



**Health
Information
and Quality
Authority**

An tÚdarás Um Fhaisnéis
agus Cáilíocht Sláinte

Statement of Outcomes

Report on the outcome of the public consultation on the draft health technology assessment (HTA) of a public access defibrillation programme.

1 December 2014

About the Health Information and Quality Authority

The Health Information and Quality Authority (HIQA) is the independent Authority established to drive high quality and safe care for people using our health and social care services. HIQA's role is to promote sustainable improvements, safeguard people using health and social care services, support informed decisions on how services are delivered, and promote person-centred care for the benefit of the public.

The Authority's mandate extends across the quality and safety of the public, private (within its social care function) and voluntary sectors. Reporting directly 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.

Supporting Improvement – Supporting health and social care services to implement standards by providing education in quality improvement tools and methodologies.

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.

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1. Introduction and overview

The Health Information and Quality Authority (hereafter referred to as “the Authority”) has a statutory remit to evaluate the clinical and cost-effectiveness of health technologies, providing advice to the Minister of Health and to the Health Services Executive (HSE). It is also recognised that the findings of a health technology assessment (HTA) may have implications for other stakeholders in the Irish healthcare system, including patient groups, clinicians, other healthcare providers, academic groups and health technology industry.

The Public Health (Availability of Defibrillators) Bill 2013 lists the types of premises and venues that would be required to install and maintain an Automated External Defibrillator (AED). This is a small portable device that can be used to restore normal heart rhythm in someone who has experienced a cardiac arrest. The Public Health Bill has the capacity to impact 43,000 premises throughout Ireland.

The HTA of public access defibrillation aims to advise on the best public access defibrillation programme for Ireland, based on Irish and international clinical evidence, data and literature. It takes into account the effectiveness and safety of a number of programme alternatives, all of which involve placing AEDs in community spaces, and examines their relative clinical benefits, cost-effectiveness and budget impact.

2. The consultation process

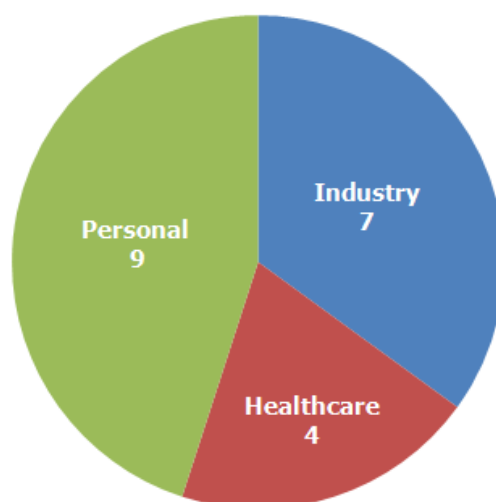
The draft health technology assessment of public access defibrillation was launched for consultation on 23 September 2014. The consultation process ran for a three and a half week period (24 days) until 17 October 2014. Key stakeholders were also targeted via e-mail to alert them to the public consultation.

A consultation feedback form (see Appendix 1) was developed to assist people make a written submission. The draft assessment and feedback form for the public consultation were made publically available in a downloadable format on the Authority’s website: www.hiqa.ie.

3. Analysis of submissions

A total of 20 submissions were received through the public consultation on the HTA of public access defibrillation – 17 via email and three via post. Of the 20 submissions, seven were submitted on behalf of medical device industries, four were submitted on behalf of healthcare organisations and nine were submitted in a personal capacity (Figure 1). Appendix 2 gives a full list of all the organisations that made a submission

Figure 1. Respondent type



Each submission was read in its entirety, broken down into individual comments, and recorded to create a database of comments. Amendments to the report, where applicable, were made and responses to comments were documented. The comments and responses are listed in Table 1 below.

4. Comments received and responses

We would like to thank all those who made submissions as part of the consultation process and express our gratitude for their contribution to ensuring that this assessment benefited from the views of people from all backgrounds and experiences. We appreciate the complimentary feedback of many respondents and value the input of those who expressed general opinions on this type of intervention. This section describes some specific points raised during the consultation process and provides a brief summary of the Authority's response. It is not an exhaustive list of all comments received, rather it is intended to address some of the issues raised in regard to the study question and analytical approach adopted in this assessment. Although not every comment is included here, all material received as part of the consultation process was given careful consideration by the evaluation team. We would be pleased to discuss any issues raised in greater detail and can be contacted using the details provided in Appendix 1 of this report

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Health Information and Quality Authority

Comment	Response
<p>In the AED Survey 2009, under 'Who is legally allowed to use an AED' it says for Ireland 'Everyone trained'. I am not aware if there is any actual legal requirement 'to be trained' in order to use an AED.</p>	<p>We agree that the current situation in Ireland is that anyone can use an AED regardless of training. The table cited in the report is based on a study* carried out before the Civil Law (Miscellaneous Provisions) Act 2011. Therefore we have clarified this point in the report. * Bahr et al, AED in Europe. Report on a survey. Resuscitation. 2010; 81(2) pp.168-74.</p>
<p>In regards to information held by companies who sell AEDs, "The data are used to contact customers regarding routine services ... and to notify when batteries and pads reach expiry dates." As an owner of AED and someone involved in the purchases of several AEDs it is not the case that all companies selling AEDs provide this service.</p>	<p>This statement was based on the contact we had with a sample of AED suppliers in Ireland and we accept that it may not be the case in all instances, so we have amended the text to reflect this.</p>
<p>In my view to establish and maintain the long awaited register of available AEDS and making this information available to first responders at the time of a call is by far the most important priority and as shown in this report is a low cost intervention in comparison to what is proposed in the legislation.</p>	<p>The report highlights the potential importance of a national AED register as one of a range of measures to increase AED utilisation. However, there is as yet a lack of reliable published evidence demonstrating the impact that linked registers have had on OHCA survival in other countries.</p>
<p>If we are to go down the mandatory route I feel the 15-20% option is far preferable to what is proposed in the pending legislation. GP surgeries, district hospitals and nursing homes, hotels with leisure centres/gyms, sports stadiums would be my priority followed perhaps by large shopping centres and main transport hubs i.e., main train bus ferry terminals.</p>	<p>We included a range of PAD configurations and found that targeted placement in higher incidence areas would likely be more cost-effective. However, the absolute clinical benefits of comprehensive programmes (e.g., PAD45%, PAD55%) exceeded those of more targeted programmes.</p>
<p>All places frequented by the public should have Defibrillators. They need to be kept in a secure and obvious place. People must be helped and trained to use these. The defibrillators must be kept in order and must be checked to see if the pads are working.</p>	<p>This is consistent with the conclusions of the report, which highlights the need for directed deployment in conjunction with ongoing maintenance and training. We did however find that targeted deployment in higher incidence building types was more cost-effective than including building types</p>

	Health Information and Quality Authority with a lower OHCA incidence.
More lives could be saved if the points above are carried out.	
Since 2005, the GAA has facilitated the purchase of over 1,500 AEDs by GAA Clubs therefore has accumulated significant experience on the acquisition, accessibility & storage, training on, and maintenance of, these machines. We now estimate that virtually every GAA Club has access to an AED, however, also acknowledge that many may not be adequately maintained. During the first quarter of 2013 we evaluated our AEDs and performed updates. The evaluation process highlighted that many machines inspected were not being adequately maintained and had batteries and/or pads that had reached their expiration date. The GAA subsequently launched an awareness campaign and developed a maintenance offer for clubs. Whilst the GAA welcome the assessment of the feasibility of providing defibrillators in public places, and would advise that a strategy also be put in place for the maintenance of these machines.	The experience of organisations that have already embarked on a programme of widespread AED deployment will be of great assistance in the setting up of a prospective national programme. In our report we emphasise that appropriate maintenance of AEDs is vital for proper operation (Chapter 2) and the costs of both acquiring and maintaining the AEDs has been included in the analysis. In addition, the report notes that health promotion or public awareness campaigns are necessary to increase knowledge and understanding of AEDs and to increase their usage in emergencies (Section 2.4).
Survival is highest where an AED is used by a member of the public before the arrival of Emergency Medical Services.	This is noted in Table 3.2 and in 3.4 of the report.
The mean response time of an ambulance is 9 minutes in urban and 18 minutes in rural areas.	This is noted in Section 3.3.1 (page 57) of the report.
Some areas are not accessible by Emergency Medical Services – transport; Ferry, Airplanes and Rail.	It is indeed the case that there are specific locations where EMS accessibility is greatly restricted, such as during a flight or ferry crossing. Where transport infrastructure has been included in the report it refers to the building associated with that transport. For instance for PAD configurations that include rail transport, the number of AEDs required (and the expected number of OHCA events) reflects the number of railway stations rather than the number of trains, and similarly for airports. Our

	<p>Health Information and Quality Authority analysis does not examine the incidence of OHCA on specific types of transport and the costs and other logistical issues surrounding the implementation of PAD programme on specific types of transportation vehicles. While this is beyond the scope of the current assessment, we are aware of some studies that have examined this issue in the past, such as "Cram et al, The Impact of Including Passive Benefits in Cost-Effectiveness Analysis: The Case of Automated External Defibrillators on Commercial Aircraft, Value In Health, Vol 6, Num 4, 2003".</p>
<p>AEDs cannot be shared. While this may lead to some areas having many AEDs and lead to an increase of those trained in CPR. If an AED is shared this will cause a serious difficulty in relation to responsibility. Imagine if fire extinguishers were shared between businesses. This option has been recognised in the report.</p>	<p>In our report we describe some of the potential issues and provide estimates of the impact of device-sharing on the total numbers of AEDs required for each PAD configuration. This issue has important implications for the implementation of a PAD programme and will need to be considered in more detail if it is decided to implement a PAD programme.</p>
<p>It is difficult to see the similarities between the research on fire and police responder and the Irish context. I believe many of the studies were in cities where both fire/police and ambulances are activated together. In the midlands (Ireland) many of our fire stations are in high populated rural areas where they are over 10 minutes from the ambulance station. This creates a significant benefit in response times (of an AED), while these fire stations are on a retained basis they have a short activation time and are very familiar with locations in their area and can reach the patients significantly earlier than Emergency Medical Services.</p>	<p>Our systematic review aimed to identify, appraise and synthesise the best available evidence on these types of intervention, and found that although there were some positive results, the pooled estimate of effect was not statistically significant and the mean estimate was less than that of a programme involving static AED provision in public areas. We agree that the applicability of these studies is questionable given that none of them were from Ireland, and we have discussed this in the text. It is possible to speculate on the potential impact of the differences in setting, but the validity of any conclusions would be questionable in the absence of Irish studies.</p>
<p>It is suggested that health and safety legislation does not put a specific obligation on the any premises to have fire extinguishers however it is</p>	<p>Under the current health and safety legislation there is no obligation for defibrillators to be installed. The proposed legislation would legally mandate the</p>

<p>unacceptable not to have them in the event of a fire. In relation to this same health and safety legislation, can it be said that there is an obligation under the health and safety legislation that defibrillator should be installed in all types premises where a cardiac arrest is likely within 2 years, so that employees and customers are protected?</p>	<p style="text-align: right;">Health Information and Quality Authority</p> <p>installation of a defibrillator at designated sites, as well as placing legal requirements in relation to its accessibility, maintenance and training requirements. There are also differences between the requirement for premises to provide a safe environment for members of the public to enter and any potential requirement for premises to make efforts to provide assistance to individuals with specific health concerns that manifest themselves while on the premises. This complicates the analogy that is often made between fire extinguishers and defibrillators. Therefore we do not conclude that the two are equivalent in terms of the obligations imposed on owners of public premises.</p>
<p>Was any contact made with Manitoba in Canada who implemented a similarly law beginning in January 2014 to compare it with Irelands proposal?</p>	<p>We reviewed the Manitoba legislation and compared their list of designated places with that proposed in the Irish legislation. Based on this analysis we modelled the impact of introducing a similar programme in Ireland. This was the PAD 25% programme evaluated in the economic analysis.</p>
<p>The report looks at the effective rate of defibrillators within 100-300 meters. While this may be acceptable in built up areas, the effective area would be nearer 2KM in more rural areas. This is justified as people are more likely to have the time to drive to the defibrillator as the ambulance will take much longer to arrive on scene. A person should be able to drive 2KM to the Defibrillator and return within a 5 minute timeframe.</p>	<p>All of the studies examining the effective range of an AED assumed that the device would be retrieved on foot. While it may technically be possible to retrieve AEDs from much farther distances in specific circumstances, there is a lack of evidence to show what these circumstances are and what the additional range might be. Therefore we based our calculation on the effective range of an AED on the assumption that, in the majority of cases, publicly accessible AEDs in the vicinity would be retrieved on foot by people witnessing or responding to an OHCA.</p>
<p>Whether in number or location. The large number of defibrillators in Ireland is due to community responsibility. The private sector should also take responsibility and legislation is needed to ensure this, so that the defibrillators are in the high footfall areas and transport.</p>	<p>The report acknowledges the prominent role of the community and community first responders for the current distribution of AEDs in Ireland. We also estimate the number of AEDs already in place in a range of public and private sector building types. This report outlines the respective contribution of each of these sectors to the</p>

	Health Information and Quality Authority proposed legislation as well as alternative PAD programme configurations.
<p>This health technology assessment of public access defibrillation report does recommend time and time again the need for a national register of defibrillators. The single biggest issue to come from the document is that a national defibrillator register is needed so that defibrillator can be linked to patients as well as ensuring they are ready for use. This register must fall with the remit of the National Ambulance Service. The one common denominator in any cardiac arrest is at some stage a call is made to the NAS. The NAS control centre play a pivotal role in: Taking the initial, calming the caller; Finding the location of the incident; Confirming cardiac arrest – breathing counter (IT programme); Advising the caller of over the phone CPR; can and could advise anyone else on scene of the location of the nearest AED and key code; Update the ambulance; Ensure advanced care is en-route and Advise the hospital of patient’s attendance. It is here in the ambulance control room that the information for a national register is needed. As the Ambulance service already has responsibility for community cardiac responders it proves that the ambulance service is the right fit. This report has put a cost on the register and it should go one step further and recommend that it lies with the NAS.</p>	<p>The establishment of a national EMS-linked AED register may contribute to increased utilisation rates of AEDs when an OHCA occurs nearby. Our analysis shows this is an important parameter in determining the overall cost-effectiveness of these types of intervention. However there is a lack of evidence on what magnitude of increase in utilisation can reasonably be expected. Such registers have been set up differently in a number of countries, and not all of them were run by the national Ambulance Service. This issue need to be considered in the overall context of how any prospective programme would be run in practice and therefore the identification of who would be responsible for any AED register is an operational issue that lies outside the remit of this HTA.</p>
<p>As signage is part of the recommended legislation, HIQA should consider recommending a national signage. There is some debate as to the use of AED versus Defibrillator. I believe the 3 versions (contained in the submission) would be acceptable and should be recommended as national signage.</p>	<p>The issue of which AED signage system should be used is outside the scope of this assessment.</p>
<p>All individuals should have equal access</p>	<p>HTA is a multidisciplinary process that</p>

<p>to lifesaving treatment, including CPR and AEDs, in the event of an emergency. This Health Technology Assessment must be passed for the sake of ensuring equality at the point of access to emergency care regardless of cost implications or calculations around the number of lives saved.</p>	<p style="text-align: right;">Health Information and Quality Authority</p> <p>summarises information about the medical, social, economic and ethical issues related to the use of a health technology. It is a decision support tool and the cost-effectiveness analysis is only one component of a HTA. Advice provided to the decision maker (Department of Health) is based on all relevant HTA aspects for investment/disinvestment in a particular technology.</p>
<p>The fundamental economic analysis carried out in this HTA is based on Quality Adjusted Life Years (QALY). A QALY was created and is typically used to compare alternative treatments and or medicines that will extend life and or improve the quality of life. However, as public access defibrillation is designed fundamentally to save lives; it is our view that the use of QALYs as a method of determining the cost-effectiveness of such a programme is not appropriate.</p>	<p>QALYs are used in economic analysis as a composite measure capturing both life expectancy and the health related quality of life over those remaining years for people who survive to hospital discharge after an OHCA. Therefore QALYs provide the best measure of the health gain associated with different PAD configurations and so are the most appropriate outcome to use in this analysis.</p>
<p>There is a significant ongoing investment by both the State and the private sector in fire prevention, training and awareness in Ireland. This includes the supply and maintenance of: Extinguishers, Emergency lighting and Exits, Signs, Wall brackets, Alarms, and ongoing training. In addition there are costs associated with fire service call out, health care costs and also the time taken and cost of the fire safety drills. There were 38 fire fatalities recorded in Ireland by the National Directorate for Fire and Emergency Management in 2011. In excess of 4,500 people die each year as a result of out of hospital cardiac arrest incidents responded to by the Emergency Services while just 260 (5.2%) of these victims survive.</p>	<p>It is inadvisable to directly compare fire prevention activities with a PAD programme. Fire prevention services are generally provided even in places where the risk to individuals is low, out of a desire to protect investments in buildings or goods, so the numbers of lives saved does not capture the utility derived from investing in fire prevention. It is also difficult to estimate the likely number of deaths in the absence of these measures, so even looking at the issue in this limited way is problematic. There are many reasons why implementing a PAD programme may be worthwhile, but we do not consider that the relatively high existing investment in fire prevention is one of them.</p>
<p>The HTA document excludes a large number of SCA cases from its scope: "Approximately 5,000 people die in Ireland each year due to out-of-</p>	<p>those that could potentially benefit from the intervention. The total number of cardiac arrest cases is not the relevant</p>

<p>hospital cardiac arrest”, EMS managed to attend 1,798 of these. The public access programme would aim to cover the 3,202 cardiac arrest cases that were not attended by EMS as well as those it did attend. For this assessment, the Authority will limit its analyses to out-of-hospital cardiac arrest 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.” We would suggest this is a fundamental error in the HTA methodology as the public access defibrillation programme will be targeting both this population and the wider cohort – i.e. those cardiac arrest patients that EMS did not attend and those who the EMS did attend but did not attempt resuscitation. The HTA also states that the chance of survival for 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.</p>	<p style="text-align: right;">Health Information and Quality Authority</p> <p>population for an analysis of a PAD programme, as cases where no EMS response was triggered and no resuscitation attempt was made would not be exposed to this type of intervention. The relevant group is rather those for whom the EMS was activated within a timeframe allowing for a resuscitation attempt, since these are the group that could potentially be in a position to benefit from bystander defibrillation.</p>
<p>We note that the median Emergency Medical Services response time in Ireland is recorded in this document as 11 minutes – this goes to the core of the argument in favour of a national public access defibrillator programme. The fundamental reason for having a public access programme in place is to treat these cardiac arrest incidents significantly faster (i.e. 3-4 minutes) than the median Emergency Medical Services response time. It is internationally recognised that the chance of survival after cardiac arrest, decreases by 10% for every minute of delay which clearly indicates that it would not be possible to successfully resuscitate any SCA victims even if the Emergency Medical Services median</p>	<p>While ambulance response times are a vital link in the chain of survival, data on this alone are not sufficient to conclude that public access defibrillation will improve outcomes. Rather this must be based on data showing the incremental benefit of PAD in addition to ambulance services, bystander CPR rates and longer term care outcomes. Given the characteristics of PAD and the fact that it is targeted to specific public locations, it is inadvisable to try to estimate the potential impact of PAD programmes on average response times across the whole cohort of OHCAs.</p>

response time is met.	
The report indicates that Emergency Medical Services attended out-of-hospital cardiac arrests is approximately 39.1 per 100,000 persons in Ireland however, a 2-1-study by Berdowski et al suggests the average in Europe is 86.4 per 100,000 persons – which suggests that Ireland lies 50% behind the European average in terms attending such out-of-hospital SCA incidents.	As explained in the preceding sentence, the 39.1 per 100,000 figure was the incidence of EMS-attended OHCA where resuscitation was attempted. The Berdowski figure of 86.4 per 100,000 is the incidence of EMS-attended OHCA regardless of whether any treatment was delivered. The comparable figure in that paper is the incidence of EMS-treated OHCA, which is 40.6 per 100,000. Therefore the Irish data is consistent with the European average. Since the public consultation, 2013 OHCAR data has become available. This has changed the estimate for Ireland to 40.3 cases per 100,000.
The report admits on numerous occasions that the available literature is not sufficient to reliably estimate the cost effectiveness of an Irish programme, or to compare the likely consequences of different portable access defibrillations programmes.	Based on a rigorous evaluation of the available evidence we concluded that it would not be appropriate to transpose the results of any previous clinical or cost-effectiveness study directly onto the Irish setting, due to differences in the type of intervention or the study setting. This meant that an original economic analysis using Irish data was required to provide a reliable estimate of the cost-effectiveness and budget impact of the prospective PAD programme included in the assessment.
Extrapolating from our customer database in a linear fashion we would predict at least 77 additional reported SCA events and 46 additional lives saved If an additional 38,400 devices were introduced. This is a conservative estimate of the potential benefit.	Our HTA used data from the Out of Hospital Cardiac Arrest Registry (OHCAR) which includes all EMS-attended OHCA occurring annually in Ireland. Databases of individual organisations involved in this area represent a subset of the overall national dataset. For the purposes of this assessment OHCAR data is preferred.
In the assessment of cost parameters, the HTA suggests that the cost of an AED is €1,189 but an appropriately managed and tendered program is likely to results in significantly lower costs. Similar reductions would also apply to consumables i.e. pads and batteries.	The scenario of lower costs for AEDs is examined in Chapter 5.
The cost of training appears to be assuming AED training is a separate	The costs were based on current prices from the suppliers of these services. While

<p>procedure whereas in practice it is more likely to be included in regular first aid training which is ongoing. Therefore training costs would be less than that estimated. The analysis on page 131-138 is dependent on the costs which have previously been challenged; similarly to survival rates and therefore suggest these findings would be open to question.</p>	<p>it is possible that these may change, it is not possible to forecast future costs with certainty.</p>
<p>"According to the OHCA Registry, in 2012, 5.2% of Irish emergency-medical-services-attended OHCA cases survived to hospital discharge" In comparison, in 2012, 28.57% of the patients recorded in our database survived to hospital discharge. It is unknown whether the emergency medical services attended these events. The percentage of survival is higher in our data because our devices are readily available –the EMS s-attended cases imply possible delayed treatment. In total, 27.78% of the Irish OHCA events recorded in the database survived to hospital discharge (the outcomes of 5 events is unknown) and 50% survived to hospital admission (the outcomes of 6 events is unknown). "For cases with a VF rhythm, survival to discharge was 17.3%" There are 17 VF events recorded in our database: 5 patients survived to hospital discharge (29.4%) 9 patients survived to hospital admission (52.94%) 3 patients did not survive. (17.66%)</p>	<p>As noted earlier, our HTA uses data from the Out of Hospital Cardiac Arrest Registry (OHCAR) which includes all OHCA's occurring annually in Ireland. Databases of individual organisations involved in this area represent a subset of the overall national dataset. For the purposes of this assessment OHCAR data is preferred.</p>
<p>Patient survival to hospital admission means that there is no further information regarding their discharge from hospital – does not necessarily mean the patient did not survive</p>	<p>OHCAR provides individual patient level data on survival to admission and subsequent discharge.</p>
<p>Witnessed OHCA events and survival by mode of intervention in Ireland, 2012 The table states that where the patient was treated by "Bystander CPR and AED", 13.4% survived to</p>	<p>As noted earlier, our HTA uses data from the Out of Hospital Cardiac Arrest Registry (OHCAR) which includes all OHCA's occurring annually in Ireland. Databases of individual organisations involved in this</p>

<p>discharge. Our data: Patient treated by CPR and AED 2014 4 events - 2 patients survived to hospital admission 2013 1 event – Patient survived to hospital admission and discharge Patient treated with just AED 2014 2 events – 2 patients survived to hospital admission 2013 2 events – 2 patients survived to hospital admission 2012 7 events – 2 patients survived to hospital admission and discharge</p>	<p>Health Information and Quality Authority area represent a subset of the overall national dataset. For the purposes of this assessment OHCAR data is preferred.</p>
<p>“AEDs are generally only available for use during opening hours” There are out-of-hours solutions available in neighbouring markets - Kesh in Fermanagh and an area in Cheltenham both have a phone box with the defibrillator located inside. Some towns and villages in England have introduced on-street AEDs : Affetside, Manchester; Stone, Staffordshire; Hurstpierpoint, Sussex</p>	<p>Recent research indicates that accessibility of AEDs outside of normal working hours continues to be a problem. We accept that external mounting of devices is possible, and discuss it as a possible solution to this challenge in Chapter 2.</p>
<p>Four studies examining the effect of police responder programmes were reported on, and although these programmes might have little or no significance on the patient outcomes in USA, programmes like these could be useful in rural Ireland, where the response time could be lengthy. If the devices are readily available in the street or in a public area, the response time will be far lower, and thus, there should be increased likelihood of patient survival.</p>	<p>We agree that there are likely to be considerable differences between Ireland and the setting in which these studies were carried out, which may have implications for the transferability of the results. However in the absence of Irish studies demonstrating effectiveness, any conclusion on the impact of these differences in setting would be speculative.</p>
<p>It is our position that if the devices are ready available and easily accessible, then the patient will receive treatment faster, and have an increased likelihood of survival.</p>	<p>While the rationale for a public access defibrillation programme that achieved these goals appears strong, the aim of our assessment was to estimate the potential incremental benefit of a structured national programme over and above the existing standard of care, which includes the widespread provision of AEDs on a voluntary basis.</p>
<p>“According to the OCHAR data the majority of Irish out-of-hospital cardiac arrests occur in residential settings</p>	<p>As noted earlier, our HTA uses data from the Out of Hospital Cardiac Arrest Registry (OHCAR) which includes all OHCAs</p>

<p>(77% in 2012) and many occur outside urban areas.” Again, according to our data none of the events took place in the home in Ireland – all were public places.</p>	<p style="text-align: right;">Health Information and Quality Authority</p> <p>occurring annually in Ireland. Databases of individual organisations involved in this area represent a subset of the overall national dataset. For the purposes of this assessment OHCAR data is preferred.</p>
<p>The figure of 2-11 potential lives saved is I believe a significant underestimate.</p> <p>With 1,800 cardiac arrests per year, a 1 minute reduction in response times, a very reasonable target for an EMS-linked community-based CFR programme would result in a 10% improvement in survival or 180 lives saved. While I agree that this may not be achievable in urban settings it would likely be exceeded in rural areas</p>	<p>There are drawbacks to estimating the effect of a national PAD programme by equating it to an average reduction in response times, and attempting to estimate the number of lives saved as a result of any such average reduction is also problematic.</p> <p>Rapid defibrillation programmes involving static AED provision can only benefit OHCA patients who arrest in the vicinity of an AED and where there is someone nearby who can retrieve and use the AED. Therefore the number of cardiac arrests that could potentially benefit is less than the total annual incidence. In the HTA we estimate the numbers of cases where an AED will be used by cross referencing the locations of AEDs under each PAD configuration with the locations of OHCA recorded in OHCAR, and applying the same probability that an AED will be used as that observed for previous OHCA that occurred in the vicinity of existing AEDs. We estimated that the introduction of the full PAD legislation will result in an extra 101 OHCA cases in a public setting and an extra 399 in a private setting that might benefit from early defibrillation (i.e. occurring within 200m of an AED). If we assume that those extra cases currently receive EMS intervention (with a survival of 5%) and switch to bystander defibrillation (survival 12.5%), then an extra 37 lives could potentially be saved. However, not all cases within 200m of an AED receive bystander defibrillation. If we apply existing rates of AED utilisation in Ireland (45% of public cases and 25% of private cases within 200m on an AED) then this equates to an extra 10 lives that will be saved annually.</p>

	<p>Applying any mean response time reduction to estimate the numbers of lives saved is problematic because it does not take account of how long the response time would otherwise be. For example a reduction in the response time from 20 minutes to 19 minutes is not likely to have as much of an impact on mortality as a reduction from 6 minutes to 5 minutes. In our assessment, clinical outcomes for those receiving the intervention were based on two years of national OHCAR data on patients who received bystander defibrillation from existing public AEDs.</p>
<p>The volunteer community first responder (CFR) model while mentioned several times in your report is not costed in this report. It is certainly a reality on the ground in many of our communities and would be seen by many of us as the most cost effective way to proceed rather than the dissemination of vast numbers of AEDs.</p>	<p>We adopted a broad scope in our systematic review of the evidence so that we could identify and synthesise the best available evidence for any type of rapid defibrillation intervention. The results of this review showed that there was poor quality evidence to show that some types of first responder schemes may be associated with a mean increase in survival to discharge (mean increase of 1% for firefighter programmes and 2% for police programmes). We found no studies involving community first responders that showed a beneficial effect on survival to discharge. There was better quality (RCT) evidence to indicate that static AED provision in public areas was associated with a mean increase in survival to discharge (mean estimate of 9%). Based on our analysis of the limitations of the available evidence and in consideration of the fact that the primary objective of the assessment was to evaluate the programme outlined in the legislation, which involves static AED provision in a range of building types, a decision was made to limit the comparators to this type of programme.</p> <p>In the report we do, however, provide a summary of the various community initiatives currently in operation in Ireland to help improve outcomes from out of</p>

Health Information and Quality Authority	
	hospital cardiac arrest, and some of the planned initiatives in this area.
The economics of out of hospital cardiac arrest and defibrillator programmes are hugely affected by the emergence of volunteer CFR groups who fundraise for their equipment and provide their services for free. I feel that this phenomenon has not received adequate attention in your report in terms of cost estimates. When the cost for the HSE and the private sector is very low as in these situations, the cost per QALY saved will be correspondingly low.	As outlined above, a decision was taken to limit the comparators assessed in the economic analysis to those involving static AED provision by building type, in keeping with the proposed legislation. Therefore we did not examine the cost-effectiveness of community first responder schemes. Were this to be done in the immediate future we would anticipate challenges in estimating the clinical effectiveness of these types of interventions and, if the same societal perspective as we used was to be adopted, it would include the costs of the equipment and volunteers' time needed, even though these costs may not directly fall on the health service.
The Community First Responder (CFR) model and its linkage into the Emergency Medical System (EMS) is in a mixed urban / rural country like Ireland the most obvious way to proceed. Communities that have been affected by a cardiac arrest and are furthest away from ambulance dispatch centres tend to naturally select / prioritise themselves out for the development of community-based CFR programmes.	Ireland has a strong track record of community initiatives of this type and we estimate in the report that there are approximately 100 community first responder groups linked in with the ambulance service already. However for the reasons outlined above, our assessment focussed the evaluation of static AED programmes of the type outlined in the Bill. Different types of PAD intervention are not mutually exclusive and we describe the work that is ongoing in this area.
Initiatives such as PHECC's Responder Alert App (RAapp) have enormous potential to reduce times to defibrillation particularly in remote areas. No costings of its national roll-out or implementation were included in the report.	In the absence of good quality evidence showing the clinical impact of such initiatives it is not feasible to derive reliable estimates of cost-effectiveness. This was beyond the scope of the current analysis, but may be worth evaluating once the required data becomes available.
Facilitation of Community First Responder (CFR) schemes with perhaps 4 regional CFR co-ordinators for the country would be a relatively inexpensive way of improving geographic coverage with community-based CFR programmes and linking such programmes into the EMS.	This is an operational issue that falls outside the scope of the current assessment, but may of relevance to those involved in implementing any prospective programme in this area.

<p>The assessment of Public access AED technology is not something that is possible to 'average' for a country like Ireland. In certain areas such as within 5 mins of an ambulance dispatch centre, it has relatively little value. In other rural areas, they are the only hope of survival in cases of cardiac arrest.</p>	<p>We agree that it would not be appropriate to attempt to express the impact of a PAD programme in terms of an average reduction in response times. Therefore, as outlined earlier, we estimated the impact of each PAD comparator using data on the number and location of each designated place and the incidence of OHCA. Therefore our analysis accounts for the fact that fewer OHCA occur in rural areas, but also that there would be fewer AEDs in rural areas due to a lower density of designated building types.</p>
<p>The 5 year HSE budget impact of €700,000 for an AED register could be largely offset going forward by a €50 registration cost for each AED sold payable by the AED manufacturers in a manner similar to the HeartRhythmIreland G Pace Register for pacemakers and ICDs. The AED Register should be maintained by a statutory body such as the Medical Devices Division of the Health Products Regulatory Authority (as should the pacemakers and ICDs register)</p>	<p>There are many issues that remain to be addressed as part of the planning phase before any prospective programme could be implemented. These operational issues are outside the scope of the current assessment.</p>
<p>You mention that PAD programmes primarily apply to public rather than residential location cardiac arrests; "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. " I don't believe this is accurate as EMS-linked CFR programmes can respond to any arrest that has triggered a 999 / 112 call be it from a residential or public location.</p>	<p>While any publicly accessible AEDs would indeed be available to use in the event of an OHCA occurring in the home, the available data show that they are used more frequently in OHCA that occur in public areas. We assume that the fact that the AEDs are located in public areas where there is a greater chance that a cardiac arrest will be witnessed and someone will be available who can intervene, contributes to this. We believe it is reasonable to assume that any measures taken to increase utilisation, such as more training or an AED register, would likely have a greater impact on publicly occurring OHCA rather than OHCA that happen in the home, for the same reasons.</p>
<p>The lack of Irish data assessing the use of public access defibrillation that you quoted missed an article from 2011;</p>	<p>This article was reviewed in preparing this HTA and is referred to in Section 3.3.5.</p>

<p>The Dublin Cardiac Arrest Registry. Temporal improvement in survival. Margey R, Browne L, Murphy E, O'Reilly M, Mahon N, Blake G, McCann H, Sugrue D, Galvin J. Europace. 2011 Aug;13(8):1157-65. In this article, survival in patients who had a cardiac arrest and were brought to the Mater Hospital A&E Dept was 3.4% (4/163) when those patients had no access to a public access AED vs 56% (13 / 23) in those who arrested at sites where an AED was available.</p>	<p>The study did not meet our inclusion criteria for the systematic review due to the absence of a comparator group that did not receive the intervention.</p>
<p>The figure that you quote for the number of patients receiving ICD (Implantable cardioverter defibrillator) because of out of hospital cardiac arrest (n=12) is unfortunately a gross underestimate of 'survival to discharge' for 3 reasons; [a] It excludes patients who received an ICD in a private hospital following cardiac arrest (as it is based on HIPE data), [b] only patients with an irreversible cause of cardiac arrest (LV dysfunction / Long QT / Cardiomyopathy) receive an ICD. The many patients who have a cardiac arrest in the setting of an acute ST elevation MI for example are generally treated with primary PCI not an ICD and [c] patients with certain co-morbidities may receive an ICD even though they survived a cardiac arrest. As a consequence, the number of 12 patients receiving an ICD in a public hospital following cardiac arrest due to an irreversible cause would be a gross underestimation of the total number of cardiac arrest survivors and those among them receiving an ICD.</p>	<p>ICD implantation rates do not reflect overall survival rates. Rather the numbers surviving to discharge who have an ICD implanted was used to calculate the long term care costs of the cohort of survivors. 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 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.</p> <p>We accept that there is uncertainty surrounding the exact proportion of OHCA survivors who receive an ICD, however sensitivity analysis shows that uncertainty in this parameter has a minimal impact on the overall cost-effectiveness results.</p>
<p>In your conclusions section, there is an inference that all forms of PAD have been examined. However, the figures quoted refer only to the stationary PAD models (15-55% and the legislative</p>	<p>We examined all forms of PAD programmes for which there was evidence available in the scientific literature, and presented the results in Chapter 4. Based on the available evidence and the fact that</p>

<p>version) and not EMS-linked community-based CFR programmes which as mentioned in the introduction was one of the PAD options you were examining.</p>	<p>the primary objective of the assessment was to examine the programme outlined in the proposed legislation, we restricted the comparators in the economic analysis to those involving static AED provision by building type.</p>
<p>The hopelessly pessimistic estimate in the conclusion section of 2-11 lives saved would occur if a PAD programme reduced cardiac arrest times by 0.2-3 seconds. A conservative anticipated response time reduction of 1-2 minutes would be associated with 180-360 lives saved. When ambulance dispatch centres are 40 minutes away from some rural parts of our country, it is likely that community-based CFR will likely do better than that.</p>	<p>As outlined earlier, there are serious drawbacks to estimating the effect of a national PAD programme by equating it to an average reduction in response times, and using this to estimate the number of lives saved as a result. We believe that the approach we adopted in the assessment provides a more valid approach to estimating the likely impact of any prospective PAD programme. We also accept that even though it represents the best option given the available data, there are also important limitations that should be considered when interpreting the results, and have outlined these limitations in the report.</p>
<p>I think this otherwise excellent report is incorrect in estimating potential lives saved as 2-11 per year (we have had 3 PAD AED saves this month) and is incomplete as it has left out costings of what most of us believe is the most reasonable, cost effective model for PAD, an EMS-linked volunteer CFR programme supported by RAapp or a similar mobile phone app.</p>	<p>The analysis uses national data from 2012 and 2013 on the total numbers of OHCA cases that survived discharge after having received bystander defibrillation, so the best available national data was used to estimate the incremental benefits of a PAD programme over and above that of the existing standard of care, which includes many AEDs provided on a voluntary basis. There were insufficient data available to estimate the cost-effectiveness of community first responder programmes. As more information becomes available, it may become possible to do so at a later stage.</p>
<p>I would submit that consideration be given to recommending that a public funded AED programme be established to place an AED outside each GP surgery. There are approximately 1,600 – 1800 GP practices in the country [Estimate ICGP, 2008]. This suggests that up to 1,000 practices are without AEDs. GPs, in particular in rural areas, are frequently required to act in a first</p>	<p>GP surgeries are included in all the PAD programme configurations examined in the assessment. Issues with externally mounted AEDs have been noted in the report. We have also added an additional section (3.3.3) to describe the relevant initiatives that are ongoing in relation to GP involvement in OHCA care.</p>

<p>responder role or as medical support in cardiac arrest situations. Research nationally* and internationally* has shown that GPs have an important role to play in the care of cardiac arrest patients in both urban and rural communities with results comparable with more structured components of the emergency response system. GPs generally perform this role in a voluntary capacity and in approximately half of these situations the patient isn't known to the doctor. The availability of an AED outside each premises would ensure that when a doctor is not on site that the AED would also be available to any other Healthcare professional (HCP) in the building. A robust training programme could support all HCPs to ensure there are skilled in AED use. When the building is closed it would be available to any member of the public who is suitably trained in its use. With adoption of such a programme it would become public knowledge that an AED is located outside each medical centre. * References on request</p>	
<p>I recommend 16-20 trained per AED in public places. Set up a standard basic training of one to one and a half hours is all that is required. Train people to:</p> <ul style="list-style-type: none"> a) Recognise a cardiac arrest; b) Call for Help 999/112; c) Perform very good deep Chest Compressions; d) Apply defibrillator and deliver shock if/when required and e) Continue Good deep Chest Compressions until medical help arrives. 	<p>Our analysis assumed that two members of staff would require training in BLS/AED in each designated place, to meet the requirements of the Bill. Using data from suppliers of training services we estimated that initial training would be 5 hours in duration, with refresher training lasting 3 hours required every 2 years. It is also worth noting that an Irish study found that approximately a quarter of people over 16 report having received training in CPR in the last 5 years.</p>

<p>I strongly believe that CPR and AED training needs to be kept very simple (a few basic steps) so that people will be more likely to perform CPR and use an AED when faced with a cardiac arrest and will not be afraid to do so. I recommend Hands Only CPR is all that is required for general public.</p>	<p>Recommending the type of training or preferred type of CPR falls outside the scope of this assessment.</p>
<p>If people are going to be charged for this training it should be limited to a standard rate of 20euro per person for this PAD programme. (otherwise commercial companies will drag people into long days of totally unnecessary training or charge large fees at huge cost to individuals. At the moment companies are charging around 120 euro for a three hour CPR and AED course which is very expensive. Create or source a computer based simulation CPR/AED teaching programme that the general public can access and review the steps of CPR(such as the new IHF promotion for restart a heart day or The Vinnie Jones as on BBC sponsored by British Heart Foundation) and to also include How to use an AED. The simulation could be similar to the one's used by American Heart Association Heartcode. Any person could access the simulation or app and learn through simulation practice and on submission of correct answers get a certificate that would fulfill the requirement of the training required by this new PAD initiative. This would be low cost easy training for the average person to access since the majority of Cardiac arrest occur at home to family, friends and loved ones. If a computer based simulation teaching programme is used where individuals sign in and enter their townland this would give information on how many people are trained by area/county. A fee of one euro could</p>	<p>There are many issues that remain to be addressed during the planning and implementation phase for any prospective PAD programme, including the requirements for and provision of training. The specific details of these are outside the scope of the current assessment.</p>

<p>be charged to access the teaching programme which could go towards funding the PAD programme. If an app is used a fee of one euro could be charged to access the technology app which would go towards funding the PAD programme. Once an AED is deployed/applied to casualty whether successful or not a central number could be set up to be called and the EKG tracing of the event downloaded. Set up a postal audit whereby a form is sent to each registered AED every 6 months to enquire if the AED has been deployed. (similar to UCD/MERIT/GP audit). If it has been deployed then the information on the AED is downloaded.</p>	
<p>Suggest locating AED's in remote areas where the ambulance response time is greater than 20 minutes. Also consider where there is a high throughput of people -one thousand + per day. (town centres) No need to have one in each retail space.</p>	<p>In keeping with the proposed legislation the HTA examined PAD programmes involving AED deployment by building type. We do, however, discuss the potential for alternative deployment rules based on location-specific incidence. However there is insufficient information currently available to support an accurate assessment of this type of PAD programme.</p>
<p>Can you justify taking millions of euro (page 12 cost of various PAD programmes) out of an already over stretched Health Budget for this initiative to save 2 to 11 lives (PAD 15%) and (PAD 100% legislation bill) when only 50% survive to 10 years. (V. Epidemiology and service configuration Page 8) ie 1-5 people. I think this is a very welcome initiative but strongly believe it should be totally funded by philanthropy not out of our health budget.</p>	<p>The aim of the assessment was to use the best available evidence to estimate the clinical and cost-effectiveness of a prospective PAD programme and any wider implications it may have, to inform decision making on matters relating to the Bill. The HTA report does not represent the actual decision.</p>
<p>It is our view that both a national AED register and a co-ordinated community response n/a 8 system (under the control of the National Ambulance</p>	<p>There are many issues that remain to be addressed during the planning and implementation phase for any prospective PAD programme, including the issue of an</p>

<p>Service) represent the best way of providing both defibrillators and personnel trained in basic life support to the community.</p>	<p>EMS linked AED register. The specific details of these are outside the scope of the current assessment. We do however describe the importance of measures to increase the utilisation of AEDs to the overall clinical and cost effectiveness of a PAD programme.</p>
<p>Our main concern with the Public Health [Availability of Defibrillators] Bill 2013 relates to the definition of owner, and ensuing onerous responsibilities around provision and maintenance of these machines, as well as training in their use. It is our contention that Occupiers/Controllers of buildings need to assume responsibility for these machines. It is not necessarily economic, as building owners, to be responsible for the provision and maintenance of defibrillators at all state-owned properties listed in Section 2(a).</p> <p>The locations listed in Section 2 need to be given further thought as there are complexities which or different buildings in State ownership, including for example Garda Stations (Section 2 (xvi)) many of which open for limited hours. For the purposes of the functions being conducted within the property, where the public might be entering, the occupier is responsible and the owner is more in the role of landlord.</p> <p>Depending on the building type it should be considered that defibrillators are only available during office opening hours. Otherwise, there could be an obligation on occupiers/controllers to locate defibrillators outside of buildings. If located outside, maintaining a register of instances of usage (Part 2 S. 9 of the Bill), as well as ensuring adequate access to, and security and reliability of the machines, becomes</p>	<p>These issues are beyond the scope of the HTA and are listed here for the benefit of those involved in considering the proposed legislation. The completed statement of outcomes report will also be provided to the Department of Health for consideration in conjunction with the HTA report.</p>

more complex (it may mean more maintenance checks are required). There are considerable costs involved in procuring and maintaining machines, as well as training employees occupying the building (Part 3 of the Bill). If these responsibilities are not carried out in a proper manner this Bill potentially leaves OPW the owner exposed to legal challenge under (Part 5 Sec 13 (2)) of the Bill.

In order to maintain consistency of service, reliability and value for money, we also propose that consideration be given to the responsibility for specification, procurement, including maintenance, management and training, being managed centrally, by an organisation with the relevant expertise. Recommendation that responsibility for specification and procurement, to include maintenance, management and training, should be managed by a central body with relevant expertise.

Recommendation to change Section 4(1) of the legislation as follows:

The owner **[or occupier/controller in the case of state-owned property]** of a designated place shall ensure that one or more defibrillators are installed and maintained at the designated place in accordance with regulations made by the Minister.

Thereafter include: **[or occupier/controller in the case of state-owned property]** after owner is stated in a clause in the Bill.

Recommendation to change Section 5 of the legislation to: a defibrillator that is required to be installed under section 4 must be easily accessible and be

<p>available for use by members of the public during office opening hours.</p>	
<p>We acknowledge and agree with the findings of the report and in particular the futility of what appears to be random placement of AEDs without reference to cardiac arrest locations or integration with the emergency medical services in any way.</p> <p>We support any initiative where uniformed responders (Garda and Fire Service) are equipped with an AED and alerted to cardiac arrests in their operational area and also any initiative where community response groups are integrated into the HSE National Ambulance Service control system and alerted to cardiac arrests in their community.</p> <p>We support the targeting of locations for AED placement, airports, large stadia etc., that have large footfall and that have a history of cardiac arrest events.</p>	<p>As outlined in the report, targeted deployment of static AEDs increases cost-effectiveness.</p> <p>We did not however, examine the cost effectiveness of police, firefighter or community first responder programmes.</p>
<p>We are totally opposed to legislation where penalties are imposed for failure to comply with AED placement as this would alienate the business community and inhibit uptake. There is a requirement for business premises to have staff members trained in first aid under health and safety legislation. Training in responding to cardiac arrests (CPR and use of AED etc.) is ongoing and what is now required is encouragement for organisations to purchase AEDs. A catalyst for this would be to zero rate VAT on AED's, currently at 23%.</p>	<p>We examine the impact of reduction in the VAT rate on AEDs in a scenario analysis as part of the economic evaluation.</p> <p>We have also added text to the discussion of the social implications of the Bill to highlight that introduction of a legislative requirement may undermine the high levels of voluntarism demonstrated in Ireland.</p>
<p>We further wish to state that an AED is only one component of successful resuscitation and that CPR is an essential component. AED use alone and no CPR could have negative unintended consequences such as increased survival rates with</p>	<p>This is noted in Chapter 3.</p>

<p>permanent brain damage. Support for CPR and AED public education initiatives is essential at both governmental and health agency level.</p>	
<p>While available primarily for the use of our staff and visitors, we are open to the use of AEDs by members of the public should its use be requested in the event of an emergency arising outside of the RSA environs. Due to the risk of theft, tampering with damage to and/or misuse. We are not in a position to consider placing AEDs in locations where they are available to the public outside of office hours.</p>	<p>The potential for AEDs to be stolen or vandalised is discussed in the report, along with the implications this has for external mounting of devices.</p>
<p>We contributed to a paper put forward to the Department for Education, providing information about children who had suffered cardiac arrest in school and died. It also showed how young people at school had survived when a defibrillator was readily available on the premises. Please see attached evidence provided to the Department for Education.</p>	<p>OHCA data used in the assessment covers all OHCA cases in Ireland, so would include those occurring in schools. Primary schools are included in the PAD45%, PAD55% and Legislation programmes and second and third level education centres are included in PAD15%, PAD45%, PAD55% and Legislation programmes.</p>
<p>HIQA conclusions regarding the broad based Public Access Defibrillation programmes are reasonable and appropriate. However, there is a place for Public Access Defibrillation in key areas, such as those with mass gatherings and at-risk groups.</p>	<p>The potential for PAD programmes involving location-specific deployment rules that identify aspects such as high risk groups congregating in subsets of a given building type (e.g., sporting or entertainment venues) is discussed in the report. However insufficient information is currently available to identify such locations.</p>
<p>The further concern about the introduction of a legislative requirement may be to undermine the high levels of voluntarism demonstrated in Ireland.</p>	<p>We have added text to the discussion of the social implications of the Bill to highlight that introduction of a legislative requirement may undermine the high levels of voluntarism demonstrated in Ireland.</p>
<p>There is significant evidence of the current GP contribution to resuscitation in Ireland. This group has operated the MERIT Project since 2006 – more than 500 practices participate and report around 50 cardiac arrests per</p>	<p>We recognise the work being done in relation to GP involvement in OHCA and have added a section to describe this.</p> <p>GP practices were included in all of the PAD comparators assessed. We did not</p>

<p>year with 10 survivors on average. Our database of 70 survivors will be reported shortly. This is particularly important in rural Ireland, which similar results are demonstrated. If, crudely, around 100 people survive OHCA in Ireland each year, it seems likely that around 20 do so with the involvement of GPs in their care. MERIT covers around 40% of practices and we have good evidence that the remaining practices now mostly have AEDs (especially in rural Ireland) and that those GPs also experience OHCA. Five year data from the MERIT project reported that in 14% of OHCA in which a GP was involved, the first AED on scene was brought by a lay first responder.</p> <p>A paper in press with the EJGP indicates that the role of GPs in cardiac arrest extends to improving the confidence of rescuers in stopping resuscitation. A paper in press with the IMJ demonstrates high levels of uptake of resuscitation training by GPs, over a 12 year period. Key findings from our data in relation to rural practice are that 49% of rural practices reported at least one cardiac arrest (Rural CARA: 55% shockable, 25% ROSC, 17% discharged)</p> <p>Our recommendations:</p> <ul style="list-style-type: none"> i. There should be state support for AEDs and training for GPs ii. We should enhance links between GPs and CFRs iii. We should enhance links between GPs and NAS iv. Structured data collection should be extended across all GPs v. GP support for targeted PAD schemes should be sought 	<p>however specifically examine a GP first responder scheme. This may require further analysis once the data required for such an analysis become available.</p>
<p>In regards to the unknown locations of existing AEDs in the community the</p>	<p>We examined the potential for a reduction in the number of AEDs required for each</p>

consultation document states that if the total proposed number of AEDs were to be provided there would be a 44% overlap in spatial coverage. When the existing AEDs are located this figure would be likely to rise close to 60%. The capital and running cost of this overlap would be considerable. The existing Danish system whereby the authorities pay for 50% of every AED and retain the right to decide on its location is an effective solution to this problem. Since 1963 the Planning Laws have governed the zoning of proposed building types and the levies paid in relation by private and commercial buildings for communal services. The planning system levies each development in relation to its scale and to the services it will require in the future.

A similar approach to the provision of AEDs would mean that buildings that are deemed to require an AED would contribute to the provision of an AED and its maintenance. The location of the AED would be decided by the authority and would be based on spatial need and 24 hour access. For instance, it may be that a town would require 4 AEDs in accordance with its spatial layout and these would be located strategically and paid for by the levies of 10 businesses and clubs in the area.

PAD configuration if sharing of devices within 50 metres was possible. However this may pose significant challenges regarding ongoing maintenance and liability. We appreciate your suggestions and have included them here for the benefit of those charged with implementation of a prospective PAD programme.

In Fig. 3.1.1. the distances of 100m, 200m, and 500m are shown in relation to number of OHCAs. This maximum distance of 500m is based on a person travelling from the site of a cardiac arrest to an AED and returning the same distance with the AED within a 4 minute period. However if the AED is connected to an alarm system it will alert a person close to it to run to the specific location of the cardiac arrest. This will half the time to get the AED to

While such innovation has the potential to increase the effective range of AEDs, in the absence of data demonstrating their effectiveness we assume that the effective range will be determined by having someone available to retrieve and bring back an AED.

the site of the cardiac arrest. In affect it will double the maximum distance of 500m as shown on Fig 3.1.1. As the graph is not a straight line this will not have the effect of doubling the number of cardiac arrests within range of the AED, however the figure will be approx. 1.5 that shown on the graph for each of the variables. This will have the effect of increasing the coverage of every AED by 1.5. (This number may be greater as the bystander may not be aware of the location if the closest AED and may go to one that is further or may not find one in the 2 minutes available.) Increasing the coverage of an AED will lower the overall capital and running costs. A heart alarm system simultaneously digitally alerts the emergency services, trained CPR responders and AEDs in the community to the GPS location and address of a cardiac arrest. It can be in the form of a home device or an app on a mobile phone.

76% of OHCAs occur in the home or residential institutions (OHCAR). The survival rate of 15% of OHCAs that occur in public places is far greater than the survival rate for OHCAs that occur in the home. A connection between the AEDs in the community and homes is required to effectively reach the areas where AEDs are most needed. The majority of OHCAs that occur in the home are witnessed and a heart alarm device would alert both the CPR trained responders and AEDs in the vicinity to the address and GPS location of the cardiac arrest. In the majority of cases the bystander in the home calls the ambulance service and it takes 11 minutes (median time) for it to arrive. Meanwhile a responder may live 4 doors away and an AED may be located close to the home where the arrest occurs. So connecting the vital

In the absence of data demonstrating the effectiveness of such a system we rely on existing data on survival from residential and public OHCAs from the national OHCAR database.

<p>required services and personnel with a patient centric approach is the fastest, most effective method of increasing survival rates by maximizing existing personnel and equipment.</p>	
<p>There are over 100 responder bodies, approx. 2000 responders in Ireland and some of these are connected to the NAS. However, there is 24% of the adult population trained in CPR. Connecting to this latter cohort is hugely more effective as the numbers are much greater. This could be done through PHECC registration.</p>	<p>This is outside the scope of the current assessment, which was primarily concerned with a programme of static AED provision.</p>
<p>When an AED is brought from a nearby sports centre or shop, it will be necessary to have insurance for those who use it in another setting. The person may be required to travel 1000m and if there is an accident during this travel period then it needs to be covered.</p> <p>Also the cost of new pads and batteries needs to be covered as no single individual, club or commercial entity should be responsible for replenishing these items. Management of capital cost, cost of maintenance, cost of training and cost of replacement of batteries and pads.</p>	<p>We do not specifically examine first responder programmes or the range of important issues that need to be addressed in order to implement them, and as such this issue is outside the scope of our assessment.</p>
<p>Requiring certain building types to pay for the capital cost of an AED when there may be an existing AED 50m away or another proposed AED 60m away is not in the public interest. Neither is having all staff from adjoining business premises trained and all 3 AEDs on the same street maintained. Taking the Planning levy model and applying it to the proposed PAD scheme is a more efficient, more equitable and less costly. The levy would enable the authority to place the AEDs in the optimum locations for the community and always in areas where they are available 24/7.</p> <p>The levy would cover the cost of</p>	<p>The aim of the assessment was to use the best available evidence to estimate the clinical and cost effectiveness of a prospective PAD programme based on static AED provision in designated buildings as outlined in the Bill and to examine any wider implications it may have, to inform decision making on matters relating to the Bill. Therefore the HTA report does not represent the actual decision, and there are many issues that will need to be addressed during the planning and implementation phase of any prospective PAD programme. The completed statement of outcomes report will be provided to the Department of Health for consideration in conjunction</p>

<p>regular checks, maintenance, replacement of batteries and pads and insurance for users. The levy would be reduced considerably for premises with an existing AED (provided it was relocated if necessary on the external wall of the premises). This would result in a voluntary disclosure to avoid the levy and mean that a register of all existing AEDs could be created. AED Training could be provided to the staff of premises who pay the levy and to community responders in the area who use the AED after hours. This would ensure that AED trained personnel are available at all times in the vicinity of the AED. The levy could fund a maintenance and checking service that would travel from AED to AED at intervals and ensure each is in working order. This system would ensure that existing AEDs would become registered, that the staff and community would be trained and that all AEDs would be in public places in optimum locations and be regularly maintained.</p>	<p>Health Information and Quality Authority with the HTA report.</p>
<p>“The key factors influencing survival in out-of-hospital cardiac arrest are time to CPR initiation, time to defibrillation and initial cardiac rhythm”. As initial cardiac rhythm deteriorates over time to asystole this means that all key factors are time dependent. A heart alarm saves time in relaying the address of the cardiac arrest to the ambulance, saves time in relaying the address to voluntary responder groups in the area (if there are any) and saves time by alarming the AED thereby having the AED come to the patient rather than having the double journey of a responder or bystander having to go to collect it. In addition to looking at past studies we need to use today’s technology to improve on the past and get the</p>	<p>While such innovation has the potential to increase the effective range of AEDs, in the absence of data demonstrating their effectiveness, we assume that the effective range of an AED is determined by having an available bystander retrieve and bring it back to the patient. We therefore rely on existing data on survival from residential and public OHCAs from the national OHCAR database to estimate clinical outcomes.</p>

maximum benefit from our trained personnel in the community, existing and proposed AEDs. By using an alarm system Ireland would be connecting the trained CPR responders and AEDs in the community and getting reliable digital locations of cardiac arrest to the emergency services faster than any other method.

In addition to looking at the rest of Europe for guidance we are the country best suited to the an alarm system as we have a centralised ambulance service, 24% of the adult population is trained in CPR and we have a track record in effective community action.

(smoking ban, foot and mouth). The outcome with the present system is for a minor increase in survival numbers for OHCA's even with the maximum provision of AEDs in the legislation. The use of the alarm system and levies will greatly increase survival rates

5. Conclusions

We received extensive feedback from a diverse range of people and organisation both within Ireland and from the UK. As a result of this we have updated various sections of the report to include additional information or to clarify certain aspects of the evaluation. This document will also serve as a useful companion report to the HTA on public access defibrillation, which clarifies some points that were raised a number of times in the public consultation.

We also received many suggestions and queries regarding the operational issues that will need to be addressed during the planning and implementation phase of any prospective PAD programme, and how it will integrate into the wider EMS and CFR environment. While these are outside the scope of this assessment, they are provided here for the benefit of those involved in any future work in this area.

Once again the Authority would like to thank all respondents for taking the time to provide valuable feedback.

6. Next steps

The next steps that the Authority intends to take in relation to this HTA reports include the following:

1. The Authority has updated the report, where applicable, based on the feedback received.
2. The Authority will present the report and advice to the Minister of Health.

Appendix 1: Consultation feedback form

Health technology assessment of public access defibrillation For public consultation



Consultation Feedback Form

September 2014

Your feedback is very important to us. We welcome responses to all questions as well as any additional comments you would like to make.

When commenting on a specific section of a document, it would help if you can identify which element you are commenting on and the relevant page number.

The closing date for consultation is 5pm on Friday 17 October 2014

You may email or post a completed form to us. You may also complete and submit your feedback online at www.hiqa.ie.

About you

Name	
Address	
Contact details	
Date	

General Information and Questions

You may provide us with feedback on the specific questions (see questions that follow), or alternatively you may provide us with general comments.

Part 1

Are you replying in a personal capacity or on behalf of an institution or organisation?

Personal capacity

On behalf of an institution

On behalf of an organisation

Part 2

Please outline any general or specific feedback on the documents. In your response, where applicable, please specify the section to which you are referring.

Please comment

Thank you for taking the time to give us your views.

After the closing date, we will assess all feedback and use it to finalise our documents. The final documents and the Statement of Outcomes (a summary of the responses) will be published on <http://www.hiqa.ie>.

If you wish to do so, you can request that your name and/or organisation be kept confidential and excluded from the published summary of responses. Please note that we may use your details to contact you about your responses. We do not intend to send responses to each individual respondent.

Please return your form to us either by email or post:



consultation@hiqa.ie



Health Information and Quality Authority

HTA on Public Access Defibrillation

George's Court



If you have any questions you can contact the consultation team by calling (01) 814 7463.

Please return your form to us either by email or post before

5pm on Friday 17 October 2014

Please note that the Authority is subject to the Freedom of Information Acts and the statutory Code of Practice regarding FOI.

For that reason, it would be helpful if you could explain to us if you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances.

Statement of Outcomes: Report on the outcome of the public consultation on the health technology assessment (HTA) of a public access defibrillation programme.

Health Information and Quality Authority

Appendix 2: List of organisations that made submissions

Arrhythmia Alliance

Gaelic Athletic Association (GAA)

HeartSine

Order of Malta

Office of Public Works (OPW)

Pre-Hospital Emergency Care Council (PHECC)

Road Safety Authority (RSA)

Sudden Arrhythmic Death Syndrome (SADS) – UK cardiac charity

UCD - Centre for Emergency Medical Science (CEMS)