information
GP	General Practitioner
HIPE	Hospital Inpatient Enquiry
HIU	Health Intelligence Unit
HRQoL	Health-related quality of life
HSE	Health Service Executive
HTA	Health technology assessment
ICD	Implantable cardioverter defibrillator
ICER	Incremental cost-effectiveness ratio
LYG	Life year gained
NACE	Nomenclature Générale des Activités Économiques dans les Communautés Européennes
OHCA	Out-of-hospital cardiac arrest
OHCAR	OHCA Register (Ireland)
PAD	Public access defibrillator
PCRS	Primary Care Reimbursement Service

PHECC	Pre-Hospital Emergency Care Council
QALY	Quality-adjusted life year
RCT	Randomised controlled trial
RD	Risk difference
ROSC	Return of spontaneous circulation
RR	Relative risk
VAT	Value added tax
VF	Ventricular fibrillation
VT	Ventricular tachycardia

1 Introduction

1.1 Background to request

On 25 July 2013, the then Minister for Health, Dr James Reilly, requested that the Health Information and Quality Authority (the Authority) undertake a health technology assessment (HTA) of a public access defibrillation programme. This was with a view to informing decision making on matters related to the Public Health (Availability of Defibrillators) Bill 2013.[4]

1.2 Terms of Reference

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- To review and summarise Irish data on the epidemiology of out-of-hospital cardiac arrest, the existing availability of automatic external defibrillators, and relevant initiatives in the management of sudden cardiac arrest and the configuration of emergency medical services.
- To review the international cost-effectiveness literature on public access defibrillation.
- To estimate the clinical benefits, cost-effectiveness, resource implications and budget impact of potential public access defibrillation programme configurations in Ireland.
- To consider any wider implications that the technology may have for patients, the general public or the healthcare system.
- Based on this assessment, to advise on the optimal configuration of an Irish public access defibrillation programme.

1.3 Overall approach

The Terms of Reference of this assessment were agreed between the Authority and the Department of Health.

The Authority convened an Expert Advisory Group (EAG) comprising representation from relevant stakeholders. The role of the EAG was to inform and guide the process, provide expert advice and information and to provide access to data where appropriate. A full list of the membership of the EAG is available in the acknowledgements section of this report. The Terms of Reference of the EAG were to:

- Contribute to the provision of high quality and considered advice by the Authority to the Health Service Executive.
- Contribute fully to the work, debate and decision-making processes of the group by providing expert guidance, as appropriate.
- Be prepared to provide expert advice on relevant issues outside of group meetings, as requested.
- Provide advice to the Authority regarding the scope of the analysis.
- Support the Evaluation Team led by the Authority during the assessment process by providing expert opinion and access to pertinent data, as appropriate.
- Review the project plan outline and advise on priorities, as required.
- Review the draft report from the Evaluation Team and recommend amendments, as appropriate.
- Contribute to the Authority's development of its approach to HTA by participating in an evaluation of the process on the conclusion of the assessment.

The Authority appointed an Evaluation Team comprising internal staff from the HTA directorate to carry out the assessment.

The terms of reference of the HTA were agreed by the EAG at the initial meeting of the group. Interim findings from the assessment and issues to be addressed, including the parameters for the cost-effectiveness model, were discussed at subsequent meetings. The Authority is currently in the process of conducting a public consultation on this final draft report to provide an opportunity for all potential stakeholders to provide comment and feedback prior to the report being finalised. The final report will be reviewed by the EAG and submitted for approval by the Board of the Authority prior to submission to the Minister for Health.

2 Public access defibrillation

The aim of public access defibrillation is to increase survival from out-of-hospital cardiac arrest by reducing the time to defibrillation. Public access defibrillation programmes make automatic external defibrillators (AEDs) available to trained volunteers or professionals or untrained bystanders for use before the arrival of emergency medical services.

2.1 Out-of hospital cardiac arrests

Cardiac arrest is a sudden loss of heart function due to a malfunction of the electrical system of the heart. Malfunction is usually caused by abnormal, or irregular, heart rhythms (called arrhythmias) which lead to inefficient blood pumping to the brain, organs and tissues. A heart attack or myocardial infarction is not a sudden cardiac arrest; it occurs when an artery supplying blood to the heart becomes blocked. This usually causes chest pain and leads to damage to the muscle of the heart. However, in some cases it may lead to sudden cardiac arrest (SCA).

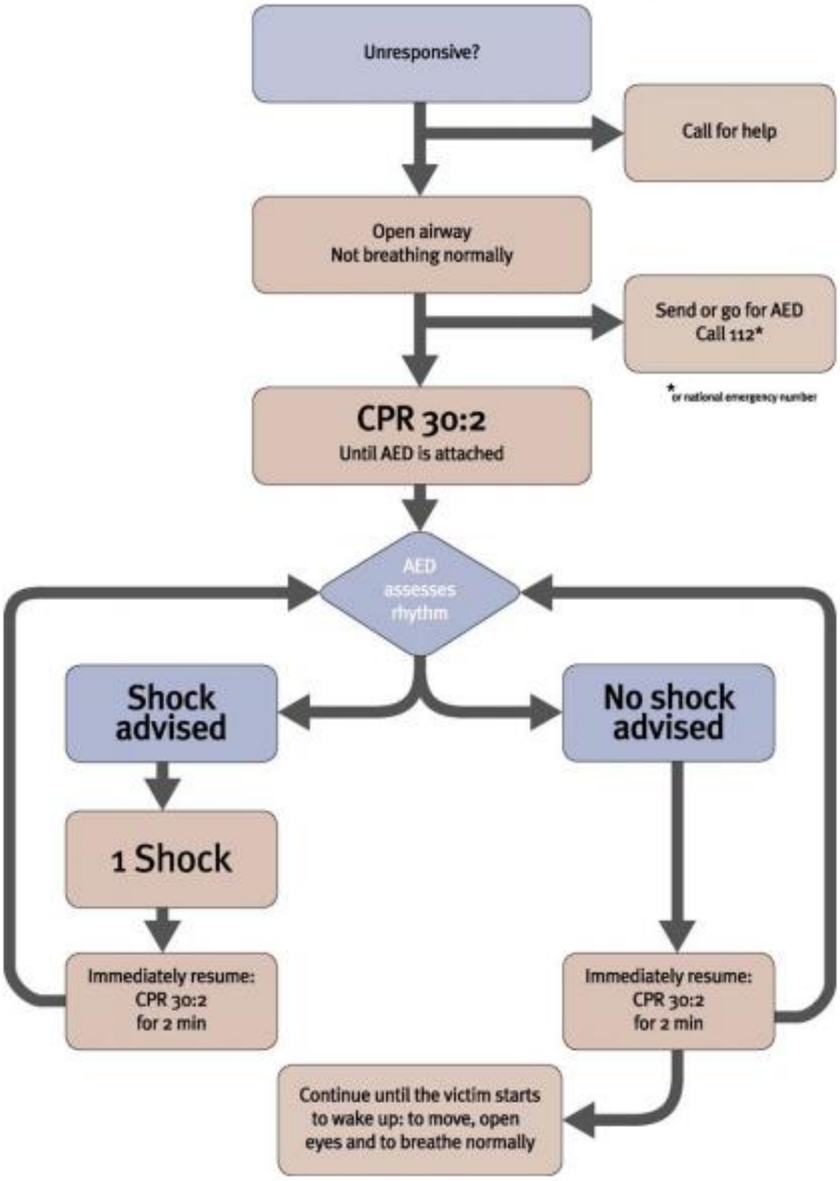
Most SCAs result from arrhythmias originating from the ventricles (ventricular fibrillation, VF). VF is short lived and deteriorates to asystole (absence of heart beat) if not treated quickly. The chance of survival drops by seven to ten percent for every minute a patient remains in VF.(5) As time passes it becomes less likely that the person can be revived and more likely that brain damage will occur.

Approximately 5,000 people die in Ireland each year due to out-of-hospital cardiac arrest.(1) In 2012, 1,798 out-of-hospital cardiac arrest attended by emergency medical services were reported, approximately 70% of these occurred in the home and 22% were due to VF rhythm.(6)

2.2 Out-of-hospital cardiac arrest and automated external defibrillation

European guidelines for resuscitation report the sequence for use of an AED, see Figure 2.1 for details.(7) In summary, while awaiting the arrival of emergency medical services, cardiopulmonary resuscitation (CPR) should be commenced on unresponsive individuals who are not breathing. This is continued until an AED is applied. The AED analyses the heart rhythm and if there is a shockable rhythm (VF or pulseless ventricular tachycardia [pVT]) the AED defibrillates the patient (delivers an electric shock) through the chest wall to the heart allowing a normal rhythm to return. The conditions for defibrillation are optimal for just a few minutes after the onset of VF, although this period can be extended if effective CPR is provided. CPR contributes to preserving heart and brain function.(8) If the AED detects asystole then no shock is delivered; CPR may help one of the shockable rhythms to be established.

Figure 2.1 Algorithm for use of an AED.[7]



[Note: CPR 30:2 refers to chest compressions and rescue breaths in a ratio of 30:2. Copyright European Resuscitation Council – www.erc.edu – 2014/023]

For AED use, the Pre-Hospital Emergency Care Council (PHECC) standards describe six categories of pre-hospital carers in Ireland, see Table 2.1 for details.[9] An untrained member of the public can also be effective in using an AED. The Public Access Defibrillation trial demonstrated a doubling of survival rates (from 17 to 34 per cent) in public places where defibrillators are placed and lay volunteers are trained to use the defibrillators.[10]

Table 2.1 PHECC pre-hospital carer categories[9]

Category	Definition	Example
Cardiac First Responder	Volunteer	Community Group
Emergency First Responder	Usually a volunteer	Voluntary first aid organisation
Emergency Medical Technician	Professional role	HSE ambulance service
Paramedic	Professional role	HSE ambulance service / Dublin Fire brigade
Advanced paramedic	Professional role	HSE ambulance service / Dublin Fire brigade
Registered medical practitioner	Registered medical practitioner	General practitioner

A typical AED system consists of a lightweight, portable AED device, battery, electrocardiograph (ECG) electrodes and pads, see Table 2.2 for further details. AEDs may use voice and/or visual prompts to guide the user to safely defibrillate. Depending on the system it may include an ECG display, paediatric capability or a time-limited warranty to cover defects. Maintenance schedules, battery life, battery rechargability and other features may vary between systems. The device may be semi-automatic (requires the operator to deliver the shock by pushing a button) or fully automatic (capable of administering a shock without the need for outside interventions).

Table 2.2 Components of a typical AED system

AED system
AED device Electrocardiograph (ECG) cable ECG electrodes 1 or 2 sets of adult pads 1 or 2 sets of paediatric pads (where AED has paediatric facility) Spare pads Wall-mountable box
Wall-mounted sign
Battery /spare battery Battery charger Supplies such as disposable face mask, scissors (cut through clothing), gloves, razor (shave a hairy chest) etc.
Software programme for reviewing events Memory card reader, if applicable Infrared (IR) or memory card or cable transfer facility to PC Carrying case

In terms of AED use, there are small differences between models; the general steps for use are included in Table 2.3.

Table 2.3 General steps involved in the use of an AED(7;8)

Step 1	Power ON. This initiates text or voice prompt.
Step 2	Attach pads. Place pads (self-adhesive) on the skin. Positions are generally shown on the pad or AED; a prompt is given if there is poor contact. If more than one rescuer is present, CPR should be continued while pads are being applied.
Step 3	Analyse rhythm (press 'analyse' for semi-automatic system). Ensure no one is touching the person in arrest and movement is minimal during analysis.
Step 4	AED will state if a shock is indicated (press 'shock' for semi-automatic system). Continue as directed by visual / voice prompts. If no shockable rhythm AED will state 'no shock advised', continue CPR and follow prompts until emergency medical services arrive.
Note: For some AEDs when the protective cases are opened or the defibrillator is removed, a buzzer alerts nearby staff of removal.	

[Note: CPR, Cardiopulmonary resuscitation; AED, Automated external defibrillator; emergency medical services, Emergency medical services].

There are additional steps which should be incorporated in special cases. These include if the person in arrest is in water, they are less than 8 years of age or weigh less than 25 kg, they have transdermal medication patches, or have an implanted pacemaker or implantable cardioverter defibrillator (ICD); see the Emergency Cardiovascular Care guidelines for full details.(8) Children over eight years of age should be treated with a standard AED. For children aged 1 to 8 years, paediatric pads are recommended as they have a built-in attenuator to reduce the shock delivered. Manual defibrillation is recommended for babies under one year of age, however if this is not available then the use of an AED with paediatric pads is advised.(11)

For all systems, appropriate maintenance of the AED is vital for proper operation. For example, battery life or expiration and electrode pad expiration dates should be monitored. AED manufacturers provide specific recommendations for maintenance and readiness, which should be followed carefully. Routine maintenance or servicing is minimal and most perform daily self-checks and display a warning if they need attention. Most AEDs now have a minimum lifespan of ten years.(12) The batteries and pads have a long shelf-life, allowing the AED to be left unattended for long intervals.(12) The Pre-Hospital Emergency Care Council (PHECC) produced detailed standards to help those purchasing AEDs for use in the community to ensure they select the right AED for their needs (2008).(9) The Health Products Regulatory Authority (HPRA) has also produced advice on selecting and purchasing AEDs with respect to, for example, storage, servicing and maintenance.(13)

A broad range of specifications such as 'easily identifiable as an AED', 'battery status indicator', 'AED has paediatric facility' etc. are classified as 'essential', 'recommended', 'optional', 'not recommended' or 'not applicable' depending on the intended user (for example, healthcare professional, trained first responder or untrained volunteer see Table 2.1).

2.3 AED device classification and manufacture

In Europe, AEDs are classified as class IIb medical devices and must carry a CE mark.(14) This demonstrates that the device meets the essential requirements of the EU Medical Devices Directive (93/42/EEC) and generally implies that relevant international standards have been met. In the US, AEDs are classified as Class III devices, but have always been regulated through a premarket pathway typically reserved for Class I and II devices and some Class III devices. AEDs have recently come under scrutiny by the US Food and Drug Administration (FDA). In 2011 the FDA began an initiative to ensure the development of safer and more effective AEDs. It requires manufacturers of AEDs and accessories to submit pre-market approval applications that focus specifically on the requirements necessary to assure AEDs are safe and reliable.[15]

2.4 Public access defibrillation programmes

In terms of AED, the crucial determinant of survival of cardiac arrest is the time between collapse and use of the AED to deliver a shock. It is reported by the European Resuscitation Council (ERC) and the American Heart Association (AHA) that public access defibrillation programmes are most likely to improve survival if the AEDs are placed in locations where a witnessed cardiac arrest is likely to occur. The guidelines for public access defibrillation from the ERC and the AHA differ in recommendations for strategic deployment of AEDs. The ERC recommends AED placement in areas with at least one cardiac arrest every two years,[16] while the AHA proposes AED placement in areas with at least one cardiac arrest every five years.[17]

Early defibrillation requires access to the AED within minutes of the onset of an arrest and logistically this can be difficult. Accessibility of AEDs outside of normal business hours and at weekends is reported as a major challenge to public access defibrillation programmes.[18;19] For example, a Danish study reported that of the 1,864 cardiac arrests occurring in public locations between 1994 and 2011, 62% occurred on weekends, in the evening, or during the night.[19] Improved access should also consider security and visibility of the AED. In addition, health promotion or public awareness campaigns are necessary to increase knowledge and understanding of AEDs and to increase their usage in emergencies.

The following points have all been identified for consideration in the design of a public access defibrillation programme:

- Access and security of the AED
  - Can be accessed quickly, prior to emergency medical services arrival.
  - Public access to AEDs at any time, mount AEDs on external walls to buildings. If codes or keys are required to access the AED then the vital time to defibrillation is affected.
  - Provide security by mounting AEDs in protective cases.
  - Improve access to the already large number of devices in the community.
- Visibility of the AED
  - Make AEDs highly visible, e.g. use universal AED sign, see Figure 2.2.
  - Ensure AED is included in any national AED database ensuring public awareness of device locations and linkage with emergency medical services.[16]

- Strategic placement of AEDs.
- Awareness of AEDs
  - Increased public awareness of AEDs and public access defibrillation programmes.

The 2010 American Heart Association Guidelines for CPR and Emergency Cardiovascular Care Science state that to reduce the time to defibrillation for those in cardiac arrest, AED use should not be limited only to persons with formal training in their use.[20] However, they also note that AED training does improve performance in simulation and continue to recommend it. The following further items have been identified for consideration in a public access defibrillation programme:

- Training
  - Merits of AED training are discussed above.
  - Training should include CPR as it increases survival time, allowing more time for the AED to arrive for use.
  - Authorise a state agency to establish requirements for training, recertification and registration.
- Maintenance
  - Ensure AEDs are ready for use.
- Quality control, for example,
  - Written emergency response plans, medically approved protocols.
  - Assurance of AED / databases maintenance (up to date and correct).
  - Ensure training programmes up to date and are appropriate.[16]
  - Include a licensed physician or medical authority to provide medical oversight to ensure quality control in a public access defibrillation programme.[21]
- AED and emergency medical services integration
  - emergency medical services personnel aware of location of AEDs in their community
  - Evaluation of out-of-hospital cardiac arrest and AED use.

Figure 2.2 AED signage developed by the International Liaison Committee on Resuscitation, recommended for use throughout the world to indicate the presence of an AED.[22]

There are several forms of public access defibrillation programmes reported in the literature. These include the following and are compared in Table 2.4:

- Mobile AEDs – community responders
  - Trained local emergency medical services or first responders carrying AEDs (such as fire-fighters, members of An Garda Síochána). They can be dispatched to the scene to start resuscitation before arrival of an ambulance. This is particularly important where the target time from contacting emergency medical services to defibrillation of five minutes cannot be achieved by emergency medical services.
  - This can also be extended to, for example, district nurses and other healthcare workers. It has been recommended that the first priority of a public access defibrillation programme should be to insure that every vehicle that transports patients at risk of cardiac arrest should carry an AED and appropriately trained personnel.[23] Trained members of the public, e.g. community first responder groups. These are volunteers carrying an AED who may be linked with the emergency-medical-services dispatch system. They should also be trained in CPR to help people in their community.
- Stationary AEDs – on site responders (including bystanders)
  - AEDs in public places: where cardiac arrests are likely to occur, accessible for use prior to emergency medical services arrival, with staff trained in CPR and AED use. Access can also be provided to untrained members of the public.
  - Private company AEDs: including small businesses, encouraged to purchase AEDs to help people in their company or community, with staff trained in CPR and AED use.

- In-hospital AEDs, in larger hospitals, time to defibrillation may be delayed by waiting for an emergency response team. AEDs can be placed in locations where some or all staff (not just healthcare professionals) are trained.

- Home AEDs – home responders
  - The majority of out-of-hospital cardiac arrest occur at home (70%[6]) and with AED prices reducing, some high risk members of the public may purchase their own AED.

Table 2.4 Comparison of public access defibrillation strategies[23]

	Community responder	On site responder	Home responder
Location of person in arrest	All areas, including home	Public/private areas excluding home	Home
Training level	High	Moderate to untrained	Moderate
Number of reachable persons in arrest	High	Limited	Low
Number of AEDs needed	Moderate	High	One per home
Time interval from collapse to defibrillation	Reduction is limited	Potentially very short	Very short

In 2010, results from a survey of AED use in Europe were published.[24] The responses with respect to legislation for AED use, who is legally allowed use an AED and whether this is confirmed by a national resuscitation council are included in Table 2.5.

Table 2.5 AEDs in Europe, a 2009 survey(24)

Country	Legislation for AED use?	Who is legally allowed use an AED?	Confirmed by National Resuscitation Council?
Ireland	No*	Everybody trained	N/A
Albania	Don't know	Emergency medical services personnel	N/A
Austria	Yes	Everybody	Yes
Belgium	Yes	Everybody	Yes
Bosnia & Herzegovina	Don't know	Everybody	N/A
Bulgaria	No	Physicians only	N/A
Croatia	No	Emergency medical services personnel	Yes
Cyprus	Yes	Everybody trained	Yes
Czech Rep	No	Everybody	No response
Denmark	No	Everybody	Yes
Estonia	No	Physicians only	N/A
Finland	No	Everybody trained	Yes
France	Yes	Everybody	Yes
Germany	No	Everybody	Yes
Greece	Yes	Everybody trained	Yes
Hungary	No	Everybody trained	Yes
Iceland	No	Everybody	Yes
Italy	Yes	Everybody trained	Yes
Lithuania	No	Emergency medical services personnel	N/A
Luxembourg	No	Emergency medical services personnel	N/A
Macedonia	No	Everybody trained	N/A
Malta	No	Everybody trained	Yes
Netherlands	No	Everybody	Yes
Norway	No	Everybody	Yes
Poland	No	Everybody trained	Yes
Portugal	No	Emergency medical services personnel	Yes
Romania	No	Emergency medical services personnel	Yes

Country	Legislation for AED use?	Who is legally allowed use an AED?	Confirmed by National Resuscitation Council?
Russian Federation	No	Don't know	Yes
Serbia	No	Emergency medical services personnel	No response
Slovenia	No	Everybody trained	Yes
Spain	Yes	Everybody trained	Yes
Sweden	No	Everybody	Yes
Switzerland	No	Everybody	Yes
Turkey	No	Emergency medical services personnel	Yes
UK	No	Everybody	Yes
Ukraine	No	Physicians only	N/A

Note: *However, proposed legislation on availability of defibrillators introduced in 2013.

Some details of public access defibrillation programmes and AED use in other countries are included for comparison. For example, in 2000, the Department of Health in England and the British Heart Foundation (BHF) introduced a formal public access defibrillation programme, placing 681 AEDs in 110 public places for use by volunteer lay first responders. Also, the UK government's 'Cardiovascular Disease Outcomes Strategy, 2013' aims to promote AED site mapping, registration and first responder programmes by ambulance services and to consider ways of increasing the numbers trained in CPR and AED use.[25]

Spain, for example, is divided into 17 autonomous communities, in 2009 it was reported that 13 had their own legislation with respect to AED use.[26] Most recommended their installation in busy areas.[26] Aragón specifically recommended a defibrillator in 'transport terminals with a transit of more than 1,000 people, shopping centres over 1,000m^2, show venues, conference halls, events or exhibitions, gymnasiums and educational centres with a transit of more than 500 people, and airplanes, trains or ships with a capacity of 100 passengers or more'.[26] In France, a decree (2007-705 of May 4) allows 'any person' to use AEDs. Proposed legislation states that any establishment open to the public referred to in Article L. 123-1 shall be equipped with an AED, under conditions determined by law.[27] It also states that there should be a national database of AED locations. In Portugal, the legal basis for out-of-hospital AED use was established in 2009 allowing laypersons who have completed training to use AEDs. In 2012, another law 'obliges' airports, commercial ports, commercial areas and transportation stations to have an AED programme.[28]

In the US, the Cardiac Arrest Survival Act of 2000 (HR 2498) provides recommendations for the placement of AEDs in federal buildings in order to improve survival rates of individuals who experience cardiac arrest in such buildings, and to establish protections from civil liability arising from the emergency use of the devices. By 2010, all jurisdictions in the US had enacted laws for public access defibrillation with respect to some of the following: targeted AED site placement, training, maintenance, emergency medical services and or medical coordination, continuous quality improvement and immunity from prosecution.[29] The most common locations include fitness facilities, school sponsored athletic events, schools. According to the National Council of State Legislatures[30], many state laws establish legislative intent that an 'AED may be used by any person for the purpose of saving the life of another person in cardiac arrest'. A summary of public access defibrillation statutes and regulations in effect in 51 US jurisdictions is included in Table 2.6.

Table 2.6 Summary of state and District of Columbia public access defibrillation statutes and regulations in effect in 51 US jurisdictions, January 2010[29]

Public access defibrillation element	Number of jurisdictions		
	Explicitly required by law	Encourage / required by law under certain conditions	Not required by law
Placement (in specified locations)	20	9	22
Anticipated rescuers trained in CPR and AED use	28	15	8
Those acquiring AEDs must maintain and test AED	31	8	12
Notification / registration with local emergency medical services	30	5	16
Activate 911 emergency medical services	29	4	18
Report clinical use of AED to emergency medical services	22	2	27
Oversight by licensed physician or medical authority	21	3	27
Written emergency response plans or medical approved protocols	13	2	36
Plan to evaluate all out-of-hospital cardiac arrest events	13	0	38
Good Samaritan immunity (GSI)	41	7	3

Public access defibrillation element	Number of jurisdictions		
	Explicitly required by law	**Encourage / required by law under certain conditions**	**Not required by law**
for untrained / trained rescuers			
GSI for AED acquirers	20	24	7
GSI for programme directors	21	11	19
GSI for owner, manager, renter of premises where AED installed	14	6	31

In Japan, public use of AEDs was legally permitted in July 2004 and the number of public-access AEDs was estimated at 297,000 in 2011. A voluntary AED registry in Osaka estimated that 31% of AEDs were located in schools, 13% in workplaces, and 5% in public transportation facilities.[31]

In some Canadian states, for example, in Manitoba under the Defibrillator Public Access Act, AEDs were required to be installed in high-traffic public places such as gymnasiums, arenas, community centres, golf courses, schools and airports by January 31, 2014. The Act requires AEDs to be registered with the Heart and Stroke Foundation of Manitoba so they can advise 911 dispatchers of their location, to enable them to assist those trying to care for a person in cardiac arrest to find the nearest AED, and to guide them through the proper use of the machine. Legislation in Canada protects individuals who use AEDs from liability when they are used in the context of saving a life.

Public access defibrillation programmes are available in Australia and New Zealand through the St John's ambulance service. This aims to place AEDs in locations where large numbers of people gather.

2.5 Key Messages

- The interval between a cardiac arrest and the use of AED to restore a normal cardiac rhythm is a key determinant of survival from out-of-hospital cardiac arrest.
- To ensure timely use of an AED, the design of a public access defibrillation programme should consider the strategic placement of AEDs, their accessibility and security, their visibility and how to raise public awareness as to their location and purpose. The success of a public access defibrillation programme also depends on training, AED maintenance, the quality control of the programme, and the integration of AED data into emergency-medical-services systems, so that they are aware of the location of available devices.

- Accessibility of AEDs outside of normal office hours is reported as a major challenge to public access defibrillation programmes. Housing AEDs in protective cases mounted on external building walls has been recommended to improve accessibility.
- For strategic AED placement, the European Resuscitation Council guidelines and the American Heart Association guidelines agree that public access defibrillation programmes are most likely to be successful if AEDs are placed in locations where a witnessed cardiac arrest is likely to occur.
- There are several forms of public access defibrillation programmes reported in the literature. These include: mobile AEDs (used by trained local emergency medical services or community responders), static AEDs (such as public, private company, in-hospital AEDs) used by trained or untrained bystanders, and AEDs placed in the homes of high-risk individuals.
- AED use should not be limited to persons with formal training in their use, however, AED training does improve performance.
- The Pre-Hospital Emergency Care Council has produced standards to help those purchasing AEDs for use in the community to ensure they select the right AED for their needs. The Health Products Regulatory Authority (HPRA) has also produced advice on selecting and purchasing AEDs.

3 Epidemiology and service configuration

As noted in Chapter 2, cardiac arrest is the abrupt loss of heart function, and is caused by a malfunction of the electrical system in the heart. The malfunction may be caused by abnormal, or irregular, heart rhythms (called arrhythmias). A common arrhythmia in cardiac arrest is ventricular fibrillation, which occurs when the heart's lower chambers suddenly start beating chaotically and fail to pump blood. Ventricular fibrillation (VF) and ventricular tachycardia (VT) are dysfunctional rhythms that can be shocked with an automated external defibrillator (AED) to normalise rhythm and achieve the return of spontaneous circulation (ROSC).

Death occurs within minutes of the heart stopping. Cardiac arrest may be reversed if cardiopulmonary resuscitation (CPR) is performed and a defibrillator is used to shock the heart and restore a normal heart rhythm within a few minutes. As cardiac arrest typically occurs instantly or shortly after symptoms appear, there is little warning and limited time for intervention. Cardiac arrest is distinct from a myocardial infarction, which is caused by a blockage that stops blood flow to the heart, although cardiac arrest may be caused by a myocardial infarction.

The purpose of this chapter is to outline the incidence and mortality of cardiac arrest in Ireland and internationally. The chapter also discusses the availability of AEDs in Ireland at present.

3.1 Incidence

Approximately 5,000 people die in Ireland each year due to out-of-hospital cardiac arrest.(1) Only a proportion of the out-of-hospital cardiac arrests are witnessed with the emergency medical services dispatched to attempt resuscitation. A witnessed out-of-hospital cardiac arrest is an arrest where someone is present when the out-of-hospital cardiac arrest occurs. In an unwitnessed out-of-hospital cardiac arrest, someone may discover the patient shortly after the event, and a resuscitation attempt may still be successful. For this assessment, the Authority will limit its analyses to out-of-hospital cardiac arrests that were attended by the emergency medical services and for whom resuscitation was attempted, as this is the target population that may benefit from public access defibrillation.

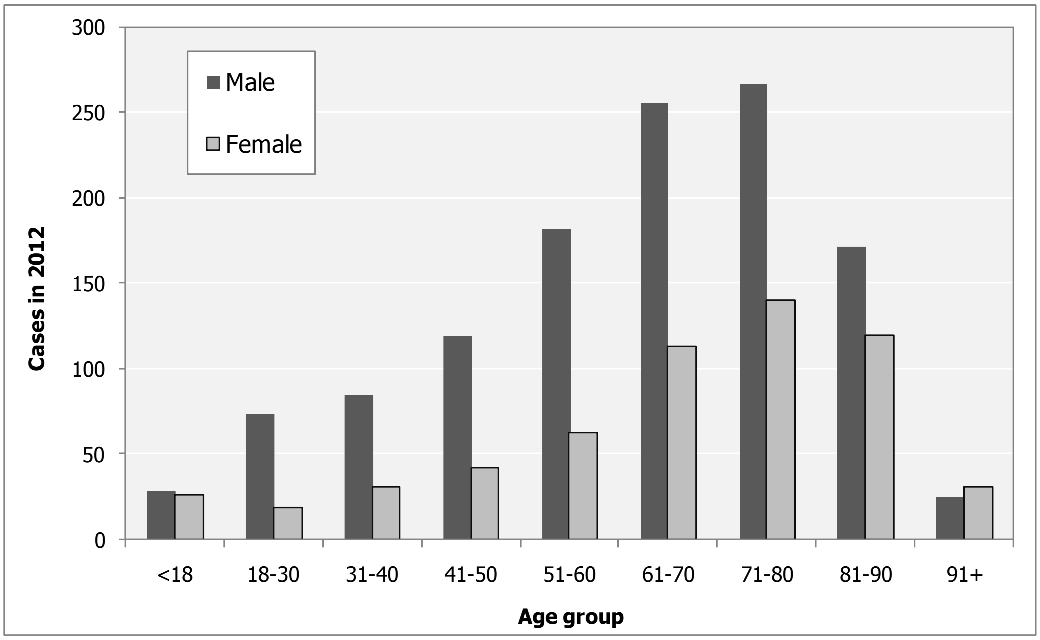
The National Out-of-Hospital Cardiac Arrest Register project was established in 2007 to record data on all emergency-medical-services-attended out-of-hospital cardiac arrests in Ireland.(6) National coverage was achieved from 2012. The Out-of-Hospital Cardiac Arrest Register is being integrated into the National Ambulance Service to provide detailed reporting regarding out-of-hospital cardiac arrests in terms of the incidence, outcomes, and the factors associated with survival.

In 2012, there were 1,798 out-of-hospital cardiac arrests in Ireland for which resuscitation was attempted by the emergency medical services.[6] The incidence was 39.1 cases per 100,000 persons for the entire population, and 50.6 per 100,000 when only considering the adult population (aged 18 years and over). Approximately 87% of cases were of presumed cardiac aetiology. Twenty two percent of cases were in a shockable VF rhythm at the time of the first rhythm analysis.

The incidence of out-of-hospital cardiac arrest varies internationally, and comparisons are affected by the variety of definitions used when reporting incidence of out-of-hospital cardiac arrest.[32] A systematic review of prospective studies reported values of 34.7 and 62.3 for incidence of attended out-of-hospital cardiac arrests for all ages and in adults only, respectively, of which 28% (adult and paediatric) were in a shockable VF rhythm.[32]. Overall the incidence in Ireland appears to broadly reflect international findings.

The average age of out-of-hospital cardiac arrest cases in Ireland in 2012 was 71 years for males and 65 years for females (see Figure 3.1).[6] The age-sex distribution in Ireland is equivalent to that reported for out-of-hospital cardiac arrests in Belfast.[33]

Figure 3.1 Age and sex distribution of out-of-hospital cardiac arrest cases in Ireland (OCHAR 2012)[6]



Notes: OHCA, out-of-hospital cardiac arrest; OHCAR, OHCA Register.

3.1.1 Risk factors

An estimated 80% of cardiac arrests are related to underlying coronary artery disease, with a further 10-15% linked to an underlying non-ischaemic myopathic process such as hypertrophic cardiomyopathy or dilated cardiomyopathy.[34] Conventional cardiac risk factors are also risk factors for cardiac arrest, including diabetes, smoking, high cholesterol, and high blood pressure.

The Reykjavik Study investigated risk factors for out-of-hospital cardiac arrest for men and women.[35] They found that the risk in men was associated with age, diastolic blood pressure, cholesterol, current smoking, and previous diagnosis of myocardial infarction (MI). The risk in women was associated with diastolic blood pressure, elevated levels of cholesterol and triglycerides, and increased voltage on ECG. Increased body mass index (BMI) was inversely related to women's risk of out-of-hospital cardiac arrest, although this may have been due to adjustment for diabetes and hypertension.

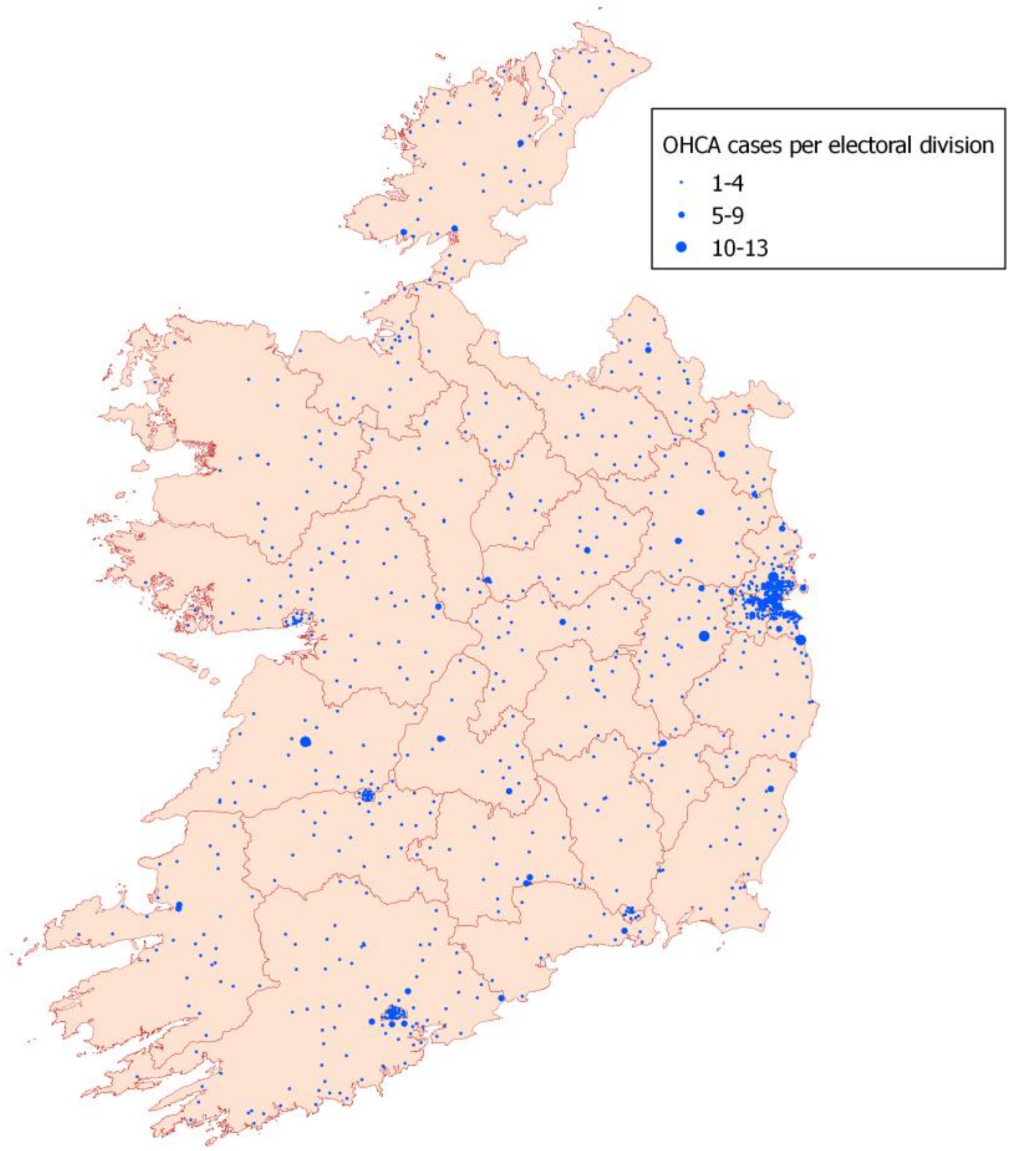
The Paris Prospective Study I found that the relative risk of sudden death in men was also associated with parental sudden death, indicating the importance of genetic risk factors.[36]

3.1.2 Geography

Marked regional variation in out-of-hospital cardiac arrest incidence has been observed in a number of studies, and may reflect regional variation in risk factors.[37-40]

At a local level, the incidence of cardiac arrest follows a socio-economic gradient such that the incidence is highest in the poorest neighbourhoods, and lowest in the most affluent neighbourhoods.[41;42] The identification of high incidence areas generally relies on using age-sex standardised rates, which do not encompass many of the important risk factors for cardiac arrest. Lower socio-economic status is often associated with increased BMI, diabetes, and elevated blood pressure, which may partly explain the existence of a socio-economic gradient in incidence.

Figure 3.2 Distribution of out-of-hospital cardiac arrests by electoral division, (OHCAR 2012)[(6)]



Out-of-hospital cardiac arrests in Ireland occur in a variety of locations, but predominantly in the home (Table 3.1). The locations reported in the Out-of-Hospital Cardiac Arrest Registry data are similar to those from other Irish studies that found approximately 70% of cases occurred in the home.[(43;44)] The likelihood of an event being witnessed, and hence the probability of a favourable outcome, will depend on the location in which it occurs.

Table 3.1 Locations of out-of-hospital cardiac arrest events in Ireland 2012[6]

Location	Cases		Witnessed (%)
	N	%	
Home	1,190	66.5	55.5
Residential institution	180	10.1	67.8
Street or road	145	8.1	67.7
Public buildings	85	4.8	80.7
Recreation or sports facilities	53	3.0	82.7
Ambulance	29	1.6	100.0
GP surgery	17	1.0	100.0
Industrial place or premises	17	1.0	56.3
Farm	13	0.7	38.5
Airport	9	0.5	100.0
Other (including water, in a car)	51	2.9	55.1

Studies from the Netherlands have reported 75% to 80% of witnessed out-of-hospital cardiac arrests occurring in the home, and between 5% and 10% occurring on the street.[45;46] It is possible that these studies defined 'home' to include residential institutions, in which case the distribution of cases is very similar to that reported in Ireland.

A US study examined public locations of out-of-hospital cardiac arrests and identified a number of higher incidence locations: international airport; county jail; large shopping mall; public sports venue; large industrial site; golf course; shelter; ferry/train terminal; health club/gym; and community/senior centre.[47] Other locations were considered lower incidence locations, including hotels, bars, schools, and restaurants. Higher incidence locations were considered suitable for the placement of AEDs to maximise the possibility of early intervention. The study was not restricted to witnessed arrests.

The Northern Ireland Public Access Defibrillation (NIPAD) study compared two areas, one urban and one rural, before and after the introduction of a public access defibrillation programme.[48] They found some evidence that a higher proportion of out-of-hospital cardiac arrests in rural areas occur in public places compared with urban areas (11.5% vs. 6.9%). OCHAR data show no statistically significant difference between urban and rural areas in Ireland in the likelihood of collapse in a public place.[6] The types of activities that people engage in are likely to differ between urban and rural areas, not least because high incidence locations such as shopping centres are more likely to be located in urban centres. As a consequence, what might be defined as a high incidence location may differ between urban and rural areas.

3.2 Clinical outcomes

Direct current defibrillation alone can restore a perfusing rhythm within one to two minutes in 80% of patients with a shockable rhythm.(49) After three to four minutes, attempts at defibrillation usually result in asystole or pulseless electrical activity (PEA).(50) A brief period of effective CPR before defibrillation during this second (hemodynamic) phase can increase the likelihood of restoration of spontaneous circulation (ROSC) following defibrillation. If spontaneous circulation is not restored within eight to nine minutes then the likely outcome is irreversible end organ injury (including anoxic brain damage) and death.

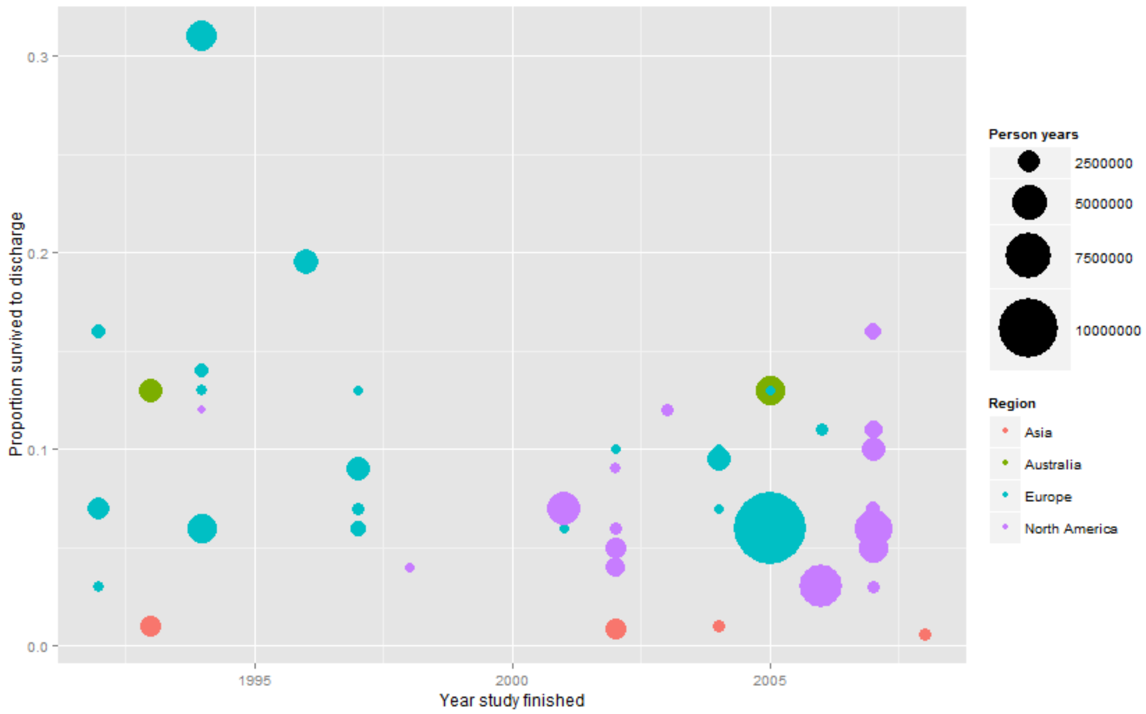
Time to defibrillation directly correlates to cardiac arrest mortality with an approximate 7%–10% decline in survival for each additional minute of ventricular fibrillation.(5) Even with an ideal emergency medical services response, it is likely to take approximately seven minutes to reach the scene of the cardiac arrest, at which point the patient will have only a 30% probability of survival.(51) For out-of-hospital cardiac arrests occurring in public places, there can be difficulties in describing the exact location that can add to time taken to reach the scene, further delaying appropriate intervention.(52)

Given the importance of timely treatment, the mode of intervention is critical. Modes may include: emergency medical services treatment; bystander CPR; bystander AED; community first responders; other uniformed responders, such as police or fire-fighters. In any setting there will usually be a combination of the above modes of intervention being used in practice. As some will tend to result in more timely treatment, they will impact on survival rates and functional outcomes.

3.2.1 Mortality and survival

According to the OCHA Registry, in 2012, 5.2% of Irish emergency-medical-services-attended out-of-hospital cardiac arrest cases survived to hospital discharge.(6) Across 68 international studies, a systematic review found that 7.1% of out-of-hospital cardiac arrests survived to discharge when adult and paediatric cases were included (see Figure 3.3).(32) Survival in individual studies ranged from 0.6% to 31.0%, showing the substantial variation across study areas (Figure 3.3). For cases with a VF rhythm, survival to discharge was 17.3%. The results of the systematic review may be biased by the number of studies that were based in urban regions or cities where emergency medical services response times may typically be shorter and hence lead to improved survival.

Figure 3.3 Survival from out-of-hospital cardiac arrest in international studies[32]



Note: circles sized by person years, estimated as the population in the study region multiplied by the duration of the study in years.

Survival to hospital discharge varied by mode of intervention in Ireland (see Table 3.2). The majority of witnessed cases had a first intervention either by a bystander or by an emergency medical services responder. The proportion of interventions by police and fire-fighters comprised less than 2.5% of cases. The survival to discharge was highest for those who had an AED shock applied by a member of the public prior to the arrival of the emergency medical services. Survival to discharge was approximately equivalent for those where the first intervention was bystander CPR or emergency medical services.

Table 3.2 Witnessed out-of-hospital cardiac arrest events and survival by mode of intervention in Ireland, 2012[6]

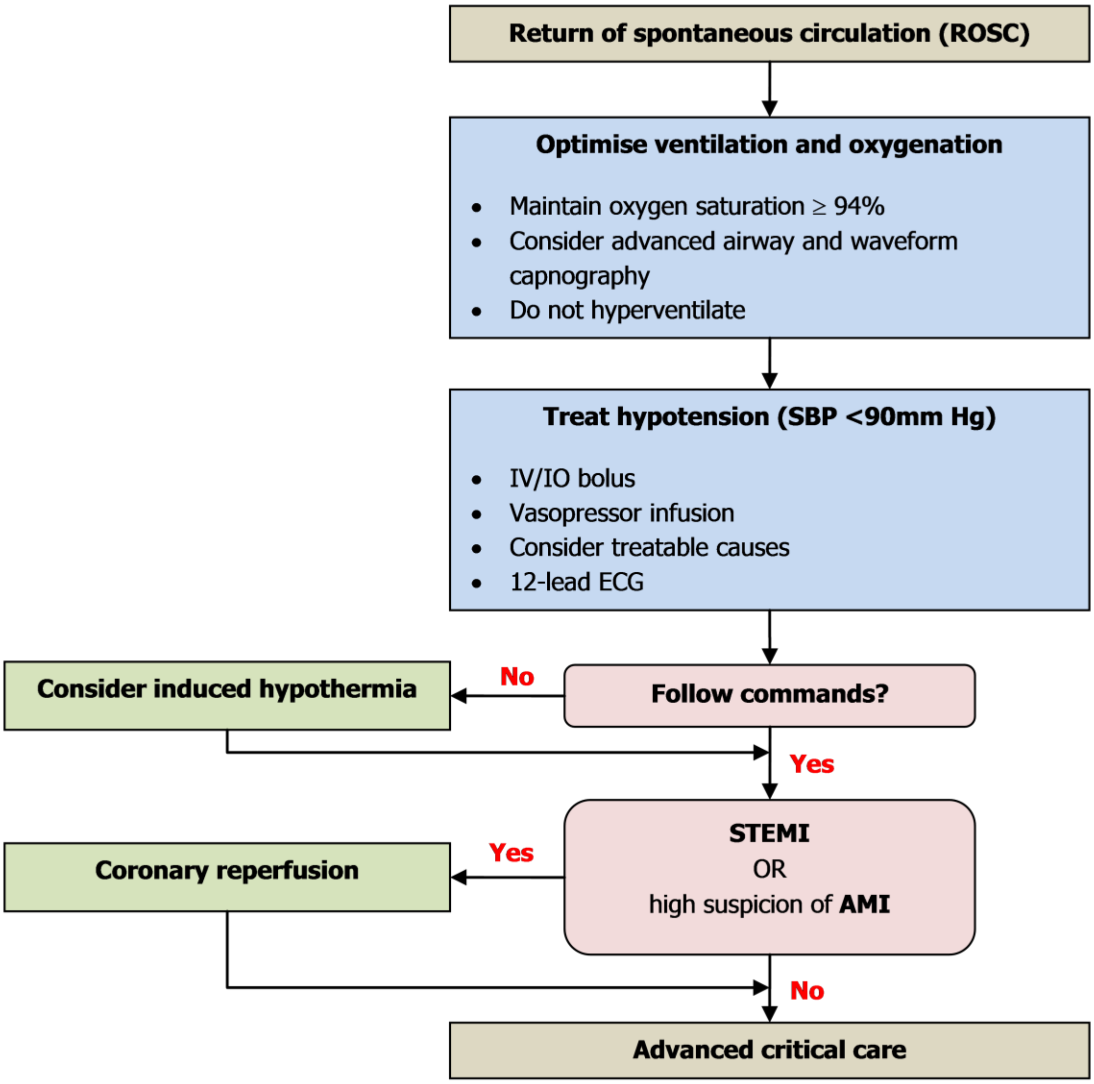
Mode of intervention	Events	Witnessed*		Survival to discharge	
		%	(95% CI)	%	(95% CI)
Bystander CPR	786	64.0	(60.5-67.4)	5.5	(4.0-7.3)
Bystander CPR+AED	119	73.9	(65.1-81.6)	13.4	(7.9-20.9)
EMS responder⊥	792	53.7	(50.1-57.2)	4.0	(2.8-5.7)
Garda Síochána	36	41.7	(25.5-59.2)	0.0	(0.0-9.7)
Fire	19	52.6	(28.9-75.6)	5.2	(0.1-26.0)

Note: ⊥ EMS (emergency medical services) responder includes bystander and EMS-witnessed.
*Witnessed means that a bystander or member of the EMS was present at the onset of the out-of-hospital cardiac arrest.

3.2.2 Pre- and in-hospital treatment

Treatment of out-of-hospital cardiac arrest cases potentially begins before the arrival of the emergency medical services. For interventions delivered by members of the public, it is restricted to CPR and defibrillation. Trained first responders or medical personnel, such as general practitioners, may be able to provide more complex interventions depending on what equipment they have available to them.

Figure 3.4 Adult immediate post-cardiac arrest care[53]



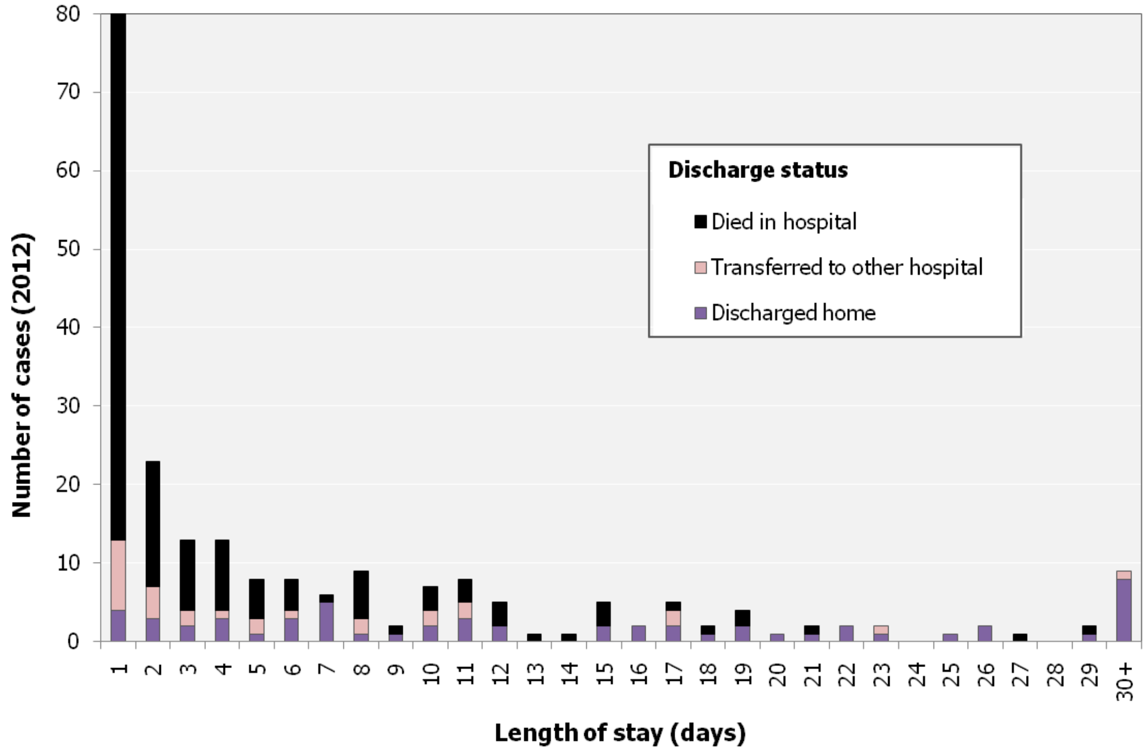
Notes: SBP, systolic blood pressure; IV, intravenous; IO, intraosseous; ECG, electrocardiogram; STEMI, ST segment elevation myocardial infarction; AMI, acute myocardial infarction.

Vasoactive drugs (such as adrenaline) may be administered after ROSC to support cardiac output, especially blood flow to the heart and brain.[53] Mild therapeutic hypothermia has been demonstrated in some studies to improve outcomes after VF/VT cardiac arrest, although its use in patients with non-VF/VT arrest has produced conflicting results generated from observational studies with substantial risk of bias.[54;55] The evidence on the benefits of induced hypothermia in out-of-hospital cardiac arrest patients is equivocal and this may be related to infrequent use and a failure to achieve appropriate temperature reductions.[56]

According to the Out-of-Hospital Cardiac Arrest Register data, there were 272 out-of-hospital cardiac arrest cases with ROSC on arrival in the emergency department (ED), 93 of whom survived to hospital discharge. Data on patients admitted to hospital in Ireland due to out-of-hospital cardiac arrest were extracted from the Hospital Inpatient Enquiry (HIPE) system. It was assumed that a primary diagnosis of ICD-AM I46 related to patients admitted to hospital due to a cardiac arrest. Where patients have a secondary code of I46, it was assumed that the cardiac arrest occurred during the course of hospitalisation or was secondary to a major trauma. Data were restricted to emergency admissions where the source was 'home' or 'other'. Inclusion of cases transferred from other hospitals would inflate the estimated number of cases, although it is understood that some out-of-hospital cardiac arrest cases will be transferred between hospitals depending on the facilities available. The cases recorded in HIPE show 85 patients with presumed out-of-hospital cardiac arrest survived to discharge in 2012, with a further 137 cases that died in hospital. The HIPE figure of 85 compares with 93 surviving to discharge in the OCHAR. The difference in numbers surviving to discharge, and potentially in numbers admitted, may reflect the use of another diagnosis code in some cases. It is assumed that all emergency-medical-services-attended out-of-hospital cardiac arrests that are brought to an ED are transferred to public acute hospitals and not to private facilities. For the following analyses it is assumed that the cases identified in the HIPE data are representative of the cohort of out-of-hospital cardiac arrest cases identified in the Out-of-Hospital Cardiac Arrest Register database.

The average length of stay across all out-of-hospital cardiac arrest patients was 9.9 days (SD 23.8 days). However, there was a substantial difference between those who survived to discharge (mean 18.8 days, SD 36.2) and those who did not (mean 4.3 days, SD 5.5) (see Figure 3.5). Seventy three percent of patients admitted for out-of-hospital cardiac arrest spent a day or more in an intensive care unit (ICU). The average length of stay in ICU was 4.3 days across all patients, and 6.6 days for patients that survived to discharge. Due to the lack of unique patient identifier, it is not possible to track patients who transferred between hospitals. The majority of cases who are discharged alive within two days are transferred to another public acute hospital for further care. The HIPE data suggest that a small number of cases are discharged home or to convalescent care within a day or two of admission.

Figure 3.5 Hospital length of stay by discharge status (HIPE 2012)



A total of 734 procedures were recorded in HIPE for 222 admitted presumed out-of-hospital cardiac arrest cases, an average of 3.3 procedures per patient. Focusing on the principal procedures, the most common procedure was management of continuous ventilatory support for three different durations (<=24 hours, 24 to 96 hours, 96 hours or more) (see Table 3.3).

Table 3.3 Most common principal procedures for out-of-hospital cardiac arrest patients admitted to hospital in Ireland, 2012 [HIPE]

Principal procedure	Frequency
Management of continuous ventilatory support (24 to 96 hours)	28
Cardiopulmonary resuscitation	27
Management of continuous ventilatory support (<= 24 hours)	25
Management of continuous ventilatory support (96+ hours)	24
Computerised tomography of brain	13
Cardioversion	11

Note: only principal procedures relating to 10 or more cases in a year listed.

In cases where an out-of-hospital cardiac arrest is due to non-reversible causes, the patient is a candidate for an implantable cardioverter defibrillator (ICD).[57] The device provides a means to manage arrhythmia. Cases recorded in HIPE which involved the insertion of an ICD were identified by the ICD-10AM procedure code 3839300 (‘insertion of cardiac defib generator’). When including cases transferred between hospitals, twelve ICDs were implanted into patients that survived to hospital discharge, giving an ICD rate of 14% in out-of-hospital cardiac arrest survivors. It is possible that some of the survivors already had ICDs, as they may have been candidates for an ICD prior to the arrest. In the absence of a unique patient identifier, it is not possible to determine how many of the cases that survived to discharge had a readmission to implant an ICD at a later date. The rate of ICD implantation varies substantially across published studies, with reported international rates varying from less than 5% to 46%.[58;59]

Patient episodes in public acute hospitals are assigned diagnosis-related groups (DRG) based on the nature and complexity of the intervention, which are used as a basis for calculating the average treatment cost. To account for the fact that some patients are transferred to another public acute hospital, data on costs were adjusted. This was achieved by calculating the mean cost of care for cases that were transferred to another public acute hospital. This mean cost was added to cases that were recorded as a transfer in to reflect the full cost of their episode of care.

Across all patients admitted with a presumed out-of-hospital cardiac arrest, the average cost in 2012 for those surviving to discharge and those dying in hospital was €22,709 and €17,792, respectively. The estimated average costs take into account long-stay patients, who are associated with a per diem payment for extended stays. The definition of long-stay is DRG-specific and is relevant in this context as some out-of-hospital cardiac arrest patients had extended lengths of stay. For example, patients with a DRG of F76A and a length of stay in excess of 26 days have an associated per diem of €529 for each additional day in hospital. Across all DRGs, 10 of the 222 patients were defined as long-stay. The average costs presented in Table 3.4 take into account the per diem incurred by long-stay patients based on 2012 HIPE data.

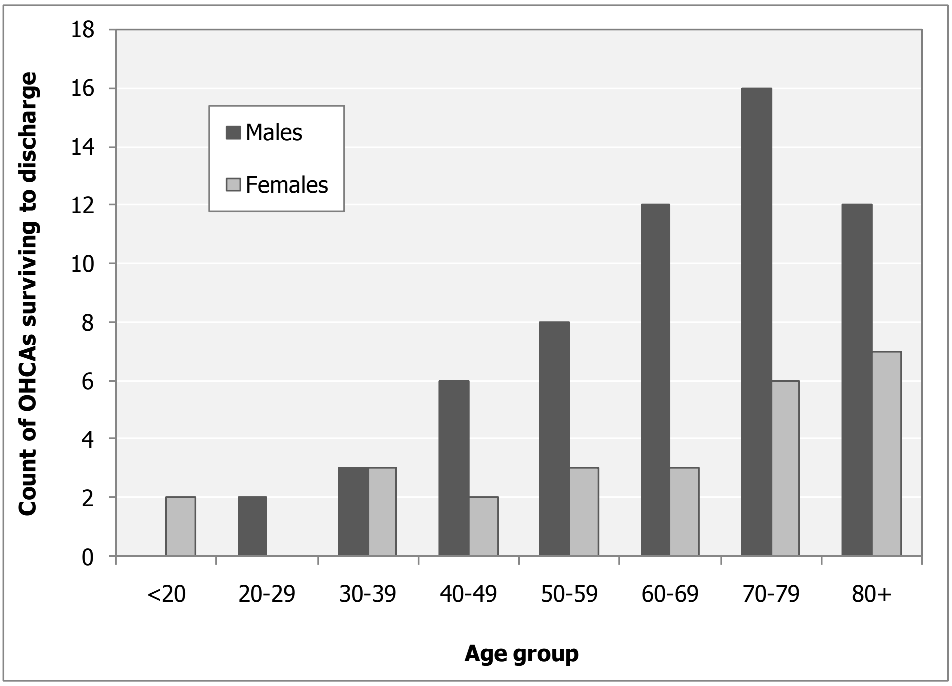
Table 3.4 Most common diagnosis related groups for out-of-hospital cardiac arrest patients admitted to hospital in Ireland, 2012 [HIPE]

Diagnosis related group	Frequency	Cost* (€)
F76A (Arrhythmia; Cardiac Arrest and Conduction Disorders with catastrophic or severe complications)	68	6,352
F76B (Arrhythmia; Cardiac Arrest and Conduction Disorders)	55	2,339
A06B (Trach W Vent >95 hours W/O Cat CC or Trach/Vent >95 hours with catastrophic complications)	27	51,568
F40B (Circulatory System Diagnosis W Ventilator Support)	18	19,536
F40A (Circulatory System Diagnosis W Ventilator Support with catastrophic complications)	16	24,862

Note: only DRGs relating to 10 or more cases in a year listed; cost relates to 2012 casemix per patient cost; * Average cost includes per diem for cases defined as long-stay.

The mean age of patients surviving to hospital discharge was 64.3 years, with 48% aged 70 years and over (see Figure 3.6).

Figure 3.6 Age distribution of out-of-hospital cardiac arrest survivors to hospital discharge (HIPE 2012)



[Notes: OHCA = out-of-hospital cardiac arrest; HIPE = Hospital In-Patient Enquiry.]

There is evidence from some studies that survival to hospital discharge is increasing; this is attributed in part to improvements in primary and secondary prevention of coronary artery disease and to changes in resuscitation and pre-hospital care.[60;61]

In addition to survival, another key outcome for out-of-hospital cardiac arrest patients is cerebral performance. During a cardiac arrest the brain can suffer from a temporary limitation in blood supply, which can lead to hypoxic brain injury giving rise to cognitive impairment.[62] Cognitive function is often measured by the cerebral performance categories (CPC). CPC scores range from 1 to 5:

- normal, or slight neurological deficits
- moderate, or mild neurological deficits
- severe neurological deficits
- chronic vegetative state
- brain death.

CPC scores of 1 and 2 are associated with sufficient cerebral function for independent activities of daily life, but a CPC score of 3 corresponds with dependence on others for daily support. Those discharged with a CPC score of 2 are able to work in a sheltered environment which can have implications for return to work, depending on the pre-arrest occupation of the out-of-hospital cardiac arrest survivor.

Cognitive impairments are common after out-of-hospital cardiac arrest and all cognitive domains can be affected, with memory being the most commonly and severely affected domain, followed by attention and executive functioning.[62] The majority of out-of-hospital cardiac arrest survivors have some degree of impairment, although the majority are still capable of independent living.[63] According to the Out-of-Hospital Cardiac Arrest Register data, the majority of out-of-hospital cardiac arrest survivors had a favourable CPC score at discharge.[6] Seventy nine percent of survivors had a CPC score of 1, suggesting cognitive function almost equivalent to pre-arrest levels. Seven percent had a CPC score of 3 or higher, indicating severe impairment. These outcomes are similar to those reported in the studies included in the systematic review of clinical effectiveness (see Chapter 4), where the percentage survivors with a CPC score of 1 (or normal neurological function) was in the range 65% to 73%.

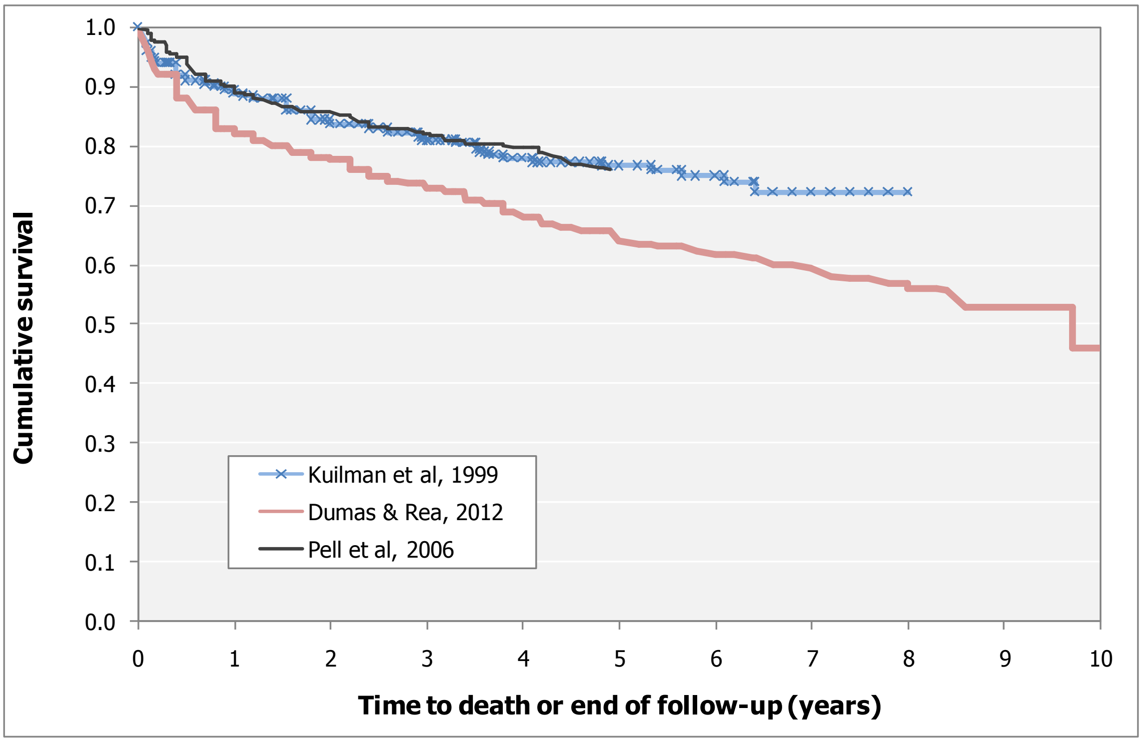
3.2.3 Longer-term outcomes

Although survival to hospital discharge is a commonly reported outcome for out-of-hospital cardiac arrest, the quality and quantity of life for those who survive to discharge is also an important consideration. Longer term survival in out-of-hospital cardiac arrest survivors is lower than for the general population matched for age and sex.[64]

Longer term survival has been measured in a number of studies and has been shown to be improving over time.[58] Five-year survival is between 64% and 76%, which is equivalent to an annual mortality rate of approximately 5% to 9% (Figure 3.7). Differences in mortality rates across studies may be due to a variety of factors including demographics, pre-hospital care, and neurological outcomes. Longer term survival is also affected by a patient's age,[64] CPC score (see Figure 3.8),[65] and by the mode of intervention (such as bystander CPR, emergency medical services).[66] Current data collection in Ireland does not facilitate following patients over time to determine longer term outcomes such as six-month or one year survival.

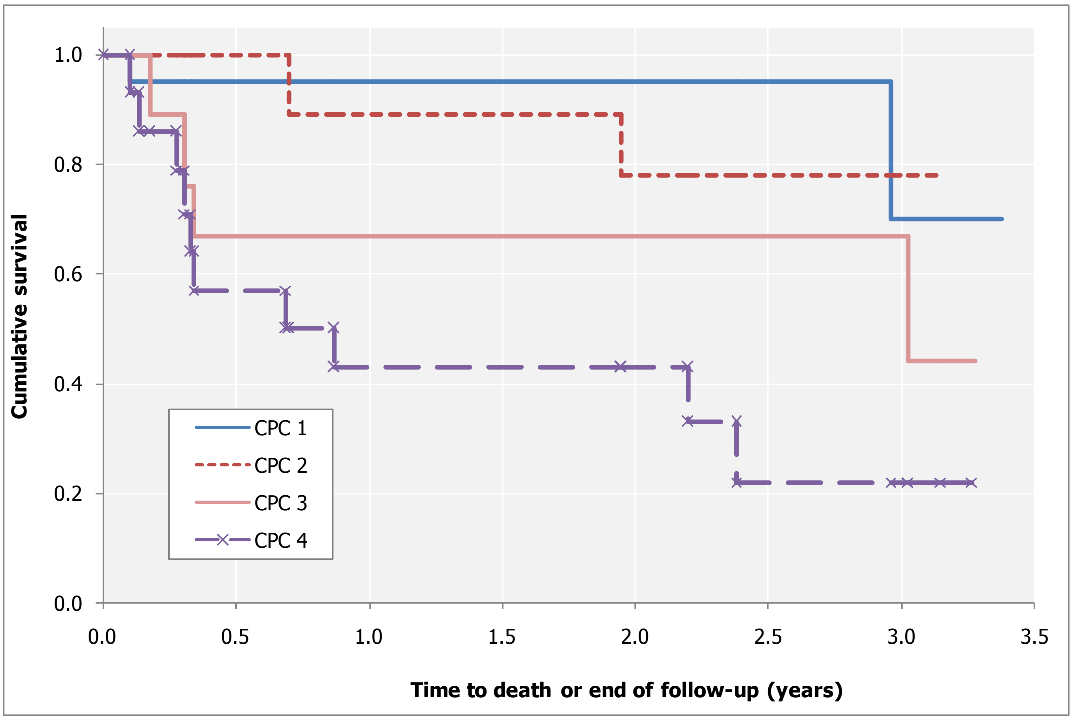
A Norwegian study using between 1 and 10 years' follow-up reported a standardised mortality rate (SMR) of 2.3 for out-of-hospital cardiac arrest survivors compared with the general population.[67] The SMR was highest in the first year after discharge (4.6), returned to 1.0 for years two to five, and then increased to 7.8 by year nine. The increased mortality in the first year is partly due to the high mortality rate in those discharged with a CPC score of 3 or higher, although this should represent a relatively small proportion of those who survived to hospital discharge.

Figure 3.7 Cumulative survival of out-of-hospital cardiac arrest patients by length of follow-up after hospital discharge



Notes: Kuilman et al., 1999;[66] Dumas & Rea, 2012;[68] Pell et al., 2006.[58]

Figure 3.8 Cumulative survival of out-of-hospital cardiac arrest patients by neurological outcome[65]



Note: CPC, Cerebral Performance Category.

Quality of life in survivors of out-of-hospital cardiac arrest has been reported to be generally good.[69] This may be explained by the generally positive outcomes in terms of cognitive impairment. Indeed, some studies have shown improvements in cognitive function over time, but the available evidence is limited. The measurement of quality of life in out-of-hospital cardiac arrest survivors has been very heterogeneous, with few studies using equivalent validated instruments.[69] A summary of the relevant studies is included in Table 3.5. Measured on a scale of 0 to 1, with one representing perfect health, a Dutch study reported mean utilities of 0.72 and 0.73 for the physical and mental health domains of the SF-36, respectively.[70] The equivalent population norms were 0.76 and 0.78, indicating only a moderate disutility for out-of-hospital cardiac arrest survivors of the order of 0.94. Using the EuroQol instrument, another Dutch study reported a mean quality of life of 0.85.[66] A study of a cohort of young Australian adults who survived out-of-hospital cardiac arrest reported a mean Health Utilities Index score of 0.84, indicating a good, but diminished quality of life after out-of-hospital cardiac arrest.[71] The results of the Canadian OPALS study assessed the health utilities index for out-of-hospital cardiac arrest survivors and estimated a mean index of 0.84, but found substantial variation by CPC score .[72] Due to small numbers, the CPC 2 and 3 cases were amalgamated. Where a score of 0.8 or higher was classified as a good level of function, 62% of CPC 1 cases had good function whereas 0% of the amalgamated CPC 2 and 3 cases had good function. The limited evidence available from the OPALS study suggested that CPC 1 cases had a higher mean health utility than CPC 2 cases. A prospective Canadian study also reported utilities of approximately 0.85 compared to the general population using the Health Utilities Index.(73) As most out-of-hospital cardiac arrest survivors have a CPC score of 1 at discharge, mean quality of life scores are driven by the CPC 1 cases with little weight given to survivors with CPC scores of 2 and 3. Response rates in the above studies varied between 72% and 94%. It is possible that response rates were higher amongst survivors with CPC scores of 1 or 2, thereby biasing the results towards those with better neurological outcomes.

Table 3.5 Health-related quality of life in out-of-hospital cardiac arrest survivors

Study	Year	Patients (n)	Age (mean)	Scale	HRQoL	
					OHCA survivor	Population norm
Moulaert(70)	2010	63	60.2	SF-36 Physical domain	0.718	0.763
				SF-36 Mental domain	0.730	0.780
Stiell(72)	2009	305	63.9	Health Utilities Index	0.840	0.850⊥
Kuilman(66)	1999	93	64.8	EuroQol	0.852	∀
Nichol(73)	1999	35	65.0	Health Utilities Index	0.780	0.850

Notes: OHCA = out-of-hospital cardiac arrest; HRQoL = health-related quality of life. Study by Deasy et al. excluded as not representative of general OHCA survivors.
⊥ Population norm quoted from Nichol et al. (1999).
∀ No population norm provided.

Although cognitive problems may have a high impact on a person's daily functioning and quality of life, CPC score alone may not be a good predictor of quality of life.(74) It is possible that the perceived benefit of survival may greatly outweigh any of the disutility associated with neurological impairment,(75) or that minor impairments do not impact on the normal daily activities of what is a predominantly older cohort.(76)

Many cardiac survivors who were in employment before their out-of-hospital cardiac arrest, do not return to work and either retire from work or go on sick leave.(77) This is partly a reflection of the age distribution of out-of-hospital cardiac arrest cases, half of whom are over 65. However, a study of young adult out-of-hospital cardiac arrest survivors found that only 68% had returned to work, and only 47% returning to their previous role.(71) The failure to return to work has consequences for both the individual and society. For the survivor, an inability to return to work can lead to isolation and diminished standard of living. For society, there are productivity costs associated with the loss of workforce.

3.3 Service distribution

As identified previously, the first pre-hospital intervention given for an out-of-hospital cardiac arrest may be delivered by an emergency medical services team, a uniformed responder (that is, a member of An Garda Síochána or a fire-fighter), or by a member of the public (that is, a bystander or community first responder). The geographic distribution of those delivering the intervention in relation to the distribution of out-of-hospital cardiac arrests is important for patient outcomes.

An analysis of 2012 time of admission data from HIPE suggests that approximately 27% of cases are admitted before 9am and a further 33% are admitted after 5pm. However, due to a large quantity of missing data (59% of records do not have time of admission), it is not possible to use these data to accurately determine time of admission for out-of-hospital cardiac arrests. It should also be noted that the lag between the out-of-hospital cardiac arrest event and time of admission could be quite substantial, given the time for emergency medical services to reach the scene, stabilise the patient and transfer to hospital. According to the Out-of-Hospital Cardiac Arrest Register data from 2012, in 42% of cases the emergency medical services call occurs between the hours of 9am and 5pm, which corresponds with the HIPE data. Time of emergency medical services call is available for 96% Out-of-Hospital Cardiac Arrest Register records. There is no evidence of a difference in survival depending on whether a case occurs between 9am and 5pm or outside those hours.

The timing and geographic location of out-of-hospital cardiac arrests will influence how the initial intervention is delivered and how timely it is.

3.3.1 Ambulance stations

Ambulances in Ireland are operated by the National Ambulance Service with the exception of the Dublin area, where service provision is shared with the Dublin Fire Brigade. Ambulances are based at 102 stations across Ireland. The National Ambulance Service also operates 111 rapid response vehicles nationally that can attend to out-of-hospital cardiac arrests. Response times and the distance that can be covered within a specific time vary across the country according to local conditions. The National Ambulance Service reports operating a system of dynamic deployment whereby ambulances and RRVs are not necessarily at stations, but are moved to locations that ensure good coverage according to need and available resources.

The median recorded emergency medical services response time in the Out-of-Hospital Cardiac Arrest Register database was 11 minutes, although there was substantial variability.[6] The median response times were nine minutes and 18 minutes in urban and rural areas, respectively, with only 16% of out-of-hospital cardiac arrests nationally reached in five minutes or less. The dispersed nature of the Irish population means that achieving the timely arrival of ambulance services is challenging. Even when ambulances are prepared for immediate dispatch, a large proportion of out-of-hospital cardiac arrests are unlikely to receive timely emergency medical services intervention, and hence rely on intervention from either a bystander or community first responder.

3.3.2 Community first responders

There are approximately 100 community first responder groups in Ireland that are linked to the emergency medical services.[78] There are likely additional groups that are not linked to the emergency medical services. Linkage implies that the community first responder group is integrated into the National Ambulance Service; that the volunteers have undergone appropriate training; the group is appropriately equipped for emergencies; and emergency calls are directed to the community first responder group from Ambulance control.[79] Linkage to the emergency medical services is essential to ensure timely dispatch, as the national emergency numbers are more commonly known and the call centres are in a better position to identify the appropriate first responder group to contact. Control through the emergency medical services also ensures dual dispatch of community first responder and emergency medical services responders. A sample survey of the Irish population found that 4.3% of people were unsure of the correct number to call in an emergency, suggesting that having additional local emergency numbers may cause confusion and affect the timely dispatch of services.[80] In the absence of linkage, the caller must have the phone number for the local community first responder group. It is assumed that the existing emergency-medical-services-linked community first responder groups are generally located in rural areas where ambulance coverage is limited. This assumption is supported by the finding that community first responder intervention is more likely to occur in rural areas than in urban areas.[81] However a number of first responder schemes are currently in operation in urban areas.

These volunteer community first responder groups operate at a local level and as yet are not centrally coordinated. However, plans are in place to launch a national first responder organisation, Cardiac First Responders Ireland, as the national umbrella Organisation for First Responder Groups in Ireland. Its aim is to network all first responder groups in Ireland, community first responder schemes linked to the National Ambulance Service, unlinked schemes, public access defibrillation schemes, sports clubs and workplace schemes. Cardiac First Responders Ireland is intended to be an information hub, which will promote best practice for first responders providing pre hospital care for people suffering heart attack or cardiac arrest. It will liaise with the relevant statutory bodies to assist the setting up of new CFR groups and will endeavour to grow community first responders in Ireland.

3.3.3 Bystander cardio-pulmonary resuscitation (CPR)

The initiation of CPR by a bystander before the arrival of the emergency medical services can increase the probability of survival for an out-of-hospital cardiac arrest patient. CPR consists of chest compressions and decompressions, which may be interspaced with ventilation, although in some jurisdictions 'hands only' CPR is recommended when resuscitation is carried out by an untrained person.(82) The success of CPR requires someone with appropriate training to be at the scene at the time of cardiac arrest or shortly afterwards. A 2008 survey of a sample of the Irish population found that 23.5% of the population had received CPR training within the previous five years.(80) Of those who had received CPR training, 70% stated that they would be willing to administer CPR in an emergency. The proportion with CPR training in Ireland compares well with other countries. The good level of coverage may be reflected in the fact that for out-of-hospital cardiac arrests that were not emergency medical services-witnessed, bystander CPR was attempted in 60% of cases.(6) Where the emergency medical services caller and other bystanders do not have CPR training, instruction may be given by the call operator on how to deliver CPR. It is not clear what proportion of bystander CPR interventions is dispatcher-assisted.

The quality of CPR affects its effectiveness. Poor quality CPR can arise for a number of reasons: chest compressions are too shallow; compressions are too slow; chest is not allowed to recoil fully; CPR is interrupted; or the patient is over-ventilated.(82) Biennial refresher training is the minimum required for individuals to maintain their Cardiac First Responder accreditation. However, it is recognised that more frequent training, such as 90-day retraining, is required to maintain CPR skills at an effective level. It has been suggested that a low-dose, high-frequency approach to CPR training is most appropriate for hospital staff and helps to maintain effective skills,(83) but this approach is not practical for community-based responders. Where bystander CPR is dispatcher-assisted, it implies that the person carrying out CPR is either untrained or not recently trained, and it is assumed that the quality of CPR will be lower than would be achieved by a person with recent training.

CPR can be associated with adverse events for the bystander who administers it.(84) CPR is physically intensive, particularly if there is a substantial time lag before arrival of the emergency medical services. The event is also traumatic for the bystander, particularly if the out-of-hospital cardiac arrest victim dies or is a relative. Stress and trauma-related adverse events were generally resolved within a few days.[84]

3.3.4 Bystander defibrillation

Given that early defibrillation is an essential component of the chain of survival, rapid defibrillation will often rely on coincidental bystanders to use an AED before the arrival of the emergency medical services. When the bystander is not a member of a community first responder group and not equipped with an AED, they need access to a locally placed AED preferably within a short distance of the event. An AED is generally used in conjunction with CPR, and even if defibrillation is successful, CPR will often be continued after defibrillation.[85] AEDs are generally simple to use, with the main difficulties being associated with the emergency context and responsibility of attempting to save a person's life. The AED records and analyses the ECG rhythm through adhesive pads or electrodes and informs the user if a shock needs to be delivered. An AED will not provide a shock to a person with a normal heart rhythm. As with CPR, the main adverse events associated with use of an AED relate to traumatic stress.[85]

A survey conducted in the Netherlands found that 53% of respondents were unable to recognise an AED and only 47% were willing to use one in an emergency.[86] Knowledge of AEDs tends to be higher in younger age groups and professionals, hence the importance of incorporating large scale training in conjunction with any public access defibrillation legislation.[87] Health promotion or public awareness campaigns are necessary to increase knowledge and understanding of AEDs and to increase their usage in emergencies. It is possible that the introduction of a national public access defibrillation programme would provide the opportunity for such a campaign.

3.3.5 Current distribution of AEDs in Ireland

All of the main suppliers of AEDs in Ireland were contacted during February 2014 and asked to indicate the number of AEDs sold to date, and when they started to sell AEDs. They were also asked if they maintained a database of AEDs sold and if they monitored use of the AEDs in resuscitation attempts. Companies selling AEDs were initially identified through a web search. Additional companies were identified through discussions with the initial list of suppliers. A total of 15 companies were contacted.

The number of AEDs sold by each company varied substantially, with some having sold fewer than 20 while others have sold several thousand. Most companies entered the market in the last five to 10 years. The estimated total number of AEDs sold in Ireland is 15,151 since 1998. As the records relate to 16 years of AED sales, a proportion of those will have come to the end of their lifespan. Assuming that the average lifespan of an AED is eight years[88] and that sales have grown over time, approximately 13,000 AEDs are still within their usable lifespan. It is probable that not all of the purchased AEDs are maintained and ready for use. An Irish study of AEDs in sports clubs found that only 76.3% were regularly maintained.[89] It is unclear whether this figure can be generalised to other locations, but it suggests that between 8,000 and 9,000 maintained AEDs are located in Ireland at present - equivalent to between 174 and 196 AEDs per 100,000 inhabitants.

Some companies record information about when the AEDs have been used. The memory card may be extracted from the AED to analyse the performance data, and some companies provide the customer with a replacement AED while the device is checked and serviced. Pads must be replaced after use and the battery may need to be replaced, depending on the amount of charge left after use. Analysis of the performance data shows whether the device functioned properly and as intended during the resuscitation attempt.

In terms of databases, all companies reported having databases recording a number of details about AEDs sold. Customer contact details are recorded, along with details of the AED (model, serial and other reference numbers), battery and pad expiry dates. The data are used to contact customers regarding routine services, which may be done in person or over the phone, and to notify when batteries or pads are reaching their expiry dates. It was noted by a number of suppliers that their databases record the details of the buyer and not necessarily the location of the AED. Anecdotally only 70% to 80% of AEDs can be located through supplier databases, with the remaining AEDs often being bought on behalf of a community group or third party. Customer databases contain commercially sensitive information that represents a supplier’s client list.

A number of attempts have been made to locate and map AEDs in Ireland, although these have usually been local databases. In the absence of centralised AED registration, the development of such databases has generally relied on owners of AEDs identifying themselves voluntarily. Evidence from client lists suggests a broad range of locations where AEDs are located including:

- government buildings
- sports clubs
- airports
- public transport stations
- Garda stations
- shopping centres
- hotels

- universities and colleges
- state and semi-state organisations
- car parks
- company buildings for a range of industries.

It is assumed that coverage within each location category is incomplete and that, for example, not all hotels have AEDs. The extent of coverage will vary and it is possible that all airports in Ireland have AEDs, whereas very few car parks may have AEDs installed. In the absence of any data on AED placement, it is pragmatic to assume that the vast majority of existing AEDs are installed within buildings, rather than being placed in an externally mounted cabinet. Cabinets for external mounting should be climate controlled or heated, as AEDs exposed to low temperatures may take a long time to switch on or fail completely. External cabinets are more expensive and customers sometimes express concern about the threat of theft or vandalism, although there is little evidence of this occurring. As a consequence of internal placement, AEDs are generally only available for use during opening hours which will depend on the main use of the building. A hotel, for example, may be open on a 24 hour basis, seven days a week, whereas government buildings will tend to only be accessible during normal office hours on weekdays.

A study of out-of-hospital cardiac arrests in Dublin noted the availability of AEDs in large sports and concert arenas.(90) An analysis of out-of-hospital cardiac arrest survivors in the North West of Ireland found that 32% (n=25) of shocks were delivered by bystanders or community first responders.(91) The vast majority (23 of 25) of these were delivered by a GP or a GP with ambulance personnel. A 2005 survey estimated that between 35% and 40% of GPs had an AED in their practice, which may represent a significant source of AED locations in rural areas.(92) Various local initiatives have raised funds to place numerous AEDs within a town or locality.

A study of registered AEDs in Copenhagen, Denmark, estimated a coverage of 92 AEDs per 100,000 inhabitants, approximately half the estimated coverage in Ireland.(19) Across all of Denmark there are more than 5,000 registered AEDs for a population of 5.5 million, although it is estimated that approximately 15,000 have been purchased – equivalent to 273 AEDs per 100,000.(93) A public access defibrillation programme was implemented in Japan, and between 2007 and 2012 the number of AEDs per 100,000 inhabitants increased from 69 to 234, although again the population density in Japan may facilitate having fewer AEDs whilst maintaining the same spatial coverage.(94;95) The differences observed between these studies and Ireland may be affected by higher population densities (requiring fewer AEDs for equivalent population coverage) and the numbers of unregistered AEDs that may have been available. The Brescia Early Defibrillation Study in Italy involved the distribution of AEDs for use by volunteers and laypersons in a mixed urban and rural region at a rate of 4.4 AEDs per 100,000 inhabitants. The public access defibrillation Trial, the only randomised controlled trial of public access defibrillation, distributed nearly 1,600 AEDs across 496 locations in the US and Canada, of which 15.5% were residential locations, but did not report the population so the coverage of AEDs per inhabitant is unknown.[96]

It is apparent that, at present, there is widespread availability of AEDs in Ireland and that they are used in resuscitation attempts. The numbers of AEDs per 100,000 inhabitants in Ireland is similar or greater than that seen in jurisdictions with formally implemented public access defibrillation. However, in the absence of a central register listing AEDs that are known to be maintained and functional, it is not possible for the Ambulance Service control centres to direct callers to the nearest static AED. The only formal link between the emergency medical services and public AEDs is through linked community first responder groups.

3.3.6 Proposed distribution in Ireland

The Public Health (Availability of Defibrillators) Bill 2013 sets out the proposed types of premises and venues that will be required to install and maintain AEDs, referred to as 'designated places'.[4] The designated places specifically identified in the Bill include:

- hospital
- medical practice
- place of worship
- place of hospitality
- entertainment venue
- sports venue
- sports club
- train station
- bus station
- ferry port
- airport or aerodrome
- supermarket
- shopping centre
- Garda station
- courthouse
- the public area of a local authority office

- the following places at which there is a regular attendance of in excess of 100 persons per day:
  - educational establishment
  - museum
  - art gallery
  - sporting events
  - exhibitions.

The list also includes commercial aircraft and passenger ferries. Other places may be prescribed by the Minister in accordance with identified needs.

To determine the number of AEDs required for the legislation, and to estimate their population coverage, it was necessary to identify the proposed designated places. The listed locations cannot easily be identified as most resources such as telephone book listings tend to be incomplete or places may be listed under a variety of headings. The only central resource that could be identified was the GeoDirectory, which is a nationwide database listing the location of every address in the country.(97) Within the GeoDirectory, each address has an associated European industrial activity classification (NACE Rev.2) code, a four-digit code that classifies the address on the basis of the principal economic activity at that address. A list was developed of NACE codes that identified the designated places (Table 3.6).

The NACE codes available in the GeoDirectory have been generated by postal workers based on an assessment of building use and are assumed to be an accurate reflection of economic activity. However, NACE codes are not very specific: the building uses included in a single NACE code can be quite broad and, in some cases, a NACE code may incorporate both designated and non-designated places. For example, the code for general medical practice activities (8621) includes: doctor's surgery, general medical practitioner, homeopath (registered medical practitioner), school medical officer (Health Board), and medical officer (Health Board). Using that code to identify general practices will also identify locations that are not designated places, such as the office of a school medical officer. Conversely, some designated places may not be adequately captured within the listing used, but the inclusion of additional codes may have incorporated too many non-designated places. The Authority determined the expected number of locations based on a wide variety of sources including telephone directories (for instance, the Golden Pages), umbrella or representative organisations (such as Restaurants Association), company websites (for example, Irish Rail), and websites (e.g., Department of Education). The Authority conservatively estimated that there should be 39,000 designated places, which is broadly similar to the 43,089 locations identified using NACE codes.

Data were extracted by the Health Intelligence Unit (HIU) of the Health Service Executive (HSE). Location data for one year of out-of-hospital cardiac arrests recorded in the Out-of-Hospital Cardiac Arrest Register database were also made available to the HIU to undertake a mapping exercise. The HIU determined the number of out-of-hospital cardiac arrests occurring within several straight line distance radii of the designated places. While only one year of out-of-hospital cardiac arrest location data were available, it was assumed that the incidence in the vicinity of different NACE code categories would be broadly representative of what would be observed in any given year (e.g., that the number of out-of-hospital cardiac arrests within 100 metres of primary schools would be similar across a number of years' data).

The legislation proposes that AEDs should be located in both sports clubs and sports venues. Many of the estimated 12,000 sports clubs in Ireland do not have dedicated premises or may share premises with a number of clubs.[98] As the GeoDirectory is a database of addresses, it cannot be used to identify sports clubs, but rather to identify addresses used by sports clubs or for sporting activities. The legislation also identifies supermarkets. The GeoDirectory does not facilitate a distinction between large and small supermarkets, which may have contrasting footfalls and the legislation may not intend to include the latter. The Authority has assumed that all supermarkets are included in the legislation.

Table 3.6 NACE codes corresponding to designated places

NACE code	Description	Locations
G WHOLESALE AND RETAIL TRADE;REPAIR OF MOTOR VEHICLES AND MOTORCYCLES		
4711	Retail Sale In Non-Specialised Stores (Food, Beverages Or Tobacco Predominating)	3,765
H TRANSPORTATION AND STORAGE		
4939	Other Passenger Land Transport N.E.C.	215
5010	Sea And Coastal Passenger Water Transport	35
5030	Inland Passenger Water Transport	2
5110	Passenger Air Transport	11
5221	Service Activities Incidental To Land Transportation	376
I ACCOMMODATION AND FOOD SERVICE ACTIVITIES		
5510	Hotels And Similar Accommodation	987
5520	Holiday And Other Short-Stay Accommodation	218
5590	Other Accommodation	5,648
5610	Restaurants And Mobile Food Service Activities	6,067

5630	Beverage Serving Activities	6,687
O PUBLIC ADMINISTRATION AND DEFENCE;COMPULSORY SOCIAL SECURITY		
8411	General Public Administration Activities	1,422
8423	Justice And Judicial Activities	776
8424	Public Order And Safety Activities	44
P EDUCATION		
8520	Primary Education	3,203
8530	Secondary Education	664
8532	Technical And Vocational Secondary Education	552
8542	Tertiary Education	181
8559	Other Education	521
Q HUMAN HEALTH AND SOCIAL WORK ACTIVITIES		
8610	Hospital Activities	52
8621	General Medical Practice Activities	1,680
8623	Dental Practice Activities	916
R ARTS, ENTERTAINMENT AND RECREATION		
9000	Creative, Arts And Entertainment Activities	20
9004	Operation Of Arts Facilities	84
9102	Museums Activities	374
9103	Operation Of Historical Sites And Buildings And Similar Visitor Attractions	241
9104	Botanical And Zoological Gardens And Nature Reserve Activities	12
9311	Operation Of Sports Facilities	634
9312	Activities Of Sport Clubs	2,616
9313	Fitness Facilities	372
9329	Other Amusement And Recreation Activities	302
S OTHER SERVICE ACTIVITIES		
9491	Activities Of Religious Organisations	4,412

The HIU determined the number of out-of-hospital cardiac arrests occurring within 100 metres, 250 metres and 500 metres of the designated places as identified using the GeoDirectory (Table 3.7).

Table 3.7 Out-of-hospital cardiac arrests within specified distances of designated places

Building type	Designated places	out-of-hospital cardiac arrests within distance of designated buildings					
		100m		250m		500m	
		N	%	N	%	N	%
G-Retail	3,765	164	9.9	519	31.5	968	58.7
H-Transport	639	30	1.8	111	6.7	279	16.9
I-Accommodation and Food	19,607	335	20.3	704	42.7	1095	66.4
O-Public Admin	2,242	76	4.6	295	17.9	593	36.0
P-Education	5,121	114	6.9	502	30.4	950	57.6
Q-Hospital and Residential	2,648	130	7.9	394	23.9	720	43.7
R-Arts and Entertainment	4,655	111	6.7	417	25.3	828	50.2
S-Churches	4,412	109	6.6	418	25.3	828	50.2
Across all building types	43,089	584	35.4	1,087	65.9	1,316	79.8

Note: OHCAs = out-of-hospital cardiac arrests. Data provided by the Health Intelligence Unit, HSE.

The incidence of out-of-hospital cardiac arrests per AED is estimated to be highest in transport-related locations (Table 3.8). The incidence is lowest in 'accommodation and food' locations. The estimates are based on only 12 months of location data. It should be noted that an out-of-hospital cardiac arrest can be within 100 metres of multiple building types and, as a consequence, the number of out-of-hospital cardiac arrests per 1,000 AEDs is lower across all building types than for any individual building type.

Table 3.8 Predicted out-of-hospital cardiac arrests per 1,000 AEDs within specified distances of proposed designated places

Building type	OHCAs per 1,000 AEDs		
	100m	250m	500m
G-Retail	44	138	257
H-Transport	47	174	437
I-Accommodation and Food	17	36	56
O-Public Administration	34	132	264
P-Education	22	98	186
Q-Hospital and Residential	49	149	272

R-Arts and Entertainment	24	90	178
S-Churches	25	95	188
Across all building types	14	25	31

Note: OHCAs, out-of-hospital cardiac arrests. Data provided by the Health Intelligence Unit, HSE.

Based on the legislation and types of public access defibrillation scheme implemented elsewhere, it was possible to define seven different programmes for economic modelling:

1. Base case – the current distribution of AEDs
2. Legislation – where AEDs are located at all of the listed designated places
3. PAD 15% – AEDs as per current distribution with additional AEDs in every building type where there is an annual probability of at least one out-of-hospital cardiac arrest case per 20 AEDs (see Appendix 1 for a full listing). This public access defibrillation scheme requires approximately 15% of the AEDs proposed in the full legislation.
4. PAD 20% – AEDs as per current distribution with additional AEDs in every building of type Hospital and Residential, Transport, and Public Administration
5. PAD 25% – AEDs as per current distribution with additional AEDs in every building of type Hospital and Residential, Transport, Public Administration, and Retail
6. PAD 45% – AEDs as per current distribution with additional AEDs in every building of type Hospital and Residential, Transport, Public Administration, Retail, and Arts and Entertainment
7. PAD 55% – AEDs as per current distribution with additional AEDs in every building type where there is an annual probability of at least one out-of-hospital cardiac arrest case per 100 AEDs (see Appendix 1 for a full listing).

Options three to seven above are alternatives to the legislation that specify a reduced set of designated places. Options three and seven, while incidence-based, still refer to designated places that are defined by building usage. Incidence-based public access defibrillation schemes implemented elsewhere may define a location, such as a thoroughfare, as requiring an AED and then identify an organisation responsible for the provision and maintenance of that AED. To ensure that the modelled public access defibrillation schemes were variations on the proposed legislation, the Authority has adhered to designated places being business addresses. An added complication of incidence-based schemes is that they often identify locations with a probability of less than one case per annum. With a single year of location data, low incidence rate locations cannot be identified.

The probability of AEDs being present in each building type in the base case scenario was estimated from a variety of data sources (see Appendix 1 for a full listing). It was assumed that the existing AED distribution will be maintained into the future. The number of AEDs required for each scenario included both those required for specific building types, and those that are already in place in the base case scenario (Table 3.8).

The estimated number of AEDs under each scheme (Table 3.9) is based on a single AED at each building location. For large venues or places, such as a sports stadium or university campus, timely arrival of emergency medical services can be hindered as large distances may have to be covered on foot. It may therefore be necessary to have multiple AEDs installed to achieve adequate coverage. While the additional AEDs required for large venues may not have been explicitly incorporated into the estimates, it is implicit in the fact that such venues often incorporate numerous designated places (e.g., supermarkets and restaurants within a shopping centre). The number of large venues is also limited and thus will have a minor impact on the estimated total number of AEDs required.

Table 3.9 Projected number of AEDs by building type for each public access defibrillation scheme modelled

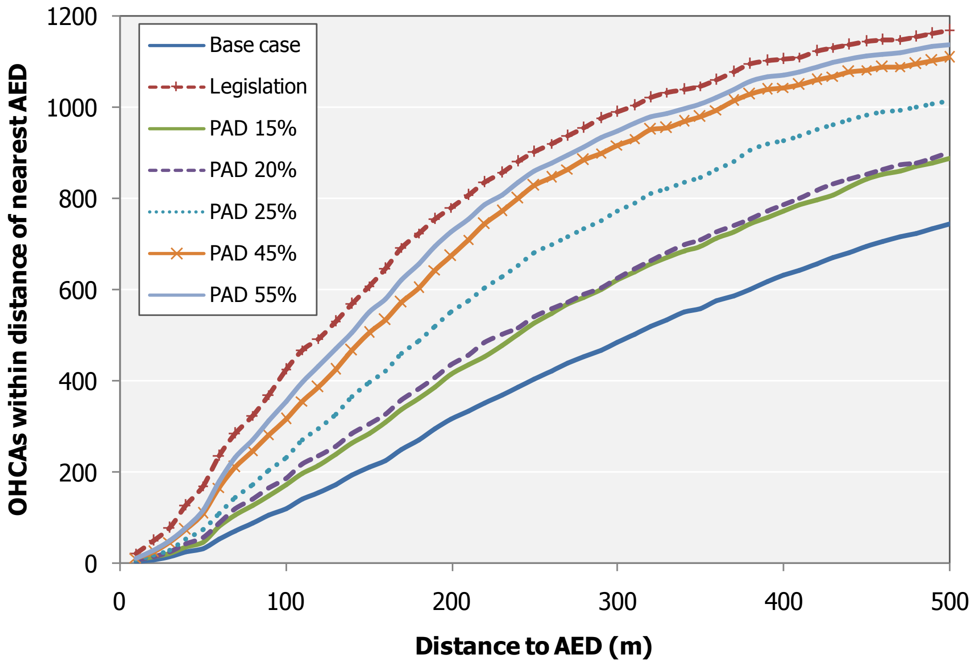
Building type	Numbers of AEDs by public access defibrillation (PAD) scheme						
	Base case	Legislation	PAD 15%	PAD 20%	PAD 25%	PAD 45%	PAD55%
G-Retail	138	3,765	138	138	3,765	3,765	3,765
H-Transport	174	639	336	639	639	639	625
I-Accommodation and Food	844	19,607	844	844	844	844	6,284
O-Public Administration	644	2,242	678	2,242	2,242	2,242	1,673
P-Education	495	5,121	1,255	495	495	5,121	5,121
Q-Hospital and Residential	1,563	2,648	2,129	2,648	2,648	2,648	2,648
R-Arts and Entertainment	710	4,655	1,065	710	710	4,655	4,043
S-Churches	103	4,412	103	103	103	103	103
Across all designated building types	4,670	43,089	6,547	7,818	11,445	20,016	24,262
AEDs/100,000 inhabitants*	193.2	1030.3	234.1	261.8	340.8	527.6	620.1

* Figure incorporates the approximate 4,200 AEDs not located in designated building types.

In any of the proposed public access defibrillation schemes, there may be a number of designated places within a short distance of each other. For example, a supermarket could be adjacent to a train station. As such, there may be areas with numerous AEDs within a short distance of each other. The duplication of coverage is a feature of a public access defibrillation scheme that is based on buildings rather than areas. An area-based scheme could allow for a reduced number of AEDs. As an example, if only a single AED was required within any given 100 metres radius, the coverage of the full public access defibrillation legislation could be achieved with approximately 24,000 AEDs. A 44% reduction in the number of required AEDs with no loss of spatial coverage would result in a substantial reduction in the cost of the programme. However, implementation on an area basis creates difficulties for assigning responsibility for the provision and maintenance of AEDs.

It can be anticipated that the increased provision of AEDs will result in greater coverage of out-of-hospital cardiac arrests within a specified distance, such as 100 metres (Figure 3.11). The coverage benefit associated with increased numbers of AEDs depends on whether high incidence locations are covered or not. It is assumed that in the current situation, as described by the base case, there are AEDs in airports and many of the larger train stations. As such, many of the high incidence locations have already been captured. An increase in coverage is achieved by expanding AED provision from the base case to a partial roll-out of the legislation (as defined by the PAD 15% and PAD 20% schemes). However, the PAD 15% scheme is targeted at high incidence locations and achieves the same coverage as the PAD 20% scheme. The coverage benefits of moving from PAD 45% to full legislation are also limited, again because the additional sites included are all low incidence.

Figure 3.11 Number of out-of-hospital cardiac arrests within a specified distance of the nearest AED by public access defibrillation scheme modelled



Note: OHCA, out-of-hospital cardiac arrest; AED, automated external defibrillator; PAD, public access defibrillation.

Depending on the public access defibrillation scheme being considered, there may be a requirement for a substantial increase in the number of AEDs available over and above current provision. For example, implementation of the proposed legislation would result in an additional 38,419 AEDs to be placed in designated places. The public access defibrillation scheme proposed under legislation would result in 1,030 AEDs per 100,000 inhabitants, well above the ratio seen in public access defibrillations schemes implemented internationally.

Where a public access defibrillation scheme is voluntary rather than legislated, there can be difficulties in ensuring appropriate coverage of AEDs. For example, a public access defibrillation programme was introduced in Austria, but a study found that the overall deployment rate of the individual devices was low as there was no strategic planning of installation locations.[99] Areas of sufficiently high incidence to justify placement of an AED can be difficult to identify. The proposed Irish legislation clearly states the designated places and hence the schemes analysed in this assessment are all based on static AEDs located in buildings associated with specific types of economic activity.

3.4 Key messages

- The incidence of emergency-medical-services-attended out-hospital-cardiac arrest in Ireland is approximately 39.1 per 100,000 persons, equivalent to 1,800 cases per annum. The incidence is similar to other countries.
- The mean age of out-of-hospital cardiac arrest cases in Ireland is 69 years and 67% are male.
- Seventy six percent of out-of-hospital cardiac arrests in Ireland occur in the home or in residential institutions.
- The survival from emergency-medical-services attended out-of-hospital cardiac arrest in Ireland is 5.2%, which is slightly lower than the international average.
- Although survival from out-of-hospital cardiac arrest is poor, neurological outcomes and long-term survival tend to be good, with approximately 80% of cases achieving pre-arrest function and 50% surviving to 10 years.
- An estimated 24% of the Irish population have had CPR training in the last five years, and 45% of emergency-medical-services-attended out-of-hospital cardiac arrests receive bystander CPR prior to the arrival of the emergency medical services.
- Survival for those who receive bystander defibrillation is 13.4%, compared with 5.5% for bystander CPR and 4.0% for emergency medical services resuscitation. Early CPR and defibrillation are critical to improving survival.
- Ireland has a dispersed population with a median emergency medical services response time of 11 minutes for out-of-hospital cardiac arrest incidents, indicating a reliance on bystander intervention to improve survival in cases of out-of-hospital cardiac arrest.
- There are approximately 100 community first responder groups linked to the emergency medical services in Ireland.
- There are an estimated 8,000 to 10,000 functional AEDs located around the country. At present, the number of AEDs per capita is similar to countries that have instigated public access defibrillation programmes.
- There is no centralised register of AEDs in Ireland or record of their maintenance.
- Implementation of the Public Health (Availability of Defibrillators) Bill 2013 would require the provision of an estimated additional 38,419 AEDs at designated places, resulting in an overall coverage of 1,030 AEDs per 100,000 inhabitants.

4 Clinical effectiveness and safety

A systematic review of public access defibrillation programmes was carried out to identify, appraise and synthesise the best available evidence on the clinical effectiveness and safety of these interventions in the management of out-of-hospital cardiac arrest, to serve as a basis for estimating the likely clinical outcomes associated with the introduction of a public access defibrillation programme in Ireland and identify the key factors that impact these outcomes.

4.1 Search strategy

A search was performed in Medline, Embase, Scopus, clinical trial registries (Cochrane Registry of Controlled Trials, ClinicalTrials.gov and the ISRCTN register) and the Cochrane Library (Database of Abstracts of Reviews of Effects [DARE], Cochrane Database of Systematic Reviews [CDSR] and the Health Technology assessment [HTA] database) for studies examining the effectiveness of public access defibrillation interventions. Detailed search strings and the number of returned results for each are provided in Appendix 2.

Preliminary screening of all returned results was undertaken by a single person to eliminate duplicates and studies that were clearly not relevant. Assessment of the eligibility of studies and identification of multiple reports from single studies was performed independently by two people according to the inclusion criteria shown in Table 4.1. Disagreements were resolved by discussion, or if necessary, by a third person.

Table 4.1 Inclusion criteria (PICOs)

Population	All adults and children who experience a sudden cardiac arrest in any location except for hospitals or other high dependency care facilities that monitor patients and routinely provide emergency medical care. This includes sporting and entertainment venues, public areas, commercial premises, long-term care facilities and public transportation services and facilities.
Intervention	Public access defibrillation interventions that include the provision of static automated external defibrillators (AEDs) in a range of publicly-accessible locations, that are designed to be used opportunistically by trained or untrained volunteers or bystanders who witness a cardiac arrest are eligible for inclusion. Also eligible are studies that involve community groups of trained lay-volunteers or lay responders such as police and fire-fighters who would not ordinarily

	have access to AEDs. Interventions that focus on the provision of AEDs in the homes of individuals who are at high risk of cardiac arrest or in hospital or other high dependency care facilities are ineligible.
Comparator	Routine emergency medical services care.
Outcomes	**Primary outcome** Survival to hospital discharge **Secondary outcomes** Neurological outcomes at hospital discharge assessed by cerebral performance category (CPC) or a similar validated scale. Rate of return of spontaneous circulation (ROSC) Survival to hospital admission Survival at 1 year
Study type	Randomised controlled trials (RCTs), non-randomised controlled trials (nRCTs), controlled before-and-after (CBA) studies, interrupted time series (ITS) studies and prospective or retrospective observational studies (cohort/cross-sectional/case-control) with a comparison group are eligible for inclusion in this review. Descriptive studies (e.g. case reports, case series) are ineligible, as are studies that model expected outcomes.

Data extraction was performed independently by two people, with any disagreements resolved by discussion, or if necessary, by a third person. Study quality was assessed using the Quality Assessment Tool for Quantitative Studies[100;101] developed by the Effective Public Health Practice Project, Canada. This validated[102] tool assesses both internal and external validity and rates study quality as strong, moderate or weak based on the following criteria relevant to public health studies:

- selection bias (external validity)
- allocation bias
- confounding
- blinding (detection bias)
- data collection methods
- withdrawals and dropouts (attrition bias)
- statistical analysis.

Evidence synthesis was carried out subject to an assessment of the clinical and statistical heterogeneity between studies.[103] Where deemed appropriate (based on an assessment of clinical and statistical heterogeneity), random effects meta-analysis was performed using Review Manager (RevMan) software.[104]

4.2 Results

The search identified 15 studies that met the inclusion criteria. A flowchart of the results is shown in Figure 4.1. There were three distinct types of intervention identified: 1) publicly-situated stationary AEDs to be deployed by bystanders or trained first responders,[96] and mobile AEDs carried and deployed by either 2) police first responders[105-108] or 3) fire-fighter first responders.[109-113] Some studies used a combination of these interventions.[48;114-117] A list of all included studies with details on the type of rapid access defibrillation intervention and the training that was provided for those involved is shown in Table 4.2.

Figure 4.1 Flowchart of search results

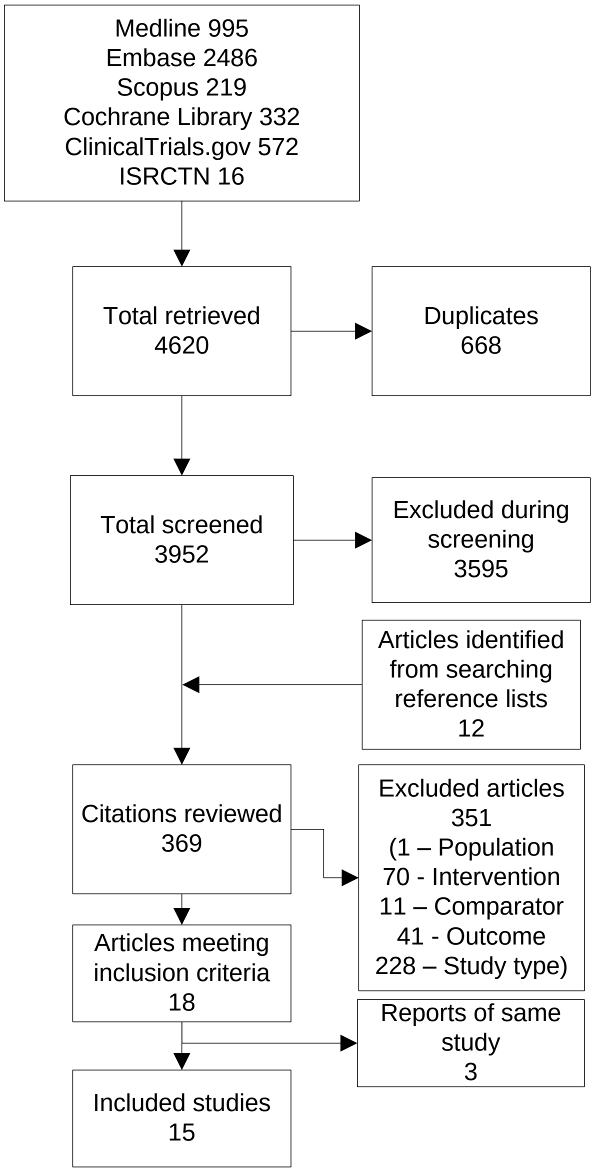


Table 4.2 Description of AED intervention (type, deployment and training) and quality appraisal of included studies

Study (Country)	Intervention	Quality	AED deployment	Training	Control
PADTrial 2004[96] **(USA)**	Public	Strong	Physical facilities where at least one out-of-hospital cardiac arrest could be expected every two years (equivalent of at least 250 adults more than 50 years of age were present for 16 hours a day or if the facilities had a history of at least one witnessed out-of-hospital cardiac arrest every two years, on average).	Volunteers trained to competency according to current AHA guidelines. Retraining was scheduled to take place after three to six months	Emergency medical services + lay volunteer CPR training
Melbourne 2001[110] **(Australia)**	Fire Service	Moderate	A dual dispatch of fire-fighter first responders equipped with AEDs and normal ambulance response occurred to 'priority 0' events (subject suspected to be unconscious and/or non-breathing) in the pilot area. The control area was covered by a normal ambulance response.	Fire officers were trained in BLS and the use of automatic defibrillators in an 8-day training course.	Emergency medical services
North Carolina 1998[111] **(USA)**	Fire Service	Moderate	Emergency medical services response system consisting of 41 Fire Department engine and ladder companies manned by fire-fighter EMTs responding from 30 stations providing basic EMT-level initial-responder services and 13 paramedic ambulances responding from seven stations.	EMTs from 24 fire companies received 15 hours of instruction from the investigators and were certified as EMT Defibrillation (EMT-D) providers. Continuing education followed State of North Carolina guidelines for six additional hours of EMT-D instruction annually.	Emergency medical services + Fire Services CPR

Memphis 1993[112] **(USA)**	Fire Service	Moderate	Thirty engine companies were initially selected to participate in the trial with two more added after the first year of the project. Each company was assigned to one of two groups with one equipped with AEDs and the other acting as a CPR control. Every 75 days the groups were switched. Fire-fighter first-responder and ambulances were dispatched simultaneously.	Each participating engine company received a total of four hours of in-station training before receiving their AED. Two to eight days later the instructor returned to provide refresher training in CPR. Each company then practiced using the AED in a series of simulated cardiac arrest scenarios.	Emergency medical services + Fire Services CPR
Ontario 1993[109] **(Canada)**	Fire Service	Weak	On identifying a call that may involve a cardiac arrest, the Central Ambulance Communication Centre dispatcher activated a full-tiered response. A BLS and a paramedic ambulance were dispatched in rapid succession, and Hamilton-Wentworth Fire Dispatch was notified simultaneously.	Automated defibrillation training for both BLS-D and Hamilton Fire Department personnel followed recommendations of the Heart and Stroke Foundation of Canada and emphasised the importance of early defibrillation.	Emergency medical services + Fire Services CPR
Cincinnati 2005[106] **(USA)**	Police	Strong	Thirty-five AEDs were deployed to ensure that all marked police cars operating in police district three carried an AED at all times. The computer-aided emergency dispatch system for the City of Cincinnati was modified to support simultaneous dispatch of police and emergency medical services to medical emergency cases that were likely to have had an out-of-hospital cardiac arrest.	The investigators modified an eight-hour CPR course to include training in the use and maintenance of AEDs. Police officers were required to demonstrate familiarity with AEDs quarterly during the two-year duration of the trial with refresher training as needed.	Emergency medical services + Fire Services CPR
Miami-Dade 2002[105] **(USA)**	Police	Weak	AEDs were deployed to all Miami-Dade County, Florida, police officers. With implementation of the programme, selected codes for medical emergencies were simultaneously relayed to both police and emergency medical services, and the service specific	The start-up process included a four-hour training session that included hands-on instruction on the use of AEDs. The education strategy used a 'train-the-trainer' system, in which selected officers	Emergency medical services

			telecommunication consoles dispatched the appropriate vehicles.	were trained as educators and participated in the training of others.	
PARADE 2001[108] **(USA)**	Police	Weak	The AEDs were distributed to active police vehicles. Simultaneous dispatch of police and existing emergency services personnel to all suspected adult (aged >18 years) non-traumatic out-of-hospital cardiac arrest cases.	The four-hour training course was similar to the current AHA Heartsaver AED program. A written and practical skills evaluation was administered after course completion. Refresher training was conducted by local paramedics at three-month intervals.	Emergency medical services
Pennsylvania 1998[107] **(USA)**	Police	Weak	The primary intervention consisted of training, equipping, and authorising police officers to use AEDs to resuscitate patients in cardiac arrest. Police were routinely dispatched with emergency medical services to medical emergencies. Police did not routinely respond to nursing homes and other healthcare facilities.	All police officers in participating departments were trained to use the AEDs in a four-hour programme based on the AHA guidelines and current medical literature. In addition, police officers attended quarterly review sessions conducted by paramedic instructors throughout the intervention phase.	Emergency medical services
Switzerland 2013[117]	Public + Fire Service	Weak	Public access AEDs were installed at the train station in the study area. AED-equipped fire-fighter first-responders and emergency medical services were simultaneously dispatched in a two-tier rescue system.	An initial four-hour training session was mandatory for all volunteers. The first responders completed a refresher course in BLS-AED skills at least every two years.	Emergency medical services

SALSA 2009[115] **(Sweden)**	Public + Fire Service	Weak	In cases of suspected cardiac arrests, the Emergency Dispatch Centre alerted the nearest available ambulance (emergency medical services) first and thereafter contacted the closest available fire engine via a special unit at the Emergency Dispatch Centre using a computer mediated alarm code. The fire brigade dispatch was intended to happen simultaneously with the emergency medical services dispatch. Simultaneously, 65 public venues (including larger malls, public transport stations, sport stadiums, and two major airports) were equipped with AEDs, and local security guards were trained in the use of AEDs and D-CPR.	Fire-fighters received an eight-hour course approved by The National Board of Health and Welfare in the use of AED and defibrillator-cardio pulmonary resuscitation (D-CPR).	Emergency medical services
NIPAD 2008[48] **(Northern Ireland)**	Lay first responders + Police	Weak	The FR AEDs were kept with the designated "on-call" FR. The "on-call" FRs brought AEDs to arrests using their own private vehicles when alerted via a pager system. Police AEDs were kept in police patrol vehicles. In total, 82 mobile AEDs were placed throughout both study areas.	Training was based on the resuscitation guidelines in 2000 for the use of AEDs. The instructor– trainee ratio was generally 1:6. Retraining occurred at six months.	Emergency medical services
BEDS 2006[116] **(Italy)**	Lay first responders + emergency medical services	Weak	42 devices were given to ambulances or ambulatory services operated by associations of volunteers active throughout the county, of which nine were located within the urban territory and 33 in the rural territory. Seven static devices (three within the city limits and four in the countryside) were placed in critical areas with a high population flow for public access defibrillation.	The training programme was conducted by 14 qualified instructors during five hours of theory and practical instruction, including training in basic life support.	Emergency medical services

Amsterdam 2003[114] **(The Netherlands)**	Police + Fire Service	Moderate	When the emergency medical system dispatch centre suspected a cardiac arrest, it dispatched two ambulances and then immediately alerted the police or fire brigade dispatch centre. After receiving the call from the dispatch centre, the police or fire dispatch centre directed a police patrol car or fire engine to the scene.	Police officers and fire-fighters were trained in the use of the AED, and their CPR skills were refreshed. Officers were trained in pairs in 3.5 hour sessions. Refresher training was conducted at eight month intervals.	Police were also dispatched along with emergency medical services in control group
OPALS II 1999[113] **(Canada)**	Emergency medical services + Fire Service	Moderate	Each study community optimised the local emergency medical services system to achieve a dispatch to arrival at scene interval to eight minutes. This optimisation process included - reduction in dispatch time intervals - more efficient deployment of existing ambulances – fire-fighters performing defibrillation.	The local base hospital directors oversaw an 8 to 12 hour fire-fighter training programme that made use of existing training networks	Emergency medical services

Key: AED: automated external defibrillator; AHA – American Heart Association; BLS – basic life support; CPR – cardiopulmonary resuscitation; D-CPR - defibrillator-cardio pulmonary resuscitation; EMT – emergency medical technician; FR – first responder.; PAD –public access defibrillation.

Table 4.3 Results of included studies

Study (Country)	Population			Call to AED arrival# in mins [mean(SD)]		ROSC		Survival to admission n (%)		Survival to discharge n (%)		Neurological outcomes		Survival at 1 year	
	Description	Int	Ctrl	Int	Ctrl	Int	Ctrl	Int	Ctrl	Int	Ctrl	Int	Ctrl	Int	Ctrl
PAD Trial 2004[96] (USA)	All cases definite cardiac arrest where resuscitation was attempted	128	107	NR	5.7	NR	NR	50 (39)	29 (27)	30 (23)	15 (14)	Normal: 22 Mild: 5 Moderate:3	Normal: 10 Mild:3 Moderate:1	NR	NR
Melbourne 2001[110] (Australia)	All emergency-medical-services-notified out-of-hospital cardiac arrests of presumed cardiac origin	161	268	5.9 (1.7)	7.5 (2.4)	NR	NR	NR	NR	6 (4)	11 (4)	NR	NR	NR	NR
North Carolina 1998[111] (USA)	Bystander-witnessed out-of-hospital cardiac arrests of cardiac origin	110	133	4.3 (1.8)	9.9 (3.3)	12	18	10 (9)	15 (11)	5 (5)	7 (5)	Normal 3 Moderate 1 Severe 1	Normal 6 Moderate 1	NR	NR
Memphis 1993[112] (USA)	All cases of presumed out-of-hospital cardiac arrest notified to the emergency medical services/FR of cardiac cause	447	432	3.5 (1.7)	5.8 (2.5)	125	124	112 (25)	101 (23)	40 (9)	27 (6)	CPC 1: 26 CPC 2/3: 14	CPC 1: 18 CPC 2/3: 9	NR	NR

Study (Country)	Population			Call to AED arrival# in mins [mean(SD)]		ROSC		Survival to admission n (%)		Survival to discharge n (%)		Neurological outcomes		Survival at 1 year	
Ontario 1993[109] (Canada)	Out-of-hospital cardiac arrest of presumed cardiac origin not occurring when emergency medical services were in attendance	140	147	6.0 (4.0)	8.5 (3.9)	NR	NR	NR	NR	8 (6)	4 (3)	NR	NR	NR	NR
Cincinnati 2005[106] (USA)	Out-of-hospital cardiac arrests of cardiac origin where resuscitation was attempted	154	427	6.1 (3.1)	5.6 (3.0)	NR	NR	NR	NR	11 (7)	16 (4)	NR	NR	NR	NR
Miami-Dade 2002[105] (USA)	All cases of emergency-medical-services-notified out-of-hospital cardiac arrest of cardiac origin	420	318	4.9 (2.9)	7.6 (3.7)	NR	NR	NR	NR	32 (8)	19 (6)	NR	NR	NR	NR
PARADE 2001[108] (USA)	All non-traumatic out-of-hospital cardiac arrests notified to emergency medical services	388	472	4.9 (3.2)	6.4 (3.9)	NR	NR	61 (16)	NR	21 (5)	20 (4)	NR	NR	NR	NR

Study (Country)	Population			Call to AED arrival[#] in mins [mean(SD)]		ROSC		Survival to admission n (%)		Survival to discharge n (%)		Neurological outcomes		Survival at 1 year	
Pennsylvania 1998[107] (USA)	All non-traumatic out-of-hospital cardiac arrests with initial VF/pVT rhythm	132	80	8.7 (3.7)[β]	11.8 (4.7)[β]	NR	NR	NR	NR	18 (14)	5 (6)	NR	NR	NR	NR
Switzerland 2013[117]	All out-of-hospital cardiac arrests where resuscitation was started	238	46	6.2 (2.4)	11.5 (6.0)	51	NR	69 (29)	NR	18 (8)	0 (0)	Normal: 18	NR	NR	NR
SALSA 2009[115] (Sweden)	All out-of-hospital cardiac arrests where any type of resuscitation was started	863	657	7.1 (NR)[§]	7.5 (NR)[§]	NR	NR	196 (23)	147 (22)	59[&] (7)	29[&] (4)	NR	NR	NR	NR
NIPAD 2008[48] (Northern Ireland)	All emergency-medical-services-attended out-of-hospital cardiac arrests	330	279	7.1 (4.9)	8.8 (5.0)	20	19	NR	NR	7 (2)	11 (4)	NR	NR	NR	NR
BEDS 2006[116] (Italy)	All emergency-medical-services-attended out-of-hospital cardiac arrests of presumed cardiac origin	702	692	6 (6)[§]	7 (4)[§]	72	50	57 (8)	38 (5)	31 (4)	10 (1)	Normal: 29	Normal: 10	21	6
Amsterdam 2003[114]	Witnessed out-of-hospital cardiac arrest where	243	226	11.1 (8.8 to	12.8 (10.1 to	139	108	103 (44)	74 (33)	44 (18)	33 (15)	NR	NR	NR	NR

Study (Country)	Population			Call to AED arrival# in mins [mean(SD)]		ROSC		Survival to admission n (%)		Survival to discharge n (%)		Neurological outcomes		Survival at 1 year	
(The Netherlands)	resuscitation was attempted			15.7)§β	16.4) §β										
OPALS II 1999[113] (Canada)	All out-of-hospital cardiac arrests of cardiac origin with resuscitation attempted by emergency responders	1641	4690	5.3 (2.0)	6.7 (2.6)	200	460	157 (10)	337 (7)	85 (5)	183 (4)	CPC 1: 62 CPC 2/3: 23	NR	66	NR

Key: AED – automated cardiac defibrillator; Int - intervention; Ctrl – control; ROSC – return of spontaneous circulation; CPC – cerebral performance category; FR – first responder; NR – not reported; VF – ventricular fibrillation; pVT – pulseless ventricular tachycardia; # - unless otherwise stated all times are from emergency medical services notification to arrival on the scene of an AED-equipped rescuer § - median (IQR); & - Survival at one month; β - time from call to defibrillation.

4.2.1 Publicly-accessible AED programmes

One study[96] examining the effect of making AEDs available in public places was identified. Two additional studies[115;117] that involved the placement of AEDs in public venues were also found, but in both cases the intervention also included providing AEDs to fire-fighter first responders, so they are discussed separately (see Section 4.2.4 Combined programmes).

PAD Trial 2004

The Public Access Defibrillation (PAD) trial[96] was a community-based randomised controlled trial that allocated 993 community groups to either a CPR-plus-AED or CPR-only response system. Residential (such as apartment buildings) and public community areas (for example, hotels, shopping centres) were eligible if they could expect an average of one witnessed out-of-hospital cardiac arrest every two years (as evidenced by out-of-hospital cardiac arrest records or the equivalent of at least 250 adults aged more than 50 years were present at that location for more than 16 hours per day). The majority (85%) of the selected locations were public areas. Volunteer responders from these communities were trained in either CPR or CPR-plus-AED. The total number of trained volunteers in the AED group was 11,015 compared with 8,361 in the CPR-only group. Within each community, as many AEDs were installed as were needed to ensure that volunteers could deliver the device to a cardiac arrest victim within three minutes. The mean number of AEDs per community was 3.2 (range 0 to 17). The study population consisted of persons aged eight years or over with an out-of-hospital cardiac arrest of cardiac cause. Patients with out-of-hospital cardiac arrest due to trauma, drug overdose or other non-cardiac cause were excluded from the analysis of the primary comparison.

The authors reported the results of the trial as the absolute number of outcome events in both groups, rather than as a rate based on the total number of presumed or definite cardiac arrests. The rationale given for this approach was that ascertainment and detection bias associated with the intervention would likely confound the calculation of rates. That is, more definite cardiac arrests were likely to be recorded in the intervention group, since volunteers with AED training were considered more likely to intervene, and AED electrocardiograms would facilitate better diagnosis of cardiac arrests. However, changing standard effect size calculation methods to adjust for a perceived bias that cannot be accurately measured increases the risk of a type II error from overcompensation. For the purposes of this review the primary outcome (survival to hospital discharge) was calculated based on the total number of definite out-of-hospital cardiac arrests where resuscitation was attempted. Using this denominator allows incidence to be taken into account and allows for comparisons with rapid out-of-hospital cardiac arrest defibrillation programmes involving police or fire-fighter first responders that are dispatched simultaneously with traditional emergency medical services paramedics. More details on the justification for this approach may be found in the discussion in Section 4.6.

There were twice as many survivors in the intervention group as in the control group, but this was not statistically significant (RR 1.67, 95% CI 0.95 to 2.94). The mean estimate of survival was 23% in the intervention group and 14% in the control group, corresponding to a risk difference (RD) of 9% (95% CI 0% to 19%). Almost all survivors had an out-of-hospital cardiac arrest in a public area; there were only two survivors in residential areas (one in each group). There was also a significant beneficial effect on survival to hospital admission (RR 2.06, 95% CI 1.41 to 3.01) and neurologically intact survival (RR 2.63, 95% CI 1.30 to 5.31). No results were reported on the rate of return of spontaneous circulation. See Table 4.3 for more details.

4.2.2 Fire service first responder programmes

Four studies[109-112] examining the effect of fire-fighter first responder AED programmes were identified. One[110] of these compared the intervention to standard emergency medical services care and three studies[109;111;112] compared it to a combination of emergency medical services care plus fire-fighter CPR.

Melbourne 2001

Smith et al.[110] reported the results of a controlled clinical trial investigating the effect of equipping fire-fighters with AEDs and simultaneously dispatching fire services with ambulance paramedics to emergency calls where the patient is suspected to be unconscious or non-breathing. The intervention group consisted of seven fire stations that provided services to approximately 20% of the population of Melbourne, Australia. The control area, which was described as being peripheral to the intervention area, was covered by the normal ambulance service only. No exclusion criteria based on age were reported, but the mean age and standard deviation (SD) of patients included in the control and intervention groups was 69 (±16) years and 71 (±14) years, respectively.

No difference in survival to discharge was observed between groups, despite a statistically significant reduction in mean time to arrival of an AED-equipped rescuer in the intervention group (mean difference -1.6 minutes, 95% CI -1.99 to -1.21). See Table 4.3 for full results.

North Carolina 1998

Sweeney et al.[111] reported the results of a crossover trial conducted in North Carolina, USA, examining the effect of adding AEDs to an existing fire-fighter first-responder service that operated in parallel with an emergency medical services ambulance service. Twenty-four fire companies were selected and trained in the use of AEDs. The group was divided in two and each was allocated AEDs on an alternating basis, rotating every one to two months over the course of the study. The companies without AEDs at a given period continued to be dispatched to out-of-hospital cardiac arrest cases and acted as the control for the group with the AEDs. Exclusion criteria included traumatic arrest, age younger than 12 years, or weight less than 90 pounds. The study was carried out from 1992 to 1995.

This study found no difference in survival to discharge between the intervention and control groups. See Table 4.3 for full results.

Memphis 1993

Kellermann et al.[112] conducted a crossover trial comparing an emergency medical services system involving dual dispatch ambulance paramedics and AED-equipped fire-fighter first responders to an emergency medical services system with dual dispatch ambulance paramedics and fire-fighter first-responders providing CPR only. The study was conducted in Memphis, USA, between March 1989 and June 1992. The study population included all out-of-hospital cardiac arrests of presumed cardiac origin and excluded cases under 18 years of age and those attributable to non-cardiac causes such as trauma or drug overdose. In year one, the study involved 30 fire stations allocated evenly between control and intervention groups. In years two and three, the number of participating stations increased to 40. Crossover between groups occurred every 75 days.

The study found no statistically significant increase in survival associated with the provision of AEDs to fire-fighter first responders. See Table 4.3 for full results.

Ontario 1993

Shuster et al.[109] conducted a before-and-after comparison to determine the effect of introducing AEDs to an existing fire-fighter first responder system in the region of Hamilton-Wentworth in Ontario, Canada. In late 1990, fire-fighters in the region were trained in the use of AEDs and dispatched to emergency calls at the same time as ambulance services. Control (pre-intervention) data were recorded for the six months prior to AED introduction (May to November 1990) and experimental data were recorded in the six months afterwards (November 1990 to April 1991). The study population consisted of adults with cardiac arrest of presumed cardiac origin. Exclusion criteria included cases due to trauma, poisoning, drowning or 'obviously dead' cases exhibiting decomposition or rigor mortis at the scene.

There was no significant difference in survival of out-of-hospital cardiac arrest before and after the intervention despite a decrease in mean time to arrival of an AED-equipped rescuer (mean difference -2.54 minutes, 95% CI -3.45 to -1.63). See Table 4.3 for full results.

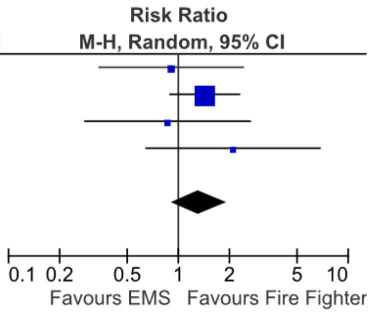
Evidence synthesis

Pooled analysis of the results of fire-fighter first responder AED programmes on the primary outcome of survival to hospital discharge is shown in Figure 4.2. Study quality appraisal rated three studies as moderate quality [110-112] and one as weak.[109] Combining the results of all four studies using random effect meta-analysis fails to show a statistically significant effect of the intervention on survival (RR 1.31, 95% CI 0.90 to 1.91).

Figure 4.2 Survival to discharge for studies involving fire-fighter first responders

	Fire fighters		EMS			Risk Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Random, 95% CI
Melbourne 2001	6	161	11	268	14.8%	0.91 [0.34, 2.41]
Memphis 1993	40	447	27	432	63.8%	1.43 [0.89, 2.29]
North Carolina 1998	5	110	7	133	11.2%	0.86 [0.28, 2.65]
Ontario 1993	8	140	4	147	10.2%	2.10 [0.65, 6.82]
Total (95% CI)		**858**		**980**	**100.0%**	**1.31 [0.90, 1.91]**
Total events	59		49			

Heterogeneity: Tau² = 0.00; Chi² = 1.83, df = 3 (P = 0.61); I² = 0%
Test for overall effect: Z = 1.43 (P = 0.15)



Two studies[111;112] (both rated to be of moderate quality) reported results for rate of return of spontaneous circulation, survival to admission and a composite outcome of survival with no neurological damage (CPC 1 or no disability). Pooled results are shown in Figures 4.3, 4.4, and 4.5, respectively. No significant effect was observed for any of these outcomes. No study reported data for survival at one year.

Figure 4.3 Return of spontaneous circulation (ROSC) for studies involving fire-fighter first responders

	Fire fighters		EMS			Risk Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Random, 95% CI
Memphis 1993	125	447	124	432	91.4%	0.97 [0.79, 1.20]
North Carolina 1998	12	110	18	133	8.6%	0.81 [0.41, 1.60]
Total (95% CI)		**557**		**565**	**100.0%**	**0.96 [0.78, 1.17]**
Total events	137		142			

Heterogeneity: Tau² = 0.00; Chi² = 0.27, df = 1 (P = 0.60); I² = 0%
Test for overall effect: Z = 0.41 (P = 0.68)

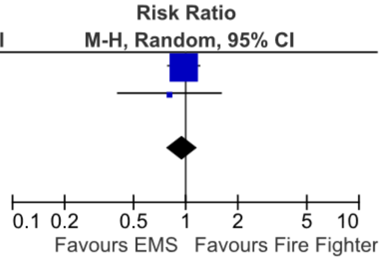


Figure 4.4 Survival to hospital admission for studies involving fire-fighter first responders

	Fire fighters		EMS			Risk Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Random, 95% CI
Memphis 1993	112	447	101	432	91.3%	1.07 [0.85, 1.35]
North Carolina 1998	10	110	15	133	8.7%	0.81 [0.38, 1.72]
Total (95% CI)		**557**		**565**	**100.0%**	**1.05 [0.84, 1.31]**
Total events	122		116			

Heterogeneity: Tau² = 0.00; Chi² = 0.50, df = 1 (P = 0.48); I² = 0%
Test for overall effect: Z = 0.39 (P = 0.70)

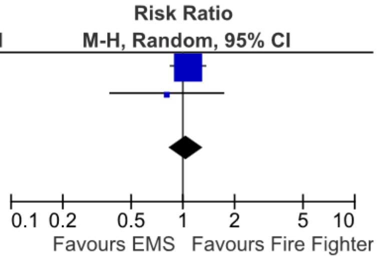
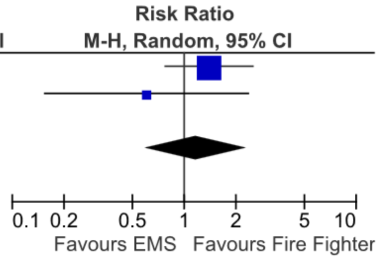


Figure 4.5 Survival to discharge without neurological damage for studies involving fire-fighter first responders

	Fire fighters		EMS			Risk Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Random, 95% CI
Memphis 1993	26	447	18	432	78.1%	1.40 [0.78, 2.51]
North Carolina 1998	3	110	6	133	21.9%	0.60 [0.15, 2.36]
Total (95% CI)		**557**		**565**	**100.0%**	**1.16 [0.59, 2.29]**
Total events	29		24			

Heterogeneity: Tau² = 0.06; Chi² = 1.22, df = 1 (P = 0.27); I² = 18%
Test for overall effect: Z = 0.43 (P = 0.66)



In summary, no significant improvement in the primary outcome (survival to hospital discharge) was reported for studies involving fire-fighter first responder AED programmes. Overall mean survival in the intervention group was 6.1% compared with 4.8% in the control group, corresponding to a risk difference (RD) of 0.01 (95%CI -0.01 to 0.03).

4.2.3 Police first responder programmes

Four studies[105-108] examining the effect of police first responder AED programmes were identified.

Cincinnati 2005

Sayre et al.[106] reported the results of a controlled trial examining the effect of adding AED-equipped police first responders to an emergency medical services system that already included dual dispatch of AED-equipped fire-fighters and ambulance paramedics to suspected out-of-hospital cardiac arrests. The study was set in Cincinnati, USA, a city with four separate police districts. One district was chosen for the intervention and the remaining three districts acted as controls. The patient population comprised all victims of an out-of-hospital cardiac arrest of cardiac origin. Patients less than eight years of age or those with obvious signs of death, such as decapitation, rigor mortis, dependent lividity or decomposition were excluded. The study duration was two years.

Over the course of the study, police were dispatched to more than 60% of treated out-of-hospital cardiac arrests in the intervention group. Among the 9.1% of cases where police arrived first at the scene no patient survived to discharge. Results of the study indicated that there was no survival benefit associated with the intervention. See Table 4.3 for full results.

Miami Dade 2002

Between February and July 1999, AEDs were supplied to all police officers in Miami-Dade, USA, and officers were dispatched simultaneously with standard emergency medical services paramedics to medical emergencies. Myerburg et al.[105] described an observational study comparing survival outcomes and response times in the period before (September 1997 to July 1999) and after (February 1999 to April 2001) the intervention, which involved 1,900 police officers being trained to use AEDs. Prior to the intervention the emergency medical services system consisted of a single-tier system involving ambulance dispatch only. Out-of-hospital cardiac arrests of non-cardiac origin, such as trauma, were excluded from the analysis.

There was no difference in overall survival rates for out-of-hospital cardiac arrest between the periods before and after the intervention. The authors did report an increase in survival rate for those with a shockable rhythm on first contact (OR 2.1, 95% CI 1.0 to 4.2). There was also a statistically significant decrease in mean time to arrival of an AED-equipped rescuer (mean difference -2.70 minutes, 95% CI -3.19 to -2.21). See Table 4.3 for full results.

PARADE study 2001

Groh and colleagues[108] conducted an observational study to assess the impact of providing AEDs to police first responders in rural and suburban Indiana, USA. Police first responders and usual emergency medical services personnel were then dispatched simultaneously to all suspected out-of-hospital cardiac arrests. This study compared OCHA outcomes before (1995 – 1996) and after (1997 – 1999) the staggered introduction of police AEDs in six Indiana counties. The study population included all patients over 18 years of age with non-traumatic out-of-hospital cardiac arrest. To be included in the study, communities had to have a mean pre-intervention emergency response time of between 8 and 15 minutes.

Over the course of the study, police responded before traditional emergency services in only 7% of cases. There was no significant difference in survival to discharge between the intervention and control groups. See Table 4.3 for full results.

Pennsylvania 1998

Mosesso et al.[107] examined the effect of dual dispatch of police officers equipped with AEDs in addition to emergency medical services paramedics to all medical emergencies by comparing out-of-hospital cardiac arrest outcomes in the two years before and three years after the introduction of a police AED programme in seven suburban municipalities in Pennsylvania, USA. Included in the analysis were all adults (≥18 years) with non-traumatic out-of-hospital cardiac arrest. Police did not respond to out-of-hospital cardiac arrests in nursing homes or other healthcare facilities and patients who were dead-on-arrival or met certain do-not-resuscitate criteria were excluded.

There was no statistically significant difference in survival to discharge between the two groups. See Table 4.3 for full results.

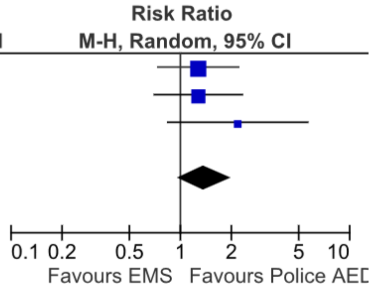
Evidence Synthesis

The relative risk (RR) of survival to discharge for all studies comparing police deployed AEDs to standard emergency medical services care is shown in Figure 4.6. The Cincinnati study[106] involved police AED provision in an area that had pre-existing dual dispatch of AED-equipped fire-fighters and standard emergency medical services, so it was not included in the meta-analysis. Quality appraisal rated all three included studies[105;107;108] as weak. No statistically significant effect was observed in any of the individual studies or when the results of the three studies were combined (RR 1.39, 95% CI 0.95 to 2.01, see Figure 4.6).

Figure 4.6 Survival to discharge for studies involving police first responders

	Experimental		Control			Risk Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Random, 95% CI
Miami-Dade 2002	32	420	19	318	46.0%	1.28 [0.74, 2.21]
PARADE 2001	21	388	20	472	38.8%	1.28 [0.70, 2.32]
Pennsylvania 1998	18	132	5	80	15.3%	2.18 [0.84, 5.65]
Total (95% CI)		**940**		**870**	**100.0%**	**1.39 [0.95, 2.01]**
Total events	71		44			

Heterogeneity: $Tau^2 = 0.00$; $Chi^2 = 1.04$, df = 2 (P = 0.60); $I^2 = 0\%$
Test for overall effect: Z = 1.72 (P = 0.09)



No study reported sufficient information to estimate the effect of police first responder AED programmes on ROSC, survival to admission, survival at one year or neurological outcomes.

In summary, although no significant improvement in the primary outcome (survival to hospital discharge) was reported for studies involving police first responder AED programmes, the mean estimate of effect in all included studies favoured the intervention. Overall mean survival in the intervention group was 7.0% compared with 5.1% in the control group, corresponding to a risk difference (RD) of 0.02 (95%CI 0.00 to 0.04).

4.2.4 Combined programmes

Six studies that examined the effect of a combined intervention involving more than one method of providing rapid defibrillation were identified. These included a combination of police and fire-fighter first responders (1), fire-fighter first responders in parallel with improvements in the emergency medical services dispatch system (1), public provision of AEDs in conjunction with fire-fighter defibrillation (2), simultaneous introduction of AEDs to ambulances and some public areas (1), and a programme involving mobile AED provision to trained lay volunteers and police officers (1). Individual study details are provided along with a description of the estimates of effect for each outcome.

Switzerland 2013

Saner et al.[117] reported the results of a study carried out in a mixed rural and urban area in Switzerland that used a combined intervention involving fire-fighters and public AED placement. Over 500 fire-fighters from 36 voluntary fire brigades were trained in the use of AEDs and dispatched to suspected cardiac emergencies at the same time as emergency medical services ambulances. The only public site selected for AED placement was the train station of the largest town in the study area, through which up to 35,000 people pass daily. Despite this being a mixture of rural and urban locations, the overall study area was relatively compact; the total area encompassed 190km^2 and the longest distance travelled by an ambulance to treat a patient was 16km. The groups were also unbalanced, with control data taken from an 18 month period ending in 1998 and treatment data taken from an eight year period (2001 to 2008) following the introduction of the intervention.

Only survival to discharge outcomes were reported, which found that there were no survivors in the 18 months prior to the intervention, compared with 18 survivors in the eight years after it was introduced. No statistically significant effect on survival was found (RR 3.10, 95% CI 0.18 to 53.60).

SALSA study 2009

The SAving Lives in the Stockholm Area (SALSA) project[115] compared out-of-hospital cardiac arrest outcomes before and after the introduction of an early defibrillation programme that involved placing AEDs in public venues as well as dispatching AED-equipped fire-fighters in parallel with traditional emergency medical responders to all suspected cases of out-of-hospital cardiac arrest. The public locations were restricted to larger venues that were selected by the steering committee on the basis of being high-risk locations, but no stringent inclusion criteria were used. Sixty-five locations were chosen, including larger shopping centres, public transport stations, sports stadiums and airports. Forty-three fire stations also received AEDs and first responder training.

The study found that fire-fighters were dispatched to 66% of all out-of-hospital cardiac arrest cases during the one year study period. Where fire-fighters and emergency medical services were dispatched simultaneously, fire-fighters arrived first in 36% of cases. Only three of the 863 out-of-hospital cardiac arrest cases occurred in public areas that were equipped with AEDs (two in an airport and one on a motorway). None of these patients survived to discharge.

Survival to one month was reported rather than survival to discharge. The overall results indicated that the intervention was associated with a statistically significant increase in survival to one month (RR 1.59, 95% CI 1.01 to 2.51, see Table 4.3). However, there was no corresponding increase observed in survival to admission (RR 1.02, 95% CI 0.80 to 1.30). No data were available for ROSC, neurological outcomes or long-term survival.

NIPAD Study 2008

The Northern Ireland Public Access Defibrillation (NIPAD) study[48] used a before-and-after design to estimate the impact of setting up a system that combined lay volunteer and police first responders who were trained and equipped with mobile AEDs. Lay volunteers operated a rota, with AEDs being kept in the possession of the person who was on-call at any particular time and brought to the cardiac arrests in the volunteer's own vehicle. Police AEDs were kept in police patrol vehicles. A pager system notified volunteers and police of medical emergencies coded as cardiac arrest by the emergency medical services dispatch service. The study setting included both rural (Antrim, Ballymena, Magherafelt) and urban (Belfast) areas. Cardiac arrests of 'obvious non-cardiac aetiology' were excluded from the analysis.

Over 80% of arrests occurred in the home and almost half (48%) occurred in people with a history of cardiac arrest. Approximately one in three out-of-hospital cardiac arrests were witnessed and only 16% had an initial shockable rhythm. First responders were paged to 53% of all emergency-medical-services-attended arrests during the study period. In cases of dual dispatch, first responders arrived before emergency medical services in 23% of cases – this differed between rural (47%) and urban areas (14%). Earlier arrival by first responders did not, however, have a significant impact on the proportion of rural out-of-hospital cardiac arrests reached within eight minutes. No significant effect on survival to discharge or ROSC was reported. No data were available on admission to hospital or neurological outcomes.

BEDS 2006

The Brescia Early Defibrillation Study[116] (BEDS) combined the public placement of seven AEDs with the addition of 42 AEDs to an ambulance service already equipped with manual defibrillators. No information was provided on how the specific sites for AED installation were chosen. A historical cohort of 692 patients treated between 1997 and 1999 were used as the control group. Over the course of the study (2000 to 2002) 702 arrests were recorded.

This study reported significant improvements in survival to discharge (RR 3.15, 95% CI 1.53 to 6.48) and ROSC (RR 1.47, 95% CI 1.01 to 2.14) in the intervention group. The effect on survival to admission was not statistically significant (RR 1.52, 95% CI 0.99 to 2.33). A significant effect was also reported for neurologically intact survival (RR 2.94, 95% CI 1.42 to 6.08) and survival to one year (RR 3.53, 95% CI 1.41 to 8.79).

Amsterdam 2003

Van Alem et al.[(114)] conducted a crossover trial examining the effect of the introduction of an AED programme involving both police and fire-fighter first responders in Amsterdam, the Netherlands, between January 2000 and January 2002. All patients with witnessed cardiac arrest in whom resuscitation was attempted were included. Patients aged less than 18 years, out-of-hospital cardiac arrests of traumatic origin and those witnessed by emergency medical services paramedics were excluded. The study groups both consisted of one fire brigade region and three police districts. Allocation of AEDs was rotated between groups every four months, with the group without AEDs at any one time serving as controls. Police were dispatched during both the experimental and control periods while the fire brigade was dispatched during the experimental periods only.

Results of the study indicated that among witnessed, emergency-medical-services-attended out-of-hospital cardiac arrests the intervention was associated with improvements in ROSC (RR 1.46, 95% CI 1.01 to 2.10) and survival to hospital admission (RR 1.51, 95% CI 1.04 to 2.20), but no significant difference in survival to discharge (RR 1.29, 95% CI 0.79 to 2.12) was observed. No data on neurological outcomes were reported.

OPALS II 1999

The Ontario Prehospital Advanced Life Support (OPALS) study[(113)] was a three phase before-and-after trial that examined the effect of a number of interventions designed to improve survival following out-of-hospital cardiac arrest. The first phase involved the introduction of ambulance AEDs and established a baseline for subsequent comparison. The second phase assessed the impact of a rapid defibrillation programme that included: 1) reduction in dispatch times; 2) more efficient deployment of existing ambulances; and 3) fire-fighter first responders equipped with AEDs. The final phase examined survival after the implementation of 'full ALS programs'. Phase II is of interest in this review, as it describes the results of a rapid defibrillation programme involving fire fighter-first responders combined with simultaneous changes to the emergency medical services dispatch system over the course of 12 months. All out-of-hospital cardiac arrests for whom resuscitation was attempted by emergency medical services were included, except where patients were aged less than 16 years or whose arrests were clearly of non-cardiac aetiology.

Results showed that the combined intervention was associated with shorter mean time to arrival of an AED-equipped rescuer (mean difference -1.40 minutes, 95% CI -1.52 to -1.28) and improved survival to discharge (RR 1.35, 95% CI 1.03 to 1.75). There was also a statistically significant increase in ROSC (RR 1.28, 95% CI 1.07 to 1.52) and survival to hospital admission (RR 1.37, 95% CI 1.12 to 1.67). No data on neurological outcomes were reported.

Data synthesis

Two studies investigated the effect of publicly located AEDs in combination with AED- equipped fire-fighter first responders on survival to discharge.(115;117) However, the extent of public diffusion of AEDs in one of these(117) was limited to one train station in the study area. Given the limited extent of public AED provision the results of these studies were not pooled.

In summary, two studies involving a combined intervention reported a significant improvement in the primary outcome of survival to hospital discharge and one reported a significant increase in survival at one month. Of these three studies, two involved improvements in routine emergency medical services provision by either equipping ambulance paramedics with AEDs(116) or improving the way ambulances were dispatched and deployed.(113) The other study(115) involved a combination of fire-fighter AED provision and public AED deployment. In this study, mean survival at one month in the intervention group was 6.9% compared with 5.0% in the control group, corresponding to a risk difference (RD) of 0.02 (95%CI 0.00 to 0.05).

4.2.5 Out-of-hospital cardiac arrest in children

Paediatric out-of-hospital cardiac arrests were explicitly excluded from the study population in 11 of the 15 studies identified. Eligibility criteria ranged from ≥8 years(96;106) to ≥18 years.(107;108;114) The mean age of the population in the four studies that included all out-of-hospital cardiac arrests was greater than 60 years. Therefore no evidence was identified on the effect of public access defibrillation in paediatric populations.

The optimal energy dose for paediatric defibrillation in unknown.(118) It is recommended that AEDs with dose attenuators are used to avoid high defibrillation doses in children between one and eight years of age and manual defibrillation is recommended in children less than one year old.(119) Descriptive studies of paediatric out-of-hospital cardiac arrests have found inconsistent results; some show a positive association between public access AED use and survival at one month[120] while others show no significant survival benefit associated with defibrillation prior to hospital arrival.[121]

A 2004 consensus statement from the American Heart Association suggested that an AED be placed in all schools with a reasonable probability of cardiac arrest in the next five years, those with any student at high risk, or those schools with an emergency to shock time of greater than five minutes.[122] Review of school-based AED programmes[123;124] reported some promising results, but no strong evidence of the effectiveness of this intervention was identified. Studies reporting data that do not support the suggestion that all schools should be equipped with defibrillators have also been published.[125]

4.3 Factors affecting survival in out-of-hospital cardiac arrest

The results of the systematic review search were combined with those of a separate search in Medline and Embase for data on factors predicting survival in out-of-hospital cardiac arrest to identify which characteristics are most strongly associated with improvements in this outcome.

A systematic review[126] of predictors of survival in out-of-hospital cardiac arrest that pooled data from 79 studies involving 142,740 patients showed that among the strongest predictors of survival are ROSC (chances of survival increase by 16% to 34%), initial shockable rhythm (15% to 23%), arrest witnessed by either a bystander (6% to 14%) or emergency medical services (5% to 18%) and receiving bystander CPR (6% to 14%). The combination of initial VF rhythm and ROSC is highlighted in a survival model[127] based on US registry data that found survival among this group was 54%. Regression analyses of data from studies[52;108;113;128;129] involving public access defibrillation have generally identified the same predictors of increased survival. However, not all have found a significant association between survival and bystander CPR[129] or increasing age.[52] The interdependency that exists between predictors of survival in out-of-hospital cardiac arrest makes it difficult to identify specific targets for improvement. That a shockable rhythm is a stronger predictor than response time has been explained by the fact that an initial VF rhythm 'tends to occur where the underlying pathology is not inevitably fatal, and it also acts as a surrogate for response interval since asystole ensues in all cases within minutes'.[130] Other variables that are also unlikely to be independent include location of arrest, which affects response times, and age, which can be a surrogate for co-morbidity. Some clinical attributes associated with improved survival, such as ROSC, are only available after resuscitation has started and so cannot be directly targeted by an intervention like public access defibrillation. Given these interdependencies the available evidence on predictive factors is considered to 'fundamentally reflect the times to effective first aid (CPR) or definitive treatment, together with comorbidity and underlying pathophysiology for which first observed rhythm is a surrogate'.[130]

The relationship between survival and emergency medical services response time is, therefore, of central importance since it provides the rationale for rapid defibrillation. In an analysis of 3,263 witnessed VF out-of-hospital cardiac arrests over a ten year period, Gold et al.[131] reported that survival does not decline at a constant rate over time. They noted no appreciable decline in survival for those treated between one and four minutes after collapse, a 5.2% absolute reduction in survival per minute for those treated within five to ten minutes, and a 1.2% reduction in survival per minute for those treated 11 to 15 minutes after collapse. However, not all studies support the notion that there is no significant decline in the odds of survival over the first four or five minutes,[132] and a study examining the relationship between out-of-hospital cardiac arrest survival and response times in England[133] that modelled survival as a linear function of time estimated that a one minute reduction in response time was associated with a 24% increase in the odds of survival. Despite the different findings regarding the first few minutes immediately after an arrest, the significant benefit associated with achieving emergency medical services response times within four or five minutes has been highlighted by a number of studies.[134;135] This finding is consistent with the three-phase model of cardiac arrest[136] that describes an initial electrical phase lasting approximately four minutes, during which defibrillation is most effective.

A number of large-scale population-based case series involving public access defibrillation are available that report overall outcomes in the study area, without the benefit of a control group against which to estimate effect. These can provide useful data on the implications of introducing public access defibrillation programmes outside of an experimental study setting.

Kitamura et al.[95] reported a large case-series of all out-of-hospital cardiac arrests in Japan between 2005 and 2007 where resuscitation was attempted. Over the course of this period a number of public and private initiatives were put in place to increase the availability of AEDs, which saw the total number of public access defibrillators increase from 9,906 (7.8 per 100,000 population) to 88,265 (69 per 100,000 population). These AEDs were located in a range of locations including schools (25%); medical/nursing facilities (19%); workplaces (16%); sports (4%), cultural (3%) or public transport (3%) facilities. Resuscitation was attempted on a total of 168,827 out-of-hospital cardiac arrests of cardiac origin, of which 55,271 (33%) were witnessed by bystanders and 12,631 (7%) had a shockable rhythm. The first shock was delivered by public access AEDs in 462 cases (3.7%), by emergency medical services in 11,697 cases (92.6%) and in 472 cases (3.7%) no shock was delivered. Survival at one month with minimal neurological impairment was 32% in the public access AED group compared with 14% in the emergency medical services group. Over the three years, a statistically significant increasing trend was reported for bystander initiated CPR (43% to 54%), ROSC (21% to 28%), survival at 1 month (19% to 28%) and neurologically intact survival at 1 month (11% to 19%) in the subset of bystander-witnessed VF out-of-hospital cardiac arrests. Multivariate regression analysis found that earlier administration of shock and earlier initiation of CPR were associated with a good neurologic outcome, but whether the shock was provided by bystanders or emergency medical services personnel was not. When the group who received a first shock from a public AED were examined in isolation, regression analysis found that increasing availability of AEDs was associated with a reduced time from collapse to defibrillation and an increased probability of neurologically intact survival.

A population-based cohort study[137] carried out in the US and Canada between 2005 and 2007 compared survival in cases where an AED was applied before the arrival of emergency medical services to cases where bystander CPR was initiated without the use of an AED. Among a total of 13,769 out-of-hospital cardiac arrests included in the study, 32% (4,402) received bystander CPR and 2% (289) had an AED applied before the arrival of emergency medical services. Pre-emergency medical services defibrillation was mainly performed by lay volunteers (35%), healthcare workers (32%) or police (26%). Overall survival to discharge was 7%. No details are provided on the diffusion of public access defibrillation programmes in the study area. The main objective of the study was to examine the association between pre-emergency medical services AED delivery and survival by performing a multivariate regression analysis adjusting for factors such as age, gender, CPR initiation, location (public or private), emergency medical services response times and initial rhythm. Results showed that early AED application was associated with increased survival (OR 1.75, 95% CI 1.23 to 2.50). Although the results indicate that early defibrillation is associated with increased survival, the study does not reveal the extent to which public access defibrillation programmes actually increase AED use.

An analysis of registry data on almost 20,000 out-of-hospital cardiac arrest events in Denmark[138] between 2001 to 2010 found that a shockable rhythm, bystander witness and bystander CPR were all strongly associated with 30-day survival, which increased from 3.5% to 10.8% over the course of the study period. Public access defibrillation was only introduced in Denmark towards the end of the study period so rates of bystander defibrillation were low throughout (1.1% in 2001, 2.2% in 2010). However, when used, bystander defibrillation was positively associated with survival (OR 4.4, 95% CI 3.3 to 6.0). A subsequent case series study[93] examining the results of the Danish public access defibrillation programme reported that 48 (6%) of the 807 AEDs included in the study were connected to an out-of-hospital cardiac arrest victim in the first 28 months of the intervention and that the 30-day out-of-hospital cardiac arrest survival rate was 52%.

In summary, time from collapse to either CPR or defibrillation is the most important predictor of survival in out-of-hospital cardiac arrest that can be directly affected by public access defibrillation interventions. The greatest improvement in survival occurs when this time period is less than four minutes. Large case series have reported that increasing availability of public AEDs is associated with a reduction in the time from collapse to defibrillation and improved outcomes for patients. However, data on the strength of this association are lacking and more work needs to be done to fully understand how diffusion of publicly available AEDs in urban and rural environments impacts on out-of-hospital cardiac arrest survival.

4.4 Safety

Potential safety implications associated with public access interventions include failure to access or dispatch AEDs when required, device malfunction, injury to patients or first responders (e.g. from improper use or inappropriate shocks) and adverse psychological reactions in responders.

No major adverse events were reported in the included studies. Only four[84;107;111;115] studies reported specific incidents that led to the failure of an AED to be dispatched or to function correctly. These included two studies[107;111] published in 1998 that reported a total of nine cases of device failure due to 'electrode drying' (3 cases), no shock and subsequent inability to recover data (4 cases), recurrent 'connect electrode' prompt from the device which prevented analysis (1 case) and inability to read the LCD screen because of cold temperature (1 case). A more recent study (2009) in which AED-equipped first responders were dispatched to only 66% of treated cardiac arrests in the study area reported that the most common reason for dispatch failures and delays were difficulties identifying true cases of out-of-hospital cardiac arrest at the time of the emergency call.[115] A comprehensive analysis of adverse events occurring during the public access defibrillation trial[84] reported 36 incidents from 649 presumed out-of-hospital cardiac arrest events. There were two patient-related adverse events (rib fractures) not related to AED use. Seven first responder adverse events were reported, including one pulled muscle, four cases of increased emotional stress and two responders who felt pressured into participating by their employer. No first responder was harmed by an AED. There were 27 device-related adverse events; 20 devices were stolen, three were moved to locations that were inaccessible and there were four incidents of mechanical difficulty or battery failure (none of which affected patient safety as another AED was available). There were no inappropriate shocks administered and no device failed to shock when indicated.

A qualitative study[139] examining the psychological profile of public access defibrillation first responders was carried out in the UK in 2008 to gain insight into possible factors contributing to the seemingly low incidence of adverse psychological reactions compared with professional ambulance crews who attend traumatic events. The results highlighted the importance of having confidence in being able to perform as trained, a realistic appreciation of one's own limitations as a lay responder and an ability to act with emotional detachment when required. An element of self selection appears to be at work, since these protective characteristics appeared to be present without formal training.

The issue of device accessibility in programmes that involve static AEDs located in public areas was examined in the context of the Danish public access defibrillation scheme,[140] which is based around a voluntary network of AEDs in sports and transport facilities, residential areas, private businesses and public buildings. A database of all registered devices is used by emergency medical services dispatch centres to identify the nearest AED in the event of a cardiac arrest. All AEDs registered in Copenhagen were included in the study (n=552), approximately half of which were located in government or municipal buildings. The study found that only 9.1% of all AEDs were accessible 24 hours a day, seven days a week and that AED coverage decreased by 53% during the evening, night-time and weekends, which is when 62% of all cardiac arrests in public locations occurred. A similar analysis examined the extent of public defibrillator use in Hampshire, UK, where programmes to raise public awareness and make public defibrillators available have been running for the past 12 years.[18] The study area had a total of 673 public defibrillators in 278 locations, including shopping centres, commercial properties and GP surgeries. The local ambulance service maintained a database of known defibrillator locations, aimed at improving the use of these devices in out-of-hospital cardiac arrest. Results showed that 1,035 out-of-hospital cardiac arrest calls to the ambulance service were received during the one year study period, with the caller being aware of an AED being available in 44 cases (4.3%). Of these, the AED was retrieved and attached to the patient prior to the arrival of ambulance paramedics in 18 cases (41%). Overall, public access AEDs were successfully deployed prior to the arrival of emergency medical services in only 1.7% of all out-of-hospital cardiac arrest events.

Two studies[141;142] examining safety and reliability of AED devices were identified, both of which used FDA-compiled data. A review[141] of recalls and safety alerts in the US between 1996 and 2005 found that 21% of AEDs were affected and every major AED manufacturer recalled products over the ten year study period. The most common reasons for issuing an FDA advisory were electrical (15%), cable (13%) or software (12%) issues, failure to shock (10%) and failure to detect (8%). A more recent study[142] analysed all adverse event reports where a patient died between the years 1993 and 2008. A total of 1,150 events were identified. The most common device failures occurred during the attempt to charge and deliver the intended shock (45%) or when the device powered on, but failed to complete rhythm analysis (22%). A cause of device failure could be identified in approximately 80% of cases, with pads/connectors (24%) and battery/power (23%) being the most frequently cited components. Backup devices were mentioned in 41% of reports and backup units delivered shocks to the patient in approximately one third of cases.

In summary, the risks posed to patients and the public from public access defibrillation interventions are small and the devices themselves are generally regarded as reliable and safe when used properly. However, maintaining the accessibility of these devices and ensuring that they are used when an out-of-hospital cardiac arrest occurs nearby has been reported as being problematic in some areas that have achieved large scale diffusion of public AEDs.

4.5 Applicability of the results in an Irish context

4.5.1 PAD trial results

To assess the relevance of the PAD trial results to the proposed Irish legislation, the study must be considered in terms of the population, intervention, comparator and measured outcomes (PICO).

Population

The PAD trial included all presumed out-of-hospital cardiac arrests in individuals aged eight years and older.[143] Patients with arrest and unconsciousness due to trauma or obvious drug overdose were excluded. The data included in the Out-of-Hospital Cardiac Arrest Register database on emergency-medical-services-attended out-of-hospital cardiac arrests in Ireland includes cases due to trauma (7% of all cases) and other non-cardiac causes including choking, drug and alcohol abuse, and haemorrhage (5% of all cases).[6]

The age-sex distribution of emergency medical services-treated out-of-hospital cardiac arrest cases is very similar between the PAD Trial (67% male, mean age 70 years) and the Out-of-Hospital Cardiac Arrest Register database (67% male, median age 67 years). However, only 30% of out-of-hospital cardiac arrests in the PAD trial were defined as residential events in contrast to 77% of OCHAR-recorded cases.

Intervention

The intervention in the PAD trial involved 1,587 AEDs and 11,015 trained volunteers across 496 community units.[96] The community units were excluded if they were within a three minute emergency medical services response catchment, had on-site medical personnel able to respond within three minutes, or had an existing defibrillation programme in place. Community units had to have an approximate

50% risk of one out-of-hospital cardiac arrest over 1.25 years. A further inclusion criterion was that the AED had to be easily accessible within the community unit. This latter criterion is not specific, but may be interpreted as suggesting that the AED should be available to volunteers at all times. The PAD trial does not state the catchment population of the community units, so it is not clear what the number of AEDs per 100,000 inhabitants were. Eighty five percent of AEDs were placed in public locations, predominantly recreational facilities and shopping centres.

The proposed Irish legislation does not stipulate proximity to emergency medical services, medical staff or other AEDs. The legislation identifies locations, but does not state if the AED needs to be accessible out-of-hours, or how many staff should be trained per device. It is not clear whether designated places with a low expected incidence will be exempt from the legislation. The proposed locations for AEDs include a wide variety of building types, with shopping centres likely to be a small minority.

The initial training required for volunteers in the PAD trial was similar to the accredited training available in Ireland. Retraining was provided subject to proficiency assessment three to six months after initial training. In Ireland, refresher training is required within two years to maintain accreditation.

Comparator

In the PAD trial, community units were excluded if they had a non-emergency medical services based defibrillation programme in place. For the comparator, 8,361 volunteers across 497 community units were trained in CPR. In the absence of population data, it is not possible to determine the number of trained individuals per capita. It was also not reported what proportion of the population had received CPR training previously. The proportion of cases receiving bystander CPR was 62% and 27% of out-of-hospital cardiac arrests were admitted to hospital.

The comparator for the present HTA is the current standard of care in Ireland, which comprises non-emergency-medical-services-linked static AEDs in a range of locations along with a number of emergency-medical-services-linked community first responder groups. Almost one quarter of the Irish population have had CPR training in the last five years.[80] In contrast to the community units in the PAD trial, Ireland includes both urban and sparsely populated rural areas. Fifty five percent of out-of-hospital cardiac arrests were bystander witnessed in 2012, and 60% of bystander-witnessed cases received bystander CPR.

Outcomes

The primary outcome measure used in the PAD trial was survival to discharge, with secondary outcomes relating to cerebral performance category (CPC), health-related quality of life and morbidity. Survival to discharge and CPC score are both collected within the Out-of-Hospital Cardiac Arrest Register database and will be incorporated into the present HTA.

The intervention and comparator evaluated in the PAD trial differ from the proposed Irish legislation in a number of important aspects. The community units modelled in the PAD trial are well described in terms of inclusion and exclusion criteria, but not in terms of population size. It is understood that they were urban centres with well defined boundaries, and this is reflected in the large proportion (70%) of out-of-hospital cardiac arrests that occurred in public settings. According to the OCHAR data the majority of Irish out-of-hospital cardiac arrests occur in residential settings (77% in 2012) and many occur outside urban areas. The proposed Irish public access defibrillation scheme will be introduced to a setting that already has widespread placement of static AEDs in high incidence areas. The PAD trial selected areas on the basis of no existing AED placement. Without population data, it is not possible to determine what the number of AEDs per inhabitant was in the PAD trial and whether it was similar to the proposed Irish programme.

Due to the important differences in the intervention and comparator, the results of the PAD trial are not applicable to the public access defibrillation programme defined in the draft Irish legislation.

4.5.3 Applicability of other studies

The major limitations to directly applying the results of other identified studies in an Irish context are differences in the setting (demographics and population density), the context (existing emergency medical services service, prior diffusion of AEDs) and the intervention (configuration of public access defibrillation programme). Results obtained in individual studies were dependent on the interaction of all three of these factors, so even adjusting for differences between Ireland and a given study setting in any one domain does not allow for a reliable estimate of the expected clinical impact.

In terms of setting, the chief limitation was that no study described a national programme that included a broad range of areas with different population densities. In studies that did include both urban and rural areas the number of AEDs and out-of-hospital cardiac arrest events was small. Included studies also differed in the type of emergency medical services service that existed at baseline and the extent to which publicly-accessible AEDs were already available. Median emergency medical services response times in the control arms of included studies was 7.5 minutes, compared with 11 minutes in Ireland[6] and Ireland already has widespread ad-hoc deployment of AEDs on a voluntary basis (see Section 3.3). The type of public access defibrillation intervention described in studies also differed considerably from that which is outlined in the proposed legislation, which provides for the deployment of AEDs in an extensive list of designated places throughout the country.

4.6 Discussion

Automatic external defibrillators (AEDs) were introduced in all ambulance services in Ireland in the late 1990's,(144) almost 30 years after Pantridge and Geddes became the first to report the use of mobile defibrillation units to treat out-of-hospital cardiac arrest in Belfast.(145) Research interest in the provision of AEDs to lay first responders through the implementation of public access defibrillation programmes has grown substantially in recent years and a wealth of literature exists on this topic. However, the results of a systematic review of effectiveness found that relatively little of this published material consists of experimental studies comparing these types of intervention to routine emergency medical services care. Fifteen primary studies were identified, which examined three main types of public access defibrillation programme: fire-fighter first responders, police first responders and public AED provision for use by bystanders who witness an out-of-hospital cardiac arrest. Assessment of study quality using a validated appraisal tool rated eight studies as weak, five as moderate and two as strong. The most common type of study design was a before-and-after comparison of cross sectional data within the study area, which was used in nine of the 15 included studies. The other six studies were controlled clinical trials, one of which was randomised. The scarcity of RCT data likely reflects the difficulty in conducting adequately powered trials given the logistical complexity of these interventions and the relatively low incidence of out-of-hospital cardiac arrest.

This review failed to identify any comparative studies showing a statistically significant improvement in survival when fire-fighter first responder AED programmes are added to standard emergency medical services care. Pooled data from four studies comparing these two interventions also failed to show a significant effect. While not statistically significant, the overall mean estimate of survival in the intervention group was 1% higher than in the control group (95% CI -1% to 3%). Results of studies involving a combination of fire-fighter AED provision and emergency medical services dispatch improvement(113) or public AED provision(115) showed an improvement in out-of-hospital cardiac arrest survival (RR 1.35 [95% CI 1.03 to 1.75] and RR 1.59 [95% CI 1.01 to 2.51], respectively), but a combined fire-fighter and police AED programme(114) did not. A lack of overall consistency of findings was also apparent; the fire-fighter plus public AED trial(115) found that survival at one month was improved, but survival to hospital admission was not, while the fire-fighter plus police first responder study(114) found improved survival to hospital admission, but no difference in survival to discharge.

No study examining police first responder AED programmes reported a significant out-of-hospital cardiac arrest survival benefit and a meta-analysis of all three studies comparing police AED provision with routine emergency medical services care also failed to identify a significant beneficial effect. Although not statistically significant, the mean estimate of effect in all three studies favoured police first responder AED provision and showed an overall mean increase in survival of 2% in the intervention group compared with controls (95% CI 0% to 4%). A combined intervention involving police and lay first responders in Northern Ireland(48) reported no benefit compared with routine emergency medical services care.

The most positive result of all the identified studies (BEDS study, Italy)(116) involved a combined intervention that saw 42 AEDs being added to the existing emergency medical services and seven AEDs installed in public locations in the study area (survival to discharge RR 3.15, 95% CI 1.53 to 6.48). However, the fact that the majority (85%) of study AEDs were added to the existing emergency medical services system, coupled with the lack of information on how public areas were selected and the fact that only 16% of survivors were treated with a public AED, limits the applicability of these results.

The best evidence for the effect of the public provision of AEDs comes from the PAD trial,(96) which compared CPR plus AED training combined with public AED provision to CPR training alone. An a priori decision was made to report the primary outcome (survival to discharge) as the absolute number of survivors of a definite out-of-hospital cardiac arrest in the control and treatment arms, as opposed to calculating it as a rate based on the number of events in each group. The reason given for this approach was that ascertainment bias and classification bias would result in an artificially low number of events being recorded in the control group, which would result in an underestimate of the overall survival benefit associated with the intervention. Ascertainment bias was anticipated to stem from 1) volunteers being more likely to report an event involving AED use or to respond to an event because of increased confidence based on the availability of an AED or 2) because emergency medical services personnel may be more likely to continue treatment when an AED is already in place. Classification bias was considered a threat because an early electrocardiogram would be available more frequently in the CPR-plus-AED arm of the trial and might therefore increase the denominator in this group, diluting the size of the effect compared with the control arm.

There are caveats associated with trying to compensate for a bias of unknown magnitude, since it is not possible to determine if it is over or under adjusting the calculation of effect size. The assumption that volunteers were more likely to respond to an event in the treatment groups does not appear to be supported by the data; resuscitation was attempted in 88 of 97 public out-of-hospital cardiac arrest events in the control group and 123 of 139 public out-of-hospital cardiac arrests in the treatment group (RR 1.03, 95% CI 0.94 to 1.12). That emergency medical services personnel would be more likely to continue treatment when an AED is already present is presumably based on the assumption that early defibrillation at least contributes to patients being in better shape when paramedics arrive, and is therefore an important factor in itself that should not be adjusted for. The potential for bias arising from out-of-hospital cardiac arrests in the treatment group being more likely to receive bystander intervention is minimal, since it is very unlikely that the rate of emergency medical services resuscitation differed for comparable events. For this to have an effect on the denominator, witnessed events with no bystander intervention would have to have a higher chance of not receiving an emergency medical services resuscitation attempt. emergency medical services resuscitation is generally attempted on everyone with non-traumatic cardiac arrest, other than those with obvious signs of death such as rigor mortis or dependent lividity.[146] Given the timeframe for the development of these signs it is unlikely that they would artificially reduce of the denominator in the control group (all out-of-hospital cardiac arrest of cardiac origin where resuscitation was attempted).

If it is assumed that the effect of these biases is negligible then it should not matter which denominator is used, since the relative risk ratio will remain constant when the denominators in each group are the same. Therefore it is still justifiable to use absolute numbers of survivors as long as both groups can be considered equal in every respect. Stratified randomisation according to both study centre and type of community unit was carried out to ensure that this was the case. However, observed presumed cardiac arrests in the control group occurred more often in residential settings (RR 1.37, 95% CI 1.16 to 1.60) and less often in public settings (RR 0.68, 95% CI 0.56 to 0.83), compared with the treatment group. Since publicly-located AEDs are designed primarily to treat out-of-hospital cardiac arrests occurring in public this may have contributed to increased survival in the treatment group. The major factor contributing to the difference in definite out-of-hospital cardiac arrests of cardiac origin was the number of presumed out-of-hospital cardiac arrests of cardiac cause who were dead on arrival and so received no emergency medical services resuscitation attempt (86 in control group compared with 62 in the treatment group [RR 1.36, 95% CI 1.03 to 1.79]). Since this is likely related to the greater proportion of residential out-of-hospital cardiac arrests in the control group, failing to calculate a survival rate using a comparable denominator (in this case all definite out-of-hospital cardiac arrests where resuscitation was started) may overestimate the effect of the intervention.

When survival to discharge in the PAD trial was calculated as a rate, the difference between groups was not statistically significant (RR 1.67, 95% CI 0.95 to 2.94), despite there being twice as many survivors in the intervention group (30, compared with 15 in the control group). This corresponds to an overall mean increase in survival of 9% in the intervention group compared with the control group (95% CI 0% to 19%). A significant beneficial effect was observed for survival to admission (RR 2.06, 95% CI 1.41 to 3.01) and neurologically intact survival (RR 2.63, 95% CI 1.30 to 5.31).

Public access defibrillation interventions are generally considered safe for both patients and rescuers. No serious adverse events were reported in included studies. Among the less serious events associated with public access defibrillation include increased emotional stress in responders, AED battery failure and devices being placed in inaccessible locations. No studies reported the delivery of inappropriate shocks and no study published after 1998 reported device failure that prevented the use of an AED on a patient.

Defibrillation is the definitive treatment for ventricular fibrillation (VF).(147) The rationale for public access defibrillation is that it reduces the time from cardiac arrest to first shock, resulting in more people being treated before VF deteriorates to asystole. To examine this premise and provide additional context to the systematic review results, an analysis of population-based registry data was carried out to identify the degree to which changes in response times can independently predict improvements in survival. This concluded that the three most important factors associated with survival in out-of-hospital cardiac arrest are time to CPR initiation, time to defibrillation and the initial rhythm detected, with initial rhythm acting as a surrogate for underlying pathology and being dependent to some extent on response time. There were conflicting reports of the effect of elapsed time on the odds of survival, but broad agreement that the strongest positive association was observed when response time was dichotomised at four minutes.

In many developed countries, public access defibrillation has been given a prominent role in efforts to increase survival rates from cardiac arrest. Various patient groups and professional bodies have published statements in support of public access defibrillation including the American Heart Association (AHA),(85) the American College of Emergency Physicians (ACEP),(148) the European Society of Cardiology (ESC) and European Resuscitation Council (ERC).(23) The need for effective initiatives in this area is apparent from the fact that out-of-hospital cardiac arrest survival rates have not significantly improved over the last 30 years despite the development of new treatments and widespread introduction of evidence-based guidelines.(126) The lack of progress in this area has been attributed to a combination of ageing populations,(149) increased emergency medical services response times due to growing urban populations(150) and a declining incidence of VF arrests.(151;152) Improved secondary treatment of ischemic heart disease(153) and the use of implantable cardioverter-defibrillators[154] have been identified as contributing factors to the observed decline in VF arrests.

Despite the widespread support for public access defibrillation interventions, caution needs to be exercised in relation to their practical implementation and expected benefits. This review found that the majority of studies were of poor methodological quality and therefore at high risk of bias. Results from the single RCT on publicly-accessible AEDs may have limited transferability beyond the specific setting and emergency medical services system in which it was conducted. Consideration must be given to how well emergency medical services response times and AED placement in specific studies align with any prospective public access defibrillation programme in Ireland, and whether the temporal and spatial characteristics of out-of-hospital cardiac arrest in this country are sufficiently similar to those of the study settings to justify an expectation of similar clinical outcomes. As pointed out elsewhere,[155] inappropriate placement and maintenance of AEDs can seriously undermine their effectiveness and lead to a decline in the organisational structure of the programme. Unrealistic expectations of the overall impact on out-of-hospital cardiac arrest must also be tempered by the fact that over 70%[33;44;90] of out-of-hospital cardiac arrests in Ireland occur in the home, so the impact of public access defibrillation on overall survival is likely to be low.

4.7 Conclusion

There is widespread international support for the introduction of public access defibrillation programmes and evidence from a range of sources indicate that decreasing the time from collapse to defibrillation is an essential part of improving survival in out-of-hospital cardiac arrest. However, there is less agreement on what type of programme should be implemented. Although the clinical justification for any system of rapid defibrillation appears strong, there is currently a lack of evidence demonstrating the effect of these interventions in practice. The highest quality evidence available is for the provision of static AEDs in public areas, with results indicating that when placement is carefully considered and appropriate training is provided this type of intervention is associated with a greater improvement in survival from out-of-hospital cardiac arrest than fire-fighter or police first responder programmes.

4.8 Key messages

- The key factors influencing survival in out-of-hospital cardiac arrest are time to CPR initiation, time to defibrillation and initial cardiac rhythm.
- No study comparing fire-fighter or police first responder programmes to standard emergency-medical-services care demonstrated a statistically significant beneficial effect on survival to hospital discharge. The pooled mean estimate of effect for both fire-fighter and police first responders favoured these intervention over routine emergency-medical-services care (mean increase of 1% and 2%, respectively in survival to discharge).
- RCT data on the provision of static AEDs in public places reported a doubling in the absolute numbers of out-of-hospital cardiac arrest survivors in the treatment group. When survival to discharge was analysed as a rate based on all out-of-hospital cardiac arrests of cardiac causes where resuscitation was attempted, this increase was not statistically significant. The mean estimate of effect for public AED provision favoured the intervention over routine emergency-medical-services care (mean increase of 9% in survival to discharge). Statistically significant increases in survival to hospital admission and neurologically intact survival were also reported.
- Case-series analyses of population-based registry data identified a positive association between survival and the implementation of public access AED programmes. This type of data can have good external validity, but is prone to bias and cannot reliably estimate the effect of interventions.
- There is widespread international support for the introduction of public access defibrillation programmes among voluntary groups and professional associations.
- No major safety concerns have been identified in relation to public access defibrillation programmes. Among the adverse events associated with these interventions are increased emotional stress in responders, AED battery failure and devices being placed in inaccessible locations.
- Measures to promote the effectiveness of public access defibrillation programmes include directed placement of AEDs, training of lay volunteers, centralised AED registration and increasing accessibility of AEDs outside of business hours and at weekends.
- No analytic studies involving public access defibrillation in paediatric populations were identified, so the effect of the intervention in this group is unknown.

5 Economic evaluation

This chapter reviews the existing evidence on the cost-effectiveness of international public access defibrillation programmes and describes a de novo decision analysis model comparing the cost-effectiveness of a number of potential configurations of a public access defibrillation programme in Ireland.

5.1 Review of published literature

A review of cost-effectiveness studies was carried out to assess the available cost-effectiveness evidence for public access defibrillation and inform the economic analysis of a prospective Irish public access defibrillation programme. Studies were included if they compared the costs and consequences of public access defibrillation to routine emergency medical services care for out-of-hospital cardiac arrest events that occurred in a public place or modelled the expected clinical and/or cost implications of different public access defibrillation programme configurations.

5.1.1 Search strategy

A search was carried out in Medline, Embase, NHS Economic Evaluation Database (EED), Health Economics Evaluation Database (HEED) and the HTA database for economic analyses of public access defibrillation programmes. The search in Medline and Embase was carried out in tandem with the systematic review of clinical effectiveness (see Appendix 2). No methodology filters were used in that search so the returned results included economic analysis studies. These were identified and recorded during the screening and review process. Searches in NHS EED and the HTA database were performed in the Cochrane library and searches in HEED were performed in the HEED search portal (Wiley online library) up until May 2014.

5.1.2 Results

A total of 16 relevant studies were identified (see Table 5.1).

Table 5.1 Cost-effectiveness literature search results

Citation Database	Relevant Studies
Medline & Embase	8
HTA Database	2
NHS EED	8
HEED	11
Total	29
Duplicates	12
Reports of same study	1
Unique studies	16

The year of study publication spanned from 1990 to 2013. There was a high degree of heterogeneity in study design, setting, measured outcomes and included costs. The identified studies included 14 modelled cost-effectiveness studies and two costing studies.

5.1.2.1 Cost-effectiveness studies

Overview of studies

Fourteen studies reporting the results of economic analyses of rapid defibrillation programmes were identified. Eleven of these were set in North America, with one set in each of Scotland, Sweden and Denmark. There was significant heterogeneity in the type of public access defibrillation intervention assessed. Four studies evaluated static automated external defibrillator (AED) provision across a range of public locations, with six others examining AED provision in only one particular type of setting (casinos, long-term care facilities, homes of high risk patients, aircraft or schools). Four studies modelled rapid defibrillation programmes involving mobile AEDs carried by police, fire-fighters or voluntary first responders. All decision analysis models consisted of a decision tree structure to model patients until hospital discharge, with studies that examined longer term outcomes adding a Markov component to model successive years post-discharge. Full details on each included study are provided in Appendix 3.

Quality of included studies

Modelled cost-effectiveness studies were assessed using the ISPOR questionnaire to assess the relevance and credibility of modelling studies.[156] Relevance was assessed on the grounds of the study population, characteristics of the intervention, outcomes measured and the overall study context. The credibility of the results was considered using criteria related to the design, validation and analysis methods, the quality of the data used, as well as how the results were reported and interpreted and whether the authors had any conflicts of interest. Results of the quality assessment are provided in Appendix 4.

Clinical outcome data

Nine studies used estimates of survival to hospital admission and discharge from parallel clinical studies or the available literature at the time the analysis was performed.(157-165) Others used local registry out-of-hospital cardiac arrest data(166) or modelled the increase in survival as a function of reduced response times.(167) One study estimated outcomes by assuming that all out-of-hospital cardiac arrests in public access defibrillation areas would have the same outcomes as those with an emergency medical services response time of less than three minutes.(168) The time horizon used in the majority of studies (10/14) was the lifetime of out-of-hospital cardiac arrest patients. The other four studies used a time horizon of between four and 10 years. Long-term quality of life data associated with different levels of neurological impairment post-discharge were taken from the literature. In addition to the utility gain for those who survive an out-of-hospital cardiac arrest, one study applied a small passive utility benefit for all people who could potentially benefit from the intervention, due to the sense of security provided by a public access defibrillation scheme.(158)

Cost data

The majority of studies (9/14) adopted a societal perspective, with the remaining five studies taking the perspective of either the health service only or the health and police/fire service, depending on the type of programme. Equipment costs were taken from clinical studies (where the cost-effectiveness analysis was being conducted alongside a study) or obtained from suppliers. Annual maintenance costs for AEDs were based on surveys of suppliers or as a percentage of the total device cost. An estimate of the lifespan of AED devices was obtained from device manufacturers. Training costs were handled differently in a number of studies: some obtained costs from training providers or based it on instructor wages,(157;161;167) while others included the cost to employers for trainee time at the routine average hourly rate,(160) or at a reduced level of one third of the average hourly rate.(159) One study combined annual training and maintenance costs as a percentage of the unit cost of the device;(162) two studies did not include training costs at all.(158;169) Treatment costs were generally obtained from the literature or from parallel clinical studies. One study did not include treatment costs on the basis that they were equal for both comparators.(162) Only two studies(165;170) did not discount future benefits or costs. With the exception of one study that used differential discounting of benefits and costs (1.5% and 6%, respectively),[168] the discount rate used was 3%, 4% or 5%. Costs reported in each of the studies were inflated to 2013 using the local consumer price index and expressed in Irish Euro using the purchasing power parity exchange rate.[171]

Summary of results – static AEDs located in public areas

Five studies reported cost-effectiveness results for programmes involving static public AEDs.[157;163;165;167;168] A 2003 US study, examining a strategy of placing AEDs in selected public locations assumed to have a 20% annual probability of an out-of-hospital cardiac arrest, calculated a cost per additional quality-adjusted life year (QALY) gained of €31,300.[157] This contrasts with a 2009 study based on the Copenhagen public access defibrillation scheme that calculated a cost per QALY gained of €44,500 for a scheme also based on AED placement in areas with a 20% annual risk of an out-of-hospital cardiac arrest event.[165] This study also calculated results for different placement strategies, highlighting the importance of guided placement of AEDs in public access defibrillation programmes. The European Resuscitation Council (ERC) recommendation of placing AED in locations with at least a 50% annual probability of an out-of-hospital cardiac arrest resulted in a cost per QALY gained of €28,900, whereas unguided placement resulted in a cost of €118,500 per additional QALY.[165] The economic evaluation carried out as part of the PAD trial (US and Canada) reported the cost-effectiveness of volunteer CPR training plus AED provision compared with volunteer CPR training only and calculated an incremental cost per QALY of €44,900.[163] This study involved AED placement in residential and public community areas with at least a 50% annual probability of a cardiac arrest (as evidenced by out-of-hospital cardiac arrest records) or the equivalent of at least 250 adults aged more than 50 years present at that location for more than 16 hours per day.

Some of the best clinical results for public access defibrillation programmes have been observed in casinos, where there are large numbers of security personnel available to respond to an out-of-hospital cardiac arrest event and public areas are constantly monitored by CCTV to detect unusual activity. A 2003 US analysis of casino-based public access defibrillation programmes calculated a cost per QALY gained of €57,900.[167] This analysis included the wage costs of training instructors, but not the wage costs for employees receiving training, on the basis that it would occur during their regular duties. When the opportunity cost of the time needed for training is taken into account the cost per additional QALY gained was over €100,000.

Finally, a 2003 study that modelled AED deployment in all major airports, railway and bus stations in Scotland, and which only included direct costs to the health service, estimated a cost per QALY gained of €62,300.[168] The modelled programme involved 31 AEDs being deployed across 17 locations compared with a situation where no public AEDs were available in any of these areas.

Summary of results – all other studies

Two studies estimated the cost-effectiveness of programmes involving police first responders. Both were based in the US and involved urban or suburban settings. Nichol (1998)[162] estimated the median cost per QALY gained at €32,600, while Forrer (2002)[170] only reported cost per life year gained, which was €19,200. The only economic evaluation of fire-fighter first responder programmes was a cost-benefit analysis set in Stockholm, using data from the SALSA trial.[164] This reported a total of 16 additional lives saved, with a cost per QALY gained of €14,600.

Two studies reported the cost-effectiveness of AED deployment on US commercial aircraft. Groeneveld (2001)[160] estimated that AED deployment on all commercial aircraft would result in a cost per QALY gained of €100,500. If AEDs were deployed only on large (>200 passengers) commercial aircraft, this reduced to €37,400 per QALY gained. Cram (2003)[158] modelled a cohort over one year based on aircraft with an average of 110 passengers per flight and reported a cost per QALY gained of €34,700.

The three remaining studies calculated the cost-effectiveness of public access defibrillation in schools, long-term care facilities and in the home. The analysis of school-based AED deployment did not estimate the clinical benefit, but instead gave incremental cost-effectiveness ratios (ICERs) ranging from €122,100 to €63,000 depending on whether it would save 5 or 10 lives over five years.[169] Foutz (2000)[166] estimated a cost per life saved of €99,000 for AED deployment in long-term care facilities in the US. Another US study examined the cost-effectiveness of AED deployment in the home and found that this was not likely to be cost-effective, with a cost per QALY gained of almost €2.5 million.[159]

5.1.2.2 Costing Studies

Two costing studies were identified in the search. The most recent of these was from 2010[172] and reported cost data for patient transport, treatment and hospital stay that was collected as part of an observational study comparing out-of-hospital cardiac arrest cases involving an onsite AED, dispatched AED or no AED. The results found total costs for survivors after onsite AED use (€32,500) were lower than for dispatched AED cases (€37,900) or no AED use (€34,800). An earlier costing study[173] examined the relationship between costs and out-of-hospital cardiac arrest case characteristics such as time to defibrillation and emergency medical services arrival, whether CPR was performed and neurological outcomes. Results indicated that the proportion of overall costs for patients with poor neurological outcomes (CPC>2) increase with longer time to arrival of emergency medical services and time to defibrillation.

5.1.3 Discussion

Decision analysis models have been used to estimate the cost-effectiveness of public access defibrillation in a range of settings. All of the models identified in the literature review were structured as either a decision tree, or as a mixed decision tree/Markov model. A decision tree structure is well suited to modelling the initial phase of out-of-hospital cardiac arrest, since it is an event-driven process where the time between the event and the primary outcome (survival to discharge) is relatively short. A Markov element is more suitable for capturing the longer term outcomes for patients, who may have different neurological status or ongoing treatment needs in the years after hospital discharge.

Relevant measures of effectiveness include cost per life saved (increase in survival to hospital discharge), cost per life year gained and cost per QALY gained. One study factored in a utility benefit for all people who could potentially benefit from the intervention whether they had an out-of-hospital cardiac arrest or not, based on a belief that public access defibrillation programmes give people a greater sense of security.[158] However, the inclusion of a passive prophylactic benefit of this type was not included in any other study. Increased CPR training and out-of-hospital cardiac arrest awareness as a result of BLS/AED training is an additional benefit of a public access defibrillation programme that can potentially increase bystander intervention rates even in the absence of a defibrillator. From a societal perspective, relevant direct costs include the equipment and training costs needed to institute, operate, maintain and coordinate a public access defibrillation programme, as well as hospitalisation and long-term treatment costs. Indirect costs include the time required to train lay responders and productivity costs associated with mortality and morbidity as a result of out-of-hospital cardiac arrest.

Applicability of the evidence

Some of the public access defibrillation programmes included in the economic evaluation literature review were outside the scope of this HTA. These included assessment of AED deployment solely in aircraft, long-term care facilities and the homes of people at increased risk of an out-of-hospital cardiac arrest.

Although there is no stated threshold below which a technology is automatically considered cost-effective in Ireland (with the exception of a current agreement for pharmaceuticals at €45k/QALY[104]), a number of included studies reported ICERs that would generally be considered acceptable. However, the transferability of these results is questionable. Many of these studies were carried out over a decade ago in the US, which has implications for their applicability to present day Ireland. The use of Irish data to inform assumptions about the treatment pathway, long-term outcomes and costs for out-of-hospital cardiac arrest survivors may result in significant changes to the incremental costs per QALY for the intervention.

Another major limitation is the differences that exist between the proposed Irish public access defibrillation scheme and the previously modelled programmes, many of which were confined to limited geographical areas or a small list of designated AED locations. Of the four studies that examined static AED provision in public areas, two were limited to densely-populated urban areas only, [163;165] one assumed that each AED would be used once every five years (instead of estimating this parameter by comparing AED distribution and out-of-hospital cardiac arrest incidence) and the final study,[168] which modelled a Scottish national public access defibrillation scheme, identified a total of 17 eligible sites involving a total of 31 defibrillators. In contrast, the draft Irish legislation outlines a nationwide scheme that encompasses both urban and rural areas, and identifies a comprehensive set of over 43,000 designated places that would need to provide AEDs and train staff.

Another important difference between Ireland and the various study settings is the degree of AED diffusion prior to the introduction of an organised public access defibrillation programme. It is estimated that there are approximately 9,000 functional AEDs in circulation throughout Ireland at present, a level comparable to some areas that have implemented a formal public access defibrillation scheme. Although placement of these AEDs has not been centrally directed, many high incidence locations (e.g. airports) already have AEDs available. This means that the incremental benefit achievable from a structured public access defibrillation programme is likely to be less than if it was being compared to a base case involving no pre-existing AED provision.

5.1.4 Conclusion

A number of previous economic analyses have estimated ICERs that would generally be considered to be within an acceptable range to support the introduction of public access defibrillation. However, the available literature does not provide enough information to reliably estimate the cost-effectiveness of an Irish programme, or to compare the likely consequences of different public access defibrillation programme configuration.

5.2 Economic analysis

5.2.1 Description of the economic model

A decision analysis model was built to compare the costs and benefits associated with different public access defibrillation programme configurations, compared with the current process of care for people who experience an out-of-hospital cardiac arrest in Ireland. The baseline comparator is a mixture of paramedic-delivered emergency medical services services, ad hoc distribution of public AEDs and a limited number of police, fire-service or community first responder groups in various locations. The objective of the economic evaluation is to aid decision making by estimating the incremental costs and benefits of each of the public access defibrillation configurations modelled compared with the current situation.

5.2.2 Study question

The study objective is to determine the cost-effectiveness and budget impact of a range of public access defibrillation configurations in Ireland.

5.2.3 Type of economic evaluation

This is a cost-utility analysis (CUA), which will calculate the cost and the utility (in quality-adjusted life years gained [QALYs]) for each public access defibrillation programme and compare these across competing alternatives. public access defibrillation programmes will also be compared in terms of effectiveness only, such as life years gains (LYG), survival to hospital discharge and neurologically intact survival (discharged in CPC 1).

5.2.4 Study perspective

Costs and benefits are assessed from an Irish societal perspective. This includes direct and indirect costs incurred by the publicly-funded health and social care system, other public sector departments, patients, and designated places with responsibility for providing AEDs and training staff in BLS/AED. Also included are the productivity losses associated with mortality and morbidity as a result of an out-of-hospital cardiac arrest.

National guidelines for the economic evaluation of health technologies in Ireland recommend that the perspective of the publicly-funded health and social care system in Ireland should be adopted when assessing costs. [174] Given the nature of public access defibrillation interventions and the degree to which costs fall outside of the health service, it is appropriate to take a wider societal perspective in this assessment. A secondary analysis will examine cost-effectiveness from the perspective of the publicly-funded health service only.

5.2.5 Technology

The technology being assessed is programmes directing deployment of static AEDs in public locations, combined with provision of BLS/AED training to staff employed in these designated locations. The aim of the intervention is to reduce the time from onset of cardiac arrest to when defibrillation is performed, thus increasing the chances of survival in out-of-hospital cardiac arrest. See Chapter 2 for a more detailed description of the technology.

5.2.6 Choice of comparators

The base case is routine care, which includes the current emergency medical services ambulance service as well as ad-hoc public AED provision and a limited number of first responder groups covering specific areas. A detailed account of the existing deployment of public AEDs and community first responder groups is provided in Chapter 3 (sections 3.3.2, 3.3.5) and Appendix 1. A systematic review of clinical effectiveness (Chapter 4) indicated that improvements in out-of-hospital cardiac arrest survival are potentially greater for public access defibrillation programmes combining static AED deployment and volunteer training than for fire-fighter or police first responder programmes.

In keeping with the proposed legislation, all comparators involved the placement of static AEDs in a given set of designated places. These comparators ranged from programmes involving the targeted provision of AEDs in building types with the highest out-of-hospital cardiac arrest incidence, to the comprehensive scheme outlined in the Bill. The comparators included are as follows:

- Legislation – As described in the Public Health (Availability of Defibrillators) Bill 2013,[4] a public access defibrillation programme which involves the deployment of AEDs in a comprehensive range of designated places throughout Ireland (see Appendix 5 for a full listing) and training of staff in these places in BLS/AED. This option involves the deployment of approximately 38,400 additional AEDs.
- PAD 15% – AEDs in every building type where there is an annual probability of at least one out-of-hospital cardiac arrest per 20 AEDs (see Appendix 5 for a full listing). This public access defibrillation scheme requires approximately 15% of the AEDs proposed in the full legislation. This option involves the deployment of approximately 1,900 additional AEDs.

- PAD 20% – AEDs in every building of type Hospital and Residential, Transport, and Public Administration (see Appendix 5 for a full listing). This option involves the deployment of approximately 3,100 additional AEDs.
- PAD 25% – AEDs in every building of type Hospital and Residential, Transport, Public Administration, and Retail (see Appendix 5 for a full listing). This option involves the deployment of approximately 6,800 additional AEDs.
- PAD 45% – AEDs in every building of type Hospital and Residential, Transport, Public Administration, Retail, and Arts and Entertainment (see Appendix 5 for a full listing). This option involves the deployment of approximately 15,300 additional AEDs.
- PAD 55% – AEDs in every building type where there is an annual probability of at least one out-of-hospital cardiac arrest per 100 AEDs (see Appendix 5 for a full listing). This option involves the deployment of approximately 19,600 additional AEDs.

5.2.7 Target population

The target population is all out-of-hospital cardiac arrest patients that are attended by emergency medical services and where resuscitation is attempted. It includes out-of-hospital cardiac arrests with any heart rhythm, witnessed and unwitnessed arrests, and those that occur in the home as well as in public. It excludes non-emergency medical services attended out-of-hospital cardiac arrests and those where no attempt at resuscitation is made due to obvious signs of death. This is the most relevant population when examining the overall impact of a potential public access defibrillation scheme, even though the effect size is likely to be greater if limited to the subgroup of witnessed out-of-hospital cardiac arrests with initial ventricular tachycardia (VT) rhythm.

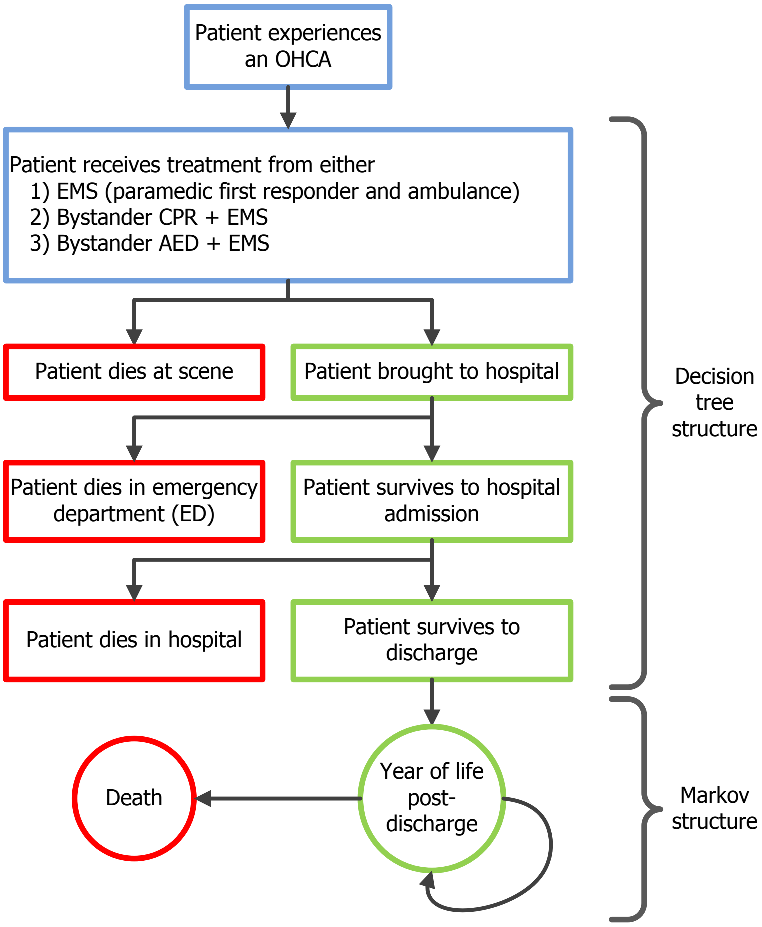
5.2.8 Time horizon

The average cost and clinical benefit per patient for each of the public access defibrillation comparators is estimated by modelling one years' cohort of emergency-medical-services-attended out-of-hospital cardiac arrest patients in whom resuscitation was attempted, from the time of the initial arrest until all members of the simulated one-year cohort have died.

5.2.9 Outline of the model structure

The primary clinical endpoint in out-of-hospital cardiac arrest is survival to hospital discharge. The patient pathway from occurrence of arrest to death or hospital discharge can be modelled as an event-driven process with a relatively short timeframe. Therefore a decision tree is an appropriate structure to capture this part of the patient pathway. Longer term outcomes such as the number of additional life years and quality of life, and subsequent long-term costs associated with ongoing treatment of the underlying cause of the cardiac arrest are captured using a two state Markov model that follows each out-of-hospital cardiac arrest survivor to life expectancy. A generic diagram of each comparator arm for the model is shown in Figure 5.1.

Figure 5.1 Model structure



5.2.10 Sensitivity analysis

A probabilistic model is used that explicitly takes into account the uncertainty in the model parameters. As part of the model evaluation, all of the key parameters are varied within plausible ranges that were derived from published evidence. Where published evidence was limited or unavailable, plausible ranges were derived with the support of the Expert Advisory Group. As the structure of the economic model presented here is inherently stochastic, the outputs are equivalent to a multivariate probabilistic sensitivity analysis.

A univariate sensitivity analysis shows how influential each parameter is and how sensitive the results are to fluctuations in each parameter. Given the uncertainty around the parameters themselves, it is important to understand how this translates into uncertainty about the results. Deterministic sensitivity analysis was used to examine this, where each parameter in turn is fixed at its upper and lower bounds while all the other parameters are held at their average value.

5.2.11 Budget impact analysis

The budget impact analysis (BIA) is conducted separately from the perspective of the publicly-funded health and social care system (Department of Health and HSE), the overall public sector (all government departments, including Health), and the private sector. The analysis reports the costs for each year in which they occur over a timeframe of five years. The timeframe represents the most immediate planning horizon over which resource use will be planned. Indirect costs due to productivity losses associated with out-of-hospital cardiac arrest morbidity and mortality were not included, and no discounting is applied. All other costs for the BIA are the same as those used in the economic analysis, inclusive of value added tax (VAT) where applicable. VAT applies to non-oral medications and to equipment when calculating amortised capital costs. In this study, VAT was applied to the cost of AEDs and device consumables (pads, batteries, signage and cabinets). No VAT was applied to the cost of BLS/AED training per Article 132 (1)(i) of the 2006 VAT Directive.[175]

5.3 Model parameters

The economic model required a range of input parameters that describe the treatment received by out-of-hospital cardiac arrest patients following a cardiac arrest across various configurations of public access defibrillation scheme, and the impact this has on survival, neurological outcomes and treatment costs. It also required estimation of the costs of establishing and maintaining each type of scheme, based on the number of AEDs and staff training sessions (initial training and refresher training) needed, as well as equipment maintenance over the lifespan of the AEDs.

The overall benefits and costs of competing public access defibrillation programmes were calculated by performing 10,000 iterations of the model. Randomly sampled individual parameter values are used in each iteration. Summarising across iterations provides an estimate of overall average costs and benefits, as well as the uncertainty associated with these values.

5.3.1 Discount rate

Discounting is a technique that allows comparison between costs and benefits that occur at different times. It reflects a societal preference for benefits to be realised in the present and costs to be experienced in the future. Costs and benefits are discounted at the rate of 5% as prescribed by the Department of Finance.[174] The discount rate is varied (from 3% to 7%) in a univariate sensitivity analysis only.

5.3.2 Estimates of effect

The Out-of-Hospital Cardiac Arrest Register database provides data on the proportion of patients who are first treated by paramedics, bystanders who perform CPR and bystanders who perform defibrillation. It also records the proportion within each of these groups who are brought to the emergency department, admitted and discharged from hospital and the cerebral performance category (CPC) scores at discharge for each group. This information is used to model the base case and estimate average outcomes associated with each type of response (emergency medical services, bystander CPR and bystander defibrillation). The modelled public access defibrillation programmes differ in terms of the list of designated places where static AEDs could be deployed. Geodirectory[97] data were used to estimate the number and location of designated places specified in each type of public access defibrillation programme (see Section 3.3.6).

It is noted that there is uncertainty about the effective range of an AED, with a previous study having modelled it between 100 metres and 300 metres.[176] The American Heart Association recommends that AEDs be placed so that they can be reached within a 1 to 1.5 minute brisk walk.[85] Given average maximum walking speeds of 2.17 m/s for people aged between 20 and 70,[177] 200 metres represents the upper limit for the distance within which AEDs can expected to be used. The proportion of patients predicted to receive bystander defibrillation was calculated based on the Out-of-Hospital Cardiac Arrest Register data on arrests that occurred within 200 metres of existing AED locations. By comparing national Out-of-Hospital Cardiac Arrest Register data on the location of out-of-hospital cardiac arrests with the locations of designated places from the Geodirectory, the number of arrests likely to occur within 200 metres of an AED was estimated for each of the proposed public access defibrillation configurations. Increases in the proportion of patients first treated by bystander defibrillation will result in a concomitant decrease in the proportions of patients first treated by either emergency medical services or bystander CPR only. These decreases were estimated by using data on the relative proportion of patients receiving each intervention at present, adjusted for the number of additional people that would be BLS/AED trained in each public access defibrillation programme. This was based on the assumption that the increase in the overall number of CPR-trained people will increase the proportion of out-of-hospital cardiac arrest patients who receive any type of bystander intervention, since trained volunteers can perform CPR even when no AED is available.

By applying the Out-of-Hospital Cardiac Arrest Register data on outcomes for patients in each of these groups it was possible to estimate the likely clinical outcomes from the initial cardiac arrest to hospital discharge associated with each type of public access defibrillation programme. Data on average life expectancy and health-related quality of life (HRQoL) post-discharge was estimated from a review of the available literature. See Section 3.2 for more details on the analysis of the national and international data on survival and quality of life following a cardiac arrest. Due to the small numbers involved, some of the outcomes are subject to substantial variability. Although national coverage of the Out-of-Hospital Cardiac Arrest Register data was achieved in 2012, data for some regions has been collected for up to five years. The Authority generated population weighted means for each outcome to make use of the additional years of data available and hence produce more reliable estimates. Hence, in some cases the parameter values differ slightly from the 2012 data.

A full list of the clinical effectiveness and utility parameters included in the model and details of how they were estimated is provided in Appendix 5. Table 5.2 shows the estimates for the main clinical outcome parameters.

Table 5.2 Outcome parameters

Parameter	Mean value (95%CI)*			Source
	Proportion of patients who are first treated by			
	Emergency medical services	CPR-Only	Public access defibrillation-CPR	
Base case	50.7%	42.1%	7.1%	Adjusted Out-of-Hospital Cardiac Arrest Register data based on out-of-hospital cardiac arrest incidence within 200 metres of proposed AED locations (see Appendix 5 for more details)
PAD15%	50.5%	41.1%	8.4%	
PAD20%	50.3%	41.2%	8.5%	
PAD25%	49.9%	40.1%	10.0%	
PAD45%	48.7%	39.1%	12.2%	
PAD55%	48.2%	39.0%	12.8%	
Legislation	45.7%	40.5%	13.8%	
Survival to emergency department (ED)				
EMS	60% (58-62)			Out-of-Hospital Cardiac Arrest Register
CPR only	57% (54-59)			
PAD-CPR	52% (46-58)			
Survival to hospital admission having survived to ED				
EMS	22% (20-25)			Out-of-Hospital Cardiac Arrest Register
CPR only	26% (23-29)			
PAD-CPR	44% (34-54)			
Survival to hospital discharge having survived to admission				
EMS	35% (30-40)			Out-of-Hospital Cardiac Arrest Register
CPR only	42% (36-48)			
PAD-CPR	63% (51-76)			
CPC scores at hospital discharge by type of initial response				
	CPC1	CPC2	CPC3	
EMS	77% (66-86)	14% (7-23)	9% (4-17)	Out-of-Hospital Cardiac Arrest Register
CPR only	71% (60-80)	9% (4-16)	20% (12-30)	
PAD-CPR	77% (63-87)	7% (2-17)	16% (7-28)	
Post-discharge annual survival				
CPC1	92% (90-94)			Pachys 2014[65]
CPC2	92% (90-94)			
CPC3	79% (77-82)			
QALY outcomes by CPC score				Kuilman 1999[66] Moulaert 2010[70] Deasy 2013[71] Stiell 2009[72] Nichol 1999[73]
Baseline QALY	0.78 (0.77-0.79)			
QALY in CPC1	0.93 (0.87-0.97)			
QALY in CPC2	0.75 (0.66-0.83)			
QALY in CPC3	0.40 (0.31-0.50)			

Abbreviations: CI – confidence interval; EMS – emergency medical services (ambulance or rapid response vehicle); CPR – cardiopulmonary resuscitation (from bystanders); PAD – public access defibrillation (from a bystander); AED – automatic external defibrillator; ED – emergency department; CPC – cerebral performance category; QALY – quality-adjusted life year; * Where no 95% CI is shown that value is derived from other (sampled) parameters, see Appendix 5 for relevant formulae.

5.3.3 Estimates of cost

Economic analysis from a societal perspective includes a broad range of direct and indirect costs to patients, health service providers and designated places. Costs for all of these groups are combined in the cost-effectiveness analysis to determine the overall cost-effectiveness of the alternative public access defibrillation programmes, but will be considered separately in the budget impact analysis.

The largest incremental cost associated with public access defibrillation schemes is the setup cost. In addition to the cost of the AEDs, this also includes the cost of wall cabinets to store the devices, signage, staff training and setup of a national AED database. Staff training costs include the cost of an accredited instructor (trainer) and the opportunity cost of staff time (trainee). There are also ongoing costs associated with the programme, including replacement AED pads and batteries and refresher training for staff (trainer and trainee). The majority of the costs are incurred immediately on the introduction of the scheme, with replacement pads and BLS/AED refresher training required approximately every two years and replacement batteries required roughly every five years.

Costs for AEDs, replacement pads, replacement batteries, signage and storage cabinets were obtained from supplier websites. The price of an AED ranged from under €900 to €7,000, depending on supplier, make and model, and technical specifications. It was noted by suppliers that buyers are very price sensitive and have a tendency to opt for less expensive models. In the absence of a survey or representative database of AEDs bought, the mean cost of an AED and associated consumables had to be estimated using the prices of available models. Less expensive models may have a shorter lifespan and tend to come equipped with batteries with a shorter lifespan, so that a reduction in the AED cost may be associated with annual running costs equivalent to a more expensive model. The mean battery lifespan used in the model reflects a better quality AED and no cost has been included for delivery and installation of the system. In the cost-effectiveness analysis the combined cost of owning and operating an AED was calculated as the equivalent annual cost (EAC), based on the upfront cost of acquisition annuitised over the lifespan of the device plus the average annual maintenance cost of replacement pads, batteries and staff retraining.(178)

The annual cost of running a national AED register is calculated as the staff cost of one full-time-equivalent (FTE) clerical officer grade plus the estimated annual cost of the required hardware and software. These IT costs were estimated based on the costs involved in running similar registries that are currently in operation, and include the cost of hosting, licensing and support services.(3)

The total number of AEDs and training sessions required is based on the number of designated places specified in each comparator, using the assumption that each designated place will require one AED and, on average, training for two members of staff.

Short term treatment costs associated with out-of-hospital cardiac arrest include the cost of an ambulance callout, the cost of care in the emergency department and in-hospital care for patients who survive to hospital admission and discharge. Since the population is all emergency medical services-attended out-of-hospital cardiac arrests where resuscitation was attempted, an ambulance callout is required for all patients across all comparators. It is assumed that the average cost of this callout is the same whether or not the patient survives to hospital, so there is no incremental cost associated with it and it can be excluded from the analysis.

Long-term care costs include medication and hospitalisation costs for the underlying aetiology as well as care costs associated with any lasting neurological impairment. In this analysis the annual cost of care for CPC 1 and CPC 2 survivors post-discharge is calculated based on HIPE[(179)] data indicating that approximately 15% will receive an implantable cardioverter defibrillator (ICD) and an assumption that the remaining 85% will receive pharmacological treatment for the secondary prevention or management of coronary artery disease and other underlying cardiac pathologies, as appropriate.

Annual care costs for patients with CPC 3 include the annual cost of pharmacological treatment plus the cost of a full-time carer, estimated as the annual full time carers allowance from the Department of Social Protection. Productivity costs associated with premature mortality and morbidity as a result of out-of-hospital cardiac arrest are also included, which are calculated using the human capital approach based on Central Statistics Office (CSO) data on employment and earnings by age and gender, weighted according to the demographics of the out-of-hospital cardiac arrest population in Ireland.

A full list of the cost parameters included in the model and details of how they were estimated is provided in Appendix 5. Table 5.3 shows the estimates for some of the main cost parameters in the model.

Table 5.3 Cost parameters

Parameter	Mean value (95%CI)	Source
Number of additional AEDs required		
Base case	0	Geodirectory data on number of places adjusted for estimated current AED availability; standard error of 10% applied
Legislation	38,419 (34,671-42,133)	
PAD15%	1,876 (1,595-2,156)	
PAD20%	3,145 (2,699-3,597)	
PAD25%	6,774 (6,067-7,485)	
PAD45%	15,346 (13,879-16,797)	
PAD55%	19,591 (17,659-21,518)	
PAD implementation parameters		
Unit cost of AED	€1,189 (973-1447)	Device manufacturers (all costs exclusive of VAT where applicable)
Unit cost of replacement pads	€46 (38-57)	
Unit cost of replacement battery	€165 (136-201)	
Lifespan of AED	8 years (6-10)	
Lifespan of AED pads	2 years (1.5-2.5)	
Lifespan of battery	5 years (4-6)	
Cost of AED signage	€12 (10-15)	Suppliers
Cost of AED storage cabinet	€134 (111-164)	
Instructor cost for initial training per person	€80 (66-96)	Training providers
Time needed for initial training	5 hours (4.5-5.5)	
Interval for retraining	2 years (1.2-3.3)	
Instructor cost for refresher training per person	€50 (41-61)	
Time required for refresher training	3 hours (2.6-3.4)	
Cost of care for death in ED	€679 (451-988)	Micro-costing
Cost of hospital care for patient who dies in hospital	€17,911 (15,290-20,868)	HIPE DRG costs
Cost of hospital care for patient surviving to discharge	€22,835 (18,287-28,150)	
Annual cost of medical care post-out-of-hospital cardiac arrest in CPC1	€3,964 (3,242-4,798)	Gillespie 2010[180] Sanders 2005[181]
Annual cost of medical care post-out-of-hospital cardiac arrest in CPC2	€3,964 (3,242-4,798)	
Annual cost of care (medical plus carer) post-out-of-hospital cardiac arrest in CPC3	€14,421 (8,220-23,772)	Gillespie 2010[180] Full time carers allowance[182]

Parameter	Mean value (95%CI)	Source
Cost of one hour of trainee time	€25 (23-28)	CSO average hourly labour costs(183)
Average productivity loss	€12,006 (10,236-14,021)	Productivity losses as a result of out-of-hospital cardiac arrest mortality and morbidity were based on average workforce participation and earnings in the out-of-hospital cardiac arrest cohort, taking account of the age-sex distribution of this group.(184)
Annual cost of AED database	€69,259 (56,786-83,872)	Annual running costs, including equipment (hardware, software, licensing, hosting and support, based on the Danish AED register and similar Irish systems) and staff(3)
Annual number of out-of-hospital cardiac arrests	1,810 (1,639-1,990)	Out-of-Hospital Cardiac Arrest Register
Number of trainees per AED	2 (1-3)	Assumption
VAT	23%	Standard VAT rate(185)

Abbreviations: CI – confidence interval; AED – automatic external defibrillator; PAD – public access defibrillation; ED – emergency department; DRG – diagnosis related group; OHCA – Out-of-hospital cardiac arrest; HIPE – Hospital in-Patient Enquiry database; CSO – Central Statistics Office.

5.4 Results of the economic analysis

The results of the comparison of each of the proposed public access defibrillation configurations compared with current practice (base case) are provided separately for effectiveness outcomes (survival to hospital discharge, neurologically intact survival [CPC1] and life years gained) and utility outcomes (quality-adjusted life years gained).

5.4.1 Out-of-hospital cardiac arrest survival

Predicted annual survival to hospital discharge and neurologically intact survival (CPC1) for the entire out-of-hospital cardiac arrest cohort for are shown in Tables 5.4 and 5.5, respectively for each of the modelled comparators

Table 5.4 Predicted annual survival to hospital discharge

Strategy	Absolute annual survival to hospital discharge n [95%CI] (%)	Relative annual increase in survival to hospital discharge compared to base case n (%)	Average cost per additional survivor to discharge (€)
Base case	109 [95-123] (6.0%)	-	-
PAD15%	111 [97-125] (6.2%)	2 (1.8)	412,031
PAD20%	111 [97-126] (6.2%)	2 (1.8)	624,149
PAD25%	113 [99-129] (6.3%)	5 (4.6)	601,687
PAD45%	117 [102-133] (6.5%)	8 (7.4)	754,459
PAD55%	118 [103-135] (6.5%)	9 (8.3)	852,274
Legislation	120 [104-138] (6.7%)	11 (10.1)	1,341,795

Table 5.5 Predicted annual neurologically intact (CPC1) survival

Strategy	Absolute annual neurologically intact discharges n [95%CI] (%)	Relative annual increase in neurologically intact discharges n (%)	Average cost per additional neurologically intact discharge (€)
Base case	81 [69-93] (4.5%)	-	-
PAD15%	82 [70-95] (4.6%)	2 (3)	520,496
PAD20%	82 [70-95] (4.6%)	2 (3)	793,638
PAD25%	84 [72-98] (4.7%)	4 (4.9)	764,203
PAD45%	87 [74-101] (4.8%)	6 (7.4)	961,518
PAD55%	88 [74-103] (4.9%)	7 (8.6)	1,088,838
Legislation	89 [75-105] (5.0%)	9 (11.1)	1,744,159

5.4.2 Life years gained (LYG)

Figure 5.2 shows where each comparator lies on the cost-effectiveness plane when outcomes are measured in life years gained (LYG). No strategy is strictly dominated (less effective and more costly than another strategy), but the PAD20% option is weakly dominated by some combination of PAD15% and PAD25%.

Figure 5.2 Cost-effectiveness plane (LYG)

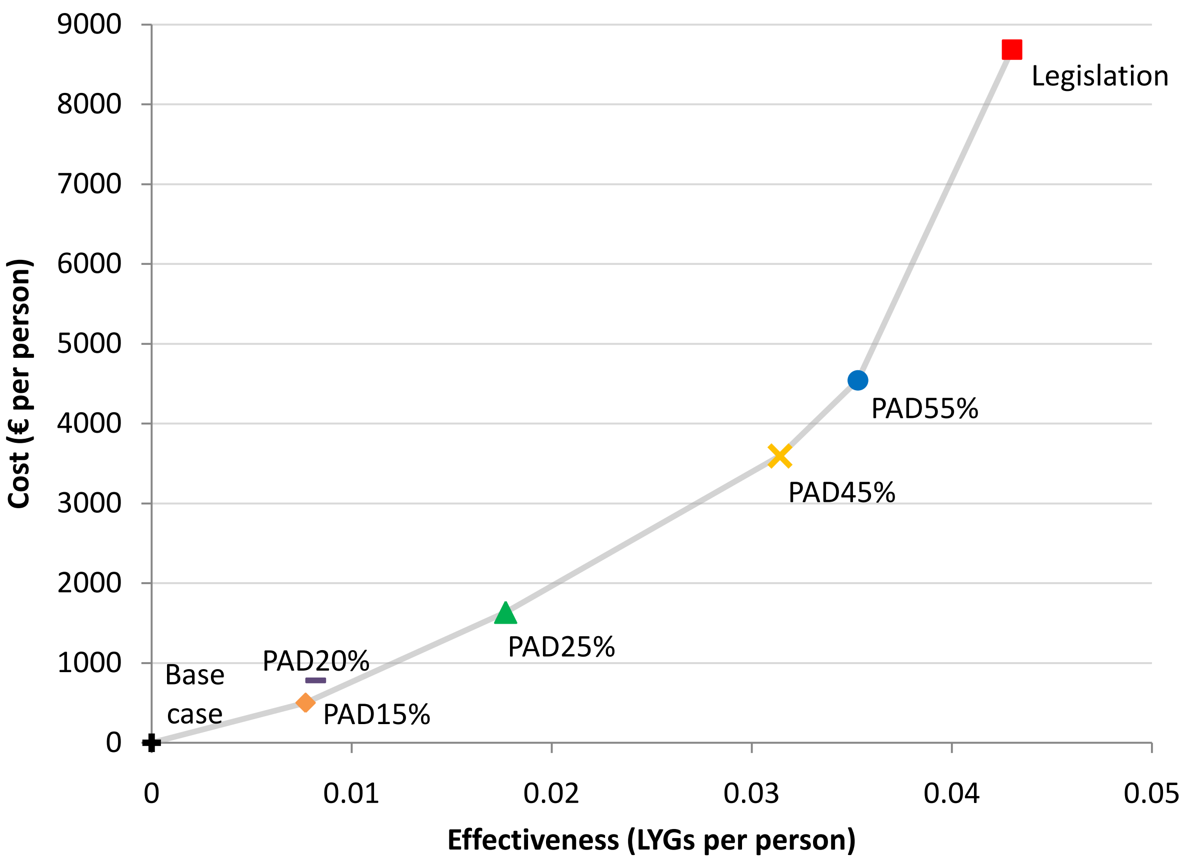


Table 5.6 shows the incremental cost-effectiveness ratios (ICERs) per LYG for each comparator relative to the next best option, excluding dominated strategies (PAD20%).

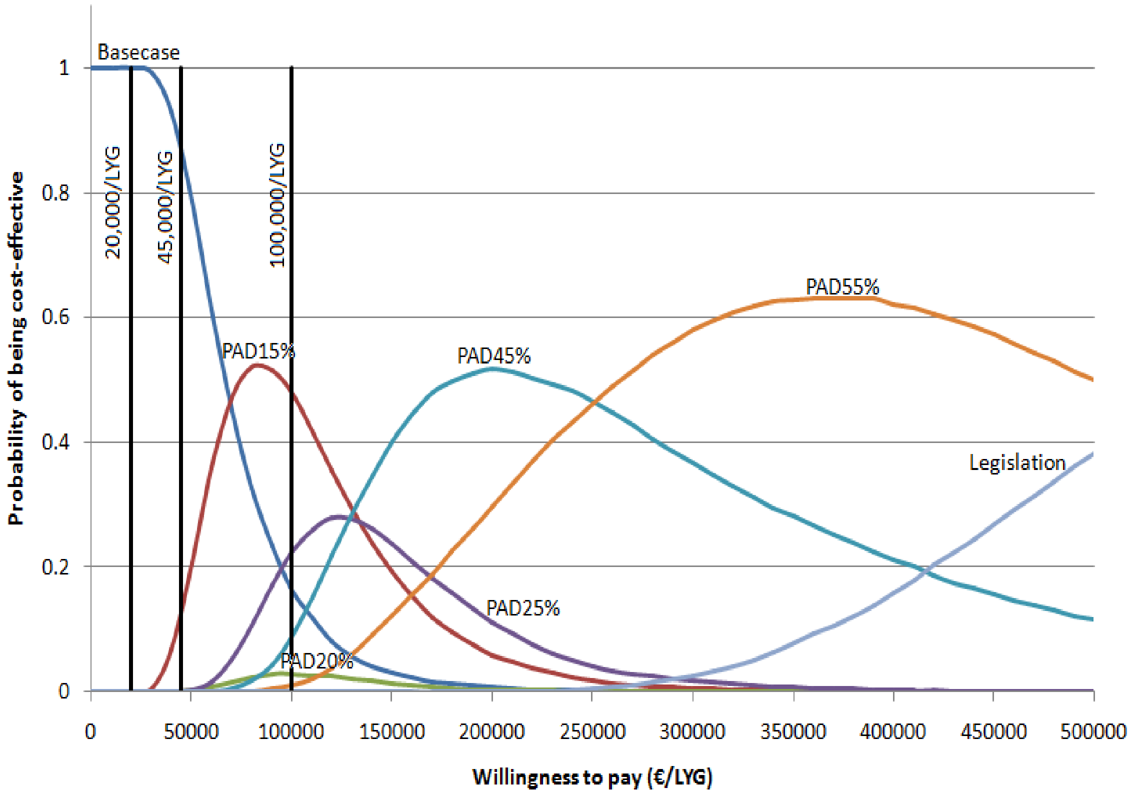
Table 5.6 Estimated incremental cost-effectiveness ratios (LYG)

Strategy	Cost (€)	Incremental Cost (€)	Effectiveness (LYG)	Incremental Effectiveness (LYG)	ICER (€/LYG)
Base case	17,039	-	0.4229	-	-
PAD15%	17,540	501	0.4306	0.0077	64,808
PAD25%	18,674	1,134	0.4406	0.0100	113,371
PAD45%	20,633	1,959	0.4543	0.0137	143,452
PAD55%	21,581	948	0.4581	0.0039	245,908
Legislation	25,724	4,142	0.4659	0.0077	534,893

The degree of uncertainty about the ICER for each intervention is examined using cost-effectiveness acceptability curves (CEAC). This shows the probability that any of the non-dominated public access defibrillation strategies is cost-effective for a given willingness to pay threshold (Figure 5.3). At a threshold of €45,000/LYG, PAD15% is the most cost-effective option in 14% of simulations and at a threshold of

€100,000/LYG it is the most cost-effective in 48% of simulations. The average cost-effectiveness ratio (ACER) for the proposed legislation compared to the base-case is €201,977/LYG.

Figure 5.3 Cost-effectiveness acceptability curve (LYG)



5.4.3 Quality-adjusted life years gained (QALYs)

Figure 5.4 shows where each comparator lies on the cost-effectiveness plane when outcomes are measured in quality-adjusted life years gained (QALYs). As with the LYG analysis, no strategy is strictly dominated (less effective and more costly than another strategy), but the PAD20% option is weakly dominated by some combination of PAD15% and PAD25%.

Figure 5.4 Cost-effectiveness plane (QALY)

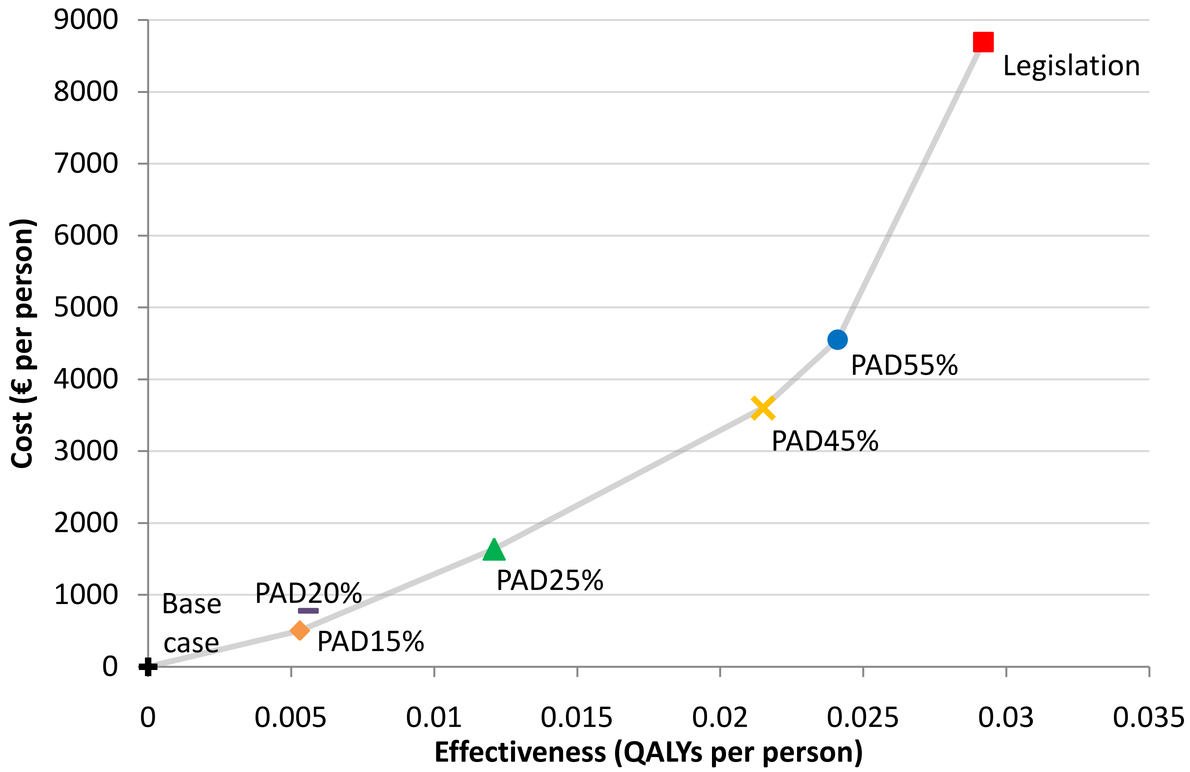


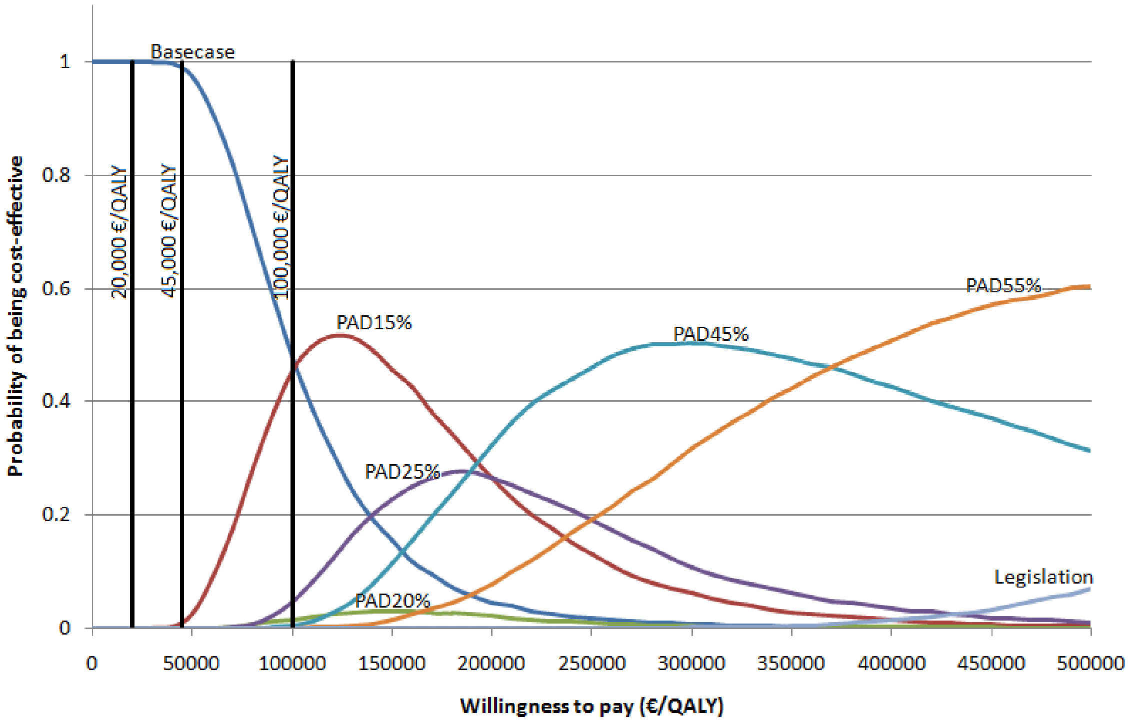
Table 5.7 shows the incremental cost-effectiveness ratios (ICERs) for each comparator relative to the next best option, excluding dominated strategies (PAD20%). The average-cost-effectiveness ratio (ACER) for the proposed legislation compared to the base-case is €297,705/QALY.

Table 5.7 Estimated incremental cost-effectiveness ratios (QALY)

Strategy	Cost (€)	Incremental Cost (€)	Effectiveness (QALY)	Incremental Effectiveness (QALY)	ICER (€/QALY)
Base case	17,039	-	0.2855	-	-
PAD15%	17,540	501	0.2908	0.0053	94,516
PAD25%	18,676	1,136	0.2976	0.0068	166,085
PAD45%	20,640	1,964	0.3069	0.0093	210,774
PAD55%	21,591	950	0.3095	0.0026	364,189
Legislation	25,732	4,141	0.3147	0.0051	805,619

The cost-effectiveness acceptability curves (CEAC) showing the probability that any of the non-dominated public access defibrillation strategies is cost-effective for a given willingness to pay threshold is shown in Figure 5.5. At a threshold of €45,000/QALY, PAD15% is the most cost-effective option in 2% of simulations and at a threshold of €100,000/QALY, it is the most cost-effective in 46% of simulations.

Figure 5.5 Cost-effectiveness acceptability curve (QALY)



As noted in Section 5.1.3, with the exception of a current agreement for pharmaceuticals,[104] there is no stated threshold in Ireland below which a technology is automatically considered cost-effective and reimbursed. Historically, for technologies evaluated from the perspective of the health services in Ireland, the probability of cost-effectiveness at thresholds of €20,000 and €45,000 per QALY have been reported, per national HTA guidelines.[174] In a cost-effectiveness analysis from a societal perspective, the threshold used should reflect how much society is prepared to pay for an additional QALY. Results of a secondary cost-utility analysis from the perspective of the publicly-funded health and social care system are provided in Appendix 6.

5.4.4 Budget impact analysis (BIA)

A budget impact analysis (BIA) was carried out to estimate the total cost of implementing each of the comparator public access defibrillation strategies over the first five years of the programme, given an average of 1,800 out-of-hospital cardiac arrests per annum. The budget impact was calculated separately for the public health service (HSE and DoH), the wider public sector, and the private sector. The public health service perspective includes the cost of installation, maintenance and staff training for all AEDs in designated places owned or operated by the HSE, the cost of setting up and running the national AED register and the costs associated with treating out-of-hospital cardiac arrest cases. The broader public service perspective includes all costs for the public health sector as well as those associated with AED installation, maintenance and staff training for all designated places owned by the state. It also includes the costs associated with funding the care of those with permanent neurological damage as a result of out-of-hospital cardiac arrest, through the full time carers allowance provided through the Department of Social Protection (see Table 5.8).

Table 5.8 Costs included in the budget impact analysis for the health service, the public sector (excluding health) and the private sector

Health Service	Public Sector (excluding health)	Private Sector
AEDs	AEDs	AEDs
AED signage	AED signage	AED signage
AED storage cabinet	AED storage cabinet	AED storage cabinet
Initial BLS/AED Training	Initial BLS/AED Training	Initial BLS/AED Training
Refresher BLS/AED Training	Refresher BLS/AED Training	Refresher BLS/AED Training
Replacement batteries and pads	Replacement batteries and pads	Replacement batteries and pads
Annual cost of AED Register	Social welfare payments in respect of full time carers allowance for out-of-hospital cardiac arrest survivors with significant neurological impairment	
Out-of-hospital cardiac arrest Treatment Costs		

In the BIA the costs are cumulative, so for example the costs in the second year include the costs associated with people who have an out-of-hospital cardiac arrest that year plus the cost of treating people who survived a cardiac arrest the previous year, and so on. It is assumed that all designated places purchase their AEDs in year one and the probability of having to replace the battery and pads, or retrain staff, is calculated using the same parameters that were used in the cost-effectiveness model (see Appendix 5). The model calculates the proportion of costs that occur in each year, over the course of the five year time horizon. The costs of existing AEDs that are already in place are not included in the BIA. Therefore the only health system costs in the BIA of the base case are treatment costs associated with out-of-hospital cardiac arrest and the only additional costs in the BIA from the public sector perspective are social welfare costs associated with home care provision.

The total and incremental five year budget impact for the health service, the public sector and the private sector for each of the modelled comparators are shown in Figures 5.6 and 5.7, respectively. The total five year budget impact includes the existing cost of treating out-of-hospital cardiac arrest patients and the incremental five year budget impact only includes additional costs associated with set-up and implementation as well as treating additional out-of-hospital cardiac arrest survivors.

Figure 5.6 Predicted total five-year budget impact (out-of-hospital cardiac arrest treatment and public access defibrillation setup costs)

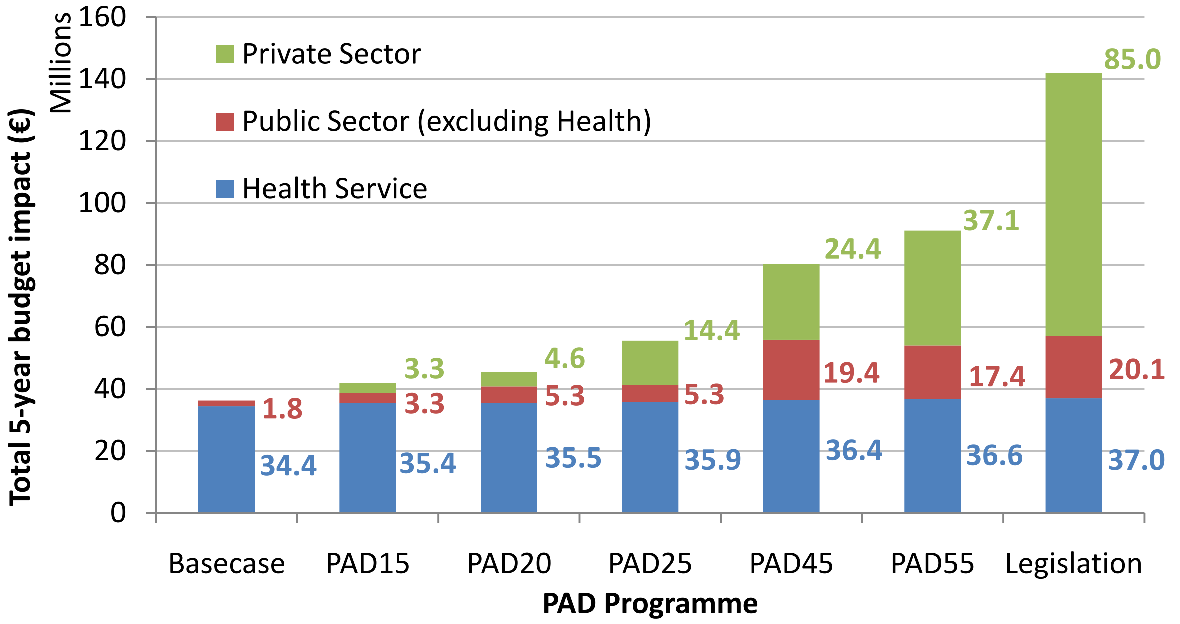
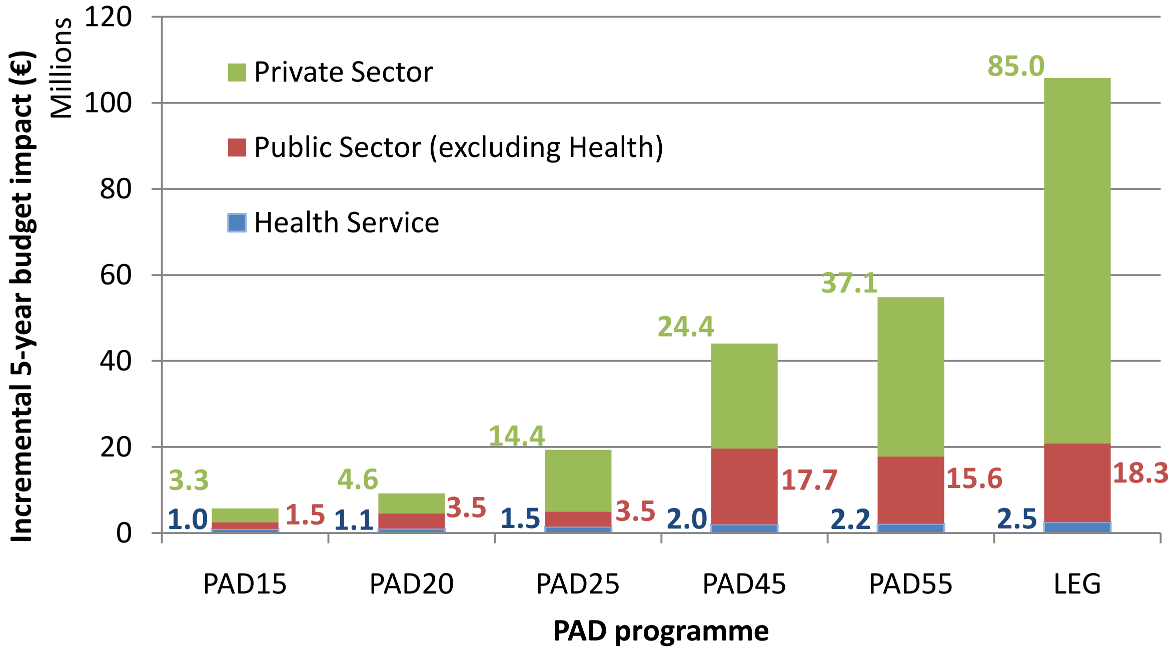
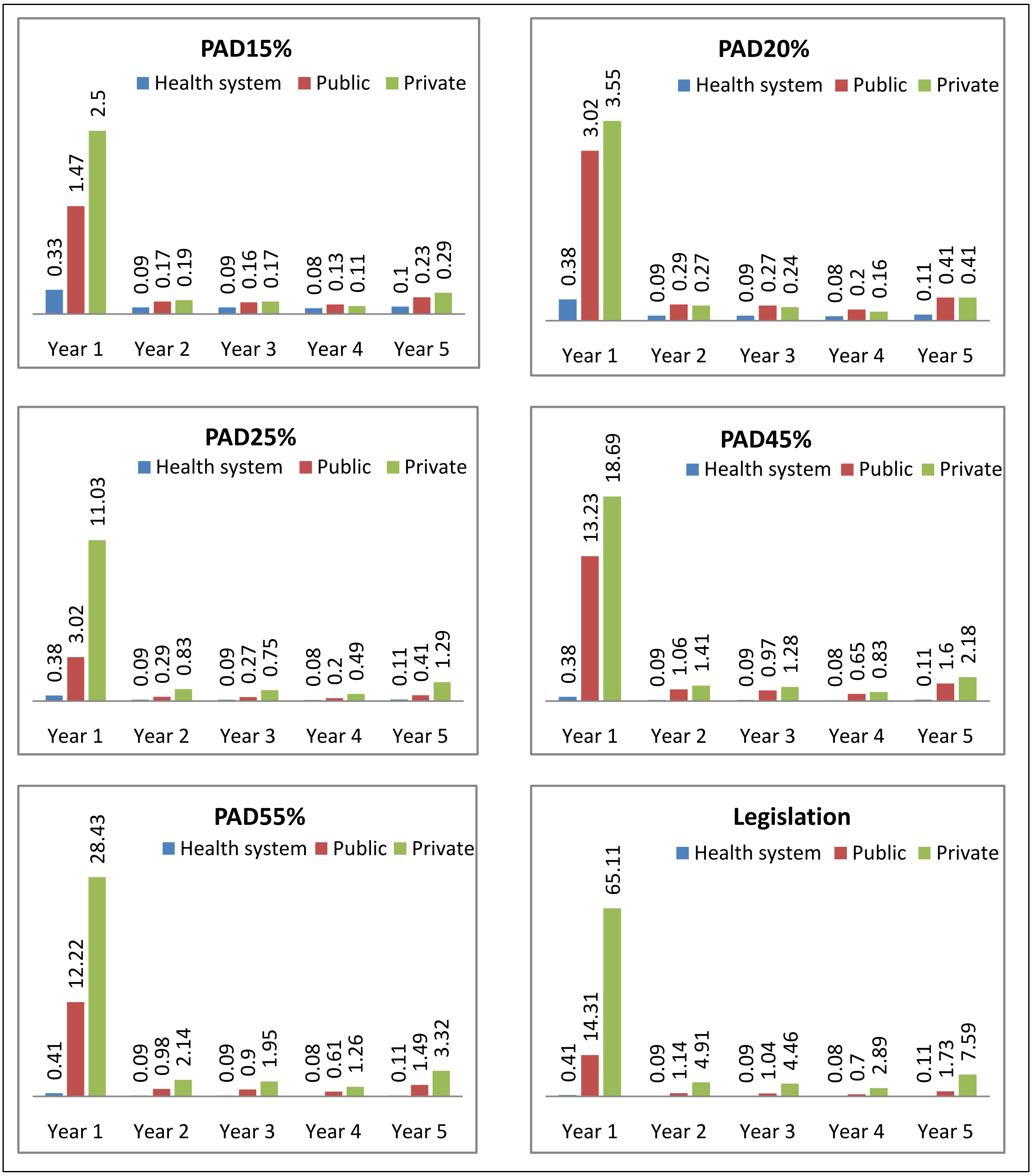


Figure 5.7 Predicted incremental five-year budget impact (out-of-hospital cardiac arrest treatment and public access defibrillation setup costs, in million €)



Disaggregated BIA results showing only the setup costs associated with each public access defibrillation strategy (that is, including costs of equipment, training, AED database) in each of the five years are shown in Figure 5.8.

Figure 5.8 Predicted programme set-up and implementation costs by year for the health system, total public sector (including Health) and the private sector over five years (in million €)



5.5 Sensitivity and scenario analyses

A number of sensitivity and scenario analyses were undertaken to determine how sensitive the results were to changes in parameter values and to estimate the cost-effectiveness given a range of different assumptions. A tornado diagram showing the most influential parameters in the deterministic sensitivity analysis of the strategy with the lowest ICER estimate in the cost-effectiveness analysis using QALY outcomes (PAD15%) is shown in Figure 5.9. Tornado plots for all ICER estimates are provided in Appendix 7. In the sensitivity analysis all costs and benefits were varied between their upper and lower plausible ranges (95% confidence intervals). These diagrams show the difference in the mean ICER estimate when each input parameters is varied. The parameters are shown in descending order of influence, providing a visual representation of those with the greatest impact on the ICER for a given strategy. Parameters at the lower end are less important, since uncertainty about the true value or potential future changes do not significantly affect the ICER estimate.

Deterministic sensitivity analysis was also carried out on the budget impact estimates of each of the strategies evaluated. BIA only examines the costs associated with each strategy, without taking account of the benefits. Sensitivity analysis in BIA helps to show what are the main drivers of the overall public access defibrillation programme costs and the extent to which costs are influenced by changes in each of the parameters. Tornado plots for set-up and maintenance costs from the perspective of the health system, the public sector and the private sector for the strategy with the lowest ICER (PAD15%) are shown in Figure 5.10. Tornado plots for all BIA analyses are provided in Appendix 8.

Figure 5.9 Sensitivity analysis of ICER estimate for PAD15% (QALY outcomes)

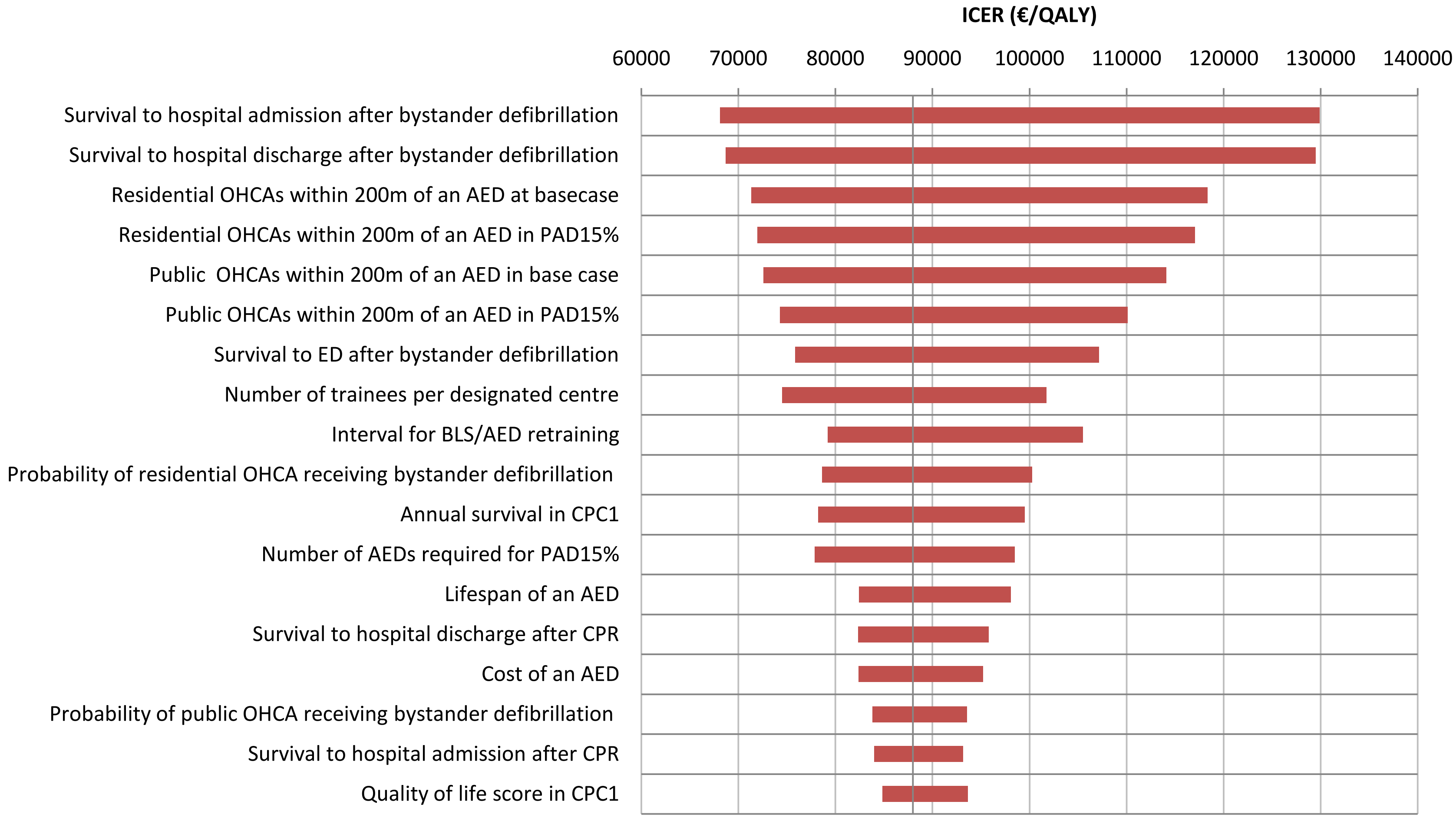
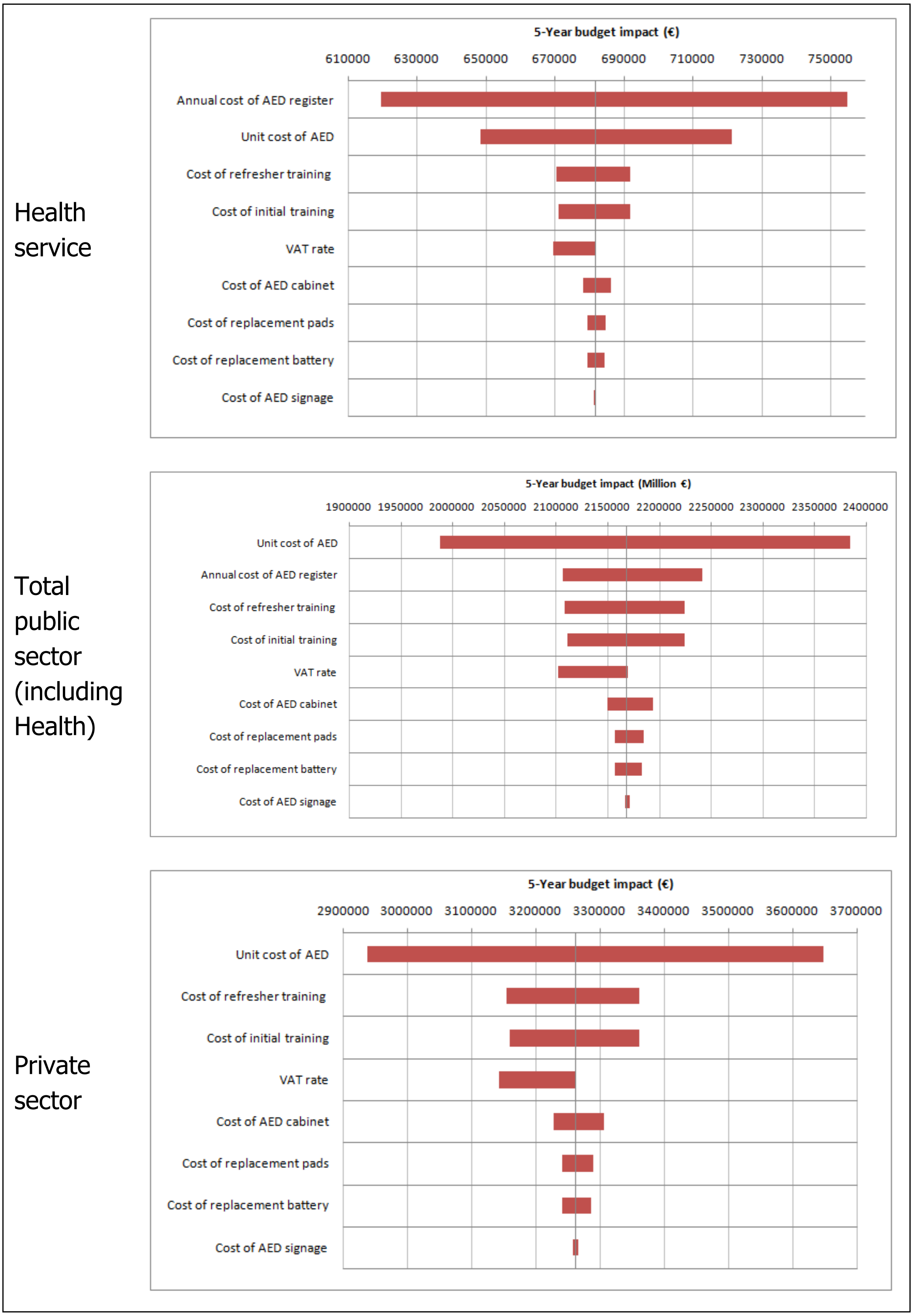


Figure 5.10 Sensitivity analysis of total cost of set-up and maintenance over five years for PAD15%



Scenario analysis allows decision makers to consider the likely costs and outcomes associated with alternative public access defibrillation programmes given potential future changes in a number of parameters. It is also a means of examining best and worst case scenarios for any given comparison.

In this analysis the impact of three possible scenarios are examined:

Scenario 1: International experience in implementing public access defibrillation programmes has shown that high-volume purchasing of AEDs has the potential to significantly decrease the unit price.[3] This is most likely to occur when there is a centralised purchaser who can negotiate with suppliers. Although this is not necessarily a feature of the proposed Irish public access defibrillation programme, it may be worth consideration if it has the potential to increase the overall cost-effectiveness of the intervention. For the purpose of this scenario analysis the unit price of an AED is reduced from approximately €1,190 to €490, exclusive of VAT.

Scenario 2: In the cost-effectiveness analysis the probability of someone receiving bystander defibrillation if they experience an out-of-hospital cardiac arrest within 200 metres of an AED is modelled using historical Irish data. The prospective national public access defibrillation programmes being evaluated include the setting up of an AED register that is linked to the emergency services. This has the potential to increase the number of people who are defibrillated by bystanders since anyone who reports a possible out-of-hospital cardiac arrest can be alerted to the presence of a nearby AED that they might otherwise have been unaware of. Bystander intervention may also be increased as a result of greater awareness of out-of-hospital cardiac arrest as a result of a national public access defibrillation initiative and an increase in the number of BLS/AED trained people. In this scenario analysis the impact of such a register is estimated by varying the overall relative risk of an out-of-hospital cardiac arrest within 200 metres of an AED being defibrillated by a bystander between 1.1 and 1.5 compared with the base case (giving a mean probability of between 0.35 and 0.47). The Authority also examined the effect of increased AED utilisation if the increase only applied to out-of-hospital cardiac arrests that occurred in a public location within 200 metres of an AED, leaving the likelihood of AED utilisation for out-of-hospital cardiac arrests in residential areas unchanged.

Scenario 3: The current VAT rate applied to the device and accessories is 23%. Community advocates and registered charities have lobbied for this to be reduced to 0%. A one-way sensitivity analysis was carried out to determine the effect on the budget impact of removing VAT from these items. Since VAT is excluded from the cost-effectiveness analysis on the basis of being a transfer cost that ultimately accrues to the state, this scenario has no impact on the CEA results.

5.5.1 Scenario 1: Reduced cost of AEDs

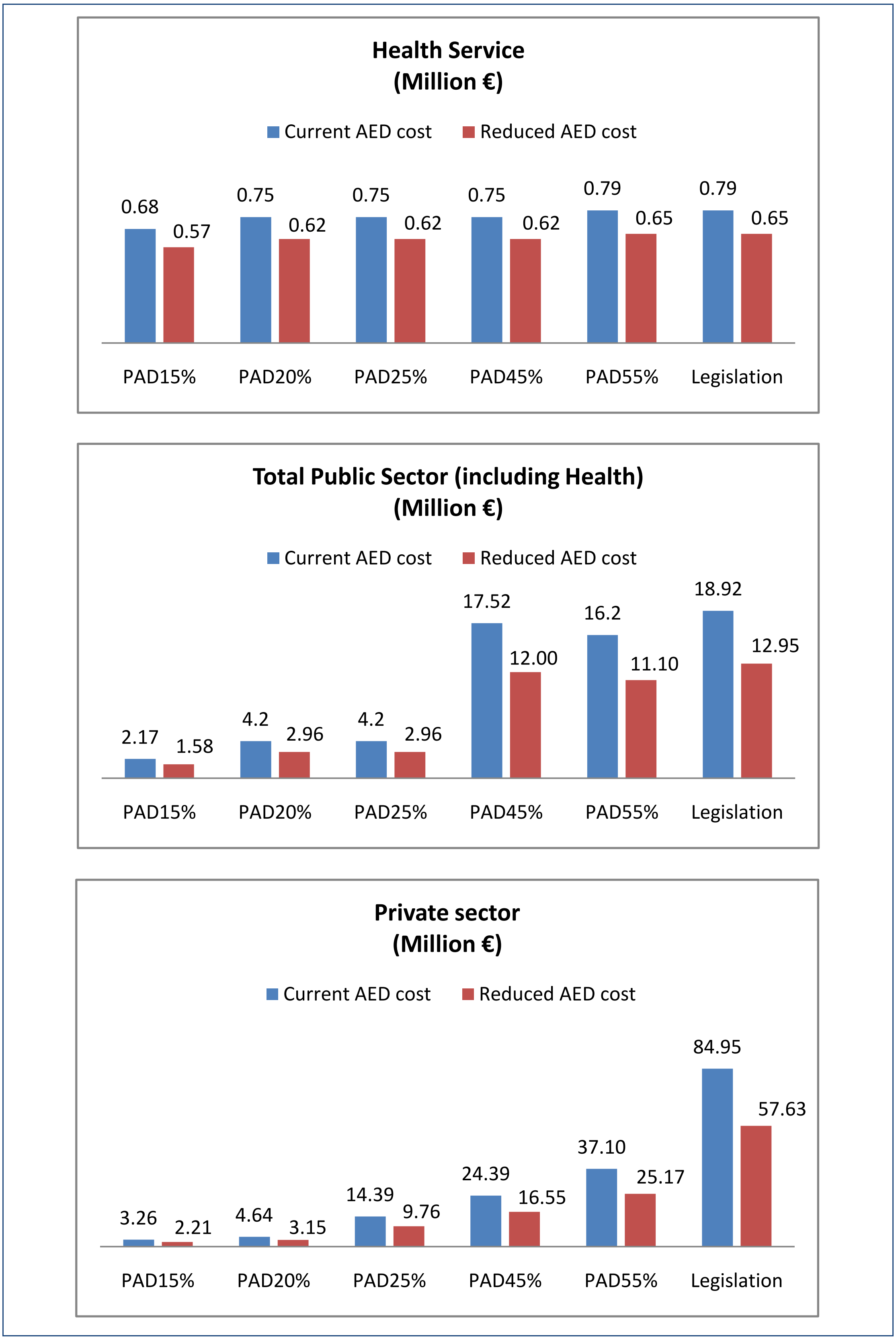
The ICERs for QALY outcomes for each of the non-dominated strategies in this scenario are shown in Table 5.9. The ICER estimate for the most cost-effective option (PAD15%) is reduced from around €95,000 to €70,000 per additional QALY.

Table 5.9 Estimated cost-effectiveness analysis results (ICER per QALY) given a substantial reduction in AED cost (Scenario 1)

Strategy	Cost (€)	Incremental Cost (€)	Effectiveness (QALY)	Incremental Effectiveness (QALY)	ICER (€/QALY)
Base case	17,036	-	0.2849	-	-
PAD15%	17,421	384	0.2904	0.0055	69,835
PAD25%	18,244	824	0.2970	0.0066	125,002
PAD45%	19,658	1,414	0.3062	0.0093	152,541
PAD55%	20,339	681	0.3088	0.0026	262,285
Legislation	23,295	2,956	0.3139	0.0051	576,366

The revised five years budget impact for setup and implementation for each comparator in this scenario is shown in Figure 5.11.

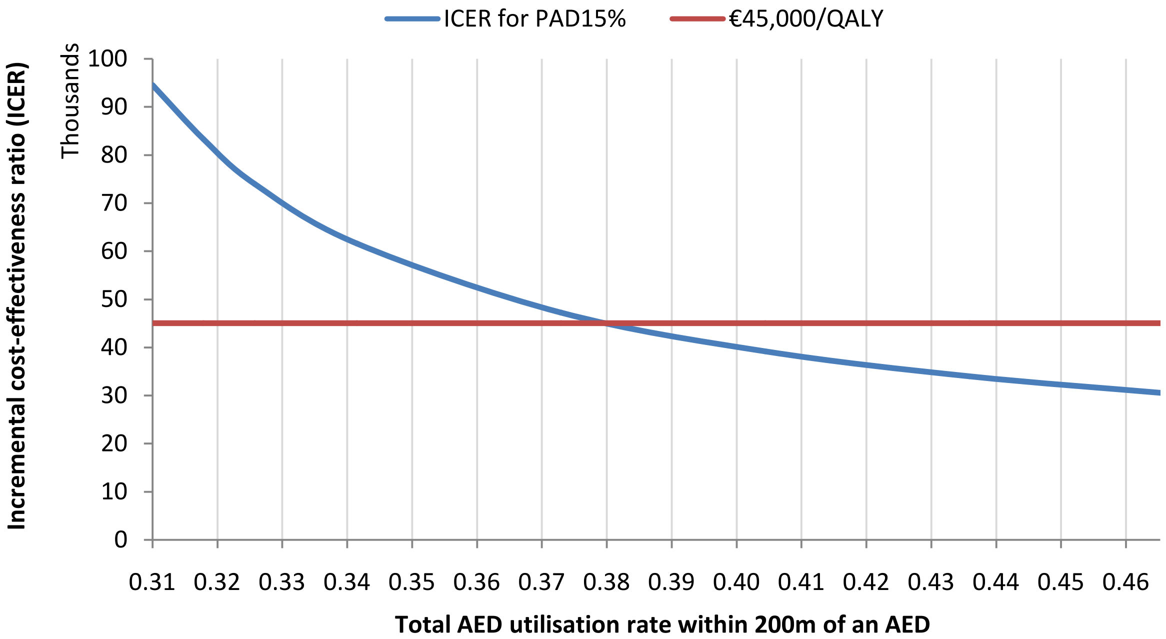
Figure 5.11 Five-year budget impact for public access defibrillation set-up and maintenance given a substantial reduction in AED cost (Scenario 1)



5.5.2 Scenario 2: Increased utilisation of AEDs in out-of-hospital cardiac arrests that occur within 200 metres of an AED

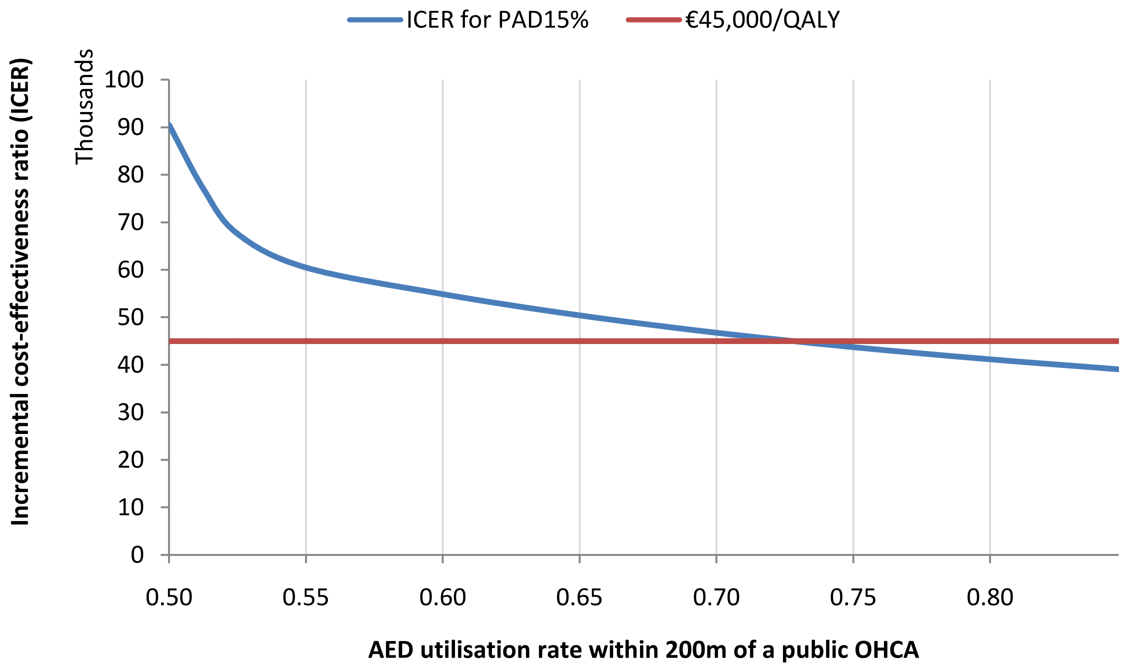
In this scenario PAD15% remains the most cost-effective option for all increases in AED utilisation rates, compared with the base case of existing (unregistered) AEDs. A threshold analysis showing the impact of increased overall utilisation (for out-of-hospital cardiac arrests in both public and residential locations) on the ICER for PAD15% is shown in Figure 5.12. This shows that to be cost-effective (that is for an ICER to approach a threshold of €45,000/QALY) an increase of at least 20% in the rate of AED use would be required for out-of-hospital cardiac arrests occurring within 200 metres of an AED.

Figure 5.12 Cost-effectiveness threshold analysis of increasing AED utilisation rates when an out-of-hospital cardiac arrest occurs in a public or residential area within 200 metres of an AED for the most cost-effective public access defibrillation programme (PAD15%)



Given the nature of public access defibrillation programmes, it could be argued that any increase in AED utilisation from having an emergency-medical-services-linked register and increased public awareness may apply to a greater extent in out-of-hospital cardiac arrests that occur in public, rather than residential, locations. Figure 5.13 shows the impact on the ICER calculation of increasing AED utilisation for out-of-hospital cardiac arrests that occur in a public area, assuming that the rate of AED use for out-of-hospital cardiac arrests in residential areas remains unchanged. This shows that an increase in excess of 45% in the rate of AED use would be required for public out-of-hospital cardiac arrests that occur within 200 metres of an AED for the ICER to approach a threshold of €45,000/QALY, assuming AED use in the vicinity of residential out-of-hospital cardiac arrests does not change.

Figure 5.13 Cost-effectiveness threshold analysis of increasing AED utilisation rates when an out-of-hospital cardiac arrest occurs in a public area within 200 metres of an AED, assuming no increase in AED utilisation for residential out-of-hospital cardiac arrests, for the most cost-effective public access defibrillation programme (PAD15%)



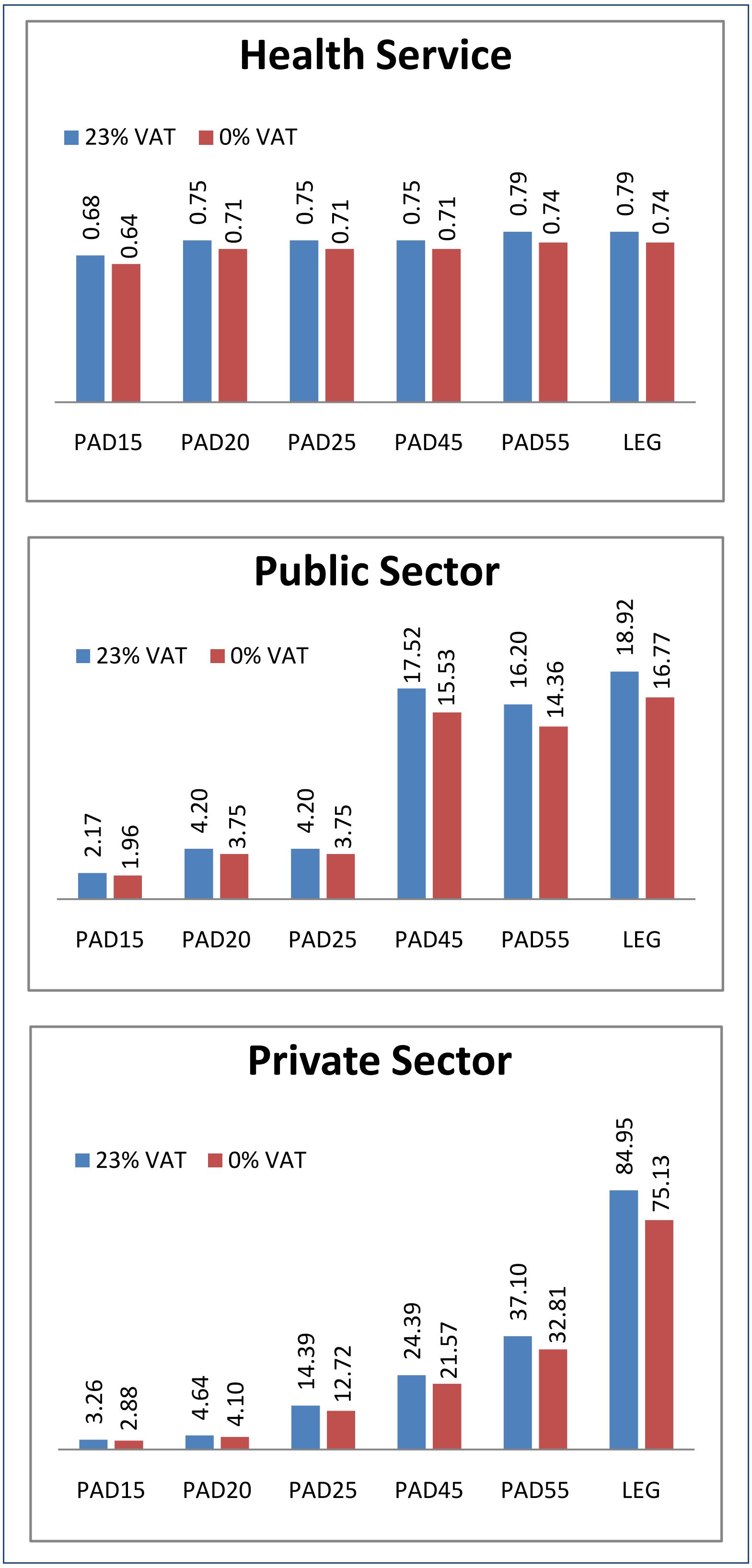
Interpretation of these results is constrained by the absence of evidence showing the impact a public access defibrillation programme involving CPR/AED training, an emergency-medical-services-linked AED register and increased public awareness of out-of-hospital cardiac arrest is likely to have on AED utilisation rates. A 2011 US study found that an emergency-medical-services-linked AED register has the potential to improve public AED usage prior to emergency medical services arrival.[186] This study examined the possibility of increased AED use when an emergency medical services dispatcher could alert callers to the presence of an AED within a 0.1 mile radius (160 metres). Over the course of the study, 22 of 763 out-of-hospital cardiac arrest cases had a public access AED applied prior to the arrival of emergency medical services in a layperson setting, while a further 59 occurred in the vicinity of an AED that could have been identified by a dispatcher with access to AED registry information when the call was received. Therefore over the course of the three year study, a linked system could have alerted an additional 7.7% (59/763) of all cases to the presence of a nearby device. However, it is unlikely that AED utilisation would ever reach 100%, since this would require the availability of a bystander who was able to retrieve and use the AED in all cases, combined with complete accessibility of all registered AED at all times. There are also major challenges in setting up the AED register itself, which is evident from the experience of those involved in developing the Irish AED register recommended in the 2006 report of the Sudden Cardiac Death Task Force.[1]

It is also important to note that this scenario analysis assumes full registration of all AEDs. While any prospective database should aim to identify as many existing AEDs as possible, the proposed legislation only stipulates that owners of designated places are required to register their device. Failure to register a large proportion of existing AEDs in any future emergency-medical-services-linked AED database may affect the applicability of the results of this scenario analysis, particularly for the more scaled down public access defibrillation configurations (PAD15% and PAD20%), where the proportion of existing AEDs in non-designated placed is highest.

5.5.3 Scenario 3: VAT rate on AEDs reduced to 0%

Since VAT is not included in the cost-effectiveness analysis this scenario will not result in any changes to the ICER estimates. The revised five years budget impact for setup and implementation for each comparator with VAT at 0% on AEDs and replacement parts (battery and pads) is shown in Figure 5.14.

Figure 5.14 Budget impact analysis for public access defibrillation set-up and maintenance with VAT at 0% on AEDs, batteries and pads (million €)



5.5.5 Implications for the number of AEDs required when adjusting for the proximity of designated places

There may be numerous instances of designated places being in neighbouring buildings. It can be argued that locating AEDs in neighbouring buildings may inflate costs without substantially changing the provision of AEDs. The Authority investigated the impact of allowing designated places within 50 metres of each other to share an AED. It was assumed that existing AEDs would not be removed, but rather that designated places not previously equipped with an AED could opt to share an AED with a neighbouring designated place. It was assumed that this would not change staff training requirements. The 50 metres cut-off was selected as it would have only a modest impact on the accessibility of the nearest AED. For example, if an out-of-hospital cardiac arrest occurred 200 metres from a designated place, the maximum distance travelled to get to an AED would be 250 metres. Table 5.10 shows the decrease in the number of AEDs required for each comparator in this scenario.

Table 5.10 Number of AEDs required when adjusted for proximity of 50 metres to another AED in each public access defibrillation configuration

Scenario	Number of additional AEDs required	
	Main model	AEDs not duplicated within 50 metres
Base case	0	0
Full legislation	38,419	27,257
PAD15%	1,877	1,758
PAD20%	3,148	2,751
PAD25%	6,775	5,902
PAD45%	15,346	13,594
PAD55%	19,591	17,342

The concept of sharing AEDs results in a modest cost reduction and hence reduction in the ICERs (strategies become more cost-effective), but it may also reduce accessibility. Unless neighbouring buildings have the same opening hours or the AED is mounted on an external wall, it is likely that sharing an AED will lead to a reduction in accessibility and availability. Currently in Ireland most owners opt to mount AEDs inside their premises. When an out-of-hospital cardiac arrest occurs in a building, it may be possible to mobilise trained staff relatively quickly to retrieve the AED and initiate resuscitation. If staff in a neighbouring building need to be alerted it is likely that time to defibrillation will increase and thereby lead to poorer outcomes. In some situations, sharing an AED between designated places may not adversely affect availability, but it could lead to complications in terms of responsibility for maintenance and replacement of equipment.

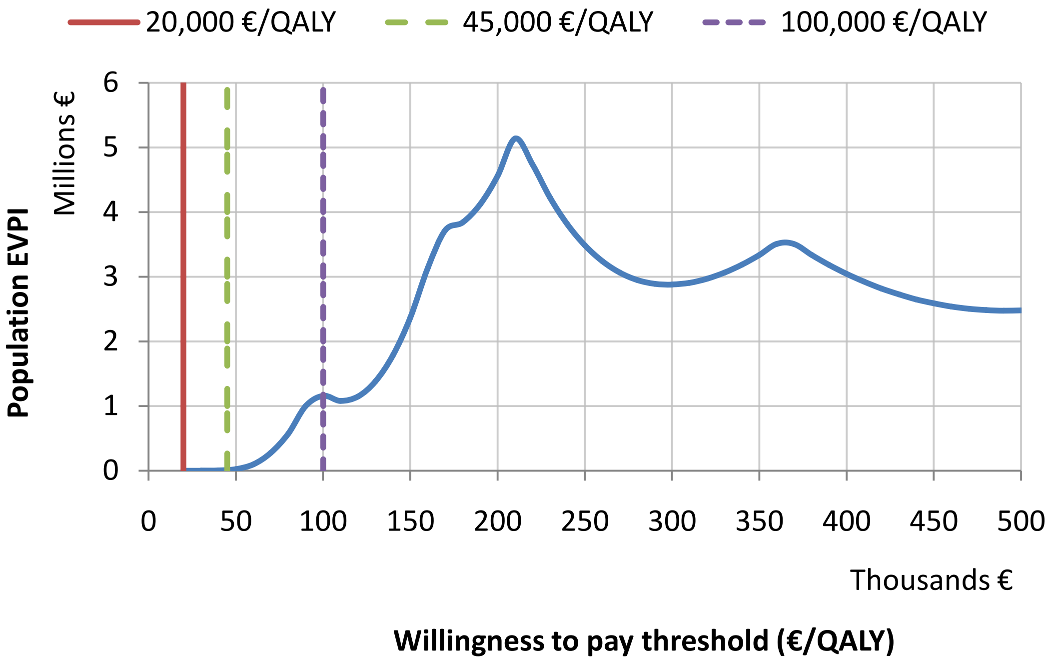
5.6 Expected value of perfect information (EVPI)

The results of the cost-effectiveness and sensitivity analyses show how the different public access defibrillation programmes compare to each other given the currently available evidence. Expected value of perfect information (EVPI) analysis provides a way to investigate the value of acquiring more evidence before deciding which public access defibrillation programme is the most cost-effective. It examines both the probability that a decision based on existing evidence will be wrong and the consequences of a wrong decision, and uses this to calculate the monetary value of acquiring perfect information, thus eliminating the possibility of taking the wrong option.[187] The results of this analysis provide an upper bound on the value of acquiring more information, since additional research would generally only inform a small subset of parameters and is unlikely to ever generate perfect information, so some level of uncertainty will remain.

EVPI analysis uses the data from the cost-effectiveness analysis to calculate the expected value of perfect information each time the decision is made for a patient. Therefore the overall EVPI for a decision maker taking a societal perspective is the combined EVPI for all patients who stand to benefit from the additional information over the lifetime of the technology. The value of additional information is low when there is little uncertainty about which option is the most cost-effective, since more information is unlikely to change the result. However, where there is a lot of uncertainty as to which comparator is the most cost-effective, the value of additional information increases. The analysis only shows the value of additional information for the comparators modelled in the analysis and does not provide any indication of the value of including alternative programmes, such as those based on location-specific out-of-hospital cardiac arrest incidence rather than out-of-hospital cardiac arrest incidence by building type.

In this analysis the EVPI was calculated over the course of ten years of a public access defibrillation programme, assuming an average annual incidence of 1,800 out-of-hospital cardiac arrests in Ireland. Figure 5.14 shows the EVPI curve for all public access defibrillation options modelled. From the CEAC for this analysis (Figure 5.5) it can be seen that there is little uncertainty that, at a willingness-to-pay threshold of less than €45,000 per QALY, the base case is the most cost-effective option. This is mirrored in the EVPI curve, which shows that the value of additional information below this threshold is negligible. As the threshold approaches €100,000/QALY, PAD15% begins to emerge as the most cost-effective option and the value of perfect information to inform decision making is approximately one million euro. The EVPI curve also has peaks at around €200,000/QALY, which is where the uncertainty regarding the choice between PAD25% and PAD45% is greatest, and again around €350,000/QALY, where the uncertainty regarding the choice between PAD45% and PAD55% is greatest. However, these threshold values are far in excess of the cost-effectiveness threshold values that have been reported in previous economic analyses in Ireland.

Figure 5.14 Population EVPI curve for all public access defibrillation options



5.7 Limitations of the economic model

There are important limitations associated with the economic analysis that need to be considered when interpreting the results. These can broadly be assigned to two categories: parameter uncertainty and model uncertainty. Parameter uncertainty arises where there is a lack of reliable data to inform model inputs, such as the clinical outcomes associated with bystander defibrillation or the costs of equipment. There can also be uncertainty related to parameter variability, since some parameters naturally vary over time even when measured accurately. Model uncertainty (also called structural uncertainty) stems from the choices made regarding the functional form of the model used to represent the real world. If the model fails to adequately capture the most important aspects of how public access defibrillation programmes would operate in reality, then there can be little expectation of an accurate result even if the true value of all input parameters were known.

5.7.1 Parameter uncertainty - availability, robustness and quality of available data

There is always a degree of uncertainty surrounding model parameters and standard methods to handle this have been used in the analysis. These include Monte Carlo simulation to quantify the level of confidence around the cost-effectiveness results, univariate deterministic sensitivity analysis to examine the effect of uncertainty associated with individual parameters and identify the principal drivers of cost-effectiveness, and scenario analysis to investigate the impact of potential major changes to key parameters. In this section, the strengths and weaknesses of the available Irish data on a number of key parameters are discussed further, along with the implications these may have for the model results.

In an ideal situation, data from high quality Irish studies showing the effect of different public access defibrillation programme configurations would be used to model cost-effectiveness. In the absence of these data, our model combined the likely number of out-of-hospital cardiac arrests that would occur within 200 metres of an AED with the probability of receiving bystander defibrillation to estimate the effect on survival and neurological status of survivors for a number of different public access defibrillation programmes. Using this approach the difference in outcomes between different public access defibrillation programmes is derived from differences in the number of out-of-hospital cardiac arrest patients who will receive bystander defibrillation, bystander CPR only or emergency medical services care as the first intervention. While the Authority believes this is the best available option for comparing the relative benefits of each of the comparators given the available data, it does have some important limitations. These are discussed below along with a list of the model parameters that are affected and the impact that any uncertainty in these parameters may have on the overall results of the cost-effectiveness analysis.

- **Uncertainty about the number and location of existing AEDs**
  There has been ad-hoc deployment of AEDs in public locations in Ireland. It is estimated that there are approximately 9,000 operational AEDs currently in circulation based on sales figures over the last number of years obtained from suppliers. About half of these are thought to be in locations that would be classified as designated places under the proposed legislation. It is also probable that existing AEDs are more likely to be placed in high incidence out-of-hospital cardiac arrest locations, such as airports and transport facilities, rather than being distributed evenly throughout all types of places specified in the bill, so there is a likelihood of decreasing marginal utility associated with expanding the coverage of AEDs into lower incidence locations. In the absence of a central AED register there remains considerable uncertainty about the number and location of functioning

AEDs that are accessible to the public. This is a major source of uncertainty in the economic model.

Parameters affected

1. Out-of-hospital cardiac arrests in a public location within 200 metres of an AED
2. Out-of-hospital cardiac arrests in a residential location within 200 metres on an AED
3. Probability of bystander AED intervention in a public out-of-hospital cardiac arrest within 200 metres of an AED
4. Probability of bystander AED intervention in a residential out-of-hospital cardiac arrest within 200 metres of an AED
5. Number of additional AEDs required for each public access defibrillation programme

All of these parameters featured prominently in the sensitivity analysis. The number of events in the vicinity of an AED combined with the probability that these will receive bystander AED intervention determines the number of people receiving public access defibrillation as a first response in each of the comparators. Therefore it is unsurprising that these parameters have a strong influence on the ICER estimate. In the analysis the Authority varied the assumed locations of existing AEDs and out-of-hospital cardiac arrest events to arrive at parameter distributions that reflect the high uncertainty associated with the data. In addition, the Authority carried out a detailed scenario analysis on the effect of varying the probability of bystander AED intervention on the overall results. Ultimately the best way to decrease the uncertainty relating to these important parameters is to establish a register of AEDs that provides high quality data on the location, accessibility, functional status and utilisation rates of publicly available AEDs and to combine this information with multiple years of national data on out-of-hospital cardiac arrest incidence from the Out-of-Hospital Cardiac Arrest Register.

- **Uncertainty about the type of first response**

The Irish Out-of-Hospital Cardiac Arrest Register is an invaluable resource that provides national data on the number and location of out-of-hospital cardiac arrest events, the type of response first received by patients and their subsequent clinical outcomes. For patients who received an AED intervention from someone other than uniformed response personnel (paramedic, fire-fighter or An Garda Síochána), it is not possible to identify with certainty the number that were bystanders who happened to witness the event and use an onsite AED or GPs or community first responders who were alerted and brought an AED to the scene. Basing survival outcomes on the type of first response involves an assumption that outcomes in these groups can be extrapolated in the comparators that involve many more AEDs.

There is a risk that different public access defibrillation programmes will result in AED coverage of areas that differ from the current areas in ways that could alter the outcomes associated with the type of first response.

Parameters affected

1. Survival to ED following bystander AED intervention
2. Survival to hospital admission following bystander AED intervention
3. Survival to hospital discharge following bystander AED intervention

The clinical outcomes of those who receive bystander AED intervention are among the most important drivers of the overall results of this economic analysis. Therefore the impact of any uncertainty in relation to these parameters requires careful consideration. The parameter values used in the economic model are based on a conservative interpretation of the o Out-of-Hospital Cardiac Arrest Register data, excluding any cases where there was reason to suspect that the AED was applied by someone other than a bystander. By using appropriately adjusted additional years of regional data from Out-of-Hospital Cardiac Arrest Register, the Authority was able to improve the precision of our parameter estimates. However, there remains a possibility that some cases may have involved GPs called to the scene or community first responders. The impact of this is not considered a major threat to the overall outcomes since there is no evidence to suggest that outcomes differ significantly between these two groups as long as the time to defibrillation is comparable. public access defibrillation schemes are designed to increase the proportion of patients who receive defibrillation prior to the arrival of emergency medical services and all those in the identified group fulfilled this criterion. Furthermore the sensitivity analysis showed that although there is a high degree of uncertainty in relation to these parameters, the intervention would not be considered cost-effective using conventional willingness to pay thresholds. Therefore although the level of parameter uncertainty is high, the risk that it will result in a wrong decision in low.

- **Lack of Irish data on health-related quality of life and long-term out-of-hospital cardiac arrest outcomes**
  No Irish data on quality of life for out-of-hospital cardiac arrest survivors by CPC category were available, so this was taken from international literature. Similarly, no data were available on long-term survival by CPC category in an Irish population, so this was also based on international studies. In an analysis using QALY outcomes, these two parameters (survival and quality of life) determine the entirety of the clinical benefit in the model, which is weighted against the overall cost to calculate the incremental cost-effectiveness of competing alternatives. Therefore any differences between Irish and international out-of-hospital cardiac arrest outcomes may have important implications for the analysis.

Parameters affected

1. Annual survival in CPC1/2/3
2. Quality of life in CPC1/2/3

The sensitivity analysis showed that these parameters were less influential in terms of the overall ICER estimates produced in the model. However, the upper and lower bounds are also derived from the international data, so they may not encompass the range of values possible in Ireland. There are no data to suggest that outcomes in Ireland vary so considerably from those published elsewhere that the overall results of the analysis would be affected. Nevertheless the use of data generated in the context of Irish out-of-hospital cardiac arrest studies would decrease the level of uncertainty in relation to the anticipated benefits of different national public access defibrillation programme configurations.

5.7.2 Model uncertainty and validation process

Uncertainty in relation to the structure of the model was dealt with by eliciting the input of the expert advisory group and other relevant people to describe the patient pathway at each stage of the process and comparing our approach with that of previous economic models of out-of-hospital cardiac arrest reported in the literature. The care pathway was developed in conjunction with experts in emergency medical services, public health, community first-responder programmes, emergency medicine, cardiology, health policy, health economics and patient advocacy. The model structure was peer reviewed by the expert group prior to finalisation and is consistent with modelling approaches adopted in previous cost-effectiveness studies identified in the literature review.

The approach adopted in this model involved deployment of AEDs based on building type (NACE code). It is possible that a more efficient distribution of AEDs may be possible using a deployment rule based on location-specific out-of-hospital cardiac arrest incidence. This would allow for differences in out-of-hospital cardiac arrest within building groups to be taken into account, if, say, a subset of sporting venues were associated with a higher out-of-hospital cardiac arrest incidence as a result of the demographic characteristics of attendees or greater footfall. Developing clear rules for the widespread implementation of such a system would pose challenges, however, and would require additional data on out-of-hospital cardiac arrest incidence, which is as yet unavailable.

5.7.3 Study perspective and willingness to pay thresholds

The question of perspective is clearly important in this analysis. The difference between the results of the analysis from the health service perspective (Appendix 6) compared with those that include costs to all sectors of society are marked. While including costs to all sectors provides a better estimate of the overall cost-effectiveness of the intervention, it is important to consider the implications of this approach when interpreting the results. Directly comparing the results with previous cost-effectiveness analyses would require an assumption that these additional costs fall within the same budget constraint as considered in previous analyses. If the ICER threshold is taken to represent the least cost-effective intervention funded in the context of a fixed health budget then this will not be true since the cost of most AEDs will fall outside of the healthcare budget. Interpreting the threshold in this way also requires a number of assumptions that do not hold in practice, such as the requirement for a known, fixed budget and complete information on all interventions funded.

An alternative definition of the threshold is that it reflects society's willingness to pay for a QALY. Using this interpretation, a decision maker taking a broader societal perspective can compare the overall cost-effectiveness of a public access defibrillation programme with a threshold that is consistent across all types of interventions, regardless of which budget the intervention costs fall under. This approach requires flexible budgets since all interventions that fall below the threshold should ideally be funded. It also requires that society's willingness to pay is known, or that appropriate ranges can be estimated based on previously funded interventions, which is questionable. Whether the results (that is the ICER) of an analysis conducted from a societal perspective can be compared with that of an analysis conducted from a limited (e.g. health service) perspective depends on the extent to which the included costs are comparable. When the health service bears the majority of the costs associated with health interventions, the limited perspective will approximate to the societal perspective. Where this is not the case, national HTA guidelines recommend that a broader perspective needs to be adopted (as in this instance).

Although the majority of costs associated with the various public access defibrillation programmes are included in the analysis, it does not capture the full economic cost of the intervention. This would require net monetary benefit to be calculated based on knowledge of the value in consumption of the net health benefits, the full economic costs (including all future health/social welfare costs and all productivity offsets both paid and voluntary) of out-of-hospital cardiac arrest survivors and the macroeconomic impact of costs on business. There is a high level of uncertainty in estimating these costs and their inclusion would not be expected to significantly affect the incremental differences between comparators, as these are primarily driven by the costs of programme set-up and maintenance, and the direct costs of out-of-hospital cardiac arrest treatment.

5.8 Interpretation of the results

Modelled public access defibrillation programmes range from those representing a relatively modest rise in the number of public AEDs (1,900 more for PAD15%) to those that would involve a very substantial increase compared with the existing situation (38,400 more for legislation). This is reflected in the projected absolute increase in survival for each programme, which ranges from an average of two extra lives saved per year for PAD15% and PAD20%, to 11 extra lives saved per year for the full legislation. The proportion of people with some degree of lasting neurological damage (CPC 2 or 3) is anticipated to remain the same across all strategies, although the absolute number will increase as a result of increased overall survival.

The choice of comparators was selected based on predicted out-of-hospital cardiac arrest incidence in different building types, with AED placement in the more scaled-down options being confined to those places with the highest likelihood of an out-of-hospital cardiac arrest event. Not surprisingly, the cost-effectiveness of successive options decreases (larger ICERs) as programmes are expanded to places with a lower incidence of out-of-hospital cardiac arrest, since a larger number of AEDs are required to gain one additional QALY. However, in the primary analysis even the ICER for the most cost-effective option (PAD15%) is not within the range of values that would ordinarily be considered cost-effective in Ireland. Taking into account the uncertainty associated with individual model parameters, the willingness-to-pay threshold for an additional QALY would have to be in the region of €100,000 for PAD15% to be more cost-effective than the base case.

The results of a value of information analysis for the modelled programmes found that, for the comparison between the base case and PAD15%, there was very little value in generating additional evidence to support decision making at a willingness-to-pay threshold of €45,000/QALY, whereas at a threshold of €100,000/QALY the upper bound on the societal value of generating additional evidence to inform the decision was approximately one million euro. A secondary analysis from the perspective of the health service showed that when only costs that fall on the publicly-funded health system are included, all of the comparators are cost-effective compared with the present situation, with the most cost-effective being the programme outlined in the draft legislation. This is potentially misleading as increasing public access defibrillation coverage shifts more of the setup and maintenance costs to the wider public and private sectors. Limiting the analysis to the perspective of the health service does not, therefore, provide a true reflection of the overall costs and benefits associated with a national public access defibrillation programme.

The results of the cost-effectiveness analysis are sensitive to changes in a number of key parameters that could potentially be affected by the introduction of a national public access defibrillation programme. International experience suggests that it may be possible to negotiate significant reductions in the unit cost of AEDs when they are being bought in large quantities, such as in a competitive tendering arrangement. A 60% reduction in the average cost of an AED would have the effect of reducing the lowest ICER estimate (PAD15%) to less than €70,000/QALY, with a 9% chance of being cost-effective at a willingness to pay threshold of €45,000/QALY.

There is a dearth of international data on bystander AED utilisation rates when an out-of-hospital cardiac arrest occurs in the vicinity of a publicly-available AED. While it is unlikely that 100% of out-of-hospital cardiac arrests occurring within 200 metres of an AED would have an AED applied by a bystander, it is plausible that some increase in AED utilisation could be achieved by having an emergency-medical-services-linked registry that would enable the emergency medical services to direct bystanders to a nearby AED. However, there is no firm basis for estimating the magnitude of any such increase in the context of an Irish public access defibrillation programme. A threshold analysis was carried out to examine the degree of change that would be required for the programme with the lowest ICER to be considered cost-effective using conventional willingness to pay thresholds. This analysis found that for out-of-hospital cardiac arrests occurring in public and residential areas within 200 metres of an AED, utilisation of an AED would need to increase by over 20% for the PAD15% ICER to approach a threshold of €45,000/QALY. If it was assumed that any increase would mainly apply to out-of-hospital cardiac arrests in a public locations (with no change in residential rates), then an increase in AED utilisation in excess of 45% would be required for the ICER for PAD15% to approach a threshold of €45,000/QALY.

The budget impact analysis was carried out separately for the health service, the state and the private sector, in order to quantify the costs falling on each group for each of the different public access defibrillation programmes. From the perspective of the health service the incremental cost of out-of-hospital cardiac arrest treatment is relatively small given the low out-of-hospital cardiac arrest survival rate, even with full implementation of the proposed legislation (five year incremental budget impact of €0.30 million to €1.72 million for PAD15% and legislation, respectively). Given the relatively few designated places operated by the health service, the incremental costs associated with set-up and maintenance of a public access defibrillation programme are also low compared with the overall public and private sectors (ranging from €0.68 million to €0.79 million over five years). In contrast, the five year incremental impact for the implementation of the most scaled down public access defibrillation option (PAD15%) for the public and private sectors were €2.17 million and €3.26 million, respectively, rising to approximately €18.92 million and €84.95 million for implementation of the full legislation. Sensitivity analysis showed that from the health system perspective the biggest driver of cost was maintaining a national AED register, while from the overall public and private sector perspective, the unit cost of AEDs was the most important parameter.

5.9 Summary

Depending on how extensively AEDs are deployed, the introduction of a national programme could potentially increase the relative survival rate from out-of-hospital cardiac arrest by 2% to 10% annually, at a total societal cost of between €6 million and €106 million over five years. A willingness to pay threshold exceeding €100,000 per QALY would be required for the public access defibrillation strategy with the lowest ICER (PAD15%) to be more cost-effective than the current situation involving ad-hoc deployment of AEDs on a voluntary basis. Therefore none of the public access defibrillation configurations assessed would be considered cost-effective using conventional willingness to pay thresholds.

This analysis is based on historical data on the probability of receiving bystander defibrillation within 200 metres of an AED. Significantly increased utilisation of AEDs as a result of a national emergency-medical-services-linked AED register and increased public awareness would render public access defibrillation programmes more cost-effective. It is likely that a targeted programme involving AED deployment in building types with the highest incidence of out-of-hospital cardiac arrest would be cost-effective if utilisation of AEDs in public areas could be increased by at least 45%. However, there is no evidence that such an increase in utilisation is achievable.

5.10 Key messages

- A review of the evidence on the cost-effectiveness of public access defibrillation identified a number of previous economic analyses reporting ICERs that would generally be considered to be within an acceptable range to support the introduction of public access defibrillation. However, the available literature is not sufficient to reliably estimate the cost-effectiveness of an Irish programme, or to compare the likely consequences of different public access defibrillation programme configurations.
- Public access defibrillation configurations modelled in this analysis include the programme outlined in the proposed legislation as well as five alternative programmes. In line with the legislation, all modelled programmes specify a list of designated places for AED deployment based on the type of business activity carried out at a given location or building.
- The base case comparator to which each of the modelled public access defibrillation strategies is being compared includes the voluntary deployment of approximately 4,500 existing AEDs in places identified as designated places under the proposed legislation. Therefore, a number of high incidence locations already have AEDs available and this analysis examines the incremental effect of implementing each strategy over and above that of the current situation.
- There is considerable uncertainty about the number and location of existing AEDs in Ireland and the current proportion of out-of-hospital cardiac arrest patients who have an AED applied by bystanders prior to the arrival of emergency medical services.
- The predicted average increase in the number of out-of-hospital cardiac arrest patients surviving to hospital discharge annually for each of the modelled strategies ranged from 1.8% (two additional people per year) for PAD15% and PAD20% to 10.1% (11 additional people per year) for legislation.
- The proportion of out-of-hospital cardiac arrest survivors with lasting neurological impairment is not anticipated to increase as a result of the introduction of any of the modelled public access defibrillation programmes, although the absolute number may increase as a result of improved overall survival.
- Results of a cost-effectiveness analysis from the societal perspective calculated an ICER of €94,516 per QALY for the most cost-effective public

access defibrillation strategy (PAD15%), which had a 47% chance of being cost-effective at a willingness-to-pay threshold of €100,000 per QALY.

- Value of information analysis for the modelled public access defibrillation programmes based on building type found little benefit associated with additional evidence generation given a willingness-to-pay threshold of €45,000 per QALY. The upper bound on the societal value of additional evidence to inform decision making at a threshold of €100,000 per QALY was approximately €1 million.
- The incremental five-year budget impact for the health service, the public sector and the private sector ranged from €0.99 million, €2.5 million and €3.26 million, respectively for PAD15% and from €2.51 million, €20.86 million and €84.95 million, respectively for the public access defibrillation programme outlined in the proposed legislation..
- Scenario analysis found that significantly increased utilisation of AEDs as a result of a national emergency-medical-services-linked AED register and increased public awareness could render public access defibrillation programmes more cost-effective. However, there is a lack of evidence that such an increase in utilisation is achievable.

6 Organisational and social implications

6.1 Introduction

This section provides a narrative review of the potential implications of a national public access defibrillation programme for the delivery of services within the health system and for society as a whole. The purpose of this review is to identify and discuss any broader issues relevant to the decision-making process, and to highlight potential changes to the organisation or delivery of services required to support the introduction of a national programme.

The methodology used in this analysis is described in the EUnetHTA core model.[188] A review of studies describing the experience of other countries in the implementation of public access defibrillation programmes was conducted alongside discussion by the evaluation team and the Expert Advisory Group to explore each of the domains included in the assessment.

6.2 Organisational implications of public access defibrillation

The analysis of the organisational implications of public access defibrillation programmes examines the likely impact on equipment and staffing, as well as changes to work processes, patient pathways and the coordination of activities across different organisations or sectors. Issues indentified as part of this analysis were grouped together under the following headings: health delivery process, structure of healthcare system, process-related costs, management, and culture.

6.2.1 Health delivery process

A national public access defibrillation programme is unlikely to be associated with a major restructuring of emergency medical services (emergency medical services) or hospital care pathways for patients. The purpose of a public access defibrillation programme is to facilitate and encourage an added intervention by bystander and other non-medical personnel rather than substitute one type of intervention for another. Therefore, public access defibrillation programmes are not associated with significant changes to existing emergency medical services and hospital services. Any changes in survival to hospital discharge may have implications for treatment costs, but the scale of these changes in relation to overall hospital activity is small (see Chapter 5: economic model predicts on average a maximum of 11 additional survivors per year nationally). The intervention will not affect the overall number of annual out-of-hospital cardiac arrest events.

The proposed legislation includes a provision for an emergency-medical-services-linked automated external defibrillator (AED) register, which will require dedicated resources to implement and maintain (see Chapter 5, estimated annual cost of staff and equipment is €70,000). The current legislation does not specify how this database should be funded or operated. The results of the decision analysis model (Chapter 5) highlighted the importance of increasing AED usage when an out-of-hospital cardiac arrest occurs in the vicinity of an AED Therefore the involvement of both designated places in registering AEDs and emergency medical services in integrating this information into their existing system will be crucial. An important element of the planning process for any potential public access defibrillation programme will therefore be deciding how an AED register will operate, who will be responsible for maintaining it, and how ongoing cooperation and communication between all the different parties involved will be facilitated.

Campaigns designed to increase public awareness of out-of-hospital cardiac arrest, bystander intervention (CPR/AED), and registration of AEDs may also be considered to coincide with the introduction of a public access defibrillation programme, or at a later stage. The costs of such a campaign were not included in the economic evaluation (Chapter 5), so it may impose additional resource demands on the health service beyond those reported in the economic evaluation if deemed necessary.

Implementation of a public access defibrillation programme would also require the mobilisation of many participants who would not ordinarily have a role in the provision of out-of-hospital cardiac arrest services. This includes the owners of designated premises, who would need to install and maintain AEDs, and also staff, who would need to volunteer for basic life support (BLS)/AED training, so they could intervene in the event of an out-of-hospital cardiac arrest. Though this would have relatively little impact on the health system itself, it does represent a significant change in the provision of out-of-hospital cardiac arrest services from the perspective of society in general.

Systems for ensuring proper education and training of staff in BLS/AED are already in place in Ireland. These include published standards and an accreditation system for training providers.[189] However, before the implementation of a prospective national public access defibrillation programme, the details of how the quality assurance and monitoring of a national public access defibrillation programme are going to be carried out will need to be developed.

6.2.2 Structure of healthcare system

Introduction of a new health technology may necessitate centralisation or decentralisation of associated services. For example, expensive technologies that require specialised staff to operate them can often only be provided in tertiary care units; this can make the technology more difficult to access. In contrast, public access defibrillation programmes are designed to promote diffusion of AEDs throughout the country that can be operated by anyone who witnesses a cardiac arrest. Therefore the intervention makes the technology more attainable, but the quality of the care provided by bystanders (particularly in relation to delivery of CPR) may vary. No significant safety risks were identified in the systematic review of the evidence (see chapter 4) and because it is an additional intervention, patients will still receive routine emergency medical services care.

An important issue in terms of patient's access to treatment is maintaining the accessibility of AEDs outside of normal business hours and at weekends. This has been identified as a major challenge in other countries that have implemented public access defibrillation programmes.[18;140] Given the importance of increasing AED usage, efforts to increase accessibility of AEDs should be considered in detail in the planning of a prospective Irish public access defibrillation scheme, such as the use of external storage cabinets to allow access outside of working hours and at weekends.

6.2.3 Process related costs

There are significant process-related costs associated with the delivery public access defibrillation programmes. These include the cost of infrastructure to provide up-to-date information on the location of functioning AEDs in a format that is accessible to emergency medical services dispatchers. As outlined earlier in this section, the cost of maintaining an AED register is estimated at €70,000 per annum. How this could potentially be implemented requires careful consideration, both in terms of ensuring an adequate supply of information from designated places, as well as handling and processing the data that are received.

Although the Bill makes reference to a register, it is not specified who will be responsible for establishing and maintaining the register. The Bill obliges the owners of designated places to provide information regarding the location of the AED and details of testing, maintenance, and usage of the AED. For such a register to contribute to improved outcomes, it must be linked to the emergency medical services so that dispatchers can alert callers to where the nearest AED is located, and whether it might be accessible at the time of the call.

Consideration should also be given to including AEDs in non-designated places in the register so that the potential for these devices to be used can be maximised. In the absence of relevant legislation, participation in the register would be voluntary which may give rise to difficulties in ensuring the quality of the registry data. Identifying the locations of AEDs is problematic and a variety of approaches have been used with varying degrees of success.[190;191] The Sudden Cardiac Death Task Force Report recommended the registration of all AEDs by both the vendor and purchaser, which would therefore include AEDs in both designated and non-designated places.[1]

The cost of owning and operating AEDs (device cost, training, replacement parts, etc) can be over €2,800 over five years for a designated place providing one AED and training two members of staff. When choosing which AED to purchase, the total cost over the lifetime of the device, including the cost of replacement parts and maintenance, needs to be considered instead of just the initial purchase price. International experience has shown that the unit price of AEDs may decrease substantially if purchased in large numbers through a competitive tender process.(3) The potential impact of this on the overall cost-effectiveness of the intervention is examined in Chapter 5. Whether any such cost reduction could be achieved in practice depends on a number of different factors. In a situation where all designated places are responsible for negotiating individual prices, such savings may not be achievable. However, centralised purchasing may not be feasible, depending on how the programme is organised and funded. Even if negotiations with suppliers were commenced, there is no guarantee these would lead to a significant reduction in price. The impact of varying the cost of an AED on the budget impact of the different public access defibrillation programmes is dealt with in more detail in the economic evaluation chapter (Chapter 5).

6.2.4 Management

Effective management of a public access defibrillation programme presents a number of challenges, including how to:

- plan how such a service will operate
- secure the resources needed to support designated places
- establish and maintain an AED register
- integrate the public access defibrillation programme with existing emergency medical services
- increase public awareness of the role of AEDs in improving survival from out-of-hospital cardiac arrest.

As with all public health programmes, it will be important to evaluate the impact of public access defibrillation on an ongoing basis to ensure that the programme is meeting its objectives and to identify whether changes are required to improve performance. Therefore an evaluation framework should be incorporated from the beginning, and included in the planning phase of any prospective national programme. Unlike some other technologies, once a national public access defibrillation programme is introduced there is no specific gate-keeper who decides who is eligible for treatment, so managing access to treatment is not a feature of the technology. However, additional information on the epidemiology of out-of-hospital cardiac arrest in Ireland or changes in the incidence profile of various locations may require changes to the list of designated places included in the public access defibrillation programme, in order to maximise the effectiveness of the intervention.

The national Out-of-Hospital Cardiac Arrest Register[192] has recently achieved national coverage, and data from coming years will be central to the evaluation of any prospective public access defibrillation programme.

6.2.5 Culture

Cultural considerations include the acceptability of the technology to the various stakeholders involved, and how the interests of each of these groups are taken into account in the planning and implementation of the technology.

Given the current high level of diffusion of AEDs in Ireland in the absence of a formal public access defibrillation programme, it is reasonable to assume that the technology is generally well accepted by patients and the organisations that would be involved in its implementation. The economic evaluation reported in Chapter 5 provides an estimate of the costs associated with the intervention for individual designated places and the combined costs from the perspective of the public health service, the public sector and the private sector. However, there are many issues as to how a prospective national public access defibrillation programme would operate in practice that would benefit from the input of stakeholders in all three of these areas. These include how registration of AEDs will be performed, who will be responsible for managing the AED register, the process in relation to the purchasing of AEDs and training services, and the methods for ensuring compliance, quality-assurance and ongoing monitoring.

6.3 Social implications of public access defibrillation

An important aspect of the introduction of any new technology is the impact it has beyond the immediate clinical event or setting where it is used. While the analysis of clinical outcomes is of the utmost importance, failure to consider the impact that the technology may have for patients in a wider context can exclude important information relevant to the overall decision. For example, some technologies can result in patients having to mobilise significant resources (people, support, money) before, during and after their use, while others may have important consequences in terms of ability to work, social relationships and attitudes of others towards users of a technology.[188] While the patient is typically the primary focus of this analysis, given the characteristics of public access defibrillation it is important to consider the implications of the technology at a number of levels, including that of designated places and society as a whole. Issues indentified as part of this analysis are grouped under the following headings: individual, major life areas, and information exchange.

6.3.1 Individual

Public access defibrillation programmes are a potentially life-saving technology for anyone who has an out-of-hospital cardiac arrest in the vicinity of a designated place. Though most survivors have good long-term outcomes, some will be left with permanent neurological deficits, seriously affecting their quality of life and imposing significant costs on them and their families and carers. The available evidence indicates that public access defibrillation is not associated with an increase in the proportion of out-of-hospital cardiac arrest survivors who are left with poor neurological function, but since overall survival increases, the absolute numbers of those with long-term neurological deficits is also anticipated to increase. Therefore, it is likely that if a national public access defibrillation programme is implemented, some patients who would otherwise have died from out-of-hospital cardiac arrest will instead survive with severe cerebral disability and will be dependent on others for daily support.

In general, the technology is positively received by patients and the public and is advocated by a range of patient groups and professional bodies.[23;85;193] However, challenges in raising awareness about the importance of early bystander intervention in out-of-hospital cardiac arrest remain, especially in relation to AED use, which has raised doubts about whether society is sufficiently prepared for its role in public access defibrillation.[86] The importance of increasing the likelihood that individuals witnessing an out-of-hospital cardiac arrest will intervene appropriately when an AED is available is a key factor in the success of public access defibrillation interventions. The implications for those who do intervene are also important, since a review of effectiveness and safety (Chapter 4) found that some may suffer adverse psychological consequences due to the traumatic nature of out-of-hospital cardiac arrest and the low survival rate.

A related issue is society's expectations regarding public access defibrillation. Any national public access defibrillation programme will require the collective efforts of large numbers of people that would not ordinarily be involved in the provision of a public health initiative. All participants should be informed of the magnitude of the expected benefit and how often individual AEDs are likely to be used, to help avoid unrealistic expectations about how the programme will perform in the years following implementation (see Chapter 5). Failure to do so may result in individual organisations questioning the rationale for continuing to invest significant time and money in maintaining AEDs that have never been used, or a lack of engagement among staff unable to see any benefit from continued voluntary participation in the programme.

6.3.2 Major life areas

For the individual out-of-hospital cardiac arrest patient, early application of an AED by a bystander is not associated with any significant implications for areas such as work or social relationships, beyond that of routine care. This is because early defibrillation increases the chances of survival without increasing the chances of long-term impairment. However, public access defibrillation may have significant implications for staff in designated places, who may feel under pressure from their employer to volunteer for BLS/AED training. Having been trained, they will then be expected to intervene in a medical emergency by initiating CPR and/or using the AED in an attempt to save the person's life. This responsibility may be perceived as an undue burden by some employees and impact negatively on their working environment.

Due to the nature of the intervention, densely populated areas containing a higher number of designated places will have more AEDs. This could be interpreted as preventing certain groups or individuals from participating in the programme, particularly those in rural parts of the country. These areas are also likely to have the longest ambulance response times, so it could be argued that it is more important to make AEDs available in low-density or rural areas. However, there is a lack of evidence showing a benefit of public access defibrillation in these locations, so equal application of a national programme in all areas would not necessarily prevent the emergence of inequalities between urban and rural out-of-hospital cardiac arrest settings. Alternative ways of improving out-of-hospital cardiac arrest survival should be considered in areas that are unlikely to benefit from a national public access defibrillation programme.

6.3.3 Information exchange

A level of knowledge and understanding of the technology already exists as a result of the diffusion of AEDs in a range of locations throughout Ireland. The AED devices themselves are designed to be user-friendly and easy to operate with minimal training. However, major challenges have been identified in increasing the overall levels of public awareness of out-of-hospital cardiac arrest and the use of AEDs to a level that will ensure that the benefits of public access defibrillation are realised.[86] Provisions in the proposed legislation requiring the training of staff in each designated place, along with the setting up of a national AED register that will be used to alert people to the presence of a nearby AED, should promote increased utilisation. Previous public access defibrillation schemes[10] have used targeted information campaigns to promote the use of public AEDs, which included regular public announcements, distribution of printed information materials, public training sessions and media reports.

Information exchange between the out-of-hospital cardiac arrest patient and the person intervening to apply the AED is also an important consideration in public access defibrillation programmes. Since the patient is unconscious at the time of arrest they are not in a position to provide consent, so there is a risk that people who do not want to receive treatment may get defibrillated against their wishes. This issue also has significant ethical and legal implications and is dealt with in Chapter 7.

6.4 Summary

Public access defibrillation programmes differ from the majority of public health interventions as responsibility for implementing the technology is not the sole preserve of the health service. Provision of AEDs and trained staff by a network of designated places across all sectors of society presents unique organisational challenges. Foremost among these is the need to establish a national register of available AEDs that is integrated with the existing emergency medical services infrastructure, as well as systems for monitoring the quality and performance of the programme. Decisions about how this will be achieved and who will assume responsibility for individual tasks should be taken in advance of implementing a national public access defibrillation programme.

Given the prior diffusion of AEDs in Ireland it is reasonable to assume that the technology is generally well accepted in Irish society. However, there is a need to focus attention on raising public awareness about the importance of CPR and early defibrillation in out-of-hospital cardiac arrest, since increasing bystander intervention and increased use of AEDs are key factors in the overall performance of public access defibrillation programmes. At the same time, it is important that realistic expectations are held by all those involved about the magnitude of the effect of public access defibrillation on out-of-hospital cardiac arrest survival and the likelihood of AEDs being used in any given location.

6.5 Key messages

- A national public access defibrillation programme would not require major reorganisation of the current emergency medical services and hospital care pathways for out-of-hospital cardiac arrest patients.
- An important element of the planning process will be deciding how an AED register will operate, who will be responsible for maintaining it and how ongoing communication between all the different parties involved will be facilitated.
- The details of how quality assurance and monitoring of a prospective national public access defibrillation programme will be carried out need to be developed prior to implementation.
- Efforts to increase the accessibility and utilisation of AEDs should be considered in the planning phase of a prospective national public access defibrillation programme along with measures for evaluating the performance of the programme.

- The placement of AEDs in public locations is generally well accepted in society and has received widespread support from patient groups and professional bodies.
- While the intervention is associated with better outcomes for individual out-of-hospital cardiac arrest patients, public access defibrillation may result in an increase in the absolute number of patients surviving with severe neurological impairment who are dependent on others for daily support.
- All participants should be made aware of the likely effect of the public access defibrillation programme on survival from out-of-hospital cardiac arrest and the probability of an AED being used in any given location.
- Staff in designated places should not feel pressured into participating in the programme if they do not feel comfortable with the prospect of intervening in a medical emergency to perform CPR and or defibrillation.
- Alternative ways of improving out-of-hospital cardiac arrest survival should be considered in areas that are not likely to benefit from a national public access defibrillation programme

7 Ethical and legal implications

7.1 Introduction

There are a number of ethical approaches that may be taken to health technology assessment (HTA) such as casuistry (solving cases by referring to paradigmatic cases for which an undisputed solution has already been found), coherence analysis (reflecting on the consistency of ethical arguments or theories without prescribing which arguments are prima facie relevant), interactive HTA (inter-subjective consensus on problematic issues reached through discourse involving relevant stakeholders), or principalism (analytical framework based on common moral principles shared in society). Principalism has recognised advantages in that it provides a comprehensive normative framework for ethical analysis rather than just a procedural approach.

The application of biomedical principles, in particular those developed by Beauchamp and Childress,(194) is the most popular approach to resolve ethical dilemmas arising from the use of technologies in general bioethical practice and in the few HTA evaluations that adopt an ethical perspective. The principles are comprised of four elements as follows:

- respect for autonomy (ensuring patient understanding, voluntariness, decision-making capacity)
- beneficence (balancing benefits and harm: risks/costs)
- non-maleficence (the minimisation of harm to others)
- justice (the fair distribution of benefits and burdens).

These principles are prima facie binding, meaning that they are always important in every situation but they are not absolute and may come into conflict with each other. The principles must always be viewed in the context of the specific matter under consideration and balanced with each other. Balancing principles can be challenging but it is worth considering that a principle should only be overridden if (i) better reasons can be provided for acting on an overriding principle, (ii) the infringement must be commensurate with achieving the primary goal, (iii) negative effects of the infringement are minimised, and (iv) the decision is reached impartially.

7.2 Application of ethical principles to a public access defibrillation programme

The aim of public access defibrillation is to reduce the time to defibrillation after an out-of-hospital cardiac arrest by making automatic external defibrillators (AEDs) available for use before the arrival of emergency personnel. The four principles approach outlined above can be applied in this context as follows:

7.2.1 Respect for autonomy

The word autonomy means self-rule, in other words making one's own deliberate decisions. In the medical context, respect for autonomy is of vital significance in relation to consulting with and informing patients about their healthcare and their choices. It requires doctors to obtain informed consent from patients before any treatment or intervention (except in cases of incapacity or medical emergency).[195] It also requires patient confidentiality to be maintained, appropriate behaviour to be practised and good communication methods to be used between patients and healthcare professionals.

In a hospital or other healthcare setting, although express consent is always preferable if possible, the defence of implied consent and/or the doctrine of necessity applies to protect healthcare professionals who provide medical treatment which is 'necessary to save life or limb' when it is not possible to seek consent from the person. These defences would apply to non-consented resuscitation in a healthcare setting as it would be justifiable to assume that a reasonable person would give their consent to resuscitation unless a Do Not Attempt Resuscitation Order (DNAR) or advance directive was known to exist for this person. Whether this would also apply to non-professional rescuers is considered below.

7.2.2 Beneficence and non-maleficence

The ultimate aim in healthcare is to produce net benefit over harm, while recognising that inevitably some risk of harm may exist when any medical intervention takes place. Beneficence is the traditional Hippocratic duty to prioritise patients' best interests, while non-maleficence is the duty not to cause harm or risk of harm to patients. These duties mean, for example, that those who treat patients must be appropriately qualified as otherwise the risk of causing harm becomes disproportionate. Healthcare professions therefore undertake to provide appropriate training and education to prospective and current practitioners to ensure adequate protection of patients.

Application of this principle in the context of public access defibrillation acknowledges that it would generally be considered to be in the best interests of the arrest victim to receive defibrillation. The benefits to be gained from a public access defibrillation system would include:

- potential benefit for the victim of arrest through rescue from imminent death
- benefit for the victim's family even if the use of the AED was unsuccessful and the outcome fatal in that they might draw comfort from knowing that everything possible was done
- benefit to the local community and the public at large in providing reassurance that AEDs are available in public places.

However, there must also be recognition that some bystanders who use AEDs in public places may not have any training or awareness of how to use them. Any risks that arise from this must be taken into account. These are considered below.

7.2.3 Justice

This is generally synonymous with fairness and may be described as the moral obligation to act on the basis of fair adjudication between competing claims. This may be divided into three categories of obligations: distributive justice which involves the fair distribution of resources; rights-based justice which involves respect for people's rights, and legal justice which involves respect for morally acceptable laws. There are many moral conflicts that can arise in this context, for example how to decide between equally deserving patients as to provision of a scarce resource. There are also issues in regard to the wider use of resources, conscious that payment must be made for those resources either by a private provider, an insurer or the State. In the context of a public health programme, this raises issues in relation to equity of access and the rationale or justification for selection of particular population groups.

The importance of saving lives and safeguarding health is something that is uncontroversial amongst policy-makers; however, the action to be taken in furtherance of good health at the expense of the State is a topic that has exercised many governments, activists, academics and medical practitioners alike. The legal and moral responsibility of the State to save life and prevent disease as well as promote good health amongst its citizens is the subject of longstanding debate.

In the context of health policy, such as considerations as to whether to introduce screening for disease, or the provision of a vaccine or in this case public access defibrillators, ethical principles must take account not only of the application of the principles to individuals but also the benefit, costs and risks to the public. Where the State decides to mandate a public health initiative, an argument may be made that the imposition of costs on owners of private premises to fund such initiatives is disproportionate and unjust on the basis that responsibility for public health lies with the State. However, there are precedents for this in the smoking ban, health and safety legislation and other public health initiatives introduced in recent years which impose compliance costs on the private sector.

7.3 Legal issues

7.3.1 Consent

Two issues arise here: the first is whether consent must be obtained prior to resuscitation; the second is what to do in circumstances when resuscitation has been expressly refused.

Under Irish law the touching of another person without consent may be legally considered a battery. In a hospital or other healthcare setting, although express consent is always preferable if possible, the defence of implied consent and/or the doctrine of necessity applies to protect healthcare professionals who provide medical treatment which is 'necessary to save life or limb' when it is not possible to seek consent from the person. In the use of AEDs, no consent is usually obtained due to the emergency circumstances that pertain. Therefore the defence of implied consent and the doctrine of necessity would justify and render lawful unconsented resuscitation and other necessary treatment of an unconscious person as such treatment is considered to be in the person's best interests.

- Do the defences of implied consent and/or the doctrine of necessity apply to a non-professional rescuer or untrained bystander?

  Although it might be the case that a court would extend the application of these defences when the procedure is carried out by a non-professional rescuer or an untrained member of the public, the less well trained the rescuer the harder it might be to justify the application of the defence. For example, as pointed out by the Resuscitation Council in the UK,[196] it may be more difficult to argue that an unconscious person has given implied consent to an untrained person performing what is in effect a medical procedure, notwithstanding that the procedure may be straightforward, automated and mechanical. Similarly, it may be harder to argue that treatment by a layperson is in their best interests. The defence of necessity may be available to the non-professional rescuer, however, provided that he acts reasonably under the circumstances. It would not be reasonable for an unqualified layperson to act, for example, if a professional rescuer was present or arrived at the scene and offered to help.

  In the absence of case law on this point and given the simplicity of the AED and its reliability, although not obliged to do so, a layperson would probably be justified in using one in an emergency situation when a more qualified person is not available. It is unlikely that a rescuer would be expected to consider the best interests of a collapsed person in anything other than a superficial way governed by the belief that the great majority of victims of sudden cardiac death would wish to be resuscitated.

- What if the person does not wish to be resuscitated?

  The second issue relates to the risk that some people may be defibrillated against their wishes, either in a healthcare setting or in the community. For example, a Do Not Attempt Resuscitation Order may be contained in a hospital or nursing home patient record. Alternatively, the person may have stated in an advance directive that in the event of a cardiac death they do not wish to be resuscitated.

  From both an ethical and legal perspective, if the person's wishes are clearly obvious at the time of the arrest, those wishes should be respected. This might occur in advance of the person losing consciousness or where the person's wishes may be known to a family member present at the time of arrest. Although there are as yet no legislative provisions for advance healthcare plans or directives in Ireland, this is expected to be introduced shortly to give effect to the principle that the advance directive will be considered valid if the victim had the capacity to make the choice at the time it was made, s/he must have done so in knowledge of the consequences of what that decision would entail, and there must not be any reason to doubt that his/her decision is still valid.[197]

- If a person was resuscitated against his/her wishes, would liability ensue?

  Survivors of cardiac arrest may suffer long-term neurological damage and or loss of capacity. It is therefore possible that the person themselves, or his/her family acting on his/her behalf, might attempt to pursue a rescuer for damages on the grounds that the person had specifically refused resuscitation in advance and has been left worse off as a result of the intervention, arguing that it would have been preferable if they had died rather than been left brain-damaged for life.

  From an ethical perspective, the bystander is not in a position to assess the likelihood of such consequences within the minutes after arrest and no assumptions should be made about the potential quality of life of the arrest victim. Legally and as a matter of public policy, the type of argument mentioned above (known as a claim for 'wrongful life') would not be likely to succeed as Irish courts generally take the view that life is not a harm that ought to be compensated for.

  In addition to the common law position, the Civil Law (Miscellaneous Provisions) Act 2011 also provides that the so-called Good Samaritan who intervenes to provide assistance, including resuscitation, will not be liable in negligence for any act done in an emergency unless it was done in bad faith or with gross negligence. However, the Act does not mention liability for trespass to the person, that is battery, which is an action that might be taken in circumstances of resuscitation being applied despite a prior refusal. As mentioned above, although it is conceivable that an action might be initiated in circumstances where it was alleged that a battery took place which resulted in harmful consequences for the victim, in my opinion the courts would be likely to dismiss such an action as contrary to public policy, and consistent with the 2011 Act, unless there was evidence of any malevolent intent.

7.3.2 Duty of care and liability

It is important to note that the 2011 Act does not apply where person owes a duty of care to assist the victim. The existence of a duty of care depends on the relationship between the victim and the Good Samaritan. The general principle is that you should not harm those people to whom you owe a duty of care by your acts or omissions. In Ireland, a duty is generally owed to any person who can be classed as your neighbour, which involves issues of proximity, foreseeability and policy considerations. For example, a duty of care exists between doctor and patient, teacher and pupil, and manufacturer and consumer. The test for the establishment of a duty of care has evolved through case law and is generally understood to be based on three criteria:

- A relationship of 'proximity' must exist between the defendant and the claimant
- Harm must be a 'reasonably foreseeable' result of the defendant's conduct;
- It must be 'fair, just and reasonable' to impose liability

This means that if the court considered that a sufficiently proximate relationship existed between the victim of an arrest and the Good Samaritan for it to be foreseeable that harm might reasonably be incurred by the victim as a result of the Good Samaritan's conduct, the court might consider it fair and reasonable to impose a duty of care on the Good Samaritan. The standard of care to be provided under the duty imposed is context-specific.

A person who witnesses a situation in a public place where resuscitation might be required is generally under no obligation to assist, provided the situation was not caused by him. However, if that person does choose to intervene to give assistance he will assume a duty of care towards the individual concerned. At common law a duty of care means that the person who intervenes must exercise reasonable care towards the individual, as measured by the standard that ought to be expected of a person in his position. This means that the more qualified or trained the rescuer, the higher the standard of care that would be expected of him/her in the resuscitation attempt. If the resuscitation was carried out negligently with the result that the victim survived with neurological consequences and/or fractured ribs/ damaged organs, it is possible that a personal injury action might be taken. However, as mentioned above, the common law position has been mitigated by the Civil Law (Miscellaneous Provisions) Act 2011 which provides that the so-called Good Samaritan who intervenes to provide assistance, including resuscitation, will not be liable in negligence for any act done in an emergency unless it was done in bad faith or with gross negligence, or unless the bystander was under a duty of care to provide such assistance to the victim.

7.3.3 Public Health (Availability of Defibrillators) Bill

It is important to note that if the Public Health (Availability of Defibrillators) Bill is passed, the issue of civil liability is dealt with in sections 13 and 14 as follows:

Section 13 applies to exempt from 'civil liability for any harm or damage' the owner of a designated place where a defibrillator is made available and who acts in good faith with respect to its availability or use. The exemption will not apply where the person has acted with gross negligence, failed to properly maintain the defibrillator, or where the premises is a healthcare facility.

Other provisions in the Bill impose an obligation on the owner to ensure that the defibrillator is easily accessible and available (section 5); display signs about the location and use of the defibrillator (section 6); ensure that it is maintained and tested (section 7); provide training to employees (section 10).

The question might arise as to whether liability would be imposed where a defibrillator was available on the premises and was not used in relevant circumstances either due to, for example, (i) a fault in the machine, (ii) failure to maintain and test it according to manufacturer's instructions, or (iii) a reluctance by an employee or member of the public to intervene.

- (i) A fault in the machine might give rise to an action against the manufacturer of the defibrillator rather than the owner of the premises.
- (ii) A failure to properly maintain it might give rise to an action against the owner (this is specifically mentioned as not covered by the statutory exemption from liability in section 13).
- (iii) There is no statutory obligation imposed on any person to use the defibrillator as this would impose a duty to rescue which might be considered inconsistent with legal policy.

If the person does intervene to provide assistance and does so in good faith, voluntarily and without expectation of reward, section 14 exempts that person from liability in damages for injury or death caused by his/her acts or omissions while using or attempting to use the machine unless s/he acted with gross negligence. Gross negligence is a reckless, blatant and conscious disregard for the rights and/or safety of others. Although the Bill does not specify whether it applies to actions in negligence and battery, it states that the rescuer 'will not be liable in damages' which must be taken to mean both forms of action.

Although the Bill states that the person will not be liable in damages for omissions related to the use or attempted use of the defibrillator, as opposed to a failure to act/intervene at all, as mentioned above there is no statutory or common law duty on any person to intervene or rescue, so no liability would ensue in these circumstances.

The exemption from liability in the Bill applies to all defibrillators whether or not they were required to be installed under the legislation.

7.3.4 Comparison to fire extinguishers

Fire extinguishers are not a legal requirement but it is standard practice to provide them. I.S. 291 of 2002 published by the Nationals Standards Authority of Ireland sets down standards for installation, testing and maintenance of fire extinguishers. These regulations do not have the status of legislation therefore failure to comply does not result in prosecution. However, evidence of non-compliance would be taken into account by a court in any action for negligence. The installation of fire extinguishers may also be a requirement under insurance policies for business or public buildings and the failure to have fire extinguishers, escape routes and plans etc in place may similarly be taken into account by a court in a negligence action against the owner of the premises.

The Fire Services Act 1981 and 2003 provides in section 18(2) that it shall be the duty of every person having control over premises to which the section applies (includes similar premises to those described under the proposed Public Health (Availability of Defibrillators) Bill), to take all reasonable measures to guard against the outbreak of fire on such premises, and to ensure as far as is reasonably practicable the safety of persons on the premises in the event of an outbreak of fire.

Section 18(3) provides that it shall be the duty of every person, being on premises to which this section applies, to conduct himself in such a way as to ensure that as far as is reasonably practicable any person on the premises is not exposed to danger from fire as a consequence of any act of omission of his.

It is an offence not to comply with the duties in Section 18. As well as being an offence, it would also be a breach of statutory duties and highly relevant in a negligence action for damages. It appears from this section that subsection (2) imposes a duty on the owner/occupier of relevant premises to take all reasonable measures to prevent fire and if a fire occurs, to take all reasonably practicable steps to ensure the safety of people on the premises. This would arguably include using a fire extinguisher if one was available. Subsection (3) also imposes a further duty on 'every person' to conduct himself in such a way as to ensure as far as practicable that others are not exposed to danger as a result of his acts/omissions – this could also impose a duty to use a fire extinguisher if one were available. It is worth noting that there are no comparable duties imposed by the Public Health (Availability of Defibrillators) Bill to take all reasonable steps to ensure that a defibrillator is used in an emergency.

Duties are also imposed on employers under section 8 of the Safety, Health and Welfare at Work Act 2005, to ensure as far as reasonable practicable the safety, health and welfare at work of his/her employees by providing plans, procedures and measures for first-aid, fire-fighting and evacuation appropriate to the environment in question. The Act imposes a duty on employers to designate employees who are required to implement those plans, procedures and measures under section 8. The Health and Safety Authority (HSA) enforces compliance with this Act with respect to employers' responsibilities under section 8, including monitoring of fire plans and procedures, fire-fighting equipment, training logs etc. The Public Health (Availability of Defibrillators) Bill will impose a similar duty on the HSA to monitor compliance with the provisions of this Act. However, there is no comparable duty in the 2013 Bill for an employer to designate a named person who will have responsibility to use a defibrillator in an emergency.

6.5 Key messages

- It is normally the duty of the State rather than private citizens to protect public health. However, there are precedents for obliging private citizens to safeguard public health: the smoking ban; health and safety statutory duties; and other public health initiatives which impose compliance and financial obligations on occupiers of public premises.
- In the absence of explicit information that a victim has stated a wish not to be defibrillated, it would be considered reasonable for a rescuer or bystander to intervene to defibrillate the victim on the basis of implied consent and the doctrine of necessity.
- Where a victim has clearly stated a wish not to be defibrillated this wish should be respected. However, if the victim's wishes are not evident at the time of arrest and the victim is resuscitated, it is unlikely that liability would ensue as the courts have generally not entertained 'wrongful life' actions which compensate for life itself as a harmful consequence.
- The Civil Law (Miscellaneous Provisions) Act 2011 provides that a Good Samaritan who intervenes to provide resuscitation will not be liable in negligence for any act done in an emergency, unless it was done in bad faith or with gross negligence. This exemption does not apply where the

person owes a duty of care to assist the victim (for example, a medical doctor treating a patient).

- A person in a public place has no legal obligation to provide defibrillation or resuscitation to a victim of out-of-hospital cardiac arrest. If the person does intervene they then owe a common law duty of care to exercise reasonable care towards the victim. The more qualified the rescuer, the higher the standard of care that would be expected of them.
- The proposed Public Health (Availability of Defibrillators) Bill exempts the owner of a designated place where a defibrillator is made available from civil liability for any harm or damage as long as they have acted in good faith. The owner will not be exempt if they have acted with gross negligence, failed to properly maintain the defibrillator, or where the premises is a healthcare facility.

8 Summary and conclusion

Public access defibrillation programmes are designed to increase survival from out-of-hospital cardiac arrest by reducing the time from arrest to defibrillation. This is achieved by increasing the availability of AEDs that can be used prior to the arrival of emergency medical services. The aim of this health technology assessment (HTA) was to examine the clinical and cost-effectiveness of a national public access defibrillation programme in Ireland.

Approximately 1,800 emergency-medical-services-attended out-of-hospital cardiac arrests occur annually in Ireland. The mean age of patients is 69 years, while over 70% of cases occur at home. In 2012, the survival rate to hospital discharge in Ireland was 5.2%. Approximately 80% of survivors have good neurological outcomes and the average life-expectancy post-discharge is 10 years. Continued efforts by a number of groups to improve the level of bystander intervention in out-of-hospital cardiac arrest have achieved considerable success. Approximately one quarter of the population has received CPR training in the last five years and there are currently an estimated 8,000 to 10,000 functional AEDs located around the country, a level of diffusion comparable to some countries after the introduction of a formal public access defibrillation programme.

A number of different approaches to implementing public access defibrillation have been described in the literature. These can be broadly separated into three groups:

1. Programmes that involve the provision of static AEDs in public buildings and communal areas that are designed to be used opportunistically by anyone who witnesses an out-of-hospital cardiac arrest.
2. Equipping uniformed first responders, such as the police or fire-service, with AEDs and simultaneously dispatching them, along with emergency medical services, to suspected out-of-hospital cardiac arrest events.
3. Community first responder groups run by volunteers that provide AEDs to members who respond to any out-of-hospital cardiac arrest events that occur in the area. These community first responder groups may, or may not, be linked to emergency medical services dispatch systems.

A systematic review of the evidence found some evidence that uniformed first responder groups were associated with (non-statistically significant) improvements in survival of up to 4%, but there was a high risk of bias in the included studies. The best evidence for public access defibrillation came from a randomised controlled trial involving the deployment of static AEDs in public areas[96] that found a 9% increase in survival to discharge. In keeping with the proposed legislation, the comparators considered in this HTA were limited to public access defibrillation programmes involving static AED provision rather than those involving uniformed or community first responders.

There were important differences between the interventions described in the literature and a prospective national public access defibrillation programme that precluded the direct application of these results in an Irish setting. Instead, the expected impact of public access defibrillation in Ireland was modelled using Irish data on the incidence of out-of-hospital cardiac arrest, the number and location of designated places under different public access defibrillation configurations, and out-of-hospital cardiac arrest outcomes by type of first response (emergency medical services, bystander CPR and bystander defibrillation). This was combined with data on the costs associated with public access defibrillation implementation and out-of-hospital cardiac arrest treatment to compare the cost-effectiveness of different public access defibrillation programmes to the existing situation and each other.

This analysis modelled one year's cohort of out-of-hospital cardiac arrest patients to life expectancy. A decision-tree structure was used to model the current treatment pathway for out-of-hospital cardiac arrest patients from the initial arrest to hospital discharge. This was combined with a Markov component that captured the long-term outcomes categorised by patients' neurological status at discharge. The primary analysis was conducted from a societal perspective, so it included costs that fall on the health system as well as the wider public and private sectors. It also included productivity costs associated with out-of-hospital cardiac arrest morbidity and mortality. This differs from previous HTAs carried out by the Authority, which were carried out from the perspective of the publicly-funded health system. Given the nature of public access defibrillation and the degree to which costs are spread across society, taking a narrow perspective would not provide a true reflection of the overall cost-effectiveness and budget impact of the intervention. This is evident from a secondary analysis performed from the Health Service Executive (HSE) perspective, which found that by excluding costs that fall outside the health sector, there are effectively no constraints on the expansion of a public access defibrillation programme to more building types, despite ever decreasing incremental benefit.

The public access defibrillation programme proposed in the Public Health (Availability of Defibrillators) Bill[4] involves AED deployment in an extensive list of over 43,000 designated places. The Authority modelled the programme outlined in the Bill as well as five other potential public access defibrillation configurations. These comparators represent scaled back versions of the Bill based on a reduced number of designated building types where AEDs would need to be provided. The number of designated places in these comparators ranged from 3,300 to 23,000.

Based on the results of this analysis, public access defibrillation is expected to result in an average of between two and 11 additional out-of-hospital cardiac arrest patients surviving to hospital discharge annually, depending on which programme is implemented. However, none of the programmes would be considered cost-effective using conventional willingness-to-pay thresholds for a QALY (€45,000 per QALY). As expected, targeted public access defibrillation programmes that involve AED deployment in building types with the highest out-of-hospital cardiac arrest incidence are the most cost-effective, with the most scaled down option (PAD15%) having the lowest ICER (€95,000 per QALY). As the intervention is expanded to include more building types with a relatively lower out-of-hospital cardiac arrest incidence, the ICERs increase significantly (that is, the programmes become less cost-effective). The ICER for the programme outlined in the Bill compared to the next best option (PAD55%) is over €800,000 per QALY.

A scenario analysis was carried out to examine the potential impact of any future changes in the cost of AEDs. This found that a 60% reduction in cost would reduce the ICER for the most cost-effective option (PAD15%) to €70,000 per QALY. Of greater significance was a scenario analysis that examined the potential impact of increased utilisation of AED as a result of increased public awareness and an emergency-medical-services-linked AED register that could be used to direct callers to the nearest available AED in the event of a suspected out-of-hospital cardiac arrest. This analysis found that the AED utilisation for out-of-hospital cardiac arrests in public and residential areas that occur within 200 metres of a device would need to increase by over 20% for the PAD15% ICER to approach a threshold of €45,000 per QALY. If it was assumed that any increase would mainly apply to out-of-hospital cardiac arrests in a public locations (with no change in residential rates), then an increase in AED utilisation in excess of 45% would be required for the PAD15% ICER to approach a threshold of €45,000 per QALY. However, there is no firm basis to suggest that such an increase is plausible in the context of an Irish public access defibrillation programme.

Cost-effectiveness analysis is designed to assess the relative value of competing alternatives by comparing the costs and benefits of each. Budget impact analysis, on the other hand, only examines the costs associated with each intervention and is designed to address the question of affordability. Results of the budget impact analysis over a five-year time horizon were disaggregated to show the cost implications for the health service, the overall public sector and the private sector. Implementation of a public access defibrillation programme is associated with total incremental costs over five years ranging from €1 million to €2.5 million for the health service, €2.5 million to €20.8 million for the public sector (including health) and €3.3 million to €85 million for the private sector, depending on which public access defibrillation programme is implemented. The majority of these costs are incurred in the first year of the programme.

There are some important limitations with regard to the data that were used in this analysis that need to be considered when interpreting the results. Differences in clinical outcomes in the decision analysis model are based on the number of out-of-hospital cardiac arrest events that occur within 200 metres of an AED in each of the comparators. This is based on the single year of national data currently available from Out-of-Hospital Cardiac Arrest Register. The use of multiple years of data would provide greater certainty on the incidence of out-of-hospital cardiac arrest in different building types. There is also considerable uncertainty on the location of existing AEDs, which poses a greater risk in the analysis of public access defibrillation configurations involving fewer AED such as PAD15% and PAD20%, as the proportion of existing AEDs to additional required AEDs is highest.

Another source of uncertainty is the estimation of clinical outcomes by type of first response. The Out-of-Hospital Cardiac Arrest Register records the outcomes of those who received CPR or defibrillation before the arrival of emergency medical services. However, it is not possible to identify those who received an AED intervention from a bystander from those who may have been treated by a community first responder or general practitioner (GP). Though this is unlikely to seriously affect the overall estimate of the relative effect of different public access defibrillation programmes, more detailed data on bystander AED outcomes would increase the reliability of the results. In this analysis the Authority used the best available data to estimate each of these parameters and applied wide bounds on the range of possible values. A sensitivity analysis was used to investigate the impact of this uncertainty. This found that although the ICER values changed as a result of fixing each parameter at its upper and lower bound, these changes were not large enough to affect the ordering of the public access defibrillation programmes and did not decrease any of the ICERs to a level that would be considered cost-effective using conventional willingness-to-pay thresholds. Therefore, although there is a high degree of uncertainty for some important parameters, this is unlikely to affect the overall results in regard to the cost-effectiveness of different public access defibrillation programmes compared with the base case and each other.

The approach adopted in this model involved deployment of AEDs based on building type. It is possible that a more efficient distribution of AEDs may be possible using a deployment rule based on location-specific out-of-hospital cardiac arrest incidence. This would allow for differences in out-of-hospital cardiac arrest within building groups to be taken into account, if, say, a subset of sporting venues were associated with a higher out-of-hospital cardiac arrest incidence. Developing clear rules for the widespread implementation of such a system would pose challenges, however, and would require additional data on out-of-hospital cardiac arrest incidence, beyond the single year of the Out-of-Hospital Cardiac Arrest Register data currently available.

The introduction of a national public access defibrillation programme is not expected to have a major impact on the organisation of health services. Annual out-of-hospital cardiac arrest incidence will not be affected and the expected number of additional survivors per year would be relatively small in the context of overall service provision.

The placement of AEDs in public locations is well accepted in society, as evidenced by the high numbers of AEDs already in place throughout the country, and such interventions have received widespread support from patient organisations and professional bodies. There are, however, many important issues that remain to be decided prior to the implementation of a national public access defibrillation programme. These include deciding:

- how quality assurance and compliance will be achieved
- how the programme can maximise the accessibility of AEDs outside of normal working hours and at weekends
- how ongoing performance evaluation will be carried out, and
- how to ensure that adequate communication and support structures are provided to set up and maintain a national network of publicly accessible AEDs.

Another important factor is the creation of a centralised, emergency-medical-services-linked register of publicly accessible AEDs, which could be used by emergency medical services dispatchers to direct callers to the nearest AED. A recommendation contained in the 2006 report of the Task Force on Sudden Cardiac Death(1) to set up such a register in Ireland has not yet been implemented.(2) Previous efforts to register AEDs have encountered significant obstacles in identifying the location and functional status of existing AEDs and maintaining the participation of designated places to update this information on an ongoing basis.(3) The challenges in implementing a national register should not be underestimated and adequate planning and resources will be required for this to be successfully achieved. The availability of a national AED register, combined with additional years of national data on out-of-hospital cardiac arrest incidence from the Out-of-Hospital Cardiac Arrest Register, will be vital in the evaluation of a public access defibrillation programme and in informing decision making about potential changes that are required to increase the clinical and cost-effectiveness of any prospective programme.

The issue of informed consent is an important consideration in public access defibrillation, since the out-of-hospital cardiac arrest patient is unconscious at the time of arrest. If the victim’s wishes are not evident, it would generally be considered reasonable for a rescuer or bystander to intervene to defibrillate the victim on the basis of implied consent and the doctrine of necessity. There is no statutory obligation imposed on any person to use the defibrillator but if they do so, the Civil Law (Miscellaneous Provisions) Act 2011 provides that a Good Samaritan who intervenes to provide assistance, including resuscitation, will not be liable in negligence for any act done in an emergency unless it was done in bad faith or with gross negligence. The exemption from liability in the 2011 Act does not apply where the person owes a duty of care to assist the victim.

The imposition of public health obligations on private citizens is a matter for consideration as the duty to safeguard public health is generally imposed on the State rather than private citizens. However, there are precedents for such obligations in the smoking ban, health and safety statutory duties and other public health initiatives which impose compliance and financial obligations on occupiers of public premises. The proposed Public Health (Availability of Defibrillators) Bill provides an exemption to the owner of a designated place – where a defibrillator is made available – from civil liability for any harm or damage as long as they have acted in good faith. The exemption will not apply where the person has acted with gross negligence, failed to properly maintain the defibrillator or where the premises is a healthcare facility.

8.1 Conclusion

Public access defibrillation has the potential to further improve survival from out-of-hospital cardiac arrest in Ireland. However, in the context of an existing high rate of diffusion of AEDs in Ireland and large numbers of the population already trained in CPR, coupled with uncertainty regarding where cardiac arrests will occur and poor out-of-hospital cardiac arrest survival rates, a high number of additional AEDs are required to increase the number of people who survive to hospital discharge. Public access defibrillation is expected to result in an average of between two and 11 additional out-of-hospital cardiac arrest patients surviving to discharge annually depending on which programme is implemented. Budget impact analysis indicates that the total incremental cost of implementing public access defibrillation over a five-year time horizon ranges from €1 million to €2.5 million for the health service, €2.5 million to €20.8 million for the public sector (including health) and €3.3 million to €85 million for the private sector, depending on which public access defibrillation programme is implemented. The majority of these costs are incurred in the first year of the programme. The model of public access defibrillation outlined in the proposed legislation is associated with highest gains in survival and with the highest costs.

Ireland already has a high level of diffusion of AEDs on a voluntary basis, however, this system is not standardised, coordinated or linked to emergency medical services. Based on current data, none of the public access defibrillation programmes evaluated would be considered cost-effective using conventional willingness-to-pay thresholds. Significantly increased utilisation of AEDs as a result of a national emergency-medical-services-linked AED register and increased public awareness could render public access defibrillation programmes more cost-effective. It is likely that a targeted programme involving AED deployment in building types with the highest incidence of out-of-hospital cardiac arrest would be cost-effective if utilisation of AEDs in public areas could be increased by 45%. However, there is no evidence that such an increase in utilisation is achievable.

If a public access defibrillation programme is introduced in Ireland, it should be considered in conjunction with measures to increase the utilisation of publicly accessible AEDs, such as CPR/AED training, increased public awareness and an emergency-medical-services-linked AED register. Any prospective programme should start by targeting the mandatory deployment of AEDs to locations with the highest incidence of out-of-hospital cardiac arrest. It is possible that a more cost-effective distribution of AEDs could be achieved using a deployment rule based on location-specific incidence rather than building type. Multiple years of data from the Out-of-Hospital Cardiac Arrest Register over and above the single year data currently available would be required to increase certainty around the identification of such high-incidence locations. A process of performance evaluation and research should be incorporated from the outset to guide ongoing tailoring of the programme to maximise efficiency.

Appendix 1 – Current and proposed distribution of static Automated External Defibrillators (AEDs)

To accurately model the impact of a public access defibrillation programme, it is necessary to know the current and proposed distributions of static AEDs. Due to the specification of designated places in the Public Health (Availability of Defibrillators) Bill 2013,[4] the set of locations can be approximated using data from the GeoDirectory.[97] However, in the absence of any national database of static AEDs, there is no comprehensive guide as to where AEDs are placed at present.

As the standard approach to economic evaluation requires determining the incremental costs and benefits of competing alternatives, some estimate of the existing distribution of AEDs was required for the economic model. An alternative is to model a scenario of no AEDs, but this could give a false sense of the benefits of a public access defibrillation scheme relative to the existing placement of AEDs.

The European industrial activity classification (NACE Rev.2) codes were used to identify addresses in the GeoDirectory that best corresponded to the designated places set out in the Public Health Bill. A set of 32 economic activity types were identified which related to 43,089 address codes (Table A.1).

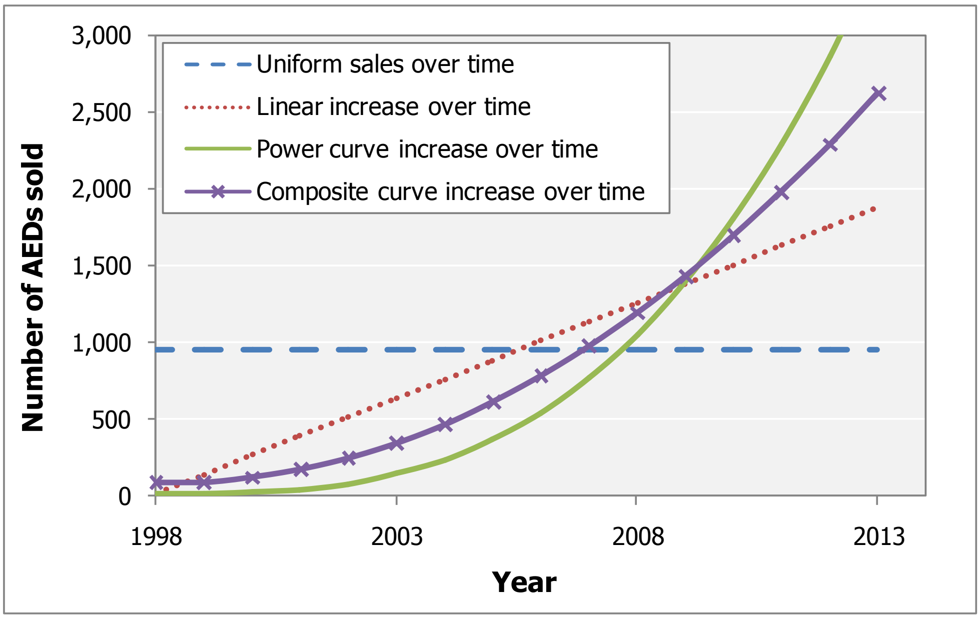
Number of AEDs at present

The Authority undertook an exercise to estimate the number of AEDs that are in Ireland at present, and are potentially available for use in a resuscitation attempt. Suppliers were contacted to determine the total number of sales over time, and when sales started.

The Authority found that, since 1998, and estimated 15,151 AEDs have been sold in Ireland. Some suppliers stated that they were resellers, so their sales were not included in the total. The number of suppliers has increased over time, although five suppliers accounted for over 95% of sales. The annual volume of sales has increased over time due to growing public awareness of AEDs, and reducing device cost.

To estimate the rate of increase of sales, the Authority tested three functions: a linear increase over time; a power curve increase over time; and a polynomial curve generated as a composite of the linear and power curves (Figure A.1). The uniform sales line is also included in Figure A.1 as a reference point.

Figure App1.1 Estimated increase in AED sales in Ireland over time (1998 - 2013



Based on discussion with suppliers, there were between 2,000 and 2,500 AED sales in 2013, which corresponds best with the composite curve. If it is assumed that AEDs have an average lifespan of eight years, then based on the composite curve there were 12,996 AEDs sold in the last eight years and therefore potentially still within their usable lifespan. Assuming a 10-year lifespan would increase the number of working AEDs to 14,082. However, it is known that not all AEDs are maintained and in working order. There are a variety of reasons why an AED may not be usable, including: the battery may no longer have any charge; the pads may have expired; the AED may no longer be in an accessible location.

One Irish study of sports clubs found that 76% were regularly maintained.[89] In the absence of other evidence around the maintenance of AEDs, the Authority has used this as a starting estimate of functional AEDs. Applying 76% to the estimated number of AEDs sold in the last eight years, there should be 9,877 maintained and functional AEDs in Ireland at present.

The applicability of the data for maintained AEDs is questionable. Amateur sports clubs around the country have purchased AEDs because of the highly publicised cases of sudden adult cardiac arrest in field sports. There may be a greater commitment to maintaining the AEDs because of the awareness of the potential benefits of early defibrillation. Equally, sports clubs often have numerous equipment and other costs competing for limited funds, and so may be less rigorous in maintaining their AEDs. Assuming the percentage maintained to be 60% and 70%, the estimated number of functional AEDs in Ireland at present is 7,798 and 9,097, respectively.

It can be assumed that for devices that have not been maintained, some proportion can be returned to a usable state by replacing the pads and battery, and having the device serviced. The Authority therefore conservatively estimates that there are between 8,000 and 9,000 potentially usable AEDs in Ireland at present.

Probability of a building having an AED

Under the assumption that some of these building types already have AEDs installed, it was necessary to estimate the probability of an AED being available at present (referred to as the base case scenario) for each building type. Using data from supplier websites, answers to parliamentary questions, and survey data, the Authority estimated the probability of an AED for each building type (Table A.1).

The plausibility of the assigned probabilities is difficult to assess, although it should be pointed out that the list of building types is comprehensive and yet the estimated total number of AEDs in these building types (4,670) represents between 52% and 58% of the functional AEDs distributed across the country.

Potential lower and upper bounds were set for the probability for each building type to account for uncertainty about the likely presence of an AED (Table A.1).

Evidence from client lists suggests a broad range of locations where AEDs are located including:

- government buildings
- sports clubs
- airports
- public transport stations
- Garda stations
- shopping centres
- hotels
- universities and colleges
- state and semi-state organisations
- car parks
- company buildings for a range of industries.

Based on the above client list, it could be assumed that the majority of AEDs sold to date are located in designated places under the proposed legislation. However, the client lists are perhaps biased towards larger organisations and may fail to mention the many small businesses or individuals who may have bought an AED.

The AEDs that are not in designated places as outlined in the legislation are assumed to be located across commercial buildings not defined in legislation. There are approximately 198,000 such commercial buildings in Ireland housing approximately 4,200 AEDs.

Table App1.1 Estimated probability at present of finding an AED by building type

Location description	Number of buildings	Probability of having an AED at present		
		Mean	Lower	Upper
Other non-designated places	197,734	0.02	0.00	0.02
Activities of religious organisations	4,412	0.02	0.00	0.03
Activities of sport clubs	2,616	0.10	0.03	0.18
Beverage serving activities	6,687	0.05	0.03	0.08
Botanical and zoological gardens and nature reserves activities	12	0.19	0.10	0.25
Creative, arts and entertainment activities	20	0.09	0.03	0.20
Dental practice activities	916	0.43	0.20	0.55
Fitness facilities	372	0.28	0.10	0.40
General medical practice activities	1,680	0.67	0.50	0.80
General public administration activities	1,422	0.30	0.01	0.40
Holiday and other short-stay accommodation	218	0.04	0.01	0.05
Hospital activities	52	0.88	0.80	0.99
Hotels and similar accommodation	987	0.05	0.00	0.08
Inland passenger water transport	2	0.48	0.00	1.00
Justice and judicial activities	776	0.27	0.05	0.50
Museums activities	374	0.17	0.01	0.25
Operation of arts facilities	84	0.17	0.01	0.25
Operation of historical sites and buildings and similar visitor attractions	241	0.17	0.01	0.25
Operation of sports facilities	634	0.33	0.15	0.40
Other accommodation	5,648	0.04	0.00	0.05
Other amusement and recreation activities	302	0.04	0.00	0.05
Other education	521	0.07	0.00	0.10
Other passenger land transport	215	0.25	0.10	0.40
Passenger air transport	11	0.93	0.90	1.00
Primary education	3,203	0.08	0.01	0.10
Public order and safety activities	44	0.23	0.10	0.40
Restaurants and mobile food service activities	6,067	0.04	0.00	0.05

Location description	Number of buildings	Probability of having an AED at present		
		Mean	Lower	Upper
Retail sale in non-specialised stores (predominantly food, beverages or tobacco)	3,765	0.04	0.00	0.05
Sea and coastal passenger water transport	35	0.62	0.20	0.80
Secondary education	664	0.08	0.01	0.10
Service activities incidental to land transportation	376	0.23	0.10	0.40
Technical and vocational secondary education	552	0.08	0.01	0.10
Tertiary education	181	0.08	0.01	0.10

Table App1.2 Number of designated places for each public access defibrillation scheme modelled in the economic evaluation

NACE code	Location description	Designated places						
		Base case	Legislation	PAD 15%	PAD 20%	PAD 25%	PAD 45%	PAD 55%
9491	Activities of religious organisations		✓					
9312	Activities of sport clubs		✓				✓	✓
5630	Beverage serving activities		✓					
9104	Botanical and zoological gardens and nature reserves activities		✓				✓	
9000	Creative, arts and entertainment activities		✓	✓			✓	✓
8623	Dental practice activities		✓		✓	✓	✓	✓
9313	Fitness facilities		✓	✓			✓	✓
8621	General medical practice activities		✓	✓	✓	✓	✓	✓
8411	General public administration activities		✓		✓	✓	✓	✓
5520	Holiday and other short-stay accommodation		✓					
8610	Hospital activities		✓	✓	✓	✓	✓	✓
5510	Hotels and similar accommodation		✓					
5030	Inland passenger water transport		✓		✓	✓	✓	
8423	Justice and judicial activities		✓		✓	✓	✓	
9102	Museums activities		✓				✓	
9004	Operation of arts facilities		✓	✓			✓	✓

NACE code	Location description	Designated places						
		Base case	Legislation	PAD 15%	PAD 20%	PAD 25%	PAD 45%	PAD 55%
9103	Operation of historical sites and buildings and similar visitor attractions		✓				✓	✓
9311	Operation of sports facilities		✓				✓	✓
5590	Other accommodation		✓					✓
9329	Other amusement and recreation activities		✓				✓	
8559	Other education		✓				✓	
4939	Other passenger land transport		✓	✓	✓	✓	✓	✓
5110	Passenger air transport		✓	✓	✓	✓	✓	✓
8520	Primary education		✓				✓	✓
8424	Public order and safety activities		✓	✓	✓	✓	✓	✓
5610	Restaurants and mobile food service activities		✓					
4711	Retail sale in non-specialised stores with food, beverages or tobacco predominating		✓			✓	✓	✓
5010	Sea and coastal passenger water transport		✓		✓	✓	✓	
8530	Secondary education		✓	✓			✓	✓
5221	Service activities incidental to land transportation		✓		✓	✓	✓	✓
8532	Technical and vocational secondary education		✓				✓	✓
8542	Tertiary education		✓	✓			✓	✓
	Total AEDs	4,670	43,089	6,547	7,818	11,445	20,016	24,262

Under the proposed legislation and the alternatives modelled in the economic evaluation, specified building types will be required to have an AED. For designated places the probability of an AED being present is set at 1 (rather than the probabilities outlined in Table A.1). The designated places in each modelled public access defibrillation scheme are outlined in Table A.2. In the legislation option, all of the listed building types are defined as designated places and must have an AED, therefore all building types have a probability of 1 for this option.

The probability of an AED being present in each building type was not known with certainty and therefore the Authority undertook a simulation exercise to model the impact of varying the probabilities. Plausible lower and upper bounds were set for each building type, and the probabilities were varied within those bounds. In each simulation, a set of calculations were carried out:

1. Vary the probability of different building types having an AED.
2. Based on the probabilities from step 1, sample buildings from each building type as locations for AEDs.
3. For each scenario modelled, ensure that all designated building types have an AED.
4. To account for uncertainty in the designated places, either increase or reduce the number of designated sites by up to 10%.
5. Determine number of cases (separately for those that occurred in public and private locations, respectively) within 200 metres of an AED.

A total of 2,500 simulations were repeated for each public access defibrillation scheme. Using the simulated data, it was possible to estimate:

- the correlations between the number of existing AEDs in designated places,
- the number of existing AEDs in non-designated places,
- the number of additional AEDs required for legislation, and
- the number of out-of-hospital cardiac arrests occurring in public and private locations, within 200 metres of an AED (Table A.3).

The correlation matrix was used in the modelling as a basis for generating correlated random variates for each of those variables. This ensured that the number of people receiving bystander defibrillation would be linked with the number of AEDs. In other words, a greater number of AEDs would potentially result in more out-of-hospital cardiac arrests receiving bystander defibrillation.

For full legislation, the number of existing AEDs in non-designated places is negatively correlated with both the number of existing AEDs in designated places and the number of new AEDs required for legislation. There is only a small link with the number of events within 200 metres of an AED.

As the Authority assumes that there are no more than 10,000 AEDs at the time of this HTA, if there are a high number in designated places then there will necessarily be a lower number in non-designated places and vice versa, which corresponds to a negative correlation. The number of out-of-hospital cardiac arrests within 200 metres of an AED is positively correlated with the number of new and existing AEDs in designated places.

Table App1.3 Estimated correlation matrix for AEDs numbers and out-of-hospital cardiac arrest cases within 200 metres for full legislation

Parameter	Current AEDs (designated)	Current AEDs (non-designated)	New AEDs	OHCAs within 200m (public)	OHCAs within 200m (private)
Current AEDs (designated)	1.0000	-0.4512	0.2288	0.0941	0.1447
Current AEDs (non-designated)		1.0000	-0.1205	-0.0270	0.0190
New AEDs			1.0000	0.2553	0.4571
out-of-hospital cardiac arrests within 200 metres (public)				1.0000	0.1382
out-of-hospital cardiac arrests within 200 metres (private)					1.0000

Notes: OHCA, out-of-hospital cardiac arrest; AED, automated external defibrillator.

Probability of an out-of-hospital cardiac arrest receiving bystander AED intervention

For bystander defibrillation to be possible, an out-of-hospital cardiac arrest must occur within a certain distance of an AED. Depending on the circumstances, that distance could be more or less. For example, if there is only one bystander then they may not be prepared to travel any distance as it would interrupt the administration of cardio-pulmonary resuscitation (CPR). In another context, where there may be multiple bystanders with knowledge of AEDs in the area and a car readily available, the AED could be retrieved from 500 metres away or more.

The Authority has assumed that an AED must be within 200 metres of the scene of the out-of-hospital cardiac arrest for it to be used in bystander defibrillation. This figure of 200 metres combines the recommendations of the American Heart Association with data on typical walking speed.[85;177]

Varying the distance impacts the number of out-of-hospital cardiac arrests that could benefit from an AED intervention. Increasing the distance results in greater coverage, although the benefits are approximately equivalent for each of the modelled public access defibrillation schemes (see Figure 3.11). As such, the impact on incremental effectiveness is minor.

From the out-of-hospital cardiac arrest Registry data, 119 out-of-hospital cardiac arrests had bystander CPR and defibrillation in 2012. From the geo-coordinates, the Authority estimated that:

- 389 out-of-hospital cardiac arrests were within 200 metres of an AED
- 120 of these were out-of-hospital cardiac arrests that occurred in public places
- 38% of out-of-hospital cardiac arrests within 200 metres of an AED received bystander defibrillation
- 56% of out-of-hospital cardiac arrests in a public place received bystander defibrillation
- 29% of out-of-hospital cardiac arrests that occurred in a private setting.

The Authority has assumed that bystander defibrillation that occurred in the home was most likely administered either by a community first responder group or a local GP. The data are observational and therefore take into account knowledge of a nearby AED, the physical access to an AED (for instance, is the nearest AED in a locked up building), and the likelihood of a bystander being willing and able to use the AED.

Whether the figure of 38% can be applied to various public access defibrillation schemes is subject to how those schemes may change behaviour with regard to AEDs. For example:

- Will people be more aware of the location of a nearby AED due to the introduction of a public access defibrillation scheme?
- Will AEDs be externally mounted on buildings or is it likely that they will continue to be mostly placed indoors?
- Will the introduction of a public access defibrillation scheme alter the likelihood of a bystander using an AED, should it be available?

If the implemented public access defibrillation scheme involves, as is proposed, to have a centralised register of emergency-medical-services-linked AEDs, then knowledge of nearby AEDs should increase noticeably.

The ambulance control centre will be able to direct the caller to the nearest AED, should one be available within approximately 200 metres. How much that will increase usage depends on how many of those AEDs are accessible at the time of the out-of-hospital cardiac arrest. The Out-of-Hospital Cardiac Arrest Register data show that 42% of cases happen during 9am and 5pm,[6] the hours during which an AED is most likely to be accessible for many of the designated places. Due to the nature of the GeoDirectory data and NACE code classification, there was no reliable way to check which locations would be likely to have standard daytime opening hours and which may have late opening.

Due to concerns about security and vandalism, unless directed otherwise, it is likely that most AEDs will continue to be placed inside buildings rather than outside. The biggest impact on out-of-hospital cardiac arrest coverage will be in the category 'General Medical Practice Activities', assumed to be predominantly GP practices. Two thirds of practices are assumed to have an AED at present, and many of those may be closed outside of normal office hours hampering the increased usage of AEDs.

There are a number of factors that will influence whether a linked system of static AEDs will result in greater usage of AEDs for resuscitation of out-of-hospital cardiac arrests. In the absence of clear evidence on the amount of effect, sensitivity analyses will be used to explore the potential impact on usage of linking AEDs to the emergency medical services.

Appendix 2 – Details of the bibliographic search and results

Pubmed 24/10/2013		Search strings	Results
Searches	#1	((((((defibrillat*[Title/Abstract]) OR arrest[Title/Abstract]) OR ohca[Title/Abstract]) OR out of hospital[Title/Abstract]) OR cardiac arrest, out of hospital[MeSH Terms]))	102388
	#2	(((((((community[Title/Abstract]) OR access[Title/Abstract]) OR public[Title/Abstract]) OR communal[Title/Abstract]) OR witness*[Title/Abstract]) OR bystander[Title/Abstract]) OR responder[Title/Abstract])	666596
	#3	#1 AND #2	4374
	#4	#3 AND Filters: Clinical Trial; Randomized Controlled Trial; Review; Systematic Reviews; Meta-Analysis; Guideline; Practice Guideline; English	995

Embase 24/10/2013		Search strings	Results
Searches	#1	defibrillat*:ab,ti OR arrest:ab,ti OR ohca:ab,ti OR (out* NEAR/3 hospital):ab,ti OR 'out of hospital cardiac arrest'/exp	148594
	#2	community:ab,ti OR access:ab,ti OR public:ab,ti OR witness*:ab,ti OR bystander:ab,ti OR responder:ab,ti OR communcal:ab,ti	796401
	#3	#1 AND #2	9731
	#4	#3 AND ([article]/lim OR [article in press]/lim OR [review]/lim) AND [public health]/lim AND [humans]/lim AND [english]/lim AND [abstracts]/lim	2486

Scopus 24/10/2013		Search strings	Results
Searches	#1	TITLE-ABS-KEY-AUTH(public access defibrillation) AND (LIMIT-TO(DOCTYPE, "ar") OR LIMIT-TO(DOCTYPE, "re")) AND (LIMIT-TO(LANGUAGE, "English"))	216

Cochrane Library 24/10/2013		**Search strings**	**Results**
Searches	#1	"public access defibrillation":ti,ab,kw (Word variations have been searched)	22
	#2	community:ti,ab or access:ti,ab or public:ti,ab or witness*:ti,ab or bystander:ti,ab or communal:ti,ab or responder:ti,ab	29754
	#3	defibrillat*:ti,ab or arrest:ti,ab or ohca:ti,ab or "out of hospital":ti,ab or "out-of-hospital":ti,ab	3135
	#4	MeSH descriptor: [Out-of-Hospital Cardiac Arrest] explode all trees	35
	#5	#3 or #4	3138
	#6	#2 and #5	350
	#7	#1 or #6	350
		Cochrane reviews	6
		Other reviews (DARE)	5
		Trials	319
		HTAs	2
		Others (excluded)	18

ClinicalTrials.gov 07/11/2013		**Search strings**	**Results**
Searches	#1	defibrillator OR defibrillate OR defibrillation	572

ISRCTN 07/11/2013		**Search strings**	**Results**
Searches	#1	defibrillator OR defibrillate OR defibrillation	16

Appendix 3 – Data extraction table for review of the cost-effectiveness literature

Study	Intervention	Analysis Details	Clinical Outcomes	Costs	Results
Nichol 2005[198] and 2009[163]	CEA based on the PAD trial (CPR only versus CPR+AED)	Country: USA & Canada Discount rate: 3% Perspective: Societal Time Horizon: Lifetime Costs: 2005 USD	PAD trial results showing twice as many survivors in intervention group compared with control group	Actual cost of equipment, training and hospital treatment were taken from the PAD trial	Defibrillation by volunteers was associated with an incremental cost of $46,700 (€44,900) per QALY
Folke 2009[165]	Public access defibrillation scheme in Copenhagen, Denmark	Country: Denmark Discount rate: 0% Perspective: Health service Time Horizon: Lifetime Costs: 2008 USD	25% survival where AED were used versus 14% where not used, this outcome data was from the literature	Treatment costs taken from previous studies. Equipment and maintenance costs derived from local data	Incremental cost per QALY calculated for different AED placement strategies; $33,100 (€28,900) for ERC guidelines*; $51,100 (€44,500) for AHA guidelines**; $79,400 for existing placement and $135,900 (€118,500) for unguided total coverage of city
Walker 2003[168]	Deployment of AEDs in all major airports, railway and bus stations	Country: Scotland Discount rate: 6% for costs; 1.5% for benefits	Applied survival data from out-of-hospital cardiac arrests attended in less	Direct costs to the health service, including AED purchase and	Total direct costs to the ambulance service of deploying 31 AEDs in 17 sites was £18,325 per

	in Scotland	Perspective: Health service Time Horizon: Lifetime Costs: 2001 GBP	than 3 minutes to all cases in an area with an AED	maintenance, training and marginal treatment costs.	year. QALY gain was 0.44, giving a cost per QALY gained of £41,146 (€62,300)
Cram 2003 B[157]	AEDs in selected public locations such as airports, sports venues, hotels and restaurants. Sites assumed to have a 20% annual probability of an out-of-hospital cardiac arrest	Country: USA Discount rate: 3% Perspective: Societal Time Horizon: Lifetime Costs: 2002 USD	Clinical outcomes data and risk of out-of-hospital cardiac arrest events obtained from the literature	Costs from a societal perspective obtained from the literature and contact with suppliers and training providers	Outcomes were reported per site; mean annual cost was $3,400 and QALY gain was 0.114, giving an annual cost of $30,000 per QALY gained (€31,300)
Sund 2012[164]	Dual dispatch of ambulance and fire services in Stockholm	Country: Sweden Discount rate: 4% Perspective: Societal Time Horizon: 10 years Costs: 2007 EUR	Clinical outcomes from SALSA trial	Equipment and treatment costs were taken from the SALSA project	16 additional lives saved, cost per QALY was €13,000 (€14,600) and cost per life saved of €60,000

Nichol 2003[167]	Public access defibrillation by lay responders in casinos in the US	Country: USA Discount rate: 3% Perspective: Societal Time Horizon: Lifetime Costs: 2003 USD	Relative benefit of public access defibrillation was calculated as a function of response time, based on the probability of VF rhythm and subsequent survival to discharge (from Valenzuela 2000) All survivors had ICD implantation	Equipment costs were obtained from suppliers. Training costs were based on instructor wages. Hospital and treatment costs were based on available literature.	Public access defibrillation provided by non-traditional responders in a casino setting had an incremental cost of $56,700 (€57,900) per additional QALY. If responder wages while being trained were included this rose to over $100,000 per QALY
Groenveld 2005[159]	Training unselected laypersons in CPR/defibrillation and deploying AEDs in their own home	Country: USA Discount rate: 3% Perspective: Societal Time Horizon: Lifetime Costs: 2004 USD	Survival with bystander defibrillation was twice that of bystander CPR only (from PAD trial), and four times that of no bystander CPR (assumed based on conflicting literature)	Equipment and training costs obtained from a survey of suppliers. Opportunity cost of training was set at 1/3 average US hourly wage. Literature used to cost treatment.	Cost per trainee was $62 and each trainee yielded 2.7 quality-adjusted hours of survival, giving a cost per QALY of $202,400. Home AED deployment increased the cost per QALY to $2,489,700 (€2.5M).

Berger 2004[169]	AED deployment in public high schools in the USA	Country: USA Discount rate: 3% Perspective: Societal Time Horizon: Lifetime Costs: 1999 USD	Survival to hospital admission, no description of how probability of survival was estimated	Only direct costs of equipment, training and treatment were included. Cost of personnel time, training resources were omitted	If the intervention saves 5 people over 5 years it was calculated to have an ICER of $108,344 (€122,100) per life year gained. If it saved 10 people over 5 years the resulting ICER would be $55,897 (€63,000)
Cram 2003 A[158]	AED deployment on commercial aircraft	Country: USA Discount rate: 3% Perspective: Societal Time Horizon: Lifetime Costs: 2003 USD	Outcome data was obtained from the literature and a small utility benefit for passive benefits (sense of security) was added	Equipment and treatment costs were taken from the literature, no training costs were included	Aircraft AED deployment increased survival to discharge from 2.1% to 16.7%, cost of AED deployment $5million, cost per QALY gained was $34,000
Forrer 2002[170]	Police AED programme in four suburban communities in the US	Country: USA Discount rate: 0% Perspective: Police and health service Time Horizon: 7 years Costs: 1999 USD	Survival benefit was estimated based on the decreased time to first shock as a result of the intervention	Costs from the community perspective, with data taken from the 7 year cohort study	Time from call to first shock reduced by 1.8 minutes, with a resulting estimated survival benefit of 0.24 lives saved per year, giving a cost per year of life saved of $16,060 (€19,200)

Groeneveld 2001[160]	AED deployment on US commercial aircraft	Country: USA Discount rate: 3% Perspective: Societal Time Horizon: Lifetime Costs: 2001 USD	Outcome data from 36 cases of out-of-hospital cardiac arrest from American Airlines, base case estimated using data from studies with emergency medical services transport times >20 minutes	Airline costs taken from FAA and air transportation association. Medical costs from literature. Training costs calculated as employee opportunity cost.	Deploying AEDs on all commercial aircraft would save 33 additional lives annually, with an ICER of $94,700 (€100,500). Only deploying AEDs on large commercial aircraft would save an additional 7 lives per annum with an ICER of $35,300 (€37,400)
Foutz 2000[166]	Placing AEDs in long-term care facilities (LTCF) in Cincinnati, Ohio, USA	Country: USA Discount rate: 5% Perspective: Health service Time Horizon: 4 years Costs: 1999 USD	Registry data showed 20% of out-of-hospital cardiac arrests in LTCFs were VF. Assumed that intervention would result in a survival to discharge rate of 25% of VF out-of-hospital cardiac arrests	Equipment and training costs incurred by LTCF over four years	5 additional lives saved (survival rate increased from 1.25% to 4.4%) at a cost of $439,185, giving a cost per life saved of $87,837 (€99,000)

Jermyn 2000[161]	Fire-fighter first responder programme in an urban and rural community in Australia.	Country: Canada Discount rate: 5% Perspective: Health & fire service Time Horizon: 6 years Costs: 1999 USD	Authors assume an incremental survival benefit of 6% for those in VF	Cost of equipment, maintenance and instructor training included. Training costs for providers excluded.	Cost per life saved was AUS$6,776 in urban areas and AUS$49,274 in rural areas.
Nichol 1998[162]	Public access defibrillation involving lay responders or police	Country: USA Discount rate: 3% Perspective: Societal Time Horizon: Lifetime Costs:1996 USD	Outcome data taken from available literature at the time. Relative survival benefit of public access defibrillation assumed to be 1.5 (from White 1996)	Cost of AED assumed to be $2500, with annual training and maintenance of 10%. Treatment costs were not included as they were equal in both comparators. Future costs were also not included.	Public access defibrillation was associated with a median incremental survival of 0.7% and a median cost per additional QALY of $44,000 (€32,600). In an urban emergency medical services system with on overall survival rate of 8%, a police AED programme was associated with a median cost of $27,200 per additional QALY

AHA – American Heart Association; CEA – Cost-effectiveness analysis; CPR – Cardiopulmonary resuscitation; ERC – European Resuscitation Council; ICER – Incremental cost-effectiveness ratio; ICD – Implantable cardioverter defibrillator; LTCF – Long-term care facility; OHCA – Out-of-hospital cardiac arrest; PAD – Public access defibrillation; QALY – Quality-adjusted life year; VF – Ventricular fibrillation.

* European Resuscitation Council (ERC) guidelines recommend placement of AED in locations with an incidence of one cardiac arrest every two years.[16]

** American Heart Association (AHA) guidelines recommend placement of AED in locations with an incidence of one cardiac arrest every five years.[17]

Appendix 4 – Appraisal of study quality for included cost-effectiveness analysis studies

	Nichol 2009[163]	Folke 2009[165]	Walker 2003[168]	Cram 2003 B[157]	Sund 2012[164]	Nichol 2003[167]	Groeneveld 2005[159]	Berger 2004[169]	Cram 2003 A[158]	Forrer 2002[170]	Groeneveld 2001[160]	Foutz 2000[166]	Jermyn 2000[161]	Nichol 1998[162]
Relevance														
Population	Yes	Yes	Yes	Yes	Yes	Yes	No	No	Yes	Yes	Yes	No	Yes	Yes
Intervention	Yes	Yes	Yes	Yes	No	No	No	No	No	No	No	No	No	No
Outcomes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	No	Yes	No	No	Yes
Context	No	Yes	No	No	No	No	No	No	No	No	No	No	No	No
Credibility														
Validation	Yes	No	No	No	No	No	No	No	No	Yes	No	No	No	No
Design	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	No	No	Yes
Data	No	No	No	No	No	No	No	No	No	No	No	No	No	No
Analysis	Yes	No	Yes	Yes	No	Yes	No	No	Yes	No	Yes	No	No	Yes
Reporting	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	No	No	Yes
Interpretation	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Conflict of interest	No	No	No	No	No	?	?	?	No	?	?	?	?	?

For full details of the criteria used to assess relevance and credibility see: Questionnaire to assess the relevance and credibility of modelling studies for informing healthcare decision making: An ISPOR-AMCP-NPC good practice task for report[156]

Appendix 5 – Economic model parameters

Name	Description	Mean (95%CI)	Notes
PADbc	Probability of an OHCA patient receiving bystander defibrillation in base case	7.1%	((pubBC*pubDefib)+(priBC*priDefib))/annual OHCAs
CPRbc	Probability of an OHCA patient receiving bystander CPR in base case	42.1%	((bystander*annualOHCAs)/annual OHCAs)-PADbc
EMSbc	Probability of an OHCA patient receiving emergency medical services care first in base case	50.7%	1-(PADbc+CPRbc)
PAD15	Probability of an out-of-hospital cardiac arrest patient receiving bystander defibrillation in PAD15%	8.4%	((pub15*pubDefib)+(pri15*priDefib))/annualOHCAs
CPR15	Probability of an out-of-hospital cardiac arrest patient receiving bystander CPR in PAD15%	41.1%	(((bystander*newCPRpad15)*annual OHCAs)/annual OHCAs)-PAD15
EMS15	Probability of an out-of-hospital cardiac arrest patient receiving emergency medical services care first in PAD15%	50.5%	1-(PAD15+CPR15)
PAD20	Probability of an out-of-hospital cardiac arrest patient receiving bystander defibrillation in PAD20%	8.5%	((pub20*pubDefib)+(pri20*priDefib))/annualOHCAs
CPR20	Probability of an OHCA patient receiving bystander CPR in PAD20%	41.2%	(((bystander*newCPRpad20)*annualOHCAs)/annualOHCAs)-PAD20

EMS20	Probability of an out-of-hospital cardiac arrest patient receiving emergency medical services care first in PAD20%	50.3%	1-(PAD20+CPR20)
PAD25	Probability of an OHCA patient receiving bystander defibrillation in PAD25%	10.0%	((pub25*pubDefib)+(pri25*priDefib))/annualOHCAs
CPR25	Probability of an out-of-hospital cardiac arrest patient receiving bystander CPR in PAD25%	40.1%	((bystander*newCPRpad25*annualOHCAs)/annualOHCAs)-PAD25
EMS25	Probability of an OHCA patient receiving emergency medical services care first in PAD25%	49.9%	1-(PAD25+CPR25)
PAD45	Probability of an out-of-hospital cardiac arrest patient receiving bystander defibrillation in PAD45%	12.2%	((pub45*pubDefib)+(pri45*priDefib))/annualOHCAs
CPR45	Probability of an out-of-hospital cardiac arrest patient receiving bystander CPR in PAD45%	39.1%	((bystander*newCPRpad45*annualOHCAs)/annuals)-PAD45
EMS45	Probability of an out-of-hospital cardiac arrest patient receiving emergency medical services care first in PAD45%	48.7%	1-(PAD45+CPR45)
PAD55	Probability of an out-of-hospital cardiac arrest patient receiving bystander defibrillation in PAD55%	12.8%	((pub55*pubDefib)+(pri55*priDefib))/annualOHCAs

CPR55	Probability of an out-of-hospital cardiac arrest patient receiving bystander CPR in PAD55%	39.0%	((bystander*newCPRpad55*annualOHCAs)/annualOHCAs)-PAD55
EMS55	Probability of an out-of-hospital cardiac arrest patient receiving emergency medical services care first in PAD55%	48.2%	1-(PAD55+CPR55)
PADleg	Probability of an out-of-hospital cardiac arrest patient receiving bystander defibrillation in a public access defibrillation programme as outlined in the current Bill	13.8%	((pubLEG*pubDefib)+(priLEG*priDefib)) /annualOHCAs
CPRleg	Probability of an out-of-hospital cardiac arrest patient receiving bystander CPR in a public access defibrillation programme as outlined in the current Bill	40.5%	((bystander*newCPRleg*annualOHCAs)/ annualOHCAs)-PADleg
EMSleg	Probability of an out-of-hospital cardiac arrest patient receiving emergency medical services care first in a public access defibrillation programme as outlined in the current Bill	45.7%	1-(PADleg+CPRleg)
edEMS	Probability of surviving to the ED if first treated by emergency medical services	60% (58 – 62)	Estimates of survival to emergency department, hospital admission, hospital discharge and CPC score at discharge are based on multiple years of OHCAR

edCPR	Probability of surviving to the EDif first treated by bystander CPR	57% (54 – 59)	data. This register achieved full national coverage in 2012. Weighted averages are calculated using up to five years of regional data in some areas. Data availability by health board region and year was as follows; Health Board — Available years of data East — 2011-2012 North East — 2010-2012 Midlands — 2009-2012 Mid West — 2011-2012 North West — 2008-2012 South — 2011-2012 South East — 2012 West — 2008-2012
edPAD	Probability of surviving to the ED if first treated by bystander defibrillation	52% (46 – 58)	
adEMS	Probability of surviving to hospital admission, having survived to ED, if first treated by emergency medical services	22% (20 – 25)	
adCPR	Probability of surviving to hospital admission, having survived to ED, if first treated by bystander CPR	26% (23 – 29)	
adPAD	Probability of surviving to hospital admission, having survived to ED, if first treated by bystander defibrillation	44% (34 – 54)	
disEMS	Probability of surviving to hospital discharge, having survived to admission, if first treated by emergency medical services	35% (30 – 40)	
disCPR	Probability of surviving to hospital discharge, having survived to admission, if first treated by bystander CPR	42% (36 – 48)	
disPAD	Probability of surviving to hospital discharge, having survived to admission,	63% (51-76)	

	if first treated by bystander defibrillation		
emsCPC	Probability of having a CPC score of 1,2 or 3 at discharge if first treated by emergency medical services	CPC1: 77% (66 – 86) CPC2: 14% (7 – 23) CPC3: 9% (4 – 17)	
cprCPC	Probability of having a CPC score of 1,2 or 3 at discharge if first treated by bystander CPR	CPC1: 71% (60 – 80) CPC2: 9% (4 – 16) CPC3: 20% (12 – 30)	
padCPC	Probability of having a CPC score of 1,2 or 3 at discharge if first treated by bystander defibrillation	CPC1: 77% (63 – 87) CPC2: 7% (2 – 17) CPC3: 16% (7 – 28)	
survCPC 1	Annual survival with CPC1	92% (90 – 94)	Estimates of average survival rates post-cardiac arrest by CPC score were obtained from the literature (Pachys 2014[65])
survCPC 2	Annual survival with CPC2	92% (90 – 94)	
survCPC 3	Annual survival with CPC3	79% (77 – 82)	
qBaseline	Quality of life score for average patient prior to out-of-hospital cardiac arrest	0.78 (0.77 – 0.79)	Estimates of average quality of life scores for out-of-hospital cardiac arrest patients pre and post-arrest by CPC score were estimated from the literature (Kuilman 1999[66], Moulaert 2010[70], Deasy 2013[71], Stiell 2009[72], Nichol 1999[73])
qCPC1	Quality of life score for patients with a CPC score of 1 at discharge	0.93 (0.87 – 0.97)	
qCPC2	Quality of life score for patients with a CPC score of 2 at discharge	0.75 (0.66 – 0.83)	
qCPC3	Average quality of life score for patients with a CPC score of 3 at discharge	0.40 (0.31 – 0.50)	

CPRtrained	Proportion of people who have received CPR training within the last two years in Ireland	16% (14 – 19)	Data were taken from a national survey of prevalence of cardiopulmonary resuscitation training in Ireland which reported that 23.5% of the population had CPR training in the last 5 years and 70% of these said they would have no difficulty administering CPR in an emergency (Jennings 2009[80])
CPRpop	Total CPR trained population at baseline	755,184 (652,371 – 862,030)	
bystander	Probability of an out-of-hospital cardiac arrest patient receiving any type of bystander intervention (bystander CPR only or defibrillation plus CPR) in base case	49% (47 – 52)	It is assumed that public access defibrillation programmes that involve a large number of people being trained in CPR/AED will have a beneficial effect on the overall probability of bystander intervention. This increase is calculated by multiplying the probability of bystander intervention at baseline with the percentage increase in the overall CPR-trained population. The estimated number of people who will receive bystander defibrillation plus CPR in each comparator is subtracted from this figure to estimate the number of patients likely to receive bystander CPR only in each comparator.
newCPRpad15	Percentage increase in CPR trained population associated with introduction of the PAD15% comparator	0.5%	((Pad15AEDs *aedTrainees)+CPRpop)/CPRpop
newCPRpad20	Percentage increase in CPR trained population associated with introduction of the PAD20% comparator	0.8%	((mtpAEDs*aedTrainees)+CPRpop)/CPRpop
newCPRpad25	Percentage increase in CPR trained population associated with introduction of the PAD25% comparator	1.8%	((mtprAEDs*aedTrainees)+CPRpop)/CPRpop

newCPR pad45	Percentage increase in CPR trained population associated with introduction of the PAD45% comparator	4.1%	((mtprcAEDs*aedTrainees)+CPRpop)/CPRpop
newCPR pad55	Percentage increase in CPR trained population associated with introduction of the PAD55% comparator	5.2%	((Pad55AEDs *aedTrainees)+CPRpop)/CPRpop
newCPR leg	Percentage increase in CPR trained population associated with introduction of a PAD programme as outlined in the current Bill	10.2%	((LegislationAEDs*aedTrainees)+CPRpop)/CPRpop
pubDefib	Probability of receiving bystander defibrillation for patients who have an arrest in public within 200m of an AED	50% (40 – 58)	Calculated based on OHCAR data on type of response for cardiac arrests that occurred in public areas and residential settings within 200 metres of current AED locations.
priDefib	Probability of receiving bystander defibrillation for patients who have an arrest in a residential area within 200 metres of an AED	26% (21 – 32)	Calculated by cross referencing the location of out-of-hospital cardiac arrest events (from OHCAR) with the location of AEDs in each public access defibrillation programme configuration (using Geodirectory data) to estimate the annual number of public and residential out-of-hospital cardiac arrests likely to occur within 200m of an AED. The number of AEDs required for each comparator and the number of public and residential out-of-hospital cardiac arrest within 200m of an AED are defined as a multinormal distribution in order for them to be correlated when sampled during a Monte Carlo simulation.
PubBC	Average number of public out-of-hospital cardiac arrest events occurring within 200 metres of an AED in the base case	120 (108 – 132)	

PriBC	Average number of residential out-of-hospital cardiac arrest events occurring within 200 metres of an AED in the base case	269 (243 – 294)	Annual incidence is based on the single year of national out-of-hospital cardiac arrest data available from the Out-of-Hospital Cardiac Arrest Register.
Pub15	Average number of public out-of-hospital cardiac arrest events occurring within 200 metres of an AED in PAD15%	136 (126 – 147)	
Pri15	Average number of residential out-of-hospital cardiac arrest events occurring within 200 metres of an AED in PAD15%	327 (302 – 351)	
Pub20	Average number of public out-of-hospital cardiac arrest events occurring within 200 metres of an AED in PAD20%	136 (126 – 147)	
Pri20	Average number of residential out-of-hospital cardiac arrest events occurring within 200 metres of an AED in PAD20%	331 (307 – 354)	
Pub25	Average number of public out-of-hospital cardiac arrest events occurring within 200 metres of an AED in PAD25%	152 (142 – 163)	
Pri25	Average number of residential out-of-hospital cardiac arrest events occurring within 200 metres of an AED in PAD25%	409 (385 – 433)	

Pub45	Average number of public out-of-hospital cardiac arrest events occurring within 200 metres of an AED in PAD45%	178 (168 – 187)
Pri45	Average number of residential out-of-hospital cardiac arrest events occurring within 200 metres of an AED in PAD45%	512 (488 – 536)
Pub55	Average number of public out-of-hospital cardiac arrest events occurring within 200 metres of an AED in PAD55%	183 (174 – 193)
Pri55	Average number of residential out-of-hospital cardiac arrest events occurring within 200 metres of an AED in PAD55%	542 (519 – 565)
PubLEG	Average number of public out-of-hospital cardiac arrest events occurring within 200 metres of an AED in a public access defibrillation programme as outlined in the current Bill	198 (189 – 207)
PriLEG	Average number of residential out-of-hospital cardiac arrest events occurring within 200 metres of an AED in a public access defibrillation programme as outlined in the current Bill	581 (557 – 604)

annualOHCAs	Annual incidence of out-of-hospital cardiac arrest in Ireland	1,810 (1,639 – 1,990)	
Pad15AEDs	Total number of additional AEDs required for the PAD15% comparator	1,876 (1,595 – 2,156)	Designated places included in this comparator are: Other Passenger Land Transport N.E.C. Passenger Air Transport Public Order And Safety Activities Secondary Education Tertiary Education Hospital Activities General Medical Practice Activities Creative, Arts And Entertainment Activities Operation Of Arts Facilities Fitness Facilities
Pad20AEDs	Total number of additional AEDs required for the PAD20% comparator	3,145 (2,699 – 3,597)	Designated places included in this comparator are: Other Passenger Land Transport N.E.C. Passenger Air Transport Public Order And Safety Activities Hospital Activities General Medical Practice Activities Sea And Coastal Passenger Water Transport Inland Passenger Water Transport Dental Practice Activities General Public Administration Activities Justice And Judicial Activities Service Activities Incidental To Land Transportation
Pad25AEDs	Total number of additional AEDs required for the PAD25% comparator	6,774 (6,067 – 7,485)	Designated places included in this comparator are: Other Passenger Land Transport N.E.C. Passenger Air Transport Public Order And Safety Activities Hospital Activities General Medical Practice Activities Sea And Coastal Passenger Water Transport Inland Passenger Water Transport Dental Practice Activities General Public Administration Activities Justice And Judicial Activities

			Service Activities Incidental To Land Transportation Retail Sale In Non-Specialised Stores
Pad45A EDs	Total number of additional AEDs required for the PAD45% comparator	15,346 (13,879 – 16,797)	Designated places included in this comparator are: Other Passenger Land Transport N.E.C. Passenger Air Transport Public Order And Safety Activities Hospital Activities General Medical Practice Activities Sea And Coastal Passenger Water Transport Inland Passenger Water Transport Dental Practice Activities General Public Administration Activities Justice And Judicial Activities Service Activities Incidental To Land Transportation Retail Sale In Non-Specialised Stores Operation Of Sports Facilities Fitness Facilities Botanical And Zoological Gardens And Nature Reserve Activities Operation Of Arts Facilities Museums Activities Operation Of Historical Sites And Buildings And Similar Visitor Attractions Secondary Education Tertiary Education Primary Education Technical And Vocational Secondary Education Activities Of Sport Clubs Creative, Arts And Entertainment Activities Other Education Other Amusement And Recreation Activities
Pad55A EDs	Total number of additional AEDs required for the PAD55% comparator	19,591 (17,659 – 21,518)	Designated places included in this comparator are: Other Passenger Land Transport N.E.C. Passenger Air Transport Public Order And Safety Activities Hospital Activities

			General Medical Practice Activities Dental Practice Activities General Public Administration Activities Service Activities Incidental To Land Transportation Retail Sale In Non-Specialised Stores Operation Of Sports Facilities Fitness Facilities Operation Of Arts Facilities Operation Of Historical Sites And Buildings And Similar Visitor Attractions Secondary Education Tertiary Education Primary Education Technical And Vocational Secondary Education Activities Of Sport Clubs Creative, Arts And Entertainment Activities Other Education Other Accommodation
LegislationAEDs	Total number of additional AEDs required for a public access defibrillation programme as outlined in the current Bill	38,419 (34,671 – 42,133)	Designated places included in this comparator are: Other Passenger Land Transport N.E.C. Passenger Air Transport Public Order And Safety Activities Hospital Activities General Medical Practice Activities Dental Practice Activities General Public Administration Activities Service Activities Incidental To Land Transportation Retail Sale In Non-Specialised Stores Operation Of Sports Facilities Fitness Facilities Operation Of Arts Facilities Operation Of Historical Sites And Buildings And Similar Visitor Attractions Secondary Education Tertiary Education Primary Education Technical And Vocational Secondary Education Activities Of Sport Clubs

			Creative, Arts And Entertainment Activities Other Education Other Accommodation Sea And Coastal Passenger Water Transport Inland Passenger Water Transport Justice And Judicial Activities Botanical And Zoological Gardens And Nature Reserve Activities Museums Activities Hotels And Similar Accommodation Beverage Serving Activities Other Amusement And Recreation Activities Holiday And Other Short-Stay Accommodation Restaurants And Mobile Food Service Activities Activities Of Religious Organisations
cAED	Unit cost of AED	€1,189 (973 – 1,447)	Based on supplier information, excluding VAT
cPADs	Unit cost of AED pads	€46 (38 – 57)	Based on supplier information and expert opinion
cBatt	Unit cost of AED battery	€165 (136 – 201)	
cSignage	Unit cost of AED signage	€12 (10 – 15)	
cStorage	Unit cost of wall mounted AED storage cabinet	€134 (111 – 164)	
lsAED	Lifespan of AED	8 years (6 – 10)	
lsPADs	Lifespan of pads	2 years (1.5 – 2.5)	
lsBatt	Lifespan of battery	5 years (4 – 6)	
cInitInstructor	Cost of instructor per trainee for initial training	€80 (66 – 96)	
cRefreshInstru	Cost of instructor per trainee for refresher	€50 (41 – 61)	

ctor	training		
tInitTraining	Duration of initial training	5 hours (4.5 – 5.5)	
tRefreshTraining	Duration of refresher training	3 hours (2.6 – 3.4)	
rRetrain	Retraining interval	2 years (1.2 – 3.3)	
aedTrainees	Number of trainees per AED	2 (1 - 3)	Assumption
cStaffTime	Cost of one hour of staff time	€25 (23 – 28)	CSO average hourly labour costs
cInitialTraining	Total cost of initial training session per AED, including instructor cost and staff time	€413	(cInitInstructor+(tInitTraining*cStaffTime))*aedTrainees
cRefresherTraining	Total cost of refresher training session per AED, including instructor cost and staff time	€252	(cRefreshInstructor+(tRefreshTraining*cStaffTime))*aedTrainees
cDatabase	Annual cost of running a central AED register	€69,259 (56,786 – 83,872)	Based on staff costs of one full time equivalent at midpoint of clerical officer grade salary scale and an average of €43,000 annual running costs for hardware, software, licensing, hosting and support, based on expert feedback and data from the Danish public access defibrillation programme.
cED	Average cost of care for patients who survive to the emergency department	€679 (451 – 988)	Staff time and resources required for patients who are brought to the pronounced dead in the emergency department was estimated based on expert opinion. A micro-costing exercise was carried out based on this information to estimate the average cost.
cDeathInHospital	Average cost of care for patients who survive to hospital admission but die in hospital	€17,911 (15,290 – 20,868)	HIPE DRG data on average costs for patients who are admitted to hospital following an out-of-hospital cardiac arrest and who die before discharge and those who are discharged alive, based on two years' data (2012-2013).

			Episodes in HIPE include a field recording the type of discharge, which distinguishes between discharge home, to another institution, or whether the patient died in hospital. There is also a code for admission source, which includes a code for patients transferred in. A large proportion of patients admitted for out-of-hospital cardiac arrest are transferred from the initial admitting hospital to another hospital for care. However, transfer coding in HIPE may not systematically capture all transfers. A patient transferred between hospitals is recorded as multiple discharges that constitute a single episode of care from the perspective of the present analysis. Mean costs for cases of out-of-hospital cardiac arrest that were marked as a 'transfer out' were combined with mean costs for cases that were recorded as a 'transfer in' to estimate mean costs associated with cases that were transferred prior to discharge. Given the small number of cases available for the analysis, bootstrapping was used to estimate a distribution for mean costs. The analysis was carried out separately for cases that survived to hospital discharge and those that died in hospital. DRG costs were from the 2013 Casemix Ready Reckoner.
cDischarge	Average cost of medical care for patients who survive to hospital discharge	€22,835 (18,287 – 28,150)	Average annual treatment costs for survivors of out-of-hospital cardiac arrest with CPC score of 1 and 2 is a weighted average of the costs of the estimated proportion who receive an implantable cardioverter defibrillator (15%) and long-term treatment for coronary heart disease (85%). Costs estimated include the cost of medication, GP visits and hospital care,
cCPC1	Average annual cost of medical care for patients with a CPC score of 1 at discharge	€3,964 (3,242 – 4,786)	

			based on study data, inflated and converted to 2013 € per national HTA guidelines[174]
cCPC2	Average annual cost of medical care for patients with a CPC score of 2 at discharge	€3,964 (3,223 – 4,802)	Average annual treatment costs for survivors of out-of-hospital cardiac arrest with CPC score of 3 is calculated based on the long-term treatment for coronary heart disease (inflated and converted to 2013 € per national HTA guidelines[174]) plus the annual full time carers allowance.[182]
cCPC3	Average annual cost of medical care for patients with a CPC score of 3 at discharge	€14,421 (8,220 – 23,772)	
upfront AEDcost	Initial upfront costs associated with AED purchase, installation and training	€1,289	Initial AED related costs minus the cost of maintenance associated with pads, batteries and training, which is calculated separately. cAED-(cBatt+cPADs)+(cInitialTraining-cRefresherTraining)+cSignage+cStorage
cMaintenanceAED	Average annual maintenance cost of AED	€176	Average annual maintenance costs associated with replacement pads, batteries and refresher training (cBatt/lsBatt)+(cPADs/lsPADs)+(cRefresherTraining/rRetrain)
EACaed	Equivalent annual cost of AED	€358	Annual cost of owning and maintaining an AED over the lifespan of the device. Annuity calculated as payable in advance rather than in arrears (see Drummond[178]) (upfrontAEDcost/(Annuity[(floor(lsAED)-1)]+1))+cMaintenanceAED
PAD15px	Annual setup and maintenance cost per out-of-hospital cardiac arrest patient for the PAD15% comparator	€421	((pad15AEDs*EACaed)+cDatabase)/Annualout-of-hospital cardiac arrests
PAD20px	Annual setup and maintenance cost per out-of-hospital cardiac arrest patient for the PAD20% comparator	€648	((pad20AEDs*EACaed)+cDatabase)/AnnualOHCAs
PAD25px	Annual setup and maintenance cost per out-of-hospital cardiac	€1,420	((pad25AEDs*EACaed)+cDatabase)/AnnualOHCAs

	arrest patient for the PAD25% comparator		
PAD45px	Annual setup and maintenance cost per out-of-hospital cardiac arrest patient for the PAD45% comparator	€3,168	((pad45AEDs*EACaed)+cDatabase)/AnnualOHCAs
PAD55px	Annual setup and maintenance cost per out-of-hospital cardiac arrest patient for the PAD55% comparator	€4,034	((pad55AEDs*EACaed)+cDatabase)/AnnualOHCAs
LegislationPx	Annual setup and maintenance cost per out-of-hospital cardiac arrest patient for a public access defibrillation programme as outlined in the current Bill	€7,874	((LegislationAEDs*EACaed)+cDatabase)/AnnualOHCAs
Productivity	Average productivity loss associated with out-of-hospital cardiac arrest mortality and morbidity	€12,006 (10,236 – 14,021)	Productivity was calculated using the human capital approach based on CSO data on employment and earnings by age and gender, weighted according to the demographics of the out-of-hospital cardiac arrest population in Ireland
VAT	VAT factor	1	Vat rate set at 0% (factor = 1.0) in cost-effectiveness analysis and 23% (factor = 1.23) in budget impact analysis
discountRate	Discount rate on future costs and benefits	5%	5% discount rate per Guidelines for the Economic Evaluation of Health Technologies in Ireland[174]

Parameter distributions

Parameter	Distribution	α	β
Probability of being admitted to hospital after emergency medical services	Beta	240	834
Probability of being admitted to hospital after CPR	Beta	210	587
Probability of being admitted to hospital after public access defibrillation	Beta	46	59
Probability of survival to discharge after emergency medical services	Beta	104	194
Probability of survival to discharge after CPR	Beta	105	146
Probability of survival to discharge after public access defibrillation	Beta	35	20
Annual survival probability in CPC1	Beta	920	80
Annual survival probability CPC2	Beta	920	80
Annual survival probability CPC3	Beta	790	210
QALY for CPC1	Beta	93	7
QALY for CPC2	Beta	75	25
QALY for CPC3	Beta	40	60
Probability of being brought to ED after emergency medical services	Beta	1232	819
Probability of being brought to ED after CPR	Beta	951	729
Probability of being brought to ED after public access defibrillation	Beta	128	118
Baseline QALY score	Beta	8424	2418
Probability of a public out-of-hospital cardiac arrest being defibrillated within 200 metres of an AED	Beta	57	58
Probability of private out-of-hospital cardiac arrest being defibrillated within 200 metres of an AED	Beta	62	177
Proportion of population that has received CPR training	Beta	160	814
Probability of bystander intervention (CPR or public access defibrillation) in base case	Beta	863	889
		α- list	
CPC scores after emergency medical services	Dirichlet	List(52.6;9.7;6.1)	

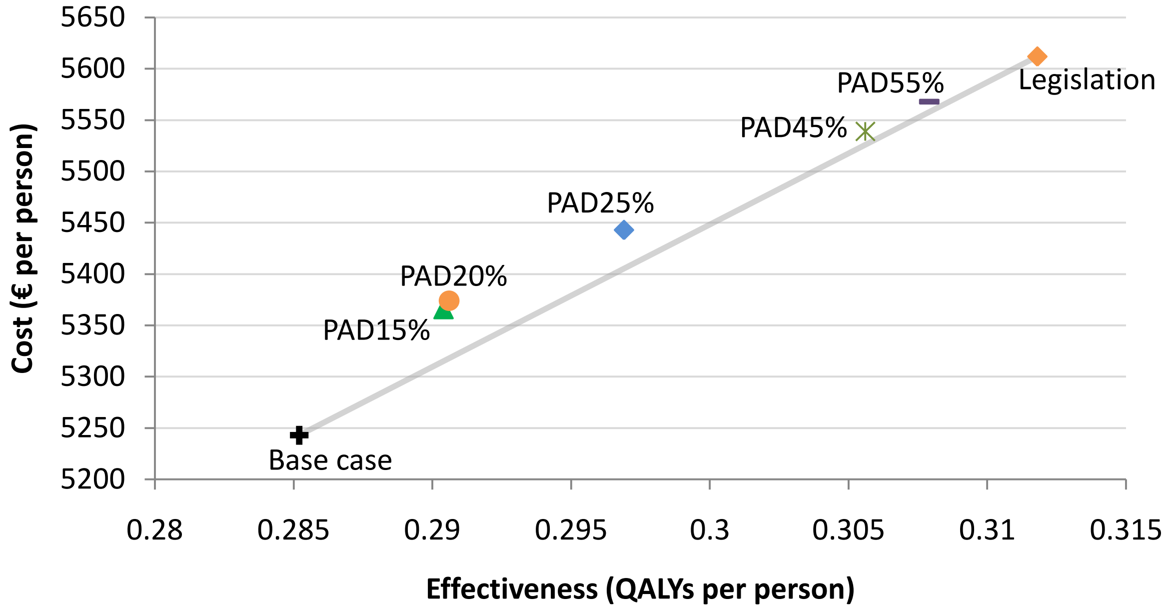
CPC scores after CPR	Dirichlet	List(53.7;6.6;15.5)	
CPC scores after public access defibrillation	Dirichlet	List(34.7;3.3;7.3)	
		α	**λ**
Number of trainees per AED	Gamma	20	10
		Mean of logs	**SD of logs**
Cost of death in hospital	LogNormal	9.79	0.08
Cost of hospital discharge	LogNormal	10.03	0.11
Annual cost of care in CPC1	LogNormal	8.28	0.10
Annual cost of care in CPC2	LogNormal	8.28	0.10
Annual care cost in CPC3	LogNormal	9.54	0.27
Cost of ED care	LogNormal	6.5	0.2
Unit cost of AED	LogNormal	7.08	0.10
Cost of replacement pads	LogNormal	3.84	0.10
Cost of replacement battery	LogNormal	5.11	0.10
Cost of initial instructor training	LogNormal	4.38	0.10
Cost of one hour of staff time	LogNormal	3.23	0.05
Interval for retraining	LogNormal	0.69	0.25
Cost of refresher training per trainee	LogNormal	3.91	0.10
Cost of AED signage	LogNormal	2.50	0.10
Cost of AED storage cabinet	LogNormal	4.90	0.10
Annual cost of AED database	LogNormal	11.14	0.1
Annual number of out-of-hospital cardiac arrests in Ireland	LogNormal	7.5	0.05
Productivity loss for death or CPC3	LogNormal	9.39	0.08
		Mean	**SD**
Lifespan of AED	Normal	8	1
Lifespan of AED pads	Normal	2	0.25
Lifespan of battery	Normal	5	0.5
Time in hours required for initial training	Normal	5	0.25
Time in hours required for refresher training	Normal	3	0.2

Appendix 6 – Cost-effectiveness analysis from the perspective of the Health Service

As outlined in chapter 5, the primary cost-effectiveness analysis for this HTA is carried out taking a societal perspective due to the high proportion of costs that fall outside the publicly-funded health and social care system. However, as the perspective of the publicly-funded healthcare system is the perspective that is recommended by national guidelines on HTA and the perspective from which all previous economic analyses conducted by the Health Information and Quality Authority have been performed, a secondary analysis was carried out to estimate the cost-effectiveness (incremental cost per QALY) of public access defibrillation programmes taking this narrower payer perspective.

This analysis excludes productivity costs and any equipment and training costs for designated places that are not run by the HSE. In this analysis it is assumed that the HSE is responsible for 100% of designated premises whose primary function is coded as 'hospital activities', 10% of premises coded as 'general medical practice activities' and 5% of premises coded as 'dental practice activities'. These were varied by ±20% to reflect the high level of uncertainty surrounding these estimates. Since these types of buildings are included in all comparators, the additional set-up costs are the same for all programmes when taking this perspective. It is also assumed that the full cost of setting up and running a national AED register will fall on the HSE and/or Department of Health. All other parameters relating to clinical outcomes and costs are retained as per the primary analysis and all costs and benefits are discounted at 5%. The relative position of each of the comparators on the cost-effectiveness plane is shown in Figure App6.1.

Figure App6.1 Cost-effectiveness plane (QALY outcomes)



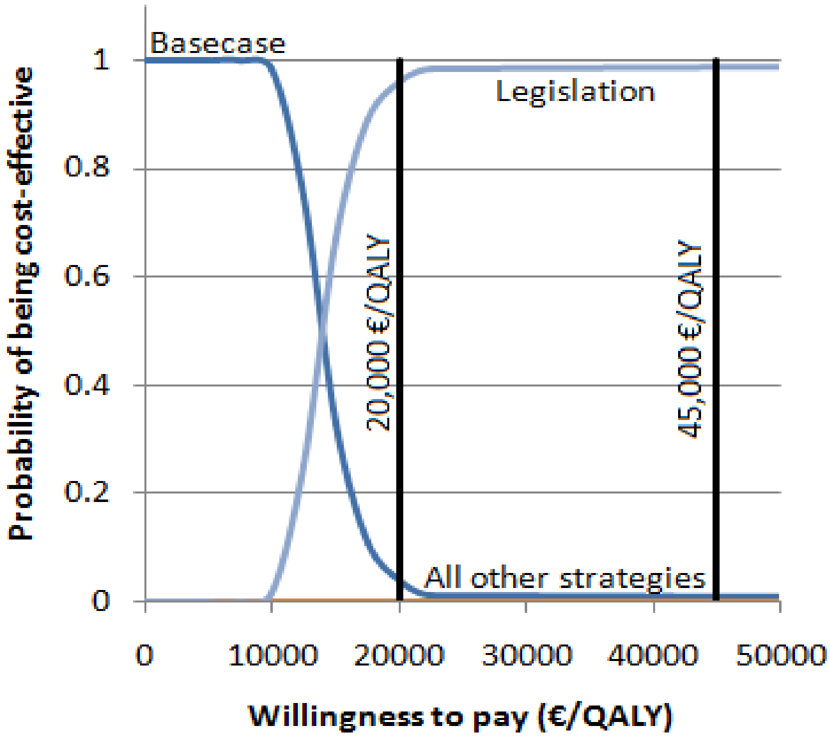
Incremental cost-effectiveness ratios for each comparison, excluding any dominated strategies, is shown in Table App6.1.

Table App6.1 Incremental Cost-Effectiveness Ratios (QALY outcomes)

Strategy	Cost (€)	Incremental Cost (€)	Effectiveness (QALY)	Incremental Effectiveness (QALY)	ICER (€)
Base case	5,243		0.2852		
Legislation	5,612	369	0.3118	0.0266	13,871

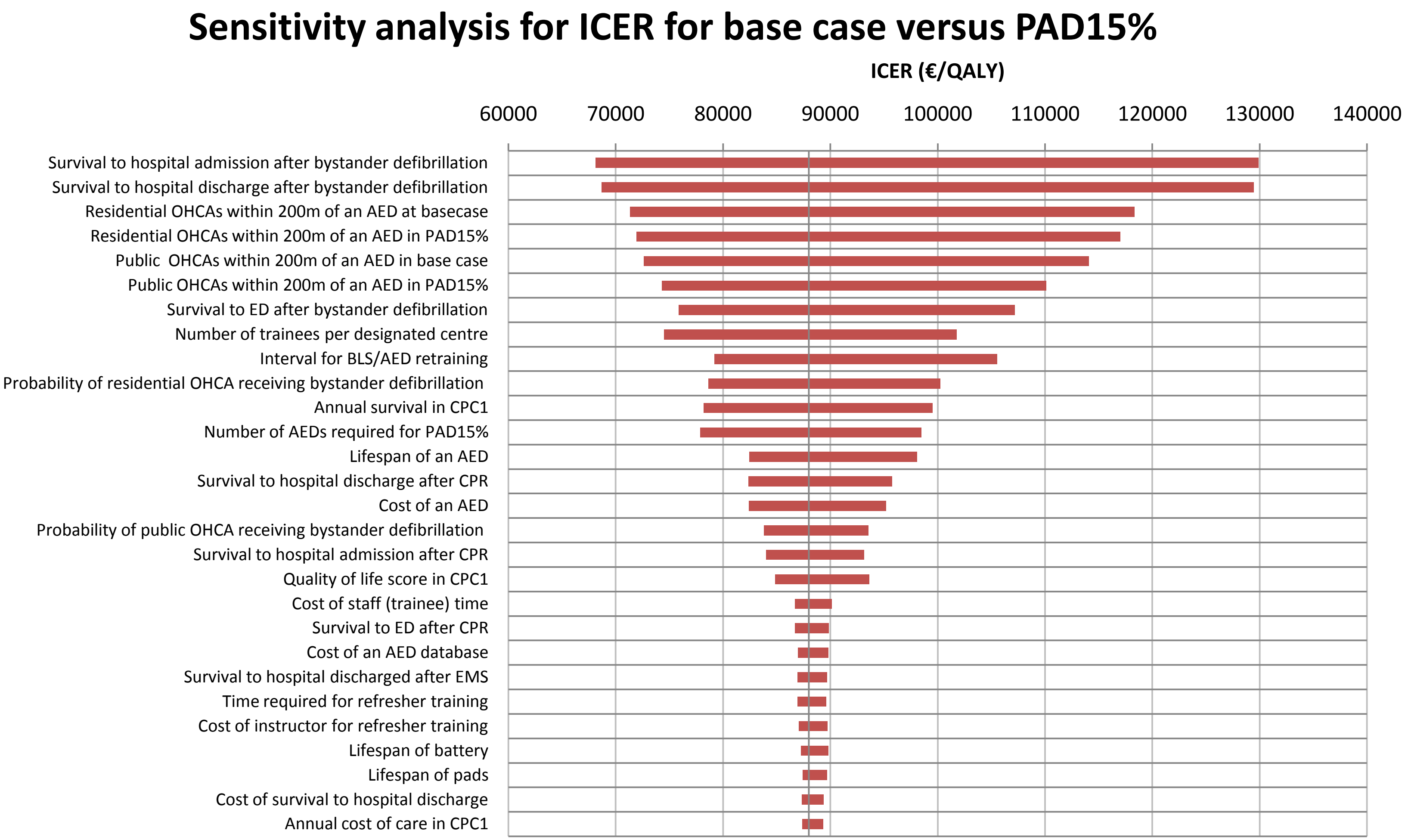
The cost-effectiveness acceptability curve taking the perspective of the public health service is shown in Figure App6.2.

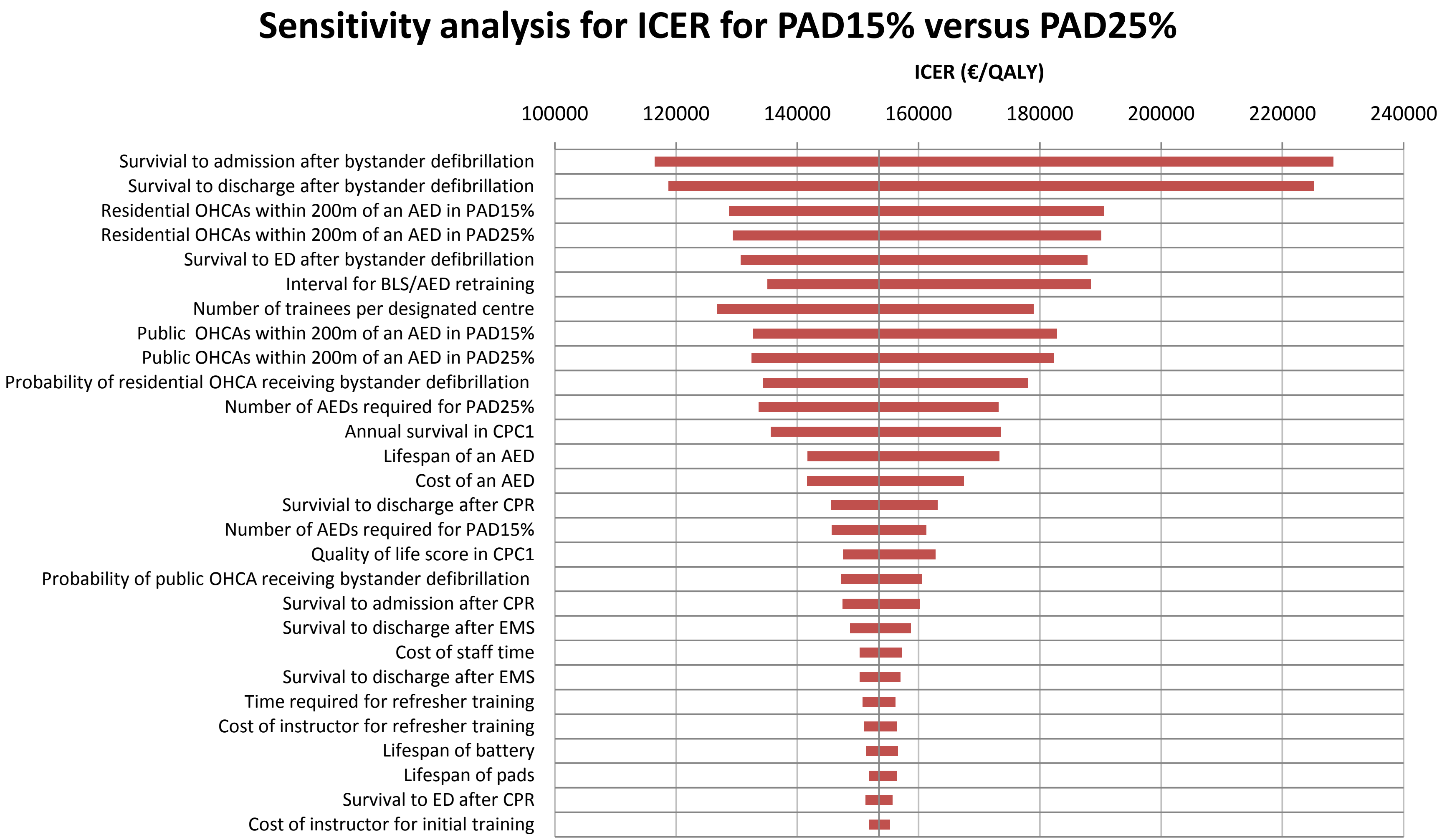
Figure App6.2 Cost-effectiveness acceptability curve (QALY outcomes)



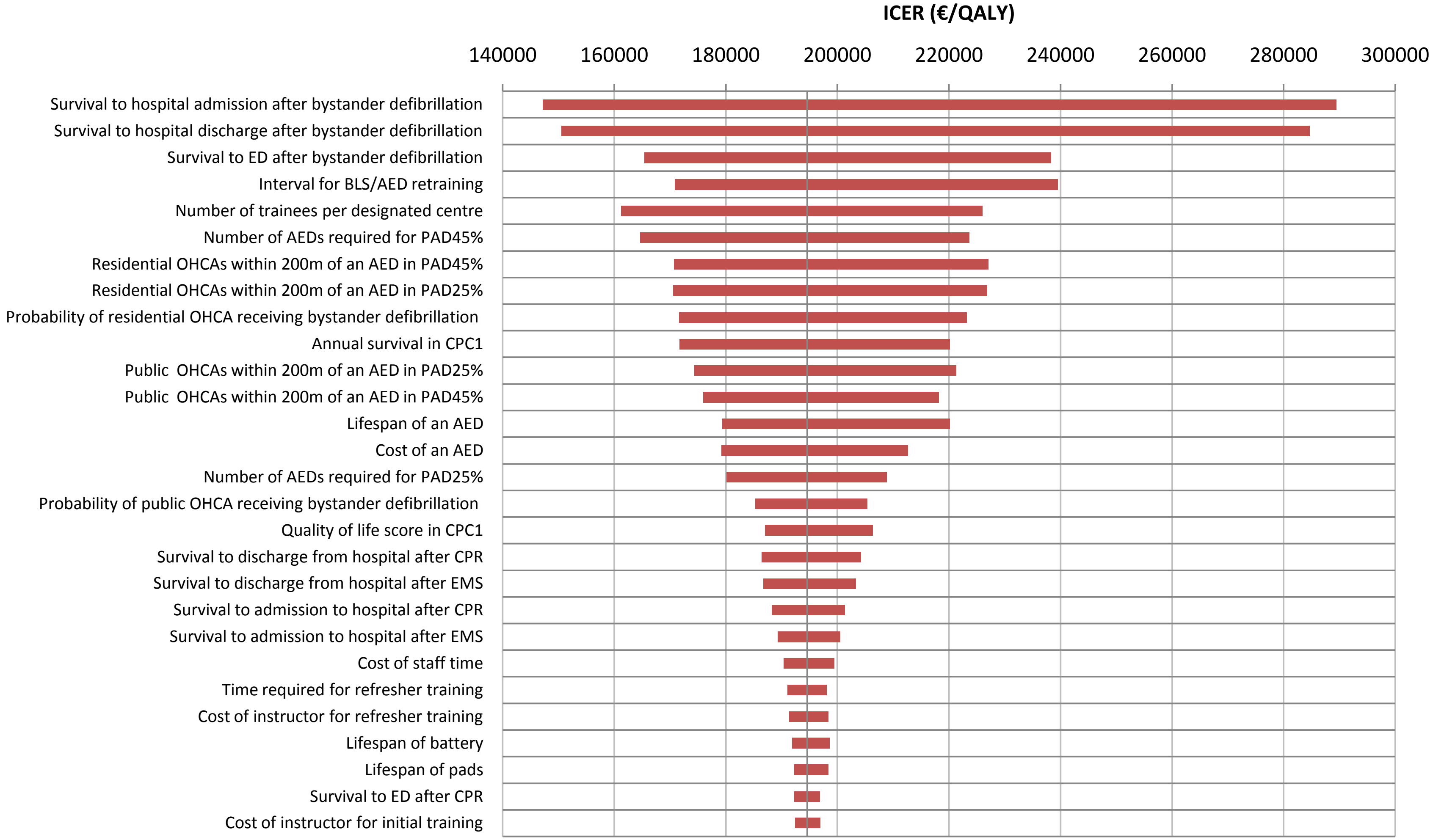
When the analysis is restricted to only take account of costs that are incurred by the health service, the proposed legislation weakly dominates all other public access defibrillation configurations, with a 96% chance of being cost-effective at a willingness to pay threshold of €20,000/QALY.

Appendix 7 – Sensitivity analysis of ICER estimates for QALY outcomes

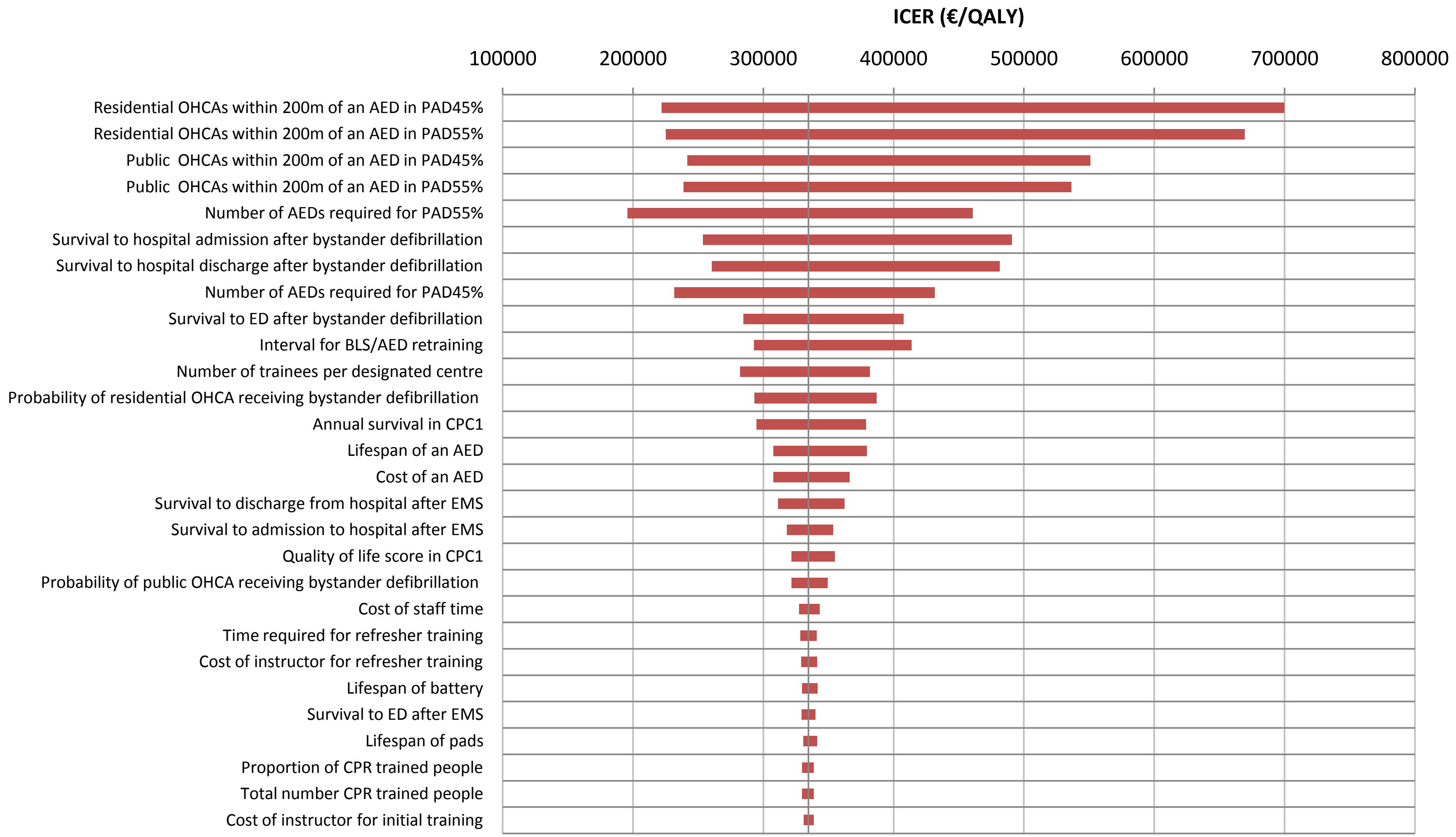


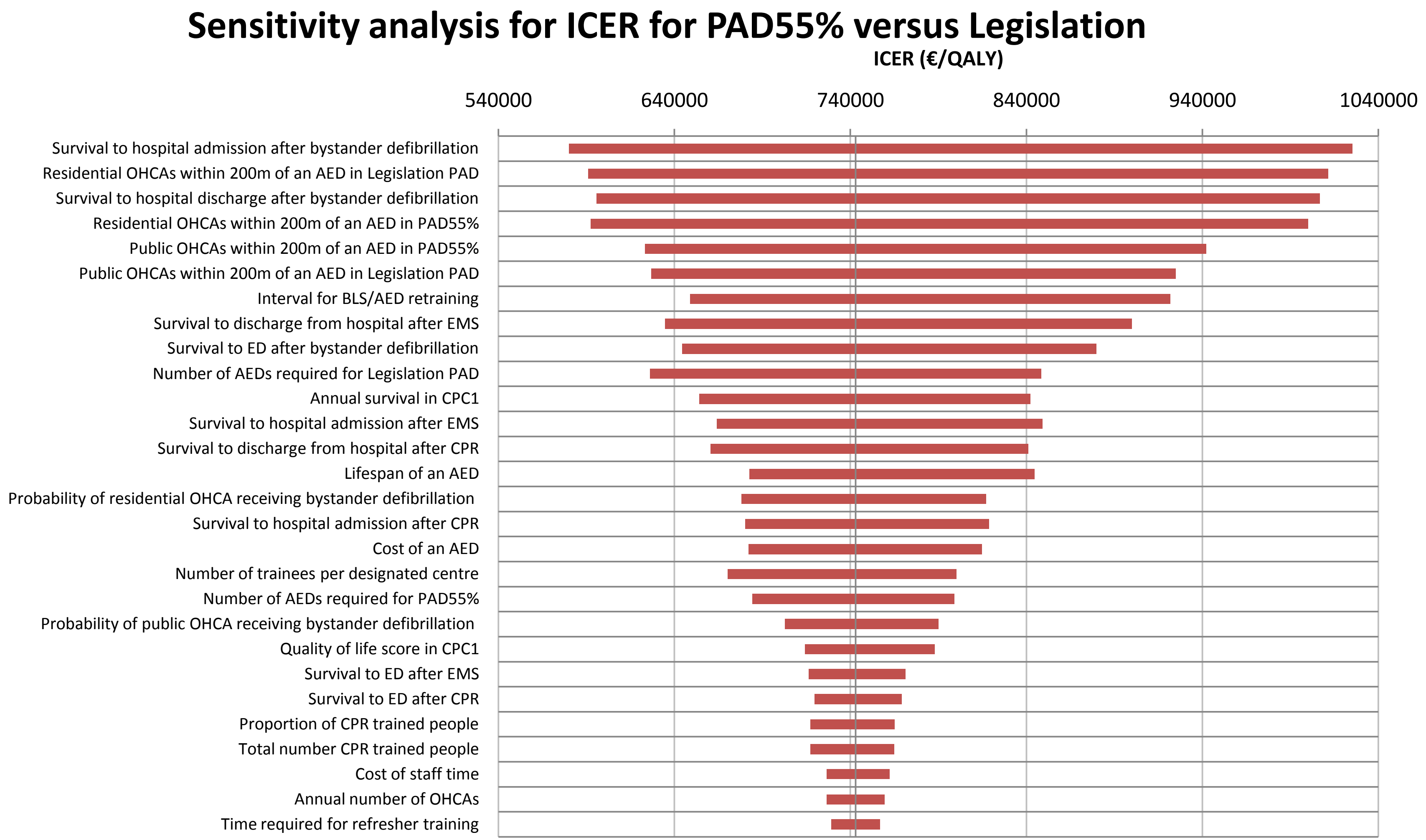

Sensitivity analysis for ICER for PAD15% versus PAD25%
ICER (€/QALY)
100000
120000
140000
160000
180000
200000
220000
240000
Survivial to admission after bystander defibrillation
Survival to discharge after bystander defibrillation
Residential OHCAs within 200m of an AED in PAD15%
Residential OHCAs within 200m of an AED in PAD25%
Survival to ED after bystander defibrillation
Interval for BLS/AED retraining
Number of trainees per designated centre
Public OHCAs within 200m of an AED in PAD15%
Public OHCAs within 200m of an AED in PAD25%
Probability of residential OHCA receiving bystander defibrillation
Number of AEDs required for PAD25%
Annual survival in CPC1
Lifespan of an AED
Cost of an AED
Survivial to discharge after CPR
Number of AEDs required for PAD15%
Quality of life score in CPC1
Probability of public OHCA receiving bystander defibrillation
Survival to admission after CPR
Survival to discharge after EMS
Cost of staff time
Survival to discharge after EMS
Time required for refresher training
Cost of instructor for refresher training
Lifespan of battery
Lifespan of pads
Survival to ED after CPR
Cost of instructor for initial training

Sensitivity analysis for ICER for PAD25% versus PAD45%

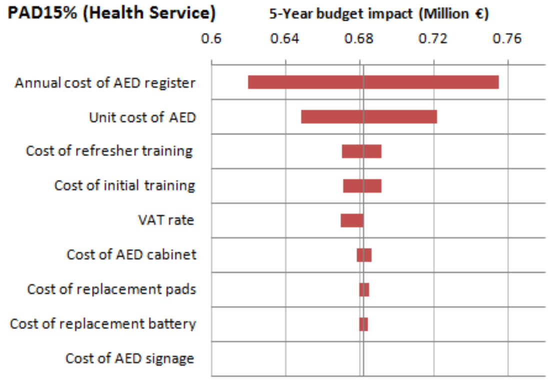


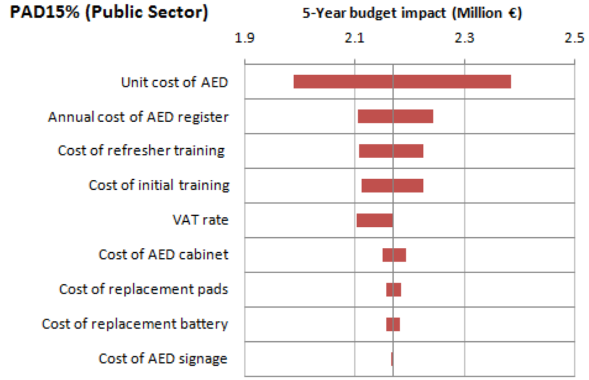
Sensitivity analysis for ICER for PAD45% versus PAD55%

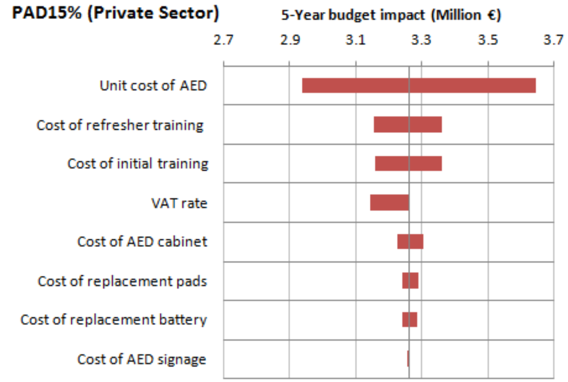


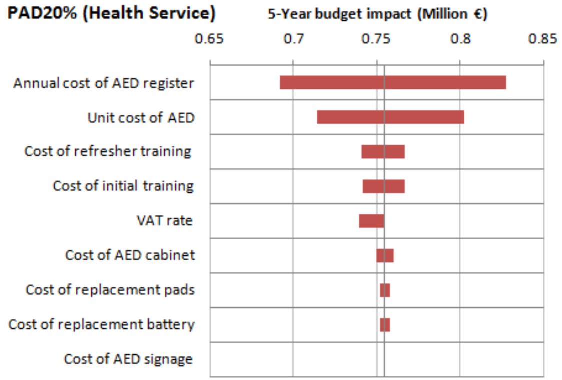

Sensitivity analysis for ICER for PAD55% versus Legislation
ICER (€/QALY)
540000
640000
740000
840000
940000
1040000
Survival to hospital admission after bystander defibrillation
Residential OHCAs within 200m of an AED in Legislation PAD
Survival to hospital discharge after bystander defibrillation
Residential OHCAs within 200m of an AED in PAD55%
Public OHCAs within 200m of an AED in PAD55%
Public OHCAs within 200m of an AED in Legislation PAD
Interval for BLS/AED retraining
Survival to discharge from hospital after EMS
Survival to ED after bystander defibrillation
Number of AEDs required for Legislation PAD
Annual survival in CPC1
Survival to hospital admission after EMS
Survival to discharge from hospital after CPR
Lifespan of an AED
Probability of residential OHCA receiving bystander defibrillation
Survival to hospital admission after CPR
Cost of an AED
Number of trainees per designated centre
Number of AEDs required for PAD55%
Probability of public OHCA receiving bystander defibrillation
Quality of life score in CPC1
Survival to ED after EMS
Survival to ED after CPR
Proportion of CPR trained people
Total number CPR trained people
Cost of staff time
Annual number of OHCAs
Time required for refresher training

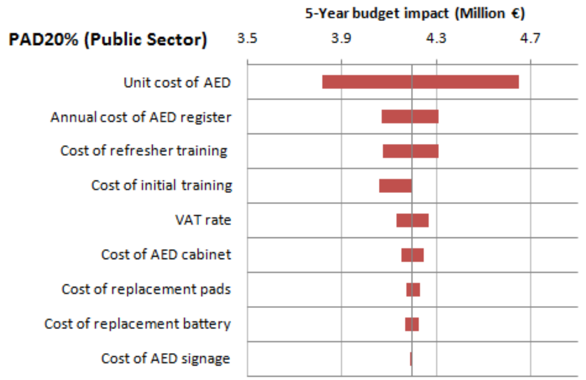
Appendix 8 – Sensitivity analysis of budget impact estimates for set-up and maintenance of public access defibrillation programmes

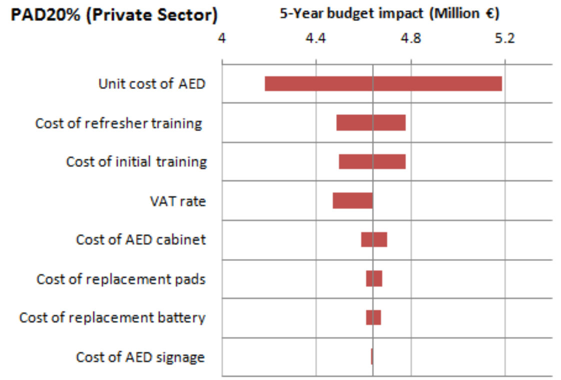


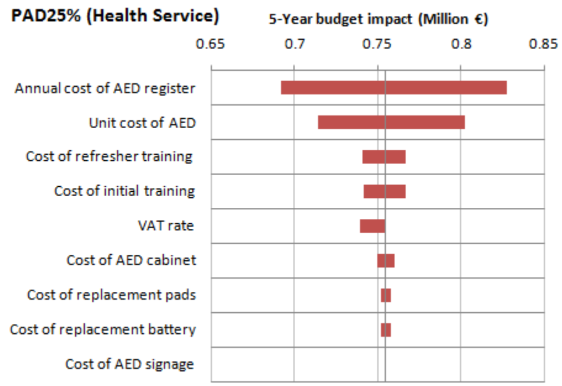


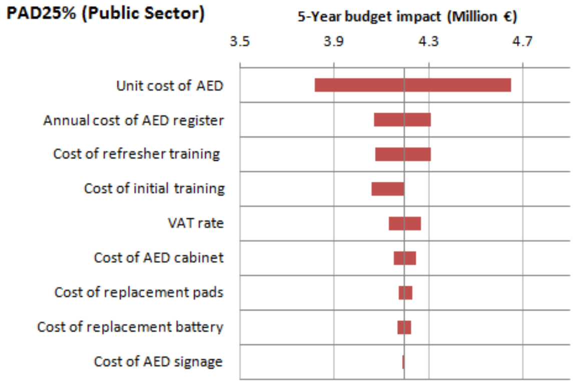


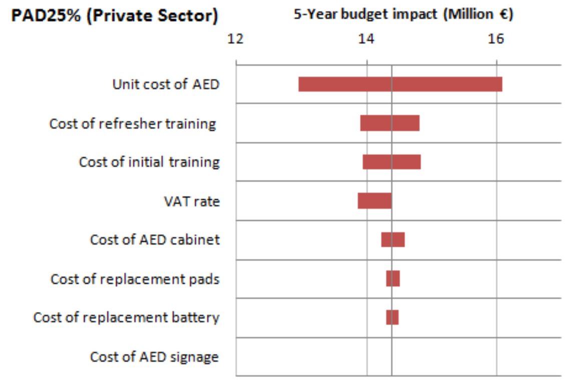


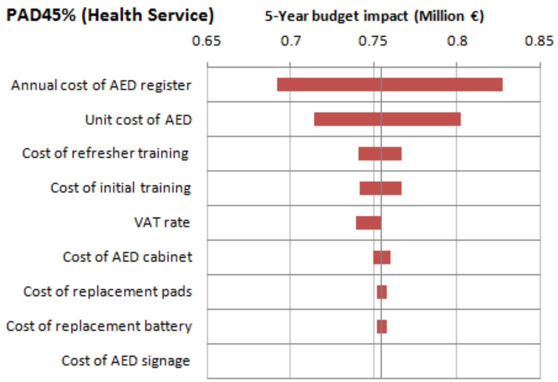


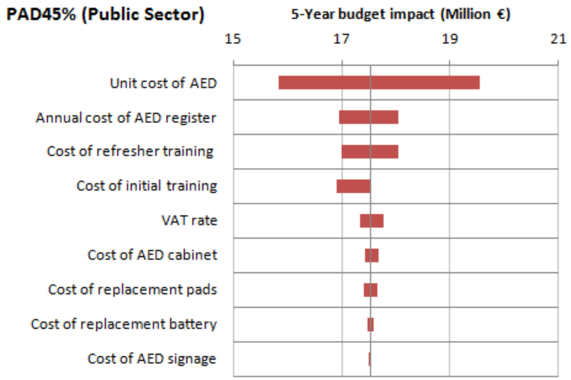


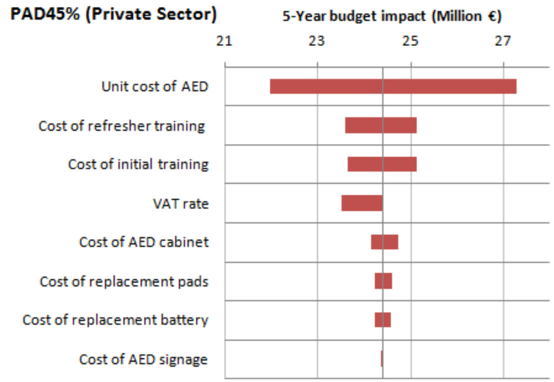

PAD25% (Health Service)
5-Year budget impact (Million €)
0.65
0.7
0.75
0.8
0.85
Annual cost of AED register
Unit cost of AED
Cost of refresher training
Cost of initial training
VAT rate
Cost of AED cabinet
Cost of replacement pads
Cost of replacement battery
Cost of AED signage

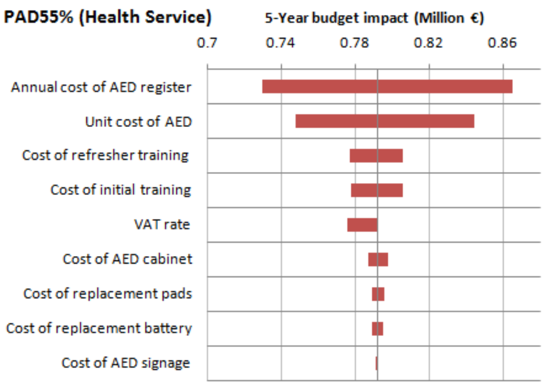

PAD25% (Public Sector)
5-Year budget impact (Million €)
3.5
3.9
4.3
4.7
Unit cost of AED
Annual cost of AED register
Cost of refresher training
Cost of initial training
VAT rate
Cost of AED cabinet
Cost of replacement pads
Cost of replacement battery
Cost of AED signage

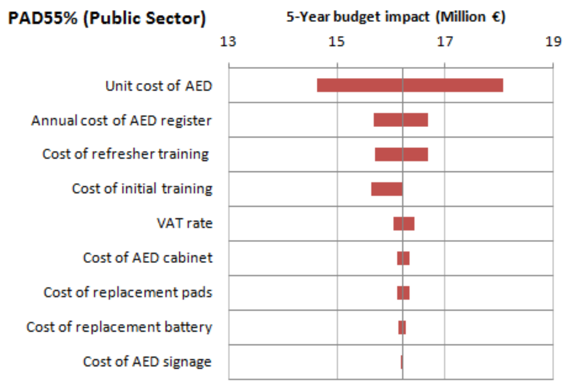

PAD25% (Private Sector)
5-Year budget impact (Million €)
12
14
16
Unit cost of AED
Cost of refresher training
Cost of initial training
VAT rate
Cost of AED cabinet
Cost of replacement pads
Cost of replacement battery
Cost of AED signage

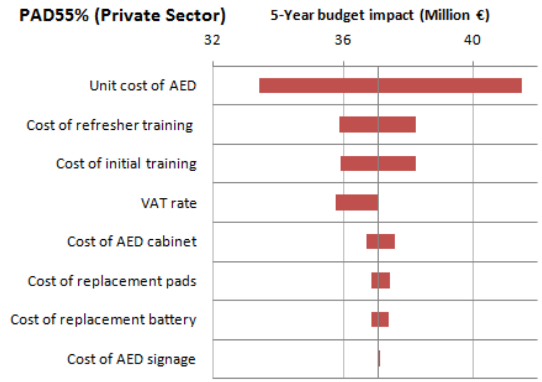

PAD45% (Health Service)
5-Year budget impact (Million €)
0.65
0.7
0.75
0.8
0.85
Annual cost of AED register
Unit cost of AED
Cost of refresher training
Cost of initial training
VAT rate
Cost of AED cabinet
Cost of replacement pads
Cost of replacement battery
Cost of AED signage

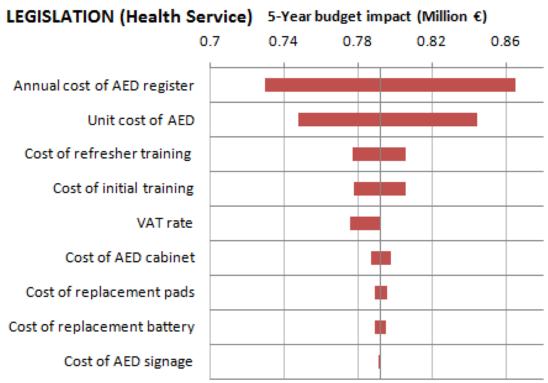

PAD45% (Public Sector)
5-Year budget impact (Million €)
15
17
19
21
Unit cost of AED
Annual cost of AED register
Cost of refresher training
Cost of initial training
VAT rate
Cost of AED cabinet
Cost of replacement pads
Cost of replacement battery
Cost of AED signage

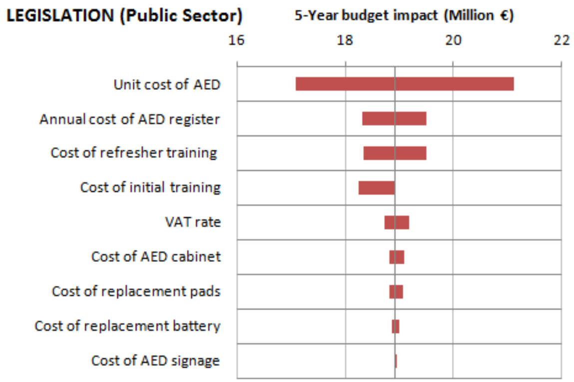

PAD45% (Private Sector)
5-Year budget impact (Million €)
21
23
25
27
Unit cost of AED
Cost of refresher training
Cost of initial training
VAT rate
Cost of AED cabinet
Cost of replacement pads
Cost of replacement battery
Cost of AED signage

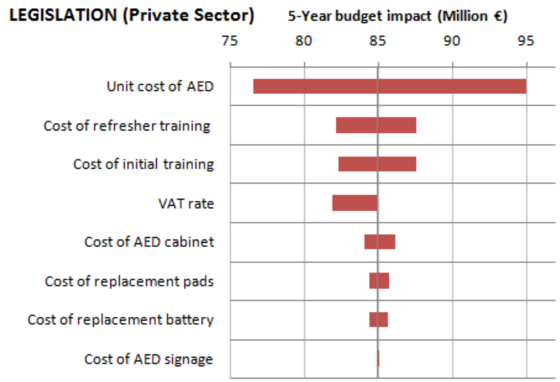

PAD55% (Health Service)
5-Year budget impact (Million €)
0.7
0.74
0.78
0.82
0.86
Annual cost of AED register
Unit cost of AED
Cost of refresher training
Cost of initial training
VAT rate
Cost of AED cabinet
Cost of replacement pads
Cost of replacement battery
Cost of AED signage


PAD55% (Public Sector)
5-Year budget impact (Million €)
13
15
17
19
Unit cost of AED
Annual cost of AED register
Cost of refresher training
Cost of initial training
VAT rate
Cost of AED cabinet
Cost of replacement pads
Cost of replacement battery
Cost of AED signage


PAD55% (Private Sector)
5-Year budget impact (Million €)
32
36
40
Unit cost of AED
Cost of refresher training
Cost of initial training
VAT rate
Cost of AED cabinet
Cost of replacement pads
Cost of replacement battery
Cost of AED signage


LEGISLATION (Health Service)
5-Year budget impact (Million €)
0.7
0.74
0.78
0.82
0.86
Annual cost of AED register
Unit cost of AED
Cost of refresher training
Cost of initial training
VAT rate
Cost of AED cabinet
Cost of replacement pads
Cost of replacement battery
Cost of AED signage


LEGISLATION (Public Sector)
5-Year budget impact (Million €)
16
18
20
22
Unit cost of AED
Annual cost of AED register
Cost of refresher training
Cost of initial training
VAT rate
Cost of AED cabinet
Cost of replacement pads
Cost of replacement battery
Cost of AED signage


LEGISLATION (Private Sector)
5-Year budget impact (Million €)
75
80
85
90
95
Unit cost of AED
Cost of refresher training
Cost of initial training
VAT rate
Cost of AED cabinet
Cost of replacement pads
Cost of replacement battery
Cost of AED signage

References

(1) SCD Task Force. *Reducing the Risk: A Strategic Approach - The Report of the Task Force on Sudden Cardiac Death*. Department of Health and Children; 2006.

(2) SCD Steering Group. *Reducing the Risk of Sudden Cardiac Death (SCD) - Steering Group Report on Implementation of SCD Task Force Recommendations (2006)*. Health Service Executive (HSE); 2010.

(3) Expert Advisory Group for the HTA on public access defibrillation. Personal communication. 25 June 2014.

(4) Quinn F, Barrett SD, Crown J, Mullen R, and Norris D. *Public Health (Availability of Defibrillators) Bill 2013.* 2013. Available online from: http://www.oireachtas.ie/documents/bills28/bills/2013/4813/b4813s.pdf.

(5) Adams BD, Anderson PI, Stuffel E. "Code Blue" in the hospital lobby: Cardiac arrest teams vs. public access defibrillation. *Int J Cardiol.* 2006; 110(3) pp.401-2.

(6) OHCAR. *National Out-of-Hospital Cardiac Arrest Register - Fifth Annual Report*. Letterkenny, Ireland: Health Service Executive; 2013.

(7) Koster RW, Baubin MA, Bossaert LL, Caballero A, Cassan P, Castren M, et al. European Resuscitation Council Guidelines for Resuscitation 2010 Section 2. Adult basic life support and use of automated external defibrillators. *Resuscitation.* 2010; 81(10) pp.1277-92.

(8) Part 4: The Automated External Defibrillator: Key Link in the Chain of Survival. *Circulation.* 2000; 102(suppl 1) p.I-60.

(9) Pre-Hospital Emergency Care Council. *External Defibrillator, Advisory. National Pre-Hospital Standards*. 2008.

(10) Caffrey SL, Willoughby PJ, Pepe PE, Becker LB. Public use of automated external defibrillators. *New Engl J Med.* 2002; 347(16) pp.1242-7.

(11) Berg MD, Schexnayder SM, Chameides L, Terry M, Donoghue A, Hickey RW, et al. Part 13: Pediatric Basic Life Support: 2010 American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care. *Circulation.* 2010; 122(18 suppl 3) p.S862-S875.

(12) Resuscitation Council (UK), British Heart Foundation. *A guide to Automated External Defibrillators (AEDs)*. 2013.

(13) Irish Medicines Board. *Our advice on automated external defibrillators.* 2014, [Online]. Available from:

http://www.flashpointsystems.ie/brochures/IMB_AED_Leaflet_Final.pdf. Accessed on: 19 September 2014.

(14) MEDDEV. *Guidelines relating to the application of the Council Directive 93/42/EEC on medical devices*. 2.4/1 Rev 9. 2010.

(15) FDA. *FDA issues proposal to improve the quality of automated external defibrillators.* 2013, [Online]. Available from: http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm345062.htm.

(16) Handley AJ, Koster R, Monsieurs K, Perkins GD, Davies S, Bossaert L. European Resuscitation Council guidelines for resuscitation 2005. Section 2. Adult basic life support and use of automated external defibrillators. *Resuscitation.* 2005; 67 Suppl 1 pp.S7-23.

(17) Aufderheide T, Hazinski MF, Nichol G, Steffens SS, Buroker A, McCune R, et al. Community lay rescuer automated external defibrillation programs: key state legislative components and implementation strategies: a summary of a decade of experience for healthcare providers, policymakers, legislators, employers, and community leaders from the American Heart Association Emergency Cardiovascular Care Committee, Council on Clinical Cardiology, and Office of State Advocacy. *Circulation.* 2006; 113(9) pp.1260-70.

(18) Deakin CD, Shewry E, Gray HH. Public access defibrillation remains out of reach for most victims of out-of-hospital sudden cardiac arrest. *Heart.* 2014; 100(8) pp.619-23.

(19) Hansen CM, Wissenberg M, Weeke P, Zinckernagel L, Ruwald MH, Karlsson L, et al. Danish AED network with linkage to emergency medical services covered more than half of public cardiac arrests in high-incidence areas. *Resuscitation.* 2013; 84(Supplement 1) p.S64-S65.

(20) Field JM, Hazinski MF, Sayre MR, Chameides L, Schexnayder SM, Hemphill R, et al. Part 1: executive summary: 2010 American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care. *Circulation.* 2010; 122(18 Suppl 3) p.S640-S656.

(21) American Heart Association. *American Heart Association. AED Programs Q & A.* 2014, [Online]. Available from: http://www.heart.org/HEARTORG/CPRAndECC/CorporateTraining/AEDResources/AED-Programs-Q-A_UCM_323111_Article.jsp.

(22) International Liason Committee on Resuscitation (ILCOR). *ILCOR presents a universal AED sign.* 2008, [Online]. Available from: http://www.ilcor.org/news/news-archive/ilcor-presents-a-universal-aed-sign.

(23) Priori SG, Bossaert LL, Chamberlain DA, Napolitano C, Arntz HR, Koster RW, et al. ESC-ERC recommendations for the use of automated external defibrillators (AEDs) in Europe. *Eur Heart J.* 2004; 25(5) pp.437-45.

(24) Bahr J, Bossaert L, Handley A, Koster R, Vissers B, Monsieurs K. AED in Europe. Report on a survey. *Resuscitation.* 2010; 81(2) pp.168-74.

(25) Cardiovascular Disease Team. *Cardiovascular Disease Outcomes Strategy : Improving outcomes for people with or at risk of cardiovascular disease*. UK: Department of Health; 2013.

(26) Gallego VF, Del Castillo JS, Martinez IM. Analysis of legislation on the use of semiautomatic external defibrillators by bystanders and the training of non-health-care professionals in Spain. *Emergencias.* 2009; 21 pp.53-61.

(27) Proposition de loi relative aux gestes de premiers secours et à l'installation de défibrillateurs cardiaques automatisés externes dans les immeubles recevant du public. 2014. Available online from: http://www.assemblee-nationale.fr/14/propositions/pion1780.asp. Accessed on: 28 August 2014.

(28) Ramos R, Cardoso I, Oliveira MSd. Implementation of a National Programme of automatic external defibrillation in our country. *Resuscitation.* 84 p.S38.

(29) Gilchrist S, Schieb L, Mukhtar Q, Valderrama A, Yoon P, Sasson C, et al. A Summary of public access defibrillation laws, United States, 2010. *Preventing Chronic Disease.* 2012; 9(3)

(30) NCSL National Conference of State Legislatures. *State Laws on Cardiac Arrest and Defibrillators.* 2013, [Online].

(31) Murakami Y, Iwami T, Kitamura T, Nishiyama C, Nishiuchi T, Hayashi Y, et al. Outcomes of out-of-hospital cardiac arrest by public location in the public-access defibrillation era. *J Am Heart Assoc.* 2014; 3(2) p.e000533.

(32) Berdowski J, Berg RA, Tijssen JG, Koster RW. Global incidences of out-of-hospital cardiac arrest and survival rates: Systematic review of 67 prospective studies. *Resuscitation.* 2010; 81(11) pp.1479-87.

(33) Moore MJ, Glover BM, McCann CJ, Cromie NA, Ferguson P, Catney DC, et al. Demographic and temporal trends in out of hospital sudden cardiac death in Belfast. *Heart.* 2006; 92(3) pp.311-5.

(34) Noseworthy PA, Newton-Cheh C. Genetic determinants of sudden cardiac death. *Circulation.* 2008; 118(18) pp.1854-63.

(35) Thorgeirsson G, Thorgeirsson G, Sigvaldason H, Witteman J. Risk factors for out-of-hospital cardiac arrest: the Reykjavik Study. *Eur Heart J.* 2005; 26(15) pp.1499-505.

(36) Jouven X, Desnos M, Guerot C, Ducimetiere P. Predicting sudden death in the population: the Paris Prospective Study I. *Circulation.* 1999; 99(15) pp.1978-83.

(37) Hasegawa K, Tsugawa Y, Camargo CA, Jr., Hiraide A, Brown DF. Regional variability in survival outcomes of out-of-hospital cardiac arrest: the All-Japan Utstein Registry. *Resuscitation.* 2013; 84(8) pp.1099-107.

(38) Nadeau A, Noording NAM, O'Neill G, Masterson S, Vellinga A. Outcomes and prevalence of adult out-of-hospital cardiac arrest (OHCA) by population density groups in the Republic of Ireland. *Resuscitation.* 2013; 84(Supplement 1) p.S51.

(39) Nichol G, Thomas E, Callaway CW, Hedges J, Powell JL, Aufderheide TP, et al. Regional variation in out-of-hospital cardiac arrest incidence and outcome. *JAMA.* 2008; 300(12) pp.1423-31.

(40) Stromsoe A, Svensson L, Claesson A, Lindkvist J, Lundstrom A, Herlitz J. Association between population density and reported incidence, characteristics and outcome after out-of-hospital cardiac arrest in Sweden. *Resuscitation.* 2011; 82(10) pp.1307-13.

(41) Raun LH, Jefferson LS, Persse D, Ensor KB. Geospatial analysis for targeting out-of-hospital cardiac arrest intervention. *Am J Prev Med.* 2013; 45(2) pp.137-42.

(42) Reinier K, Thomas E, Andrusiek DL, Aufderheide TP, Brooks SC, Callaway CW, et al. Socioeconomic status and incidence of sudden cardiac arrest. *CMAJ.* 2011; 183(15) pp.1705-12.

(43) Byrne R, Constant O, Smyth Y, Callagy G, Nash P, Daly K, et al. Multiple source surveillance incidence and aetiology of out-of-hospital sudden cardiac death in a rural population in the West of Ireland. *Eur Heart J.* 2008; 29(11) pp.1418-23.

(44) Henry K, Murphy A, Willis D, Cusack S, Bury G, O'Sullivan I, et al. Out-of-hospital cardiac arrest in Cork, Ireland. *Emerg Med J.* 2013; 30(6) pp.496-500.

(45) de Vreede-Swagemakers JJ, Gorgels AP, Dubois-Arbouw WI, Van Ree JW, Daemen MJ, Houben LG, et al. Out-of-hospital cardiac arrest in the 1990's: a population-based study in the Maastricht area on incidence, characteristics and survival. *J Am Coll Cardiol.* 1997; 30(6) pp.1500-5.

(46) Straus SM, Bleumink GS, Dieleman JP, van der LJ, Stricker BH, Sturkenboom MC. The incidence of sudden cardiac death in the general population. *J Clin Epidemiol.* 2004; 57(1) pp.98-102.

(47) Becker LJ, Eisenberg M, Fahrenbruch C, Cobb L. Public locations of cardiac arrest: Implications for public access defibrillation. *Circulation.* 1998; 97(21) pp.2106-9.

(48) Moore MJ, Hamilton AJ, Cairns KJ, Marshall A, Glover BM, McCann CJ, et al. The Northern Ireland Public Access Defibrillation (NIPAD) study: effectiveness in urban and rural populations. *Heart.* 2008; 94(12) pp.1614-9.

(49) Yannopoulos D, Aufderheide T. Acute management of sudden cardiac death in adults based upon the new CPR guidelines. *Europace.* 2007; 9(1) pp.2-9.

(50) Ornato JP, Peberdy MA. Prehospital and emergency department care to preserve neurologic function during and following cardiopulmonary resuscitation. *Neurol Clin.* 2006; 24(1) pp.23-39.

(51) DeJesus PW. Charging up the public for automated external defibrillators. *Crit Care.* 2005; 9(2) pp.147-8.

(52) Ko PCI, Ma MHM, Yen ZS, Shih CL, Chen WJ, Lin FY. Impact of community-wide deployment of biphasic waveform automated external defibrillators on out-of-hospital cardiac arrest in Taipei. *Resuscitation.* 2004; 63(2) pp.167-74.

(53) Peberdy MA, Callaway CW, Neumar RW, Geocadin RG, Zimmerman JL, Donnino M, et al. Part 9: post-cardiac arrest care: 2010 American Heart Association guidelines for cardiopulmonary resuscitation and emergency cardiovascular care. *Circulation.* 2010; 122 p.S768-S786.

(54) Kim YM, Yim HW, Jeong SH, Klem ML, Callaway CW. Does therapeutic hypothermia benefit adult cardiac arrest patients presenting with non-shockable initial rhythms?: A systematic review and meta-analysis of randomized and non-randomized studies. *Resuscitation.* 2012; 83(2) pp.188-96.

(55) Sandroni C, Cavallaro F, Antonelli M. Therapeutic hypothermia: is it effective for non-VF/VT cardiac arrest? *Crit Care.* 2013; 17(2) p.215.

(56) Nichol G, Huszti E, Kim F, Fly D, Parnia S, Donnino M, et al. Does induction of hypothermia improve outcomes after in-hospital cardiac arrest? *Resuscitation.* 2013; 84(5) pp.620-5.

(57) Bunch TJ, Hammill SC, White RD. Outcomes after ventricular fibrillation out-of-hospital cardiac arrest: Expanding the chain of survival. *Mayo Clin Proc.* 2005; 80(6) pp.774-82.

(58) Pell JP, Corstorphine M, McConnachie A, Walker NL, Caldwell JC, Marsden AK, et al. Post-discharge survival following pre-hospital cardiopulmonary arrest due to cardiac aetiology: temporal trends and impact of changes in clinical management. *Eur Heart J.* 2006; 27(4) pp.406-12.

(59) Wachelder EM, Moulaert VR, van HC, Verbunt JA, Bekkers SC, Wade DT. Life after survival: long-term daily functioning and quality of life after an out-of-hospital cardiac arrest. *Resuscitation.* 2009; 80(5) pp.517-22.

(60) Arawwawala D, Brett SJ. Clinical review: beyond immediate survival from resuscitation-long-term outcome considerations after cardiac arrest. *Crit Care.* 2007; 11(6) p.235.

(61) Fothergill RT, Watson LR, Chamberlain D, Virdi GK, Moore FP, Whitbread M. Increases in survival from out-of-hospital cardiac arrest: a five year study. *Resuscitation.* 2013; 84(8) pp.1089-92.

(62) Moulaert VR, Verbunt JA, van Heugten CM, Wade DT. Cognitive impairments in survivors of out-of-hospital cardiac arrest: a systematic review. *Resuscitation.* 2009; 80(3) pp.297-305.

(63) Van Alem AP, de VR, Schmand B, Koster RW. Cognitive impairment in survivors of out-of-hospital cardiac arrest. *Am Heart J.* 2004; 148(3) pp.416-21.

(64) Holler NG, Mantoni T, Nielsen SrL, Lippert F, Rasmussen LS. Long-term survival after out-of-hospital cardiac arrest. *Resuscitation.* 2007; 75(1) pp.23-8.

(65) Pachys G, Kaufman N, Bdolah-Abram T, Kark JD, Einav S. Predictors of long-term survival after out-of-hospital cardiac arrest: The impact of Activities of Daily Living and Cerebral Performance Category scores. *Resuscitation.* 2014;

(66) Kuilman M, Bleeker JK, Hartman JA, Simoons ML. Long-term survival after out-of-hospital cardiac arrest: an 8-year follow-up. *Resuscitation.* 1999; 41(1) pp.25-31.

(67) Lindner T, Vossius C, Mathiesen WT, Soreide E. Life years saved, standardised mortality rates and causes of death after hospital discharge in out-of-hospital cardiac arrest survivors. *Resuscitation.* 2014;

(68) Dumas F, Rea TD. Long-term prognosis following resuscitation from out-of-hospital cardiac arrest: role of aetiology and presenting arrest rhythm. *Resuscitation.* 2012; 83(8) pp.1001-5.

(69) Elliott VJ, Rodgers DL, Brett SJ. Systematic review of quality of life and other patient-centred outcomes after cardiac arrest survival. *Resuscitation.* 2011; 82(3) pp.247-56.

(70) Moulaert VR, Wachelder EM, Verbunt JA, Wade DT, van Heugten CM. Determinants of quality of life in survivors of cardiac arrest. *J Rehabil Med.* 2010; 42(6) pp.553-8.

(71) Deasy C, Bray J, Smith K, Harriss L, Bernard S, Cameron P. Functional outcomes and quality of life of young adults who survive out-of-hospital cardiac arrest. *Emerg Med J.* 2013; 30(7) pp.532-7.

(72) Stiell IG, Nesbitt LP, Nichol G, Maloney J, Dreyer J, Beaudoin T, et al. Comparison of the Cerebral Performance Category score and the Health Utilities Index for survivors of cardiac arrest. *Ann Emerg Med.* 2009; 53(2) pp.241-8.

(73) Nichol G, Stiell IG, Hebert P, Wells GA, Vandemheen K, Laupacis A. What is the quality of life for survivors of cardiac arrest? A prospective study. *Acad Emerg Med.* 1999; 6(2) pp.95-102.

(74) Hsu JW, Madsen CD, Callaham ML. Quality-of-life and formal functional testing of survivors of out-of-hospital cardiac arrest correlates poorly with traditional neurologic outcome scales. *Ann Emerg Med.* 1996; 28(6) pp.597-605.

(75) Eisenburger P, List M, Schorkhuber W, Walker R, Sterz F, Laggner AN. Long-term cardiac arrest survivors of the Vienna emergency medical service. *Resuscitation.* 1998; 38(3) pp.137-43.

(76) Torgersen J, Strand K, Bjelland TW, Klepstad P, Kvale R, Soreide E, et al. Cognitive dysfunction and health-related quality of life after a cardiac arrest and therapeutic hypothermia. *Acta Anaesthesiol Scand.* 2010; 54(6) pp.721-8.

(77) Sunnerhagen KS, Johansson O, Herlitz J, Grimby G. Life after cardiac arrest; a retrospective study. *Resuscitation.* 1996; 31(2) pp.135-40.

(78) Kelly, Des. Personal communication. 5 June 2014. Recipient: Health Information and Quality Authority.

(79) National Ambulance Service. *Policy: Community AED Cardiac First Responder Schemes*. Health Service Executive; NASCG007 Revision No. 4. 2012.

(80) Jennings S, Hara TO, Cavanagh B, Bennett K. A national survey of prevalence of cardiopulmonary resuscitation training and knowledge of the emergency number in Ireland. *Resuscitation.* 2009; 80(9) pp.1039-42.

(81) Masterson S, Robinson E, Wright P, Dowling J, Murphy A. Community cardiac first responders in Ireland. *Resuscitation.* 2013; 84(Supplement 1) p.S33.

(82) Rea TD, Page RL. Community approaches to improve resuscitation after out-of-hospital sudden cardiac arrest. *Circulation.* 2010; 121(9) pp.1134-40.

(83) Sutton RM, Niles D, Meaney PA, Aplenc R, French B, Abella BS, et al. Low-Dose, High-Frequency CPR Training Improves Skill Retention of In-Hospital Pediatric Providers. *Pediatrics.* 2011; 128(1) p.e145-e151.

(84) Peberdy MA, Ottingham LV, Groh WJ, Hedges J, Terndrup TE, Pirrallo RG, et al. Adverse events associated with lay emergency response programs: the public access defibrillation trial experience. *Resuscitation.* 2006; 70(1) pp.59-65.

(85) Hazinski MF, Idris AH, Kerber RE, Epstein A, Atkins D, Tang W, et al. Lay rescuer automated external defibrillator ("public access defibrillation") programs: Lessons learned from an international multicenter trial advisory statement from the American Heart Association Emergency Cardiovascular Committee; the Council on Cardiopulmonary, Perioperative, and Critical Care; and the Council on Clinical Cardiology. *Circulation.* 2005; 111(24) pp.3336-40.

(86) Schober P, Van Dehn FB, Bierens JJLM, Loer SA, Schwarte LA. Public access defibrillation: Time to access the public. *Ann Emerg Med.* 2011; 58(3) pp.240-7.

(87) Kozlowski D, Klosiewicz T, Kowalczyk A, Kowalczyk AK, Kozluk E, Dudziak M, et al. The knowledge of public access to defibrillation in selected cities in Poland. *Arch Med Sci.* 2013; 9(1) pp.27-33.

(88) Kuisma M, Castr+®n M, Nurminen K. Public access defibrillation in Helsinki - Costs and potential benefits from a community-based pilot study. *Resuscitation.* 2003; 56(2) pp.149-52.

(89) Cronin O, Jordan J, Quigley F, Molloy MG. Prepared for sudden cardiac arrest? A cross-sectional study of automated external defibrillators in amateur sport. *Br J Sports Med.* 2013; 47(18) pp.1171-4.

(90) Margey R, Browne L, Murphy E, O'Reilly M, Mahon N, Blake G, et al. The Dublin cardiac arrest registry: temporal improvement in survival from out-of-hospital cardiac arrest reflects improved pre-hospital emergency care. *Europace.* 2011; 13(8) pp.1157-65.

(91) Masterson S, Wright P, Dowling J, Swann D, Bury G, Murphy A. Out-of-hospital cardiac arrest (OHCA) survival in rural Northwest Ireland: 17 years' experience. *Emerg Med J.* 2011; 28(5) pp.437-8.

(92) O'Dowd T, O'Kelly M, O'Kelly F. *Structure of General Practice in Ireland*. Dublin: Trinity College Dublin; 2006.

(93) Nielsen AM, Folke F, Lippert FK, Rasmussen LS. Use and benefits of public access defibrillation in a nation-wide network. *Resuscitation.* 2013; 84(4) pp.430-4.

(94) Iwami T. Effectiveness of public access defibrillation with AEDs for out-of-hospital cardiac arrests in Japan. *Japan Med Assoc J.* 2012; 55(3) pp.225-30.

(95) Kitamura T, Iwami T, Kawamura T, Nagao K, Tanaka H, Hiraide A. Nationwide public-access defibrillation in Japan. *New Engl J Med.* 2010; 362(11) pp.994-1004.

(96) Hallstrom AP, Ornato JP, Weisfeldt M, Travers A, Christenson J, McBurnie MA, et al. Public-access defibrillation and survival after out-of-hospital cardiac arrest. *The New England journal of medicine.* 2004; 351 pp.637-46.

(97) An Post. *GeoDirectory.* 2014, [Online]. Available from: https://www.geodirectory.ie/. Accessed on: 4 June 2014.

(98) Indecon International Economic Consultants. *Assessment of economic impact of sport in Ireland*. The Irish Sports Council; 2010.

(99) Fleischhackl R, Roessler B, Domanovits H, Singer F, Fleischhackl S, Foitik G, et al. Results from Austria's nationwide public access defibrillation (ANPAD) programme collected over 2 years. *Resuscitation.* 2008; 77(2) pp.195-200.

(100) Effective Public Health Practice Project (EPHPP). *Quality assessment tool for quantitative studies.* 2010, [Online]. Available from: http://www.ephpp.ca/PDF/Quality%20Assessment%20Tool_2010_2.pdf.

(101) Effective Public Health Practice Project (EPHPP). *Quality Assessment Tool for Quantitative Studies - Dictionary.* 2009, [Online]. Available from: http://www.ephpp.ca/PDF/QADictionary_dec2009.pdf.

(102) Thomas BH, Ciliska D, Dobbins M, Micucci S. A process for systematically reviewing the literature: providing the research evidence for public health nursing interventions. *Worldviews Evid Based Nurs.* 2004; 1(3) pp.176-84.

(103) Cochrane Handbook for Systematic Reviews of Interventions Version 5.0.2 [updated September 2009]. Higgins JPT, Green S, (Eds) The Cochrane Collaboration; 2009.

(104) IPHA, DoH, HSE. *Framework agreement between the Irish Pharmaceutical Healthcare Association Ltd and the Department of Health and the Health Services Executive on the supply terms, conditions and prices of medicines.* 2012, [Online]. Available from: http://www.hse.ie/eng/about/Who/cpu/IPHA_Agreement_2012.pdf. Accessed on: 10 June 2014.

(105) Myerburg RJ, Fenster J, Velez M, Rosenberg D, Lai S, Kurlansky P, et al. Impact of community-wide police car deployment of automated external defibrillators on survival from out-of-hospital cardiac arrest. *Circulation.* 2002; 106(9) pp.1058-64.

(106) Sayre MR, Evans J, White LJ, Brennan TD. Providing automated external defibrillators to urban police officers in addition to a fire department rapid defibrillation program is not effective. *Resuscitation.* 2005; 66(2) pp.189-96.

(107) Mosesso VN, Davis EA, Auble TE, Paris PM, Yealy DM. Use of automated external defibrillators by police officers for treatment of out-of-hospital cardiac arrest. *Ann Emerg Med.* 1998; 32(2) pp.200-7.

(108) Groh WJ, Newman MM, Beal PE, Fineberg NS, Zipes DP. Limited response to cardiac arrest by police equipped with automated external defibrillators: lack of survival benefit in suburban and rural Indiana--the police as responder automated defibrillation evaluation (PARADE). *Acad Emerg Med.* 2001; 8(4) pp.324-30.

(109) Shuster M, Keller JL. Effect of fire department first-responder automated defibrillation. *Ann Emerg Med.* 1993; 22(4) pp.721-7.

(110) Smith KL, Peeters A, McNeil JJ. Results from the first 12 months of a fire first-responder program in Australia. *Resuscitation.* 2001; 49(2) pp.143-50.

(111) Sweeney TA, Runge JW, Gibbs MA, Raymond JM, Schafermeyer RW, Norton HJ, et al. EMT defibrillation does not increase survival from sudden cardiac death in a two-tiered urban-suburban EMS system. *Ann Emerg Med.* 1998; 31(2) pp.234-40.

(112) Kellermann AL, Hackman BB, Somes G. Impact of first-responder defibrillation in an urban emergency medical services system see comments. *JAMA.* 1993; pp.1708-13.

(113) Stiell IG, Wells GA, Field BJ, Spaite DW, Maio VJ, Ward R, et al. Improved out-of-hospital cardiac arrest survival through the inexpensive optimization of an existing defibrillation program: OPALS study phase II. Ontario Prehospital Advanced Life Support. *JAMA.* 1999; pp.1175-81.

(114) Van Alem AP, Vrenken RH, de VR, Tijssen JG, Koster RW. Use of automated external defibrillator by first responders in out of hospital cardiac arrest: prospective controlled trial. *BMJ.* 2003; 327(7427) p.1312.

(115) Hollenberg J, Riva G, Bohm K, Nordberg P, Larsen R, Herlitz J, et al. Dual dispatch early defibrillation in out-of-hospital cardiac arrest: The SALSA-pilot. *Eur Heart J.* 2009; 30(14) pp.1781-9.

(116) Cappato R, Curnis A, Marzollo P, Mascioli G, Bordonali T, Beretti S, et al. Prospective assessment of integrating the existing emergency medical system with automated external defibrillators fully operated by volunteers and laypersons for out-of-hospital cardiac arrest: the Brescia Early Defibrillation Study (BEDS). *Eur Heart J.* 2006; 27(5) pp.553-61.

(117) Saner H, Morger C, Eser P, von PM. Dual dispatch early defibrillation in out-of-hospital cardiac arrest in a mixed urban-rural population. *Resuscitation.* 2013; 84(9) pp.1197-202.

(118) Topjian AA, Berg RA. Pediatric Out-of-Hospital Cardiac Arrest. *Circulation.* 2012; 125(19) pp.2374-8.

(119) Samson RA, Berg RA, Bingham R, Members of the PALS Task Force, Biarent D, Coovadia A, et al. Use of Automated External Defibrillators for Children: An Update: An Advisory Statement From the Pediatric Advanced Life Support Task Force, International Liaison Committee on Resuscitation. *Circulation.* 2003; 107(25) pp.3250-5.

(120) Akahane M, Tanabe S, Ogawa T, Koike S, Horiguchi H, Yasunaga H, et al. Characteristics and outcomes of pediatric out-of-hospital cardiac arrest by scholastic age category. *Pediatr Crit Care Med.* 2013; 14(2) pp.130-6.

(121) Moler FW, Donaldson AE, Meert K, Brilli RJ, Nadkarni V, Shaffner DH, et al. Multicenter cohort study of out-of-hospital pediatric cardiac arrest. *Crit Care Med.* 2011; 39(1) pp.141-9.

(122) Hazinski MF, Markenson D, Neish S, Gerardi M, Hootman J, Nichol G, et al. Response to cardiac arrest and selected life-threatening medical emergencies: the medical emergency response plan for schools. A statement for healthcare providers, policymakers, school administrators, and community leaders. *Pediatrics.* 2004; 113(1 Pt 1) pp.155-68.

(123) Berger S. Cardiopulmonary resuscitation - Automated external defibrillation programs for children and adolescents: Is public access defibrillation directed at our youth justifiable? *Paediatr Child Health (GBR).* 2009; 14(3) pp.183-4.

(124) Kovach J, Berger S. Automated external defibrillators and secondary prevention of sudden cardiac death among children and adolescents. *Pediatr Cardiol.* 2012; 33(3) pp.402-6.

(125) Deasy C, Bernard SA, Cameron P, Jaison A, Smith K, Harriss L, et al. Epidemiology of paediatric out-of-hospital cardiac arrest in Melbourne, Australia. *Resuscitation.* 2010; 81(9) pp.1095-100.

(126) Sasson C, Rogers MA, Dahl J, Kellermann AL. Predictors of survival from out-of-hospital cardiac arrest: a systematic review and meta-analysis. *Circ Cardiovasc Qual Outcomes.* 2010; 3(1) pp.63-81.

(127) Abrams HC, Moyer PH, Dyer KS. A model of survival from out-of-hospital cardiac arrest using the Boston EMS arrest registry. *Resuscitation.* 2011; 82(8) pp.999-1003.

(128) Fabbri A, Marchesini G, Spada M, Iervese T, Dente M, Galvani M, et al. Monitoring intervention programmes for out-of-hospital cardiac arrest in a mixed urban and rural setting. *Resuscitation.* 2006; 71(2) pp.180-7.

(129) Swain AH, Barry T, Hoyle SR, Haywood G, Cameron H, Larsen PD. Outcomes from out-of-hospital cardiac arrest in the Wellington region of New Zealand.

does use of the fire service make a difference? *New Zealand Med J.* 2011; 124(1344) pp.81-9.

(130) Chamberlain D. Predictors of survival from out-of-hospital cardiac arrest. *Heart.* 2010; 96(22) pp.1785-6.

(131) Gold LS, Fahrenbruch CE, Rea TD, Eisenberg MS. The relationship between time to arrival of emergency medical services (EMS) and survival from out-of-hospital ventricular fibrillation cardiac arrest. *Resuscitation.* 2010; 81(5) pp.622-5.

(132) De Maio VJ, Stiell IG, Wells GA, Spaite DW. Optimal defibrillation response intervals for maximum out-of-hospital cardiac arrest survival rates. *Ann Emerg Med.* 2003; 42(2) pp.242-50.

(133) O'Keeffe C, Nicholl J, Turner J, Goodacre S. Role of ambulance response times in the survival of patients with out-of-hospital cardiac arrest. *Emerg Med J.* 2011; 28(8) pp.703-6.

(134) Pons PT, Haukoos JS, Bludworth W, Cribley T, Pons KA, Markovchick VJ. Paramedic response time: does it affect patient survival? *Acad Emerg Med.* 2005; 12(7) pp.594-600.

(135) Pell JP, Sirel JM, Marsden AK, Ford I, Cobbe SM. Effect of reducing ambulance response times on deaths from out of hospital cardiac arrest: cohort study. *BMJ.* 2001; 322

(136) Weisfeldt ML, Becker LB. Resuscitation after cardiac arrest: A 3-phase time-sensitive model. *JAMA.* 2002; 288(23) pp.3035-8.

(137) Weisfeldt ML, Sitlani CM, Ornato JP, Rea T, Aufderheide TP, Davis D, et al. Survival after application of automatic external defibrillators before arrival of the emergency medical system: evaluation in the resuscitation outcomes consortium population of 21 million. *J Am Coll Cardiol.* 2010; 55(16) pp.1713-20.

(138) Wissenberg M, Lippert FK, Folke F, Weeke P, Hansen CM, Christensen EF, et al. Association of national initiatives to improve cardiac arrest management with rates of bystander intervention and patient survival after out-of-hospital cardiac arrest. *JAMA.* 2013; 310(13) pp.1377-84.

(139) Davies E, Maybury B, Colquhoun M, Whitfield R, Rossetti T, Vetter N. Public Access Defibrillation: Psychological consequences in responders. *Resuscitation.* 2008; 77(2) pp.201-6.

(140) Hansen CM, Wissenberg M, Weeke P, Ruwald MH, Lamberts M, Lippert FK, et al. Automated external defibrillators inaccessible to more than half of nearby cardiac arrests in public locations during evening, nighttime, and weekends. *Circulation.* 2013; 128(20) pp.2224-31.

(141) Shah JS, Maisel WH. Recalls and safety alerts affecting automated external defibrillators. *J Am Med Assoc.* 2006; 296(6) pp.655-60.

(142) DeLuca Jr LA, Simpson A, Beskind D, Grall K, Stoneking L, Stolz U, et al. Analysis of Automated External Defibrillator Device Failures Reported to the Food and Drug Administration. *Ann Emerg Med.* 2012; 59(2) pp.103-11.

(143) Ornato JP, McBurnie MA, Nichol G, Salive M, Weisfeldt M, Riegel B, et al. The Public Access Defibrillation (PAD) Trial: Study design and rationale. *Resuscitation.* 2003; 56(2) pp.135-47.

(144) Eastern Regional Health Authority (ERHA). *Strategic review of the ambulance service 2001: executive summary*. Available in Lenus,The Irish Health Repository: http://hdl.handle.net/10147/43296; 2001.

(145) Pantridge JF, Geddes JS. A mobile intensive-care unit in the management of myocardial infarction. *Lancet.* 1967; 2(7510) pp.271-3.

(146) Pepe PE, Swor RA, Ornato JP, Racht EM, Blanton DM, Griswell JK, et al. Resuscitation in the out-of-hospital setting: medical futility criteria for on-scene pronouncement of death. *Prehosp Emerg Care.* 2001; 5(1) pp.79-87.

(147) Mitchell LB. The prevention of sudden cardiac death: the role of the automated external defibrillator. *Can J Cardiol.* 2005; 21 Suppl A pp.41A-6A.

(148) American College of Emergency Physicians (ACEP). *Public Training in Cardiopulmonary Resuscitation and Public Access Defibrillation.* 2014, [Online]. Available from: http://www.acep.org/Clinical---Practice-Management/Public-Training-in-Cardiopulmonary-Resuscitation-and-Public-Access-Defibrillation/. Accessed on: 22 August 2014.

(149) Herlitz J, Andersson E, Bang A, Engdahl J, Holmberg M, Lindqvist J, et al. Experiences from treatment of out-of-hospital cardiac arrest during 17 years in Goteborg. *Eur Heart J.* 2000; 21(15) pp.1251-8.

(150) Rea TD, Eisenberg MS, Becker LJ, Murray JA, Hearne T. Temporal trends in sudden cardiac arrest: a 25-year emergency medical services perspective. *Circulation.* 2003; 107(22) pp.2780-5.

(151) Cobb LA, Fahrenbruch CE, Olsufka M, Copass MK. Changing incidence of out-of-hospital ventricular fibrillation, 1980-2000. *JAMA.* 2002; 288(23) pp.3008-13.

(152) Polentini MS, Pirrallo RG, McGill W. The changing incidence of ventricular fibrillation in Milwaukee, Wisconsin (1992-2002). *Prehosp Emerg Care.* 2006; 10(1) pp.52-60.

(153) Bunch TJ, White RD. Trends in treated ventricular fibrillation in out-of-hospital cardiac arrest: Ischemic compared to non-ischemic heart disease. *Resuscitation.* 2005; 67(1) pp.51-4.

(154) Hulleman M, Berdowski J, de G, Jr., van Dessel PF, Borleffs CJ, Blom MT, et al. Implantable cardioverter-defibrillators have reduced the incidence of resuscitation for out-of-hospital cardiac arrest caused by lethal arrhythmias. *Circulation.* 2012; 126(7) pp.815-21.

(155) Atkins DL. Realistic expectations for public access defibrillation programs. *Curr Opin Crit Care.* 2010; 16(3) pp.191-5.

(156) Caro JJ, Eddy DM, Kan H, Kaltz C, Patel B, Eldessouki R, et al. *Questionnaire to Assess Relevance and Credibility of Modeling Studies for Informing Health Care Decision Making: An ISPOR-AMCP-NPC Good Practice Task Force Report*. Value in health : the journal of the International Society for Pharmacoeconomics and Outcomes Research 17[2], pp.174-82. 2014.

(157) Cram P, Vijan S, Fendrick AM. Cost-effectiveness of automated external defibrillator deployment in selected public locations. *J Gen Intern Med.* 2003; 18(9) pp.745-54.

(158) Cram P, Vijan S, Wolbrink A, Fendrick AM. The impact of including passive benefits in cost-effectiveness analysis: The case of automated external defibrillators on commercial aircraft. *Value Health.* 2003; 678(4) pp.466-73.

(159) Groeneveld PW, Owens DK. Cost-effectiveness of training unselected laypersons in cardiopulmonary resuscitation and defibrillation. *Am J Med.* 2005; 118(1) pp.58-67.

(160) Groeneveld PW, Kwong JL, Liu Y, Rodriguez AJ, Jones MP, Sanders GD, et al. Cost-effectiveness of automated external defibrillators on airlines. *JAMA.* 2001; 286(12) pp.1482-9.

(161) Jermyn BD. Cost-effectiveness analysis of a rural/urban first-responder defibrillation program (Structured abstract). *Prehosp Emerg Care.* 2000; 4 pp.43-7.

(162) Nichol G, Hallstrom AP, Ornato JP, Riegel B, Stiell LG, Valenzuela T, et al. Potential cost-effectiveness of public access defibrillation in the United States. *Circulation.* 1998; 97(13) pp.1315-20.

(163) Nichol G, Huszti E, Birnbaum A, Mahoney B, Weisfeldt M, Travers A, et al. Cost-effectiveness of lay responder defibrillation for out-of-hospital cardiac arrest. *Ann Emerg Med.* 2009; 54 pp.226-35.

(164) Sund B, Svensson L, Rosenqvist M, Hollenberg J. Favourable cost-benefit in an early defibrillation programme using dual dispatch of ambulance and fire

services in out-of-hospital cardiac arrest. *Eur J Health Econ.* 2012; 13(6) pp.811-8.

(165) Folke F, Lippert FK, Nielsen SL, Gislason GH, Hansen ML, Schramm TK, et al. Location of Cardiac Arrest in a City Center: Strategic Placement of Automated External Defibrillators in Public Locations. *Circulation.* 2009; 120(6) pp.510-7.

(166) Foutz RA, Sayre MR. Automated external defibrillators in long-term care facilities are cost-effective. *Prehosp Emerg Care.* 2000; 4(4) pp.314-7.

(167) Nichol G, Valenzuela T, Roe D, Clark L, Huszti E, Wells GA. Cost effectiveness of defibrillation by targeted responders in public settings. *Circulation.* 2003; 108(6) pp.697-703.

(168) Walker A, Sirel JM, Marsden AK, Cobbe SM, Pell JP. Cost effectiveness and cost utility model of public place defibrillators in improving survival after prehospital cardiopulmonary arrest. *Br Med J.* 2003; 327(7427) pp.1316-9.

(169) Berger S, Whitstone BN, Frisbee SJ, Miner JT, Dhala A, Pirrallo RG, et al. Cost-effectiveness of Project ADAM: A project to prevent sudden cardiac death in high school students. *Pediatr Cardiol.* 2004; 25(6) pp.660-7.

(170) Forrer CS, Swor RA, Jackson RE, Pascual RG, Compton S, McEachin C. Estimated cost effectiveness of a police automated external defibrillator program in a suburban community: 7 years experience (Structured abstract). *Resuscitation.* 2002; 52 pp.23-9.

(171) OECD. *Purchasing Power Parities (PPP) Statistics.* 2014, [Online]. Available from: http://stats.oecd.org/Index.aspx?DataSetCode=PPPGDP. Accessed on: 10 June 2014.

(172) Berdowski J, Kuiper MJ, Dijkgraaf MG, Tijssen JG, Koster RW. Survival and health care costs until hospital discharge of patients treated with onsite, dispatched or without automated external defibrillator. *Resuscitation.* 2010; 81(8) pp.962-7.

(173) Bur A, Kittler H, Sterz F, Holzer M, Eisenburger P, Oschatz E, et al. Effects of bystander first aid, defibrillation and advanced life support on neurologic outcome and hospital costs in patients after ventricular fibrillation cardiac arrest. *Intensive Care Med.* 2001; 27(9) pp.1474-80.

(174) Health Information and Quality Authority. *Guidelines for the Economic Evaluation of Health Technologies in Ireland*. Dublin: Health Information and Quality Authority; 2014.

(175) Office of the Revenue Commissioners. *VAT and Education and Vocational Training and Retraining Services.* 2012, [Online]. Available from: http://www.revenue.ie/en/tax/vat/leaflets/vat-and-education.html. Accessed on: 19 August 2014.

(176) Siddiq AA, Brooks SC, Chan TCY. Modeling the impact of public access defibrillator range on public location cardiac arrest coverage. *Resuscitation.* 2013; 84(7) pp.904-9.

(177) Bohannon RW. Comfortable and maximum walking speed of adults aged 20-79 years: reference values and determinants. *Age Ageing.* 1997; 26(1) pp.15-9.

(178) Drummond MF, O'Brien B, Stoddart G, Torrance G. *Methods for the economic evaluation of health care programmes. 2nd Edition*. Oxford Medical Publications; 1997.

(179) Economic and Social Research Institute. *Hospital In-Patient Enquiry Scheme (HIPE).* 2014, [Online]. Available from: http://www.esri.ie/health_information/hipe/. Accessed on: 29 April 2011.

(180) Gillespie P, O'Shea E, Murphy AW, Byrne MC, Byrne M, Smith SM, et al. The cost-effectiveness of the SPHERE intervention for the secondary prevention of coronary heart disease. *Int J Technol Assess Health Care.* 2010; 26(3) pp.263-71.

(181) Sanders GD, Hlatky MA, Owens DK. Cost-effectiveness of implantable cardioverter-defibrillators. *N Engl J Med.* 2005; 353(14) pp.1471-80.

(182) Citizens Information Board. *Social welfare carer's allowance.* 8 April 2014, [Online]. Available from: http://www.citizensinformation.ie/en/social_welfare/social_welfare_payments/carers/carers_allowance.html.

(183) CSO. *Employment, Hours and Earnings by Type of Employee, Statistic, Industry Sector NACE Rev 2 and Quarter.* 28 May 2014, [Online]. Available from: http://www.cso.ie/quicktables/GetQuickTables.aspx?FileName=EHQ03.asp&TableName=Earnings+and+Labour+Costs&StatisticalProduct=DB_EH.

(184) CSO. *National employment survey 2009.* 2009, [Online]. Available from: http://www.cso.ie/px/pxeirestat/Database/eirestat/National%20Employment%20Survey/National%20Employment%20Survey_statbank.asp?sp=National%20Employment%20Survey&Planguage=0. Accessed on: 19 May 2014.

(185) *Office of the Revenue Commissioners*. 2014, [Online]. Available from: http://www.revenue.ie/en/index.html. Accessed on: 17 September 2014.

(186) Rea T, Blackwood J, Damon S, Phelps R, Eisenberg M. A link between emergency dispatch and public access AEDs: Potential implications for early defibrillation. *Resuscitation.* 2011; 82(8) pp.995-8.

(187) Briggs A, Claxton K, Sculpher M. *Decision modelling for health economic evaluation. 1st Edition*. Oxford University Press; 2006.

(188) EUnetHTA Joint Action 2 WP8. *HTA Core Model version 2.0.* 2013, [Online]. Available from: www.corehta.info/BrowseModel.aspx.

(189) PHECC. *Pre-Hospital Emergency Care Council.* 2014, [Online]. Accessed on: 21 August 2014.

(190) CPR Nation. *MyHeartMap Challenge.* 2014, [Online]. Available from: http://www.cprnation.org/myheartmap_challenge. Accessed on: 21 August 2014.

(191) Leung AC, Asch DA, Lozada KN, Saynisch OB, Asch JM, Becker N, et al. Where are lifesaving automated external defibrillators located and how hard is it to find them in a large urban city? *Resuscitation.* 2013; 84(7) pp.910-4.

(192) OHCAR. *Out of Hospital Cardiac Arrest Register.* 2014, [Online]. Available from: http://www.nuigalway.ie/ohcar/. Accessed on: 21 August 2014.

(193) Public training in cardiopulmonary resuscitation and public access defibrillation. *Ann Emerg Med.* 2006; 47(6) p.585.

(194) Beauchamp TL, Childress JF. *Principles of Biomedical Ethics. 7th Edition*. Oxford University Press; 2013.

(195) Health Services Executive (HSE). *National Consent Policy.* 2014, [Online]. Available from: http://www.hse.ie/eng/about/Who/qualityandpatientsafety/National_Consent_Policy/. Accessed on: 8 August 2014.

(196) Resuscitation Council (UK). *The legal status of those who attempt resuscitation.* 2010, [Online]. Available from: http://www.resus.org.uk/pages/legal.pdf. Accessed on: 8 August 2014.

(197) Assisted Decision-Making (Capacity) Bill.2013. Available online from: http://www.oireachtas.ie/documents/bills28/bills/2013/8313/b8313d.pdf. Accessed on: 8 August 2014.

(198) Nichol G, Wells GA, Kuntz K, Feeny D, Longstreth W, Mahoney B, et al. Methodological design for economic evaluation in Public Access Defibrillation (PAD) trial. *Am Heart J.* 2005; 150(2) pp.202-8.

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