Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Health technology assessment (HTA) of public access defibrillation

1 December 2014

Safer Better Care

Executive summary

I. Background

On 25 July 2013, the then Minister for Health, Dr James Reilly, requested that the Health Information and Quality 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 were:

- 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.
- The draft report was made available as part of a public consultation process to elicit feedback and comments from all interested parties and members of the public prior to being finalised.

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 their 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 their 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 out-of-hospital cardiac arrests attended by emergency medical services (EMS-attended) in Ireland is approximately 40.3 per 100,000 persons, equivalent to approximately 1,850 cases each year. 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. Between 2012 and 2013, the survival from emergency medical services-attended out-of-hospital cardiac arrest in Ireland was 5.8%, which is slightly lower than the international average of 7.1%. 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 over 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 EMS-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 12.5%, compared with 5.4% for bystander CPR only and 5.1% 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 Service 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 firefighter 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 firefighter 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 firefighter 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 analytical 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 next best option. 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 ten 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 (ten additional lives saved annually) and with the highest costs (€105 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) (€96,000 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 with the next best option (PAD55%) is €928,000 per QALY whilst

the average cost-effectiveness ratio (ACER) comparing the proposed legislation with the base-case is €301,000/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 €2.4 million for the health service, €2 million to €20 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 (1.7)	96,000	€1.0M	€1.0M	€3.3M
PAD20%	3,100	2 (1.9)	Dominated*	€1.1M	€2.9M	€4.6M
PAD25%	6,800	4 (4.0)	151,000	€1.5M	€2.9M	€14.4M
PAD45%	15,300	7 (6.9)	214,000	€2.0M	€17.0M	€24.4M
PAD55%	19,600	8 (7.7)	374,000	€2.2M	€14.9M	€37.1M
Legislation	38,400	10 (9.3)	928,000	€2.4M	€17.6M	€85.0M

*Note: M = million. * PAD20% was weakly dominated, meaning that it was more costly and as, or less effective than some combination of PAD15% and PAD25%*

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 usage of AEDs as a result of increased public awareness and an EMS-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 usage 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 usage of approximately 40% would be required for the PAD15% ICER to approach a threshold of €45,000 per QALY. However there is no evidence to indicate what magnitude of increase could reasonably be expected.

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 two years of national data currently available from the Out-of-Hospital Cardiac Arrest Register. The use of additional 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 did not decrease any of the ICERs to a level that would be considered cost-effective compared with the current situation using conventional willingness-to-pay thresholds. The potential importance of uncertainty about the estimate for the number of public OHCA events was highlighted in the comparison of PAD45% and PAD55%, which showed that this could potentially result in PAD55% being dominated by PAD45%. However, although there is a high degree of uncertainty for some important parameters, it is unlikely to affect the overall results in regard to the cost-effectiveness of different public access defibrillation programmes compared with the current standard of care.

In keeping with the proposed legislation, the Authority modelled deployment of static 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 multiple years of data on the precise location of each OHCA event would be required to identify such high-incidence locations. This data, and therefore any estimate of the cost-effectiveness of such a programme, is as yet unavailable.

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
- the programme can maximise the accessibility of AEDs outside of normal working hours and at weekends
- ongoing performance evaluation will be carried out
- 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, EMS-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 geocoded data on OHCA incidence from the OHCA 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 dispersal 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 2 and 10 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 €2.4 million for the health service,

€2 million to €20 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 usage of AEDs as a result of a national EMS-linked AED register and increased public awareness could render public access defibrillation programmes more cost-effective. However there is no evidence to indicate how much of an increase could reasonably be expected. 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 on the precise location of OHCA events would be required to identify such high-incidence locations. This data, and therefore any estimate of the cost-effectiveness of such a programme, is as yet unavailable.

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, expanded CPR and AED training and an EMS-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.

Published by the Health Information and Quality Authority.

For further information please contact:

Health Information and Quality Authority
Dublin Regional Office
George's Court
George's Lane
Smithfield
Dublin 7

Phone: +353 (0) 1 814 7400
URL: www.hiqa.ie