KCE REPORT 294C

Federaal Kenniscentrum voor de Gezondheidszorg
Centre Fédéral d'Expertise des Soins de Santé
Belgian Health Care Knowledge Centre

SHORT REPORT

STATIC AUTOMATED EXTERNAL DEFIBRILLATORS FOR OPPORTUNISTIC USE BY BYSTANDERS


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HEALTH TECHNOLOGY ASSESSMENT

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SHORT REPORT

STATIC AUTOMATED EXTERNAL DEFIBRILLATORS FOR OPPORTUNISTIC USE BY BYSTANDERS

HANS VAN BRABANDT, SOPHIE GERKENS, NICOLAS FAIRON, CECILE DUBOIS, MARCEL VAN DER AUWERA, CHRISTOPHE VANSIMPSEN, DOMINIQUE ROBERFROID

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■ SHORT REPORT

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LIST OF ABBREVIATIONS

ABBREVIATION	DEFINITION
AED	Automated External Defibrillator
AHA	American Heart Association
CPR	Cardiopulmonary Resuscitation
EMS	Emergency Medical Services
ERC	European Resuscitation Council
FPS	Federal Public Service
HTA	Health Technology Assessment
ICER	Incremental Cost-Effectiveness Ratio
OHCA	Out of Hospital Cardiac Arrest
PAD	Public Access Defibrillation
QALY	Quality-Adjusted Life-Year
RCT	Randomized Controlled Trial
SD	Standard Deviation
SR	Systematic Review of the literature
VF	Ventricular Fibrillation
AED	Automated External Defibrillator

1 BACKGROUND

1.1 Out of Hospital Cardiac Arrest

A cardiac arrest is defined by the absence of signs of circulation[1]. A victim who is unresponsive and not breathing normally is suspected to be in cardiac arrest[2]. An out of hospital cardiac arrest (OHCA) is a cardiac arrest that occurs outside a hospital setting. The average yearly incidence of OCHA attended by Emergency Medical Service (EMS) has been consistently estimated at around 85 per 100 000 person-years in Europe[3, 4]. The median age of victims is 70 years and more than 60% are males.

When considering EMS-treated OHCA, the average incidence was estimated at 45.0 per 100 000 person-years in Europe, and 35.0 per 100 000 person-years for OHCA of cardiac origin[3]. The rate difference between EMS-attended and EMS-treated OHCAs can be explained by the high proportion of victims found dead at EMS arrival on the scene.

OHCA is predominantly (70-80%) of cardiac origin[a] ("primary cardiac arrest") and caused by ventricular fibrillation (VF)[5]. VF (or pulseless ventricular tachycardia) can be abolished by electrical defibrillation whereby the application of an electrical shock to the chest depolarises the heart and enables normal heart rhythm to resume. This can be done with an Automated External Defibrillator (AED).

However, VF deteriorates to asystole rapidly. Usually, only between 22%[4] and 32%[3] of OCHA of cardiac origin EMS-treated have a VF as first monitored rhythm, although this proportion can go up to 45%-50% in places with a rapid response system[5, 6].

Each minute of delay to defibrillation reduces the probability of survival by 10 to 12%[2]. Defibrillation of a VF within 3 to 5 min of collapse can produce survival rates as high as 50 to 70%[2, 7]. However, survival rate to hospital discharge of EMS-treated OHCA is globally low in Europe as elsewhere with a reported average between 9.4%[3] and 10.3%[4], although great variations can be observed across countries (from 1.1% to 26.1%)[4, 8].

OHCA of cardiac origin which are witnessed and present a VF as first-monitored rhythm are called hereafter the Utstein comparator group. The proportion of shockable cases (i.e. VF) is a reflection of how well the chain of survival (see point 1.2) functions. The proportion of all OHCA patients that belong to the Utstein comparator group varies between 3% and 27% in Europe[3%, 4]

1.2 Automated External Defibrillators

AEDs are small, portable devices to be connected to the chest of the victim. Most AEDs are fully automatic: they give spoken instructions, analyse the heart rhythm, and if a shockable rhythm is detected, they automatically deliver an electric shock to the patient.

AEDs can be static or mobile. Static AEDs remain at a given location and are intended for opportunistic use by anyone who witnesses an OHCA. Mobile AEDs are often used by first responders, i.e. individuals responding to a medical emergency in an official capacity as part of an organised medical response team but who are not the designated transporter of the patient to the hospital, e.g. police officers, fire fighters, or trained volunteers[9]. In Belgium, the majority of AEDs are static.

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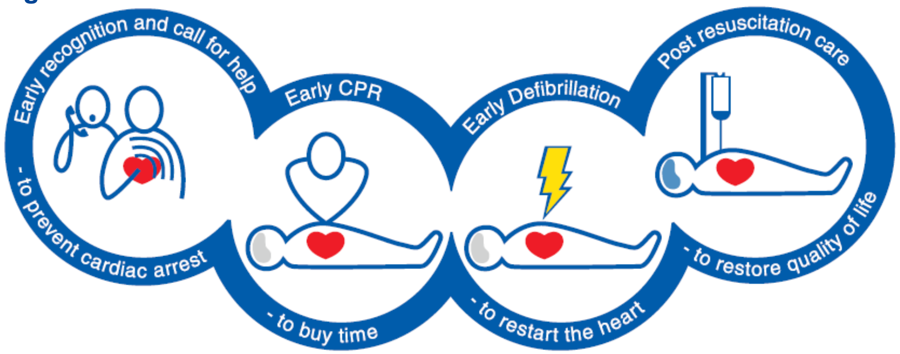
[a] A cardiac arrest of non-cardiac origin may be due to other medical causes (e.g. anaphylaxis, asthma, exsanguination), trauma, drug overdose, drowning, electrocution, asphyxia (airway obstruction, hanging, or strangulation)[1, 2].

Public access defibrillation (PAD) programmes have been developed to promote the use of AEDs, with the aim of increasing survival from OHCA by reducing the time to defibrillation. AEDs can be incorporated into a comprehensive public access defibrillation (PAD) programme involving training programmes, community groups of lay-volunteers, geolocation of AEDs, delivery of AEDs with drones, dispatched or non-dispatched first responders[10]. The European Resuscitation Council (ERC)[11] and the American Heart Association (AHA)[12] recommend implementing the placement of AEDs in public places with a high density and movement of citizens, such as airports, railway stations, bus terminals, sport facilities, shopping malls, offices, etc... The ERC recommends AED placement in areas with at least 1 cardiac arrest every five years[11].

Defibrillation - and hence AEDs - are an element in the "chain of survival" of OHCA[13]. Early recognition is critical to enable rapid activation of the EMS and promptly starting cardiopulmonary resuscitation (CPR). Immediate CPR of an OHCA victim provides a small but critical blood flow to the heart and brain, limiting brain damage and slowing down deterioration of the VF to asystole[1, 14]. Chest compressions are especially important if a defibrillation shock cannot be delivered within the first few minutes after collapse. CPR should be started and continued until a defibrillator is connected to the victim[2].

Figure 1 – The chain of survival



Source: Perkins et al.[1]

2 AIMS AND SCOPE

The first research question submitted to KCE concerned the clinical- and cost-effectiveness of the provision of publicly accessible automated external defibrillators (AED) intended for opportunistic use by bystanders who witness a cardiac arrest. The report focuses on the use of AEDs as a stand-alone intervention, i.e. not incorporated into a coordinated public access defibrillation (PAD) programme (see section 1.3), because this is currently the dominant practice in Belgium (see section 5.3). The question was not to advise the government about the most effective strategies for PAD, as the governmental involvement in PAD is very limited, but rather if it should support (also financially) the current practice or not (as currently most AEDs are privately owned).

A secondary question concerned the utility of the mandatory central registration of AEDs by the SPF Public Health.

3 METHODS

3.1 Systematic literature review

The literature search was organised in two steps, following KCE procedures for rapid HTA: identify a recent high-quality Health Technology Assessment (HTA) or systematic review (SR) to serve as the core evidence source; assess if an update of the core source was relevant based on the publication of more recent primary studies. More details can be found in the scientific report.

3.2 External experts and stakeholders

External experts were consulted on 3 occasions to discuss the research results and provide insights on organisational issues, especially with respect to the Belgian EMS and PAD practice (see colophon).

Commercial data on AEDs in Belgium were obtained from AED distributors. We also invited Heart Saver vzw to participate because of their field knowledge of AED use in Belgium.

The scientific report was validated by three additional external experts not involved in previous steps.

3.3 Search for Belgian data on AED

Data on the number of AEDs in Belgium were extracted from the Federal Public Service (FPS) database (see section 5.1). For statistics on OHCAs and potential use of AED, we analysed data from the MUGREG/SMUREG registry. The MUG/SMUR is a second tier unit, staffed with emergency physicians and nurses. It is deployed when the presence of a physician at an emergency scene is considered crucial. By law, its interventions have to be registered. Finally, the Belgian data of the European EuReCa-ONE study[4] were made accessible to us and re-analysed.

Additional data on Belgian AED practice were obtained from external clinical experts, Belgian distributors of AEDs, and through on-line searches.

4 RESULTS

4.1 Effectiveness of PAD

We identified one recent high-quality HTA published by the Ireland's Health Information and Quality Authority (HIQA)[15]. We retrieved no additional comparative primary studies published afterwards. Therefore, we based our analysis on the HIQA HTA[15].

This HTA identified only one comparative study on the provision of static AEDs in public locations: the Public Access Defibrillation Trial, published in 2004[16]. HIQA graded the study high-quality.

The PAD-trial studied the use of AEDs by trained volunteers in selected public areas at high risk of OHCA across the US. High risk locations were physical facilities with a history of at least one witnessed OHCA every two years on average, or where one could expect at least one OHCA during the study period, i.e. if the equivalent of at least 250 adults more than 50 years of age were present for 16 hours a day. Almost 1000 public areas (e.g. recreational facilities, shopping malls, residential complexes) were randomly assigned to Cardiopulmonary Resuscitation (CPR) or CPR+AED. A summary of findings is displayed in Table 1.

Table 1 – Main characteristics and summary of findings of the PAD trial

PICO	Description
Population	Individuals aged ≥8 years with an out-of-hospital cardiac arrest of cardiac cause were included. Patients with arrest and unconsciousness due to trauma and obvious drug overdose were excluded.
Intervention	11 015 trained (retraining after 3-6 months and at one or more additional times) volunteers in CPR+AED in 496 residential or public community groups[b] with the ability to deliver an AED within 3 minutes to a person having a cardiac arrest. Volunteers were alerted to events in various ways (e.g. overhead paging, security notification), depending on the facility's response plan Within each community, as many AEDs were installed as were needed to ensure that volunteers could deliver the device to a cardiac arrest victim within three minutes. 1 587 AEDs were placed, 85% of which in public locations (facilities where at least one out-of-hospital cardiac arrest could be expected every two years (equivalent of at least 250 adults more than 50 years of age present for 16 hours a day or if the facilities had a history of at least one witnessed out-of-hospital cardiac arrest every two years, on average)). Density of AEDs was unknown because the catchment population was unknown.
Comparator	8 361 volunteers across 497 community units (without a pre-existing PAD) trained in CPR
Outcomes	235 definite OHCA occurred over a period of 21.5±5.5 months. EMS-treated OHCA cases were 67% male and had a mean age of 70 years, and 72% of arrests were witnessed. The prespecified primary outcome chosen was the number of survivors of definite OHCAs. Survivors to hospital discharge after a definite OHCA were 30 in the CPR+AED group vs. 15 in the CPR only group, yielding a twofold difference in survival (RR=2.0; 95%CI: 1.07 to 3.77; p=0.03).
Study type	RCT[c]

Source: PAD trial[16]

Survivors to hospital discharge after a definite OHCA were 30 in the CPR+AED group vs. 15 in the CPR only group, yielding a twofold difference in survival (RR=2.0; 95%CI: 1.07 to 3.77; p=0.03). However, there have been some methodological discussions over the way of computing results in the PAD trial. The authors of the HIQA HTA redid the computation based on risk ratio of survival in patients with a definite OHCA (30/128 (23%) in intervention vs. 15/107 (14%) in control communities, and reached a RR=1.67 (95%CI: 0.95 to 2.94; p=0.074) which was no more statistically significant, with a risk difference of 9 % (95%CI: 0% to 19%).

On top of these statistical uncertainties, it should be noted that the PAD trial included an "optimally" trained lay-person-enacted response plan (11 000 volunteers and the deployment of 1 600 AEDs in selected high-risk places), i.e. the results cannot be extrapolated to implementation without such a response plan.

[b] The catchment population of the community unit is not reported. The community units were excluded if they were within a three minute EMS response catchment, had on-site medical personnel able to respond within three minutes, or had an existing defibrillation programme in place.

[c] The randomized groups were stratified according to center and stratified within each center according to location (residential vs. public)

4.2 Safety

According the HIQA HTA, the AED devices are generally regarded as reliable and safe when used properly[15]. This claim has been confirmed by the external clinical experts who participated in the present report.

However, cases of AED malfunction have been reported[15, 17-19], although their frequency is unknown. Problems with pads/connectors and battery/power are the most often cited[30]. Errors in the assessment of shockability (4% of ECG tracings were false-positives and 16% were false negatives) have been reported in a Belgian study[20]. The sample size was small (135 patients) and only a specific brand of AED was considered. The external validity of these results need to be assessed in further studies. A recent study reported that errors associated with AED use were rare[21].

Finally, increased psychological stress in AED users has been mentioned as an adverse event[2, 22, 23].

4.3 Cost-effectiveness

No additional relevant publications were identified after the HIQA HTA study. The HIQA HTA included a systematic review of economic evaluations of static AED provision across a range of public locations[35-38]. Details on the methods, quality appraisal and results of these studies can be found in the scientific report. In ideal conditions, i.e. with the intervention of well-trained people to both CPR and AED use expected within three minutes or with a 100% probability of AED use in case of cardiac arrest, three out of these four studies showed that a targeted use of AED in high incidence area could be considered as cost-effective compared to no AED[24-26]. They showed that Incremental Cost-Effectiveness Ratio (ICER) were mostly sensitive to the OHCA incidence in the area of AED placement, the probability of AED use in case of OHCA, and the survival with or without AED.

The HIQA HTA also included an economic evaluation of AED provision in Ireland[15]. The aim of this economic evaluation[15] was to assess the cost-effectiveness impact of the Irish Public Health (Availability of Defibrillators) Bill 2013 (hereafter called “Legislation”), proposing a substantial increase in the availability of static AEDs in a range of designated places for use by trained staff or members of the public in the event of a cardiac arrest in the vicinity.

The base case comparator was the situation at the time of the assessment, i.e. with medical emergency services, first responders groups, and out of 8 to 10 000 AEDs voluntarily placed (for which only 4670 were located in places proposed by the Legislation). This base case situation was compared to differed level of implementation of the legislation.

These different deployment programmes of static AEDs in public locations proposed by the legislation were all combined with the training of staff employed in these locations. The different level of implementation as well as other study characteristics are described in Table 2. As described in this table, the AED use rate was determined according to the number of OHCA that arrived within 200m of an AED placement and the probability of use in such situation observed in the Irish OHCA register database[15].

Table 2 – Description of the economic evaluation performed in the HIQA HTA

Elements	Description of the IRISH economic evaluation
Population	Individuals with OHCA attended by EMS and for which resuscitation is attempted.
Country	Ireland
Intervention	• Current process of care: EMS + ad hoc distribution of public AEDs + a limited number of police, fire-service or community first responder groups in various locations. • Deployment programmes of static AEDs in public locations combined with the training of staff employed in these locations: • 100% legislation: (38 400 additional AEDs) • PAD 15%: in site with an annual probability of at least one OHCA per 20 AEDs (1900 additional AEDs) • PAD 20%: in every building of type hospital and residential, transport and public administration (3100 additional AEDs) • PAD 25%: in every building of type hospital and residential, transport, public administration and retail (6800 additional AEDs) • PAD 45%: in every building of type hospital and residential, transport, public administration, retail, and arts & entertainment (15 300 additional AEDs) • PAD 55%: in site with an annual probability of at least one OHCA per 100 AEDs (19 600 additional AEDs)
Design	Cost-effectiveness and cost-utility analyses; Lifelong Markov Model
Perspective	Societal
Clinical outcomes	Assumption: The proportion of patients predicted to receive bystander defibrillation was based on the number of OHCA that occurred within 200 m of existing AED location. For the base case strategy, proportions observed in the Irish OHCA register database were used. Survival at discharge: EMS: 5.1%; CPR only: 5.5%; CPR + AED: 12.4% (Based on the Irish OHCA register database).
Costs	Direct (medical and material costs) and indirect costs (time and productivity losses) for patients, health service providers and the designated places; including an annual cost of AED database (€69 259). (€2013).
Discounting	5% for both costs and outcomes

AED = Automated external defibrillator; CPR = Cardiopulmonary resuscitation; EMS = Emergency medical services; OHCA = Out of Hospital Cardiac Arrest; PAD = Public access defibrillation

Results of the study showed that, depending on the programme, the predicted average increase in the number of OHCA patients surviving to hospital discharge annually ranged from 1.7% (2 additional people per year) for PAD15% to 9.3% (10 additional people per year) for the full legislation[15].

PAD programmes that involved AED deployment in buildings with the highest OHCA incidence (i.e. PAD15%) was the most cost-effective approach compared to the current situation (see Table 3). Nevertheless, the ICER of this strategy was €95 640 per QALY, with a probability of 5% to be the most cost-effective approach at a threshold of €45 000/QALY (i.e. the threshold used in Ireland to determine the cost-effectiveness of an intervention). PAD programs were therefore not considered as cost-effective[15].

The budget impact analysis over a five-year time horizon showed that the implementation of a PAD programme would be associated with total incremental costs over five years ranging from €2 million to €20 million for the public sector (including the health sector), and €3.3 million to €85 million for the private sector, depending on which PAD programme is implemented. The majority of these additional costs were related to the procurement of AEDs[15].

Table 3 – Results of the economic evaluation performed in the HIQA HTA

Scenario	Costs	Incremental costs	QALYs	Incremental Qalys	ICER
Base case	€ 16 954	-	0.3004	-	-
PAD15%	€ 17 446	€ 492	0.3055	0.0051	€ 95 640/QALY
PAD25%	€ 18 577	€ 1 131	0.313	0.0075	€ 151 243/QALY
PAD45%	€ 20 518	€ 1 941	0.322	0.009	€ 214 108/QALY
PAD55%	€ 21 467	€ 949	0.3246	0.00254	€ 373 545/QALY
Legislation	€ 25 589	€ 4 122	0.329	0.0044	€ 928 450/QALY

PAD = Public access defibrillation; ICER = Incremental cost-effectiveness; QALY = Quality-adjusted Life-Year.

The univariate sensitivity analysis showed that results were mostly influenced by the relative risk of survival with and without AED use (at hospital discharge and/or hospital admission) and the number of (public or residential) OHCA within 200m of an AED (influencing the probability of AED use). Nevertheless, in each univariate sensitivity analysis performed, the ICER was superior to €45 000/QALY[15].

Different scenario analyses were also performed. The scenario analysis on the cost of AEDs for example indicated that even with a 60% reduction in the average cost of an AED, conclusions remained similar (ICER > $45 000). They also showed that if the use of AEDs by bystanders increased significantly (approximately 40%), the PAD15% strategy could become cost-effective. This scenario is based on the assumption that a PAD programme would increase AED use in case of a cardiac arrest event due to the (i) improved public awareness about OHCA, (ii) the increasing number of people trained in basic life support, and (iii) the use of an EMS-linked AED register. However, there is no evidence to indicate what magnitude of increase could reasonably be expected[15].

The authors also argued that a more cost-effective distribution of AEDs could be achieved using a deployment rule based on location-specific incidence rather than building type. Sufficient data to support such an analysis were nevertheless not available at the time of the HIQA HTA[15].

5 BELGIAN CONTEXT

5.1 Belgian AED legislation

The use of AEDs is regulated in Belgium by the Royal Decree of 21 April 2007 and the Ministerial Circular of 29 July 2011[d]. The Royal Decree authorises the use of an AED by professionals and lay rescuers alike in patients with an OHCA.

Formal registration of an AED at the FPS Public Health by the owner, including its exact geographic location, is mandatory before its installation ((https://www.health.belgium.be/sites/default/files/uploads/fields/fpshealth_theme_file/defibrilateur_fr.pdf).

The Royal Decree also stipulates the terms and conditions for making an AED publicly[e] and permanently[f] available[g]. The AED has to be placed in a "sealed" (meaning that it cannot be opened unnoticed) case in the conditions required by the manufacturer. The case needs to specify the name of the owner, including his address, phone number, e-mail. The Ministerial Circular of 29 July 2011 provides detailed instructions on a label with the FPS registration number that should be attached to the AED and the case.

At least every month, as well as after each use of the AED, the owner has to assess the function of the device (AED, battery, pads) in agreement with the instructions by the manufacturer, and has to check whether alarms have been produced by the device. When the AED has been used, the doctor of the patient who was shocked can request from the owner data stored by the AED. Yearly the owner has to report to the FPS all data recorded within the AED.

In Art.7 the Royal Decree refers to the obligation to report operational changes related to the AED within one month. However, the Royal Decree does not describe how this should happen.

The Ministerial Circular formulates recommendations where an AED could most effectively be installed in a public place: public buildings, fitness and sport centres, industry zones, railway stations, airports, pharmacies…

AEDs need to be properly maintained. The Royal Decree provides for a control in its Art. 13: The health inspectors referred to in Article 10a of the Law of 8 July 1964 on urgent medical care, and the health inspectors of the FPS Public Health referred to in Article 5 of the Law of 12 June 2006, are authorised to monitor the implementation of the provisions of this Decree.

However, so far no AED on the Belgian territory has been controlled by a health inspector. Moreover, the yearly report of activity of the AED is not transmitted to the FPS Public Health.

AED malfunctions must be reported to the Federal Agency for Medicines and Health Products.

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d https://www.health.belgium.be/nl/e-services/automatische-externe-defibrillatoren-aed

e « publieke plaats » : elke plaats, inclusief winkels, scholen, bedrijfsgebouwen en –terreinen, stations, luchthavens, filmzalen en sportterreinen, waar mensen verzamelen en evenementen kunnen worden georganiseerd; « lieu public » : tout lieu, y compris les magasins, écoles, bâtiments et sites d'entreprise, gares, aéroports, salles de cinéma et terrains de sport, où des personnes se rassemblent et où des événements sont susceptibles d'être organisés;

f « permanent » : op langdurige en duurzame wijze; « en permanence » : de manière prolongée et durable;

g « ter beschikking stellen » : het gratis aanbieden van een automatische externe defibrillator voor gebruik in geval van een hartstilstand; « mettre à disposition » : proposer gratuitement un défibrillateur externe automatique destiné à être utilisé en cas d'arrêt cardiaque;

5.2 Number and location of AEDs

The exact number and location of AEDs in Belgium is not known with precision. The deployment of AEDs in Belgium is predominantly done by private actors (e.g. managers of sports clubs, building owners). It is estimated that ±70% of the devices is privately owned. They are mostly installed indoor, e.g. at an industrial or commercial site (reception, medical service …). The remaining 30% is installed outdoor with 25% of them being static (e.g. street, market place) and 5% mobile (e.g. police).

The registration of AEDs by the FPS Public Health (see point 5.1) is incomplete. Currently (June 2017), 8 204 registrations are included in the database, of which 631 are incomplete because additional information requested to the AED owner were not provided[h]. The most common missing items are the Lambert coordinates and the topographic maps. Moreover, the proportion of AEDs still in function is unknown.

A monthly up-to-date extract from the database is made available since the beginning of 2014 through the website of the FPS Public Health Service. It is stipulated that it cannot be guaranteed the data are correct and complete.

Other parties such as the Belgian Red Cross-Flanders (www.rodekruis.be/hartveilig), the Belgian Heart Rhythm Association (http://www.mijnhartritme.be/index.php?lang=1), the EMURgency project (http://emurgency.eu/), StayingAlive (http://www.stayingalive.org/en.php) are active in the field of registration and visualisation of AEDs on geographic maps, but they are confronted with the same limitations.

According to external experts consulted, since 2003 an estimated 14 000 AEDs have been sold in Belgium. The operational lifetime of an AED is 7 to 8 years. It is estimated that presently 10 000 devices are still operational, i.e. 0.9 per 1000 inhabitants. As a comparison, in the Netherlands 0.6 devices are installed per 1 000 inhabitants[27], versus 3.4 per 1 000 in Japan[28], and 1.7 to 2.0 in Ireland[15]. The price of an AED ranges from 1 100 to 1 995 €, depending on the presence of specific features such as battery capacity, full or semi-automatic mode, synchronous/asynchronous defibrillation mode, etc.

The placement of AEDs is not coordinated. Some high risk public places, as defined by the legislation, are not covered (e.g. metro in Brussels). Elsewhere, several AEDs can be very close to each other.

5.3 OHCA & AED use in Belgium

Data on the use of AEDs in Belgium were obtained from several sources. All of them however suffered from severe limitations with regard to data quality and completeness.

5.3.1 Transmission of information by AED owners

It is assumed that the owner of an AED always contacts the distributor of the device after it has been used, in order to renew the pads and to interrogate the device to recover electrocardiograms stored before and after a shock. This practice should enable distributors to assess how often a particular AED is used, but reportedly these data are not stored. They are not transmitted neither to the FPS Public Health. One distributor estimates that of 8 000 AEDs, one is used every day (this would mean a use of once per 22 years).

5.3.2 EuReCa-ONE study

The EuReCa-ONE study included data about Belgium[4]. In order to isolate the Belgian results, the corresponding dataset was provided to us by Prof. Mols (Hospital St-Pierre, Brussels) and were analyzed in Stata 12.0. In October 2014, data on 105 OHCAs were registered by 14 MUG/SMUR services located either in Brussels, Flanders or Wallonia, covering 15% of the general population. The mean age was 69.6 (±54.1) (median 70 years) and 65.7% were males. 74.3% of OHCA occurred at private home, and only 17.1% (18/105) in public location (7.6% occurred in rest house and 1% in

h In the first quarter of 2017, 472 new files were submitted, of which 90 (19%) were incomplete.

workplace). The vast majority of OHCAs were of medical/cardiac origin (85.7%; 90/105). Overall, 63.8% of OCHAs were witnessed. This proportion amounted to 88.9% in public locations, and 44.4% (8/18) were witnessed by a passer-by or a family member. An AED was reportedly available in 69.5% of the OCHAs (73/105; missing data in 12/105), and used in 46.7% of overall OHCAs (49/105) and in 47.8% (43/90) of OHCAs of cardiac origin. The vast majority of users was the EMS (85.7%; 42/49). Most of the 7 remaining users had some training in resuscitation (1 MD; 3 rescuers; 1 policeman; 2 others). Eventually, a shock was given in 15 cases, i.e. in 14.3% (15/105) of all OCHAs. In the OCHAs of cardiac origin, this proportion amounted to 15.6% (14/90). The overall survival was 9.5% (95%CI: 4.7%; 16.8%; 10/105), 10% (95%CI: 4.7%; 18.1%; 9/90) in OHCAs of cardiac origin, and 33% (95%CI: 10%; 65%; 4/12) in those with an OHCA of cardiac origin bystander-witnessed and with a VF as first monitored rhythm (Utstein comparator group). In conclusion, a minority of OHCAs occurred in public location, and although 44% of cases were witnessed by a bystander, an AED was used by a bystander in none of these cases.

5.3.3 The MUGREG – SMUREG registry

The “Mobiele Urgentie Groep (MUG)” or “Service Mobile d'Urgence (SMUR)” is deployed when the presence of a physician at an emergency scene is considered crucial. The SMUReg-MUGReg is a compulsory registration of SMUR – MUG interventions data for all authorised SMUR – MUG functions in Belgium.

Since 2012, there were approximately 11 000 EMS interventions for cardiac arrest registered yearly (Figure 2). Around 80% of the cardiac arrest were deemed of cardiac origin, i.e. not caused by an external agent (fall, accident, burns…). Further analyses concern only cardiac arrest of cardiac origin. The median age of patients was around 70 years (IQR: 57y-80y) and in 6 cases out of 10 were males. In 2016, there were 8 939 OHCA of cardiac origin. Therefore, the incidence of EMS-attended OHCA of cardiac origin would be 82 per 100 000 person-years in Belgium.

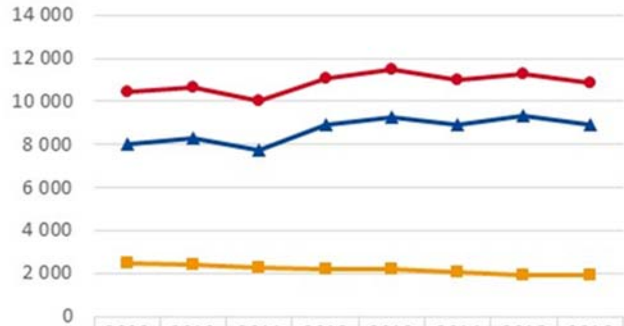
As regards the number of shocks by an AED before the arrival of the SMUR-MUG, the field on the SMUR-MUG form was unfortunately left empty in the vast majority (around 85%) of cases. If we consider that missing information can be assimilated to no shocks, in the majority of the cases (93%) there were no shocks in the period before the arrival of the SMUR-MUG service. In 2016, AED shocks were given before the arrival of the SMUR-MUG service in 6% of the cases and mainly by the ambulance staff (only 24 occurrences reported for bystanders).

AED shocks given by the SMUR-MUG team were reported in around 15% of the cases. However, the same problem of missing information was encountered (75%).

The overall percentage of survival at hospital arrival was 20%. That percentage was around 53% in patients with an AED shock given either before the arrival of the SMUR-MUG or by the SMUR-MUG.

In 2015, according to the annual report of the SMUR-MUG, 76.7% of the cases of OHCA for whom the SMUR-MUG was called upon died on the scene. Of 4 206 resuscitated patients (CPR), only 648 (15%) had a shockable rhythm (VF or VT) registered. This is a lower proportion than reported in international literature (between 22%[4] and 32%[3]). Asystole represented the most often entered cardiac rhythm in the database (2907/4206=69.1%).

Figure 2 – Evolution number of primary interventions for cardiac arrest (2009 – 2016)



	2009	2010	2011	2012	2013	2014	2015	2016
All interventions for cardiac arrest	10 470	10 676	10 011	11 063	11 451	11 008	11 292	10 880
Not caused by external agent	8 001	8 267	7 749	8 905	9 287	8 939	9 353	8 939
Caused by external agent	2 469	2 409	2 262	2 158	2 164	2 069	1 939	1 941

Source: Federal Public Service (FPS) Health, Food Chain Safety and Environment: Mobile Intensive Care Units (MICU) data 2009-2016

5.4 CPR/AED training

We retrieved few data on the CPR training level of the general population and on its awareness of AEDs or acceptance for using them. According to an unpublished on-line survey conducted by the Belgian Heart Rhythm Association in 2017 (n=3 761), two thirds never followed a CPR course, and 39% of respondents never saw an AED[i]. In another survey, 85 volunteers were randomly selected among visitors in a hospital's main entrance[29]. Less than half the volunteers had been trained in CPR or felt they could intervene in a cardiac arrest. Fifty-one (60%) participants attested that they did not feel capable of using an AED in a real life situation. The major reasons given were: 'I don't know how the device works' (45%), 'I am too stressed' (4%), and 'I am afraid to harm the victim' (2%). However, when put in situation in a simulation room with a CPR manikin and an AED placed visibly in the corner of the room, 74% (63/85) of the volunteers performed CPR and 62% (53/85) delivered an electrical shock. Among the latter, 47% (25/53) had stated they did not feel able to use an AED in the pre-test questionnaire. This study tends to show that a majority of volunteers do not feel self-confident in performing resuscitation, but may apply it when confronted with the situation. Whether such findings are valid in a real-life situation is questionable: the sample size was moderate, participants might not be representative of the general population (visitors of a general hospital volunteering to participate), and the simulation room within the hospital and with a visible AED might induce specific behaviours.

Up to now, Belgium has no compulsory training of CPR/AED during the secondary school cursus to the contrary of several other European countries. According to experts, 2 initiatives were recently developed in the French speaking part of Belgium (http://www.minipop.be/fr/accueil.html; http://lfbs.org/fr/formation-58c17c95a1e48.html). The number of students trained is of course very small (a few hundred per year) because these are initiatives by non-profit organizations with limited means. During their studies to become gym teachers, some of them are also trained to later be able to teach Basic Life Support to students. In Flanders it is part of the curriculum (Vak Overschrijdende Eindtermen) since 2010, which means every school has to do "something" about CPR. The Flemish ministry of Education launched a website "EHBO op school" in order to give some expert guidance on content and facilitate the instruction of first aid and CPR-AED (https://onderwijs.vlaanderen.be/nl/wat-moeten-je-leerlingen-minimaal-kunnen). However, there is still no obligation to do so.

i http://www.knokke-heist.be/nieuws/initiatiesessies-voor-reanimatie-en-gebruik-van-defribillator ; additional data provided by L. Discart, VADEMECOM.

5.5 What results could be expected from PAD in Belgium?

We set up a number of scenarios to figure out the benefit of PAD at the population level. The baseline of EMS-attended OCHAs of cardiac origin in Belgium in 2015 was 82.8 per 100 000 person-years. In all scenarios, the % of OHCA of cardiac origin occurring in public locations (30%) and witnessed by a bystander (50%) were maintained constant as these parameters are not amenable to changes (except if the public area is fully covered by video surveillance, which is unlikely). The survival rate of EMS-treated OCHA of cardiac origin was set at 10%, consistently with the results of many studies (see section 1.1). In all scenarios, we also considered that all currently EMS-treated OCHAs were shockable, a realistic hypothesis if the time of intervention decreases dramatically. The factors that were variables across scenarios are the % of bystander applying CPR and/or AED, as a reflection of public awareness and training, and the survival rate following the utilization of public AED, as a reflection of rapidity of intervention and high accessibility of AED. Given what we know of the current practice of CPR/AED in Belgium and that in many countries, the use of AED by bystander remains low (for example, in Japan, a shock by public AED was delivered in only 10% of the Utstein comparator group with a survival rate of 38%[30]), scenarios 2 and 3 are probably the closest to the Belgian reality. The scenario 7 which implies that 50% of the bystander-witnessed OCHA of cardiac origin occurring in a public location would be shocked within 2 minutes after collapse would allow a gain of 3.7 survivors per 100 000 person-years, or 421 extra survivors. However, this scenario is unlikely within the current Belgian practice, but could be reached with other strategies. For example, in the North Holland province of The Netherlands, where 2 ambulances together with a first responder are dispatched for every suspected OHCA, an AED was used in nearly 60% (but a minority by bystander) and the survival rate in patients with a shockable first rhythm (45% of the cases) was 36%[6]. A survival rate of 70% with public AEDs in the Utstein comparator group was reported in Stockolm[5].

Table 4 – Gain in survival according to different scenarios

	PAD by bystander among bystander-witnessed OHCA	Survival % in the Utstein comparator group when a shock is delivered by a bystander	Overall survival rate per 100 000 person-years	Absolute numbers of survivors per year	Increased in survival rate per 100 000 person-years	Increased survivors numbers per year
1	0%	0%	8.3*	936		
2	2%	30%	8.3	941	0.05	6
3	10%	30%	8.5	964	0.2	28
4	30%	30%	9.0	1 020	0.7	84
5	50%	30%	9.5	1 076	1.2	140
6	50%	50%	10.8	1 216	2.5	281
7	50%	70%	12.0	1 357	3.7	421

** The survival rate was set at 10% for EMS-attended OHCA as described in the international literature and in Belgium*

6 DISCUSSION

6.1 Clinical effectiveness of PAD

We retrieved only one comparative study (a randomised controlled trial)[16] assessing the clinical effectiveness of static AEDs in public locations. It reported a twofold difference in survival (RR=2.0; 95%CI: 1.07 to 3.77; p=0.03). As explained in section 4.1, there have been some methodological discussions over the way of computing results in the PAD trial. Based on risk ratio of survival in patients with a definite OHCA (30/128 (23%) in intervention vs. 15/107 (14%) in control groups, the RR was 1.67 (95%CI: 0.95 to 2.94; p=0.074). There are thus quite statistical uncertainties regarding the effect of the PAD program.

It should be noted that 11 000 optimally trained volunteers in selected public areas at high risk of OHCA were mobilized to deliver a shock within 3 minutes after collapse. The expected effect of PAD by lay bystanders is likely to be even lower, all other conditions being kept equal. In the North Holland Province of the Netherlands, it was estimated that 0.36 lives per 100 000 person-years were saved because of the use of on-site AEDs[27], whereas in Japan it was 0.16 per 100 000 person-years[28], and these figures are close to the simulation made for Belgium (see section 5.5)

How to explain the limited impact of PAD on a society level? There are two main reasons:

1. The Utstein comparator group, the target group of PAD, is relatively small.
    a. A minority of OCHA occur in public locations (around 30%) [4, 15, 16, 31-34], and only around 50% of OHCA (33%-54%) is witnessed by a bystander[5, 9, 15, 28, 34, 35]. These two conditions reduce considerably the proportion of OHCA which management could be improved with PAD. These two conditions are interrelated (i.e. they do not simply sum up) but studies report rarely the category "OHCA witnessed by bystander in a public location". An exception is the study by Ringh where 54% of OHCA of cardiac origin were witnessed and 45% of those were in public location, so in total there were only 20% of OHCA of cardiac origin witnessed by a bystander in public location[5].
    b. Not all OCHA are of cardiac origin (usually around 80%)
    c. Not all OCHA of cardiac origin will present a shockable initial rhythm, 20% of VF is often reported in the literature. However, this percentage very much depends of the time elapsed between collapse and first rhythm assessment (see point 2). Even in advanced PAD programs, the % of initial shockable rhythm did not go higher than 50%[5, 6].

Based on these figures, it can be inferred that only around 8% of all OCHAS are bystander-witnessed shockable OHCA of cardiac origin[j]. For example, in Japan, they represented only 7.5% of all OHCAs in whom resuscitation was attempted, between 2005 and 2013[28]. Therefore, although PAD makes a difference in survival of patients in the Utstein comparator group, this difference is diluted in the overall picture.

2. The occurrence of AED use by bystander is reportedly low in various settings
    a. In England in 2014, PAD use was reported in only 2.4% of the 16 811 non-EMS witnessed cases[35]. In Denmark in 2010, an AED was used by a bystander in 2.2% of OHCA although the proportion of OCHA witnessed by a bystander was 53.9% and a CPR was initiated by a bystander in 44.9%[36]. Similar rates were reported in England[35] or the USA[34]. Even settings where efforts had been put to improve the accessibility and use of AED, the % remained low. In the PAD trial cited above, a shock was delivered with a public AED in 34.4% (44/128) of definite OCHA in the intervention group, whereas an AED could be reached by a trained volunteer within 3 minutes[16]. As mentioned previously, in Japan a shock by public

[j] 20% witnessed in public locations*80% of cardiac origin*50%VF

AED was delivered in only 10% of the Utstein comparator group in spite of the high AED density[30]. In Stockholm, 15.6% of bystander witnessed OHCA of cardiac origin in public location were shocked[5]. Accessibility to the devices is part of the problem, i.e. AEDs are not accessible 24 hours a day, seven days a week[37,38], they may lack in the direct environment or be difficult to locate.

b. When an AED is used, it might be with too much delay. This might explain that the survival rate with PAD was below 40% in a number of observational studies [36.0% (1018/2858) in the Netherlands[6]; 32.7% (8573/26 165) in the USA[39]; and 38.4% (1731/4499) in Japan in the Utstein comparator group[28]]. A similar average survival rate of 29.7% was reported for the Utstein comparator group in the study by Grasner, without consideration regarding who administered the shock[4].

6.2 Cost-effectiveness

Given the lack of robust evidence on the effectiveness of AED use by lay bystanders in public locations as well as the lack of robust Belgian data on current AED use, it was not possible to properly evaluate the cost-effectiveness impact of AED provision in Belgium. Nevertheless, our review of the literature allowed us to identify the main elements impacting the cost-effectiveness of this intervention. The analysis has shown that results were mostly influenced by the incidence of OHCA in the area of AED locations, the probability of AED use in case of OHCA and the relative risk of survival after (bystander) defibrillation compared to other interventions. The four economic evaluations identified by the HIQA HTA were rather optimistic concerning these parameters[24-26, 40].

In ideal conditions, i.e. with the intervention of well-trained people to both CPR and AED use expected within three minutes or with a 100% probability of AED use in case of cardiac arrest, three out of these four studies showed that a targeted use of AED in high incidence area could be considered as cost-effective compared to no AED[24-26]. Nevertheless, as described in section 6.1, it is possible that in practice and in non-specific area, an AED would only be used in around 2% of cases. Moreover, a significant impact of AED use on the survival at discharge was assumed (e.g. a RR of 2.0; 95%CI 1.07-3.77 was used in the model performed by Nichol et al. based on the study of Hallstrom et al[16]). If the risk ratio recalculated by the authors of the HIQA HTA had been used, i.e. 1.67 (95%CI: 0.95-2.94), results would be worst (non-significant impact). It should also be mentioned that the study of Nichol et al.[38] added that if they were no ascertainment bias in the PAD trial, results would unlikely be cost-effective.

The fourth study (Walker et al.)[40], even with these positive assumptions, concluded that other alternatives would provide better value for money. It should nevertheless be noted that this study assumed few difference in patients survival with or without AED (i.e. the survival rate at discharge was 16.7% with AED and 14.7% without AED) compared to other studies based on the assumption that survival after AED use was similar than for patients attended by an ambulance staff within 3 minutes.

The economic evaluation performed in the HIQA HTA was more realistic and used estimates observed in their national OHCA register databases. This study concluded that compared to the current situation, PAD programs were not cost-effective. Nevertheless, they added that some elements could improve the cost-effectiveness of a PAD program, such as focusing on high incidence area (rather than focusing on specific building types), improving public awareness of OHCA, increasing the number of people trained in basic life support, and implementing an EMS-linked AED register. They nevertheless added that there is currently not enough evidence to analyse the magnitude of such an impact.

Results were also highly influenced by the base case comparator used in the analysis. In the Irish study, the base case scenario was based on the current situation, in which around 9000 AEDs were already deployed on a voluntary basis. Results were therefore dependent of the effectiveness of this base case situation. It should also be noted that the strategy of no AED provision was not investigated but removing all AEDs already bought has no sense. The cost-effectiveness of a public PAD program will therefore depend of the “current situation” in terms of AED unguided provision in each country.

It should also be noted that all studies identified focused on AED provision and not on all possible interventions to improve survival. Alternative strategies such as the training of first responders groups or other strategies to reduce the response times should also be considered. Moreover, in those studies, same hospitalization costs for survivors were assumed (with or without the use of an AED) while the study of Berdowski et al.[41] showed that for survivors, in-hospital health care costs were lower for patients treated with AED onsite than for patients treated with dispatched AED or without AED. This could be taken into account in further economic evaluations.

According to this analysis, the statement that AED used by lay bystander in public location would provide value for money is therefore quite doubtful.

6.3 The way forward?

No firm recommendation can be generated concerning the provision of static AEDs to be used by bystanders in Belgium, given the lack of high-quality evidence on the effectiveness and cost-effectiveness of such program. This is not to say that static AEDs by lay bystanders have no potential to save lives, but, as explained in section 6.1, their impact on overall OHCA mortality will remain limited, particularly if other difficulties identified in the chain of survival in the Belgian setting are not addressed. The results of the 2015 MUGREG/SMUREG registry (median time for arrival=12 min; VF/VT rate as initial rhythm in 15%) underscores the need for improvements. As stated by the Global Resuscitation Alliance the main principle is to shorten as much as possible the time period between collapse and defibrillation[k]. The European Resuscitation Council (ERC)[11] and the American Heart Association (AHA)[12] provided guidelines to shorten this delay, based on the ILCOR recommendations[42]. These recommendations, which have been translated in French (https://resuscitation.be/fr/directives/basic-life-support-new/) and in Dutch (https://resuscitation.be/nl/richtlijnen/basic-life-support-new/) by the Belgian Resuscitation Council, focused on early recognition of OHCA and call for help, high-performance CPR, and early access to an AED.

6.3.1 Early recognition and call for help

As explained in section 5.4, the level of awareness of the Belgian population might be low. Raising awareness may reduce the time of intervention, as demonstrated by the “6-minute zone” campaign launched by the Netherlands Heart Foundation to increase the number of resuscitation attempts in which a defibrillation shock is delivered within 6 minutes after the first call[6]. Similar campaign could be also replicated in Belgium.

6.3.2 Provision of high-performance CPR

6.3.2.1 CPR training for the general public

Bystander CPR slows down VF deterioration[14]. Increasing occurrence of bystander CPR presumably also increases the number of cases where EMS personnel will undertake resuscitation efforts. As explained in section 5.4, the level of training of the Belgian population might be low to moderate. Two recent studies showed that national initiatives to increase bystander CPR have improved substantially survival rates in Denmark and Sweden (although the co-occurrence of other related initiatives hinders making a strong causal relationship)[36, 43]. Quality of the CPR is also important for a better survival[44, 45]. There is a need to **raise public awareness on the importance of early CPR resuscitation**. Understanding the facilitators to use CPR by bystanders is important to increase the effectiveness of training[46]. Mandatory training in CPR/AED could be considered to be part of the school curriculum as this is already the case in Norway, Denmark, and 27 states in the USA[47], as well as in high schools and companies. For both training and awareness raising, wide dissemination and promotion of educational videos could be made through mass media.

k https://foundation915.files.wordpress.com/2016/07/a-call-to-establish-a-global-resuscitation-alliance-2016.pdf

6.3.2.2 Telephone-CPR by EMS dispatchers

EMS dispatchers represent a critical link in the chain of survival. They must be able to diagnose cardiac arrest in order to provide Telephone CPR (T-CPR) guidance or identify close-by AEDs. Such a strategy was deemed effective in several case reports, with a steep increase in the rate of bystander-CPR[47]. The quality of CPR could also be improved[48, 49]. However, diagnosing cardiac arrest and providing T-CPR can be difficult and stressful, resulting in delays[50] or even failed dispatch[51]. This emphasizes the need for standardized procedures and well-trained dispatchers. Our external experts indicated that T-CPR has been initiated in all 112 dispatch centres in Belgium for 4-5 years. A study in Liège reported a significant increase in bystanders CPR[52]. However, some experts mentioned that that there is currently huge variability of T-CPR by 112 dispatchers both in terms of simply happening and also in terms of quality.

In the coming years, smart technologies may allow strengthening the agency between the EMS dispatcher and the bystander at the side of the victim of an OHCA. For example, video feeds could allow the dispatcher to see the CPR quality live and adapt his/her advices[53].

6.3.3 Maximise the use of existing AEDs

6.3.3.1 AED number and location

Although the AED density per 1000 inhabitants is lower in Belgium than in other countries (e.g. Ireland, Japan), there is no one-for-all recommendation in terms of dispatch and number of AEDs. We don't know if the current number and dispatch is appropriate or not. The current Belgian legislation, following European and US guidelines, already recommends **targeting the placement of AEDs in high risk public places**[l] (airports, railway stations, bus terminals, sport facilities, shopping malls, offices and casinos)[2, 54]. However, as demonstrated in the HIQA HTA[15], simply increasing the number of AEDs, even in high-incidence locations, will result in high costs and no cost-effectiveness.

6.3.3.2 Accessibility and traceability

A second important issue is the accessibility and traceability of AEDs. For now, most of AEDs in Belgium are placed indoor (offices, train station, shops…). Most of them are not available on a 24/7 base. That indoor public AEDs are not accessible on a permanent basis (e.g. during public holiday or in the evenings) is difficult to overcome. To increase accessibility to AED and reduce time to defibrillation, other strategies that the stand-alone static AEDs for opportunistic use by bystanders, can be considered. There are two main ones[7]:

- Professional first responders (police, fire fighters) with mobile AEDs and dispatched by the emergency medical dispatch centre (112).
- Lay first responders dispatched by the 112 service (activated by a text-message) using either a mobile AED or being guided to the closest static AED[10].

The first approach increases the incidence of PAD. In North-Holland, currently more than 50% of all defibrillations is done by AED (personal communication R.W. Koster). However, the survival in first-responder defibrillated patients is lower than in those defibrillated by a bystander[7]. While local fixed AEDs may reduce the time to defibrillation most and therefore may result in dramatically increased survival (to 50-70%), the smaller benefit in response time and therefore less dramatic increase in survival of mobile AEDs may effectively save more lives because it can be applied in the whole population[27]. The second approach is promising but more evidence is needed[10].

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[l] The MUGREG – SMUREG registry could be useful to define such places, provided that the registry contains accurate locations and is comprehensive (see section 6.3.4).

Facilitating the retrieval of neighbouring AEDs by increased visibility is crucial. That can be done with clear and systematic advertisement outside the building and/or with mapping apps (e.g. the Staying Alive app). The listing of AEDs done by the FPS Public Health should be kept up to date and easily accessible to any user. Automatic geolocation of the AED would help to keep the mapping up to date[25]. Such mapping could also be used to referring bystanders of OHCAs to existing AEDs by EMS dispatchers[38].

6.3.3.3 Appropriate use of AED

As for CPR, **raising awareness and training is an important first step in the utilization of AED**. Explaining that the device is fully automatic and will provide all necessary information may help to decrease fear of use. Insisting that the bystander will not be held legally responsible in case of resuscitation failure is also important. And as for CRP, EMS dispatchers can provide guidance on the use of AEDs. This role could also be played by volunteers, as it is done in other countries (the Netherlands, Ireland). When the AED is used appropriately, the error rate is reportedly low[21]. The ERC also recommends considering the development of a team with responsibility for monitoring, maintaining the devices, training and retraining individuals who are likely to use the AED, and identification of a group of volunteer individuals who are committed to using the AED[2, 54]. Ensuring that accessible AEDs are well functioning is also crucial, particularly as the majority of AEDs will serve very rarely. A maintenance contract with a specialized company should be compulsory, and maintenance should be done yearly.

6.3.4 Data collection and quality control

Good-quality data are important to improve the utilization and monitoring of AEDs. Our study has demonstrated that many data are already collected and available. However, their validity is questionable and it is quite impossible today to have a clear picture of PAD in Belgium (see section 5). Therefore, we suggest to **make the utilization of existing registers more efficient**.

1. The registration of AED by the PFS Public Health, which is compulsory, should be optimised, i.e. every AED placed should be registered. There is a need to simplify the registration by AED owners, e.g. by online registration. Also, providing the address where the AED stands should be sufficient, i.e. providing the Lambert coordinates and the topographic maps should not be on the shoulders of the AED owner. Companies in charge of AED maintenance could be charged of that responsibility (concentration on fewer actors). The register should be updated in real-time. It could serve as a base for geographical mapping and facilitating of AED retrieval in case of OHCA.
2. The centralized registration of AED utilization which is mentioned in the Belgian law should be implemented (the current legislation stipulates that a report activity of each AED should be submitted yearly to the FPS Public Health). In principle, when an AED is used the company in charge of its maintenance will be called upon to check the device. This company could send the report to the FPS Public Health.
3. A centralized registration of EMS-attended OHCA is already in place (the MUGREG-SMUREG registry). However, strong quality procedure should be implemented to allow using the collected data for epidemiology and evidence-based policy.

REFERENCES

1. Perkins GD, Jacobs IG, Nadkarni VM, Berg RA, Bhanji F, Biarent D, et al. Cardiac Arrest and Cardiopulmonary Resuscitation Outcome Reports: Update of the Utstein Resuscitation Registry Templates for Out-of-Hospital Cardiac Arrest: A Statement for Healthcare Professionals From a Task Force of the International Liaison Committee on Resuscitation (American Heart Association, European Resuscitation Council, Australian and New Zealand Council on Resuscitation, Heart and Stroke Foundation of Canada, InterAmerican Heart Foundation, Resuscitation Council of Southern Africa, Resuscitation Council of Asia); and the American Heart Association Emergency Cardiovascular Care Committee and the Council on Cardiopulmonary, Critical Care, Perioperative and Resuscitation. Resuscitation. 2015;96:328-40.
2. Perkins GD, Handley AJ, Koster RW, Castren M, Smyth MA, Olasveengen T, et al. European Resuscitation Council Guidelines for Resuscitation 2015: Section 2. Adult basic life support and automated external defibrillation. Resuscitation. 2015;95:81-99.
3. Berdowski J, Berg RA, Tijssen JG, Koster RW. Global incidences of out-of-hospital cardiac arrest and survival rates: Systematic review of 67 prospective studies. Resuscitation. 2010;81(11):1479-87.
4. Grasner JT, Lefering R, Koster RW, Masterson S, Bottiger BW, Herlitz J, et al. EuReCa ONE-27 Nations, ONE Europe, ONE Registry: A prospective one month analysis of out-of-hospital cardiac arrest outcomes in 27 countries in Europe. Resuscitation. 2016;105:188-95.
5. Ringh M, Jonsson M, Nordberg P, Fredman D, Hasselqvist-Ax I, Hakansson F, et al. Survival after Public Access Defibrillation in Stockholm, Sweden--A striking success. Resuscitation. 2015;91:1-7.
6. Blom MT, Beesems SG, Homma PC, Zijlstra JA, Hulleman M, van Hoeijen DA, et al. Improved survival after out-of-hospital cardiac arrest and use of automated external defibrillators.[Erratum appears in Circulation. 2014 Dec 23;130(25):e436]. Circulation. 2014;130(21):1868-75.

7. Baekgaard JS, Viereck S, Moller TP, Ersboll AK, Lippert F, Folke F. The Effects of Public Access Defibrillation on Survival After Out-of-Hospital Cardiac Arrest: A Systematic Review of Observational Studies. Circulation. 2017;136(10):954-65.

8. Einsenberg M, Lippert FK, Shin SD, Bobrow BJ, Castren M, Moore FP, et al. Improving Survival from Out-of-Hopsital Cardiac Arrest: A call to establish a Global Resuscitation Alliance. 2015. Available from: https://foundation915.files.wordpress.com/2016/07/a-call-to-establish-a-global-resuscitation-alliance-2016.pdf

9. Malta Hansen C, Kragholm K, Pearson DA, Tyson C, Monk L, Myers B, et al. Association of Bystander and First-Responder Intervention With Survival After Out-of-Hospital Cardiac Arrest in North Carolina, 2010-2013. Jama. 2015;314(3):255-64.

10. Zijlstra JA, Stieglis R, Riedijk F, Smeekes M, van der Worp WE, Koster RW. Local lay rescuers with AEDs, alerted by text messages, contribute to early defibrillation in a Dutch out-of-hospital cardiac arrest dispatch system. Resuscitation. 2014;85(11):1444-9.

11. Monsieurs KG, Nolan JP, Bossaert LL, Greif R, Maconochie IK, Nikolaou NI, et al. European Resuscitation Council Guidelines for Resuscitation 2015: Section 1. Executive summary. Resuscitation. 2015;95:1-80.

12. Neumar RW, Shuster M, Callaway CW, Gent LM, Atkins DL, Bhanji F, et al. Part 1: Executive Summary: 2015 American Heart Association Guidelines Update for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care. Circulation. 2015;132(18 Suppl 2):03.

13. Perkins GD, Handley AJ, Koster RW, Castrén M, Smyth MA, Olasveengen T, et al. Adult basic life support and automated external defibrillation.: Section 2 of the European Resuscitation Council Guidelines for Resuscitation 2015. Notf. Rettungsmed. 2015;18(8):748-69.

14. Waalewijn RA, Nijpels MA, Tijssen JG, Koster RW. Prevention of deterioration of ventricular fibrillation by basic life support during out-of-hospital cardiac arrest. Resuscitation. 2002;54(1):31-6.

15. Health Information and Quality Authority Ireland. Health technology assessment (HTA) of public access defibrillation. HIQA; 2014. Health Technology Assessment Database 4 Available from: https://www.hiqa.ie/reports-and-publications/health-technology-assessments/hta-public-access-defibrillation

16. Hallstrom AP, Ornato JP, Weisfeldt M, Travers A, Christenson J, McBurnie MA, et al. Public-access defibrillation and survival after out-of-hospital cardiac arrest. N Engl J Med. 2004;351(7):637-46.

17. Mosesso VN, Jr., Davis EA, Auble TE, Paris PM, Yealy DM. Use of automated external defibrillators by police officers for treatment of out-of-hospital cardiac arrest. Ann Emerg Med. 1998;32(2):200-7.

18. Sweeney TA, Runge JW, Gibbs MA, Raymond JM, Schafermeyer RW, Norton HJ, et al. EMT defibrillation does not increase survival from sudden cardiac death in a two-tiered urban-suburban EMS system. Ann Emerg Med. 1998;31(2):234-40.

19. DeLuca LA, Jr., Simpson A, Beskind D, Grall K, Stoneking L, Stolz U, et al. Analysis of automated external defibrillator device failures reported to the Food and Drug Administration. Annals of Emergency Medicine. 2012;59(2):103-11.

20. Calle PA, Mpotos N, Calle SP, Monsieurs KG. Inaccurate treatment decisions of automated external defibrillators used by emergency medical services personnel: incidence, cause and impact on outcome. Resuscitation. 2015;88:68-74.

21. Zijlstra JA, Bekkers LE, Hulleman M, Beesems SG, Koster RW. Automated external defibrillator and operator performance in out-of-hospital cardiac arrest. Resuscitation. 2017;118:140-6.

22. Peberdy MA, Ottingham LV, Groh WJ, Hedges J, Terndrup TE, Pirrallo RG, et al. Adverse events associated with lay emergency

response programs: the public access defibrillation trial experience. Resuscitation. 2006;70(1):59-65.

23. Zijlstra JA, Beesems SG, De Haan RJ, Koster RW. Psychological impact on dispatched local lay rescuers performing bystander cardiopulmonary resuscitation. Resuscitation. 2015;92:115-21.
24. Cram P, Vijan S, Fendrick AM. Cost-effectiveness of automated external defibrillator deployment in selected public locations (Structured abstract). Journal of General Internal Medicine. 2003;18(9):745-54.
25. Folke F, Lippert FK, Nielsen SL, Gislason GH, Hansen ML, Schramm TK, et al. Location of cardiac arrest in a city center: strategic placement of automated external defibrillators in public locations (Provisional abstract). Circulation. 2009;120(6):510-7.
26. Nichol G, Huszti E, Birnbaum A, Mahoney B, Weisfeldt M, Travers A, et al. Cost-effectiveness of lay responder defibrillation for out-of-hospital cardiac arrest. Ann Emerg Med. 2009;54(2):226-35 e1-2.
27. Berdowski J, Blom MT, Bardai A, Tan HL, Tijssen JG, Koster RW. Impact of onsite or dispatched automated external defibrillator use on survival after out-of-hospital cardiac arrest. Circulation. 2011;124(20):2225-32.
28. Kitamura T, Kiyohara K, Sakai T, Matsuyama T, Hatakeyama T, Shimamoto T, et al. Public-access defibrillation and out-of-hospital cardiac arrest in Japan. New Engl. J. Med. 2016;375(17):1649-59.
29. Maes F, Marchandise S, Boileau L, Le Polain de Waroux JB, Scavee C. Evaluation of a new semiautomated external defibrillator technology: a live cases video recording study. Emergency Medicine Journal. 2015;32(6):481-5.
30. Kitamura T, Kiyohara K, Sakai T, Matsuyama T, Hatakeyama T, Shimamoto T, et al. Public-Access Defibrillation and Out-of-Hospital Cardiac Arrest in Japan. New England Journal of Medicine. 1649;375(17):1649-59.
31. Girotra S, Van Diepen S, Nallamothu BK, Carrel M, Vellano K, Anderson ML, et al. Regional variation in out-of-hospital cardiac arrest survival in the United States. Circulation. 2016;133(22):2159-68.
32. Hawkes C, Booth S, Ji C, Brace-McDonnell SJ, Whittington A, Mapstone J, et al. Epidemiology and outcomes from out-of-hospital cardiac arrests in England. Resuscitation. 2017;110:133-40.
33. Lai H, Choong CV, Fook-Chong S, Ng YY, Finkelstein EA, Haaland B, et al. Interventional strategies associated with improvements in survival for out-of-hospital cardiac arrests in Singapore over 10 years. Resuscitation. 2015;89:155-61.
34. Weisfeldt ML, Sitlani CM, Ornato JP, Rea T, Aufderheide TP, Davis D, et al. Survival after application of automatic external defibrillators before arrival of the emergency medical system: evaluation in the resuscitation outcomes consortium population of 21 million. J Am Coll Cardiol. 2010;55(16):1713-20.
35. Hawkes C, Booth S, Ji C, Brace-McDonnell SJ, Whittington A, Mapstone J, et al. Epidemiology and outcomes from out-of-hospital cardiac arrests in England. Resuscitation. 2017;110:133-40.
36. Wissenberg M, Lippert FK, Folke F, Weeke P, Hansen CM, Christensen EF, et al. Association of national initiatives to improve cardiac arrest management with rates of bystander intervention and patient survival after out-of-hospital cardiac arrest. JAMA. 2013;310(13):1377-84.
37. Hansen CM, Wissenberg M, Weeke P, Ruwald MH, Lamberts M, Lippert FK, et al. Automated external defibrillators inaccessible to more than half of nearby cardiac arrests in public locations during evening, nighttime, and weekends. Circulation. 2013;128(20):2224-31.
38. Agerskov M, Nielsen AM, Hansen CM, Hansen MB, Lippert FK, Wissenberg M, et al. Public Access Defibrillation: Great benefit and potential but infrequently used. Resuscitation. 2015;96:53-8.

39. CARES. Utstein Survival Report. All Agencies/National Data. Service Date: From 1/1/13 Through 12/31/16. 2017. Available from: https://mycares.net/sitepages/uploads/2017/2013-2016%20Non-Traumatic%20National%20Utstein%20Report.pdf

40. Walker A, Sirel JM, Marsden AK, Cobbe SM, Pell JP. Cost effectiveness and cost utility model of public place defibrillators in improving survival after prehospital cardiopulmonary arrest. BMJ. 2003;327(7427):1316.

41. Berdowski J, Kuiper MJ, Dijkgraaf MGW, Tijssen JGP, Koster RW. Survival and health care costs until hospital discharge of patients treated with onsite, dispatched or without automated external defibrillator (Provisional abstract). Resuscitation. 2010;81(8):962-7.

42. Perkins GD, Travers AH, Berg RA, Castren M, Considine J, Escalante R, et al. Part 3: Adult basic life support and automated external defibrillation: 2015 International Consensus on Cardiopulmonary Resuscitation and Emergency Cardiovascular Care Science with Treatment Recommendations. Resuscitation. 2015;95(69).

43. Hasselqvist-Ax I, Herlitz J, Svensson L. Early CPR in Out-of-Hospital Cardiac Arrest. N Engl J Med. 2015;373(16):1573-4.

44. Meaney PA, Bobrow BJ, Mancini ME, Christenson J, de Caen AR, Bhanji F, et al. Cardiopulmonary resuscitation quality: improving cardiac resuscitation outcomes both inside and outside the hospital. A consensus statement from the American Heart Association. Circulation. 2013;128(4):417-35.

45. Talikowska M, Tohira H, Finn J. Cardiopulmonary resuscitation quality and patient survival outcome in cardiac arrest: A systematic review and meta-analysis. Resuscitation. 2015;96:66-77.

46. Malta Hansen C, Rosenkranz SM, Folke F, Zinckernagel L, Tjornhoj-Thomsen T, Torp-Pedersen C, et al. Lay Bystanders' Perspectives on What Facilitates Cardiopulmonary Resuscitation and Use of Automated External Defibrillators in Real Cardiac Arrests. J Am Heart Assoc. 2017;6(3).

47. Eisenberg M, Rea T. Accelerating progress in community resuscitation. Heart. 2014;100(8):609-10.

48. Spelten O, Warnecke T, Wetsch WA, Schier R, Bottiger BW, Hinkelbein J. Dispatcher-assisted compression-only cardiopulmonary resuscitation provides best quality cardiopulmonary resuscitation by laypersons: A randomised controlled single-blinded manikin trial. Eur J Anaesthesiol. 2016;33(8):575-80.

49. Rea TD, Eisenberg MS, Culley LL, Becker L. Dispatcher-assisted cardiopulmonary resuscitation and survival in cardiac arrest. Circulation. 2001;104(21):2513-6.

50. Oman G, Bury G. Use of telephone CPR advice in Ireland: Uptake by callers and delays in the assessment process. Resuscitation. 2016;102:6-10.

51. Hollenberg J, Riva G, Bohm K, Nordberg P, Larsen R, Herlitz J, et al. Dual dispatch early defibrillation in out-of-hospital cardiac arrest: the SALSA-pilot. Eur Heart J. 2009;30(14):1781-9.

52. Stipulante S, Tubes R, El Fassi M, Donneau AF, Van Troyen B, Hartstein G, et al. Implementation of the ALERT algorithm, a new dispatcher-assisted telephone cardiopulmonary resuscitation protocol, in non-Advanced Medical Priority Dispatch System (AMPDS) Emergency Medical Services centres. Resuscitation. 2014;85(2):177-81.

53. Stipulante S, Delfosse AS, Donneau AF, Hartsein G, Haus S, D'Orio V, et al. Interactive videoconferencing versus audio telephone calls for dispatcher-assisted cardiopulmonary resuscitation using the ALERT algorithm: a randomized trial. Eur J Emerg Med. 2016;23(6):418-24.

54. Travers AH, Perkins GD, Berg RA, Castren M, Considine J, Escalante R, et al. Part 3: Adult Basic Life Support and Automated External Defibrillation: 2015 International Consensus on Cardiopulmonary Resuscitation and Emergency Cardiovascular Care Science With Treatment Recommendations. Circulation. 2015;132(16 Suppl 1):S51-83.

COLOPHON

Title:	Static automated external defibrillators for opportunistic use by bystanders – Short Report
Authors:	Hans Van Brabandt (KCE), Sophie Gerkens (KCE), Nicolas Fairon (KCE), Cécile Dubois (KCE), Marcel Van Der Auwera (PFS Public Health), Christophe Vansimpsen (PFS Public Health), Dominique Roberfroid (KCE)
Project coordinator:	Dominique Paulus (KCE)
Senior supervisor:	Dominique Roberfroid (KCE)
Reviewers:	Audrey Cordon (KCE), Christian Léonard (KCE), Sabine Stordeur (KCE)
External experts:	Rufij Baeke (Heartsaver®), Ivan Blankoff (BEHRA [Belgian Heart Rhythm Association]; CHU Charleroi), Paul Calle (BeSEDiM [Belgian Society of Emergency and Disaster Medicine]; UGent), Marc Clevers (bvba CLINITEC, bvba RECOMEX), André De Landtsheer (VVIB-AMTI [Vereniging Voor Interne Bedrijfsartsen – Association des Médecins du Travail des services internes]), Thierry Hosay (Belgian Red Cross & ERC [European Resuscitation Council]), Tony Hosmans (Ecole Provinciale d'Aide Médicale Urgente, Liège), Mouloud Kalaai (IDEWE [Externe Dienst voor Preventie en Bescherming op het Werk]), Luc Ketele (Heartsaver®), Jorien Laermans (Rode Kruis-Vlaanderen), Frédérique Meulders (FAGG-AFMPS [Federaal Agentschap voor Geneesmiddelen en Gezondheidsproducten – Agence Fédérale des Médicaments et des Produits de Santé]), Pierre Mols (CHU Saint-Pierre, Bruxelles), Koen Monsieurs (UZA [Universitair Ziekenhuis Antwerpen]), Walter Renier (KULeuven), Christophe Scavée (Cliniques universitaires Saint-Luc), Peter Thiebaut (AED Partners), David Vancraeynest (Cliniques universitaires Saint-Luc), Marcel Van der Auwera (FOD Volksgezondheid), Steven Vercammen (EVapp [Emergency Volunteer Application]), Hans Verstraeten (Rode Kruis-Vlaanderen)
External validators:	Alexandre Ghuysen (ULG), Ruud W. Koster (Academisch Medisch Centrum, Universiteit van Amsterdam), Rik Willems (KULeuven)
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Layout:	Ine Verhulst
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