

# Use of Automated External Defibrillators in Cardiac Arrest

An Evidence-Based Analysis

December 2005



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The Medical Advisory Secretariat also provides a secretariat function and evidence-based health technology policy analysis for review by the Ontario Health Technology Advisory Committee (OHTAC).

The Medical Advisory Secretariat conducts systematic reviews of scientific evidence and consultations with experts in the health care services community to produce the *Ontario Health Technology Assessment Series*.

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# Table of Contents

<b>Executive Summary .....</b>	<b>6</b>
Objective .....	6
Clinical Need.....	6
The Technology .....	6
Methods.....	7
Summary of Findings .....	7
Conclusions.....	8
<b>Abbreviations .....</b>	<b>9</b>
<b>Objectives .....</b>	<b>10</b>
<b>Background .....</b>	<b>10</b>
Clinical Need: Target Population and Condition .....	10
Existing Treatments Other Than Technology Being Reviewed .....	10
<b>New Technology Being Reviewed .....</b>	<b>11</b>
Regulatory Status.....	11
<b>Literature Review on Effectiveness .....</b>	<b>12</b>
Objectives.....	12
Methods.....	12
Search Engines .....	12
Results of Literature Review.....	12
Summary of Existing Health Technology Assessments.....	12
Summary of Medical Advisory Secretariat Review.....	13

<b>Economic Analysis.....</b>	<b>14</b>
Objective .....	14
Literature Review: Objectives and Methods.....	14
Results of Literature Review on Economics .....	15
Public settings.....	15
Aircraft Setting.....	16
Home Setting .....	16
High-School Setting .....	17
Ontario-Based Economic Analysis .....	17
Hospital Settings.....	17
Out-of-Hospital Settings .....	18
Existing Guidelines for Use of Technology .....	21
The American Heart Association Guidelines (2005).....	21
Lay Rescuer Automated External Defibrillator Programs .....	21
Conclusions .....	22
<b>Appendices .....</b>	<b>23</b>
Appendix 1: Literature Review Search Strategy .....	23
Appendix 2: Literature Review and Search Strategy: 2 .....	25
<b>References .....</b>	<b>27</b>

# Executive Summary

## Objective

The objectives were to identify the components of a program to deliver early defibrillation that optimizes the effectiveness of automated external defibrillators (AEDs) in out-of-hospital and hospital settings, to determine whether AEDs are cost-effective, and if cost-effectiveness was determined, to advise on how they should be distributed in Ontario.

## Clinical Need

Survival in people who have had a cardiac arrest is low, especially in out-of-hospital settings. With each minute delay in defibrillation from the onset of cardiac arrest, the probability of survival decreases by 10%. (1) Early defibrillation (within 8 minutes of a cardiac arrest) has been shown to improve survival outcomes in these patients. However, in out-of-hospital settings and in certain areas within a hospital, trained personnel and their equipment may not be available within 8 minutes. This implies that “first responders” should take up the responsibility of delivering shock. The first responders in out-of-hospital settings are usually bystanders, firefighters, police, and community volunteers. In hospital settings, they are usually nurses. These first responders are not trained in reading electrocardiograms and identifying abnormal heart rhythms restorable by defibrillation.

## The Technology

An AED is a device that can analyze a heart rhythm and deliver a shock if needed. Thus, AEDs can be used by first responders to deliver early defibrillation in out-of-hospital and hospital settings. However, simply providing an AED would not likely improve survival outcomes. Rather, AEDs have a role in strengthening the “chain of survival,” which includes prompt activation of the 911 telephone system, early cardiopulmonary resuscitation (CPR), rapid defibrillation, and timely advanced life support.

In the chain of survival, the first step for a witness of a cardiac arrest in an out-of-hospital setting is to call 911. Second, the witness initiates CPR (if she or he is trained in CPR). If the witness cannot initiate CPR, or the first responders of the 911 system (e.g., firefighters/police) have arrived, the first responders initiate CPR. Third, the witness or first responders apply an AED to the patient. The device reads the patient’s heart rhythm and prompts for shock when indicated. Fourth, the patient is handed over to the advanced life-support team with subsequent admission to an intensive care unit in a hospital.

The use of AEDs requires developing and implementing a program at sites where the cardiac arrest rate is high, where a number of potential first responders are trained and retained, and where patients are transferred to an advanced care facility after initiating resuscitation. Obviously, placing an AED at a site where no cardiac arrests are likely to occur would be futile, as would placing an AED at a site where no one knows how to use it. Moreover, abandoning patients after initial resuscitation by not transferring them to an advanced care facility would negate all earlier efforts. Thus, it is important to identify the essential components of an AED program that might also optimize the effectiveness of AED use.

## Methods

There is a large body of literature on the use of AEDs in various settings ranging from closed environments such as hospitals, airlines, and casinos to open places such as sports fields and highways. There is little doubt regarding the effectiveness and safety of AEDs to treat people in cardiac arrest. It is intuitive that these devices should be provided in hospitals in areas that are not readily accessible to the traditional responders, the “code blue team.” Similarly, it is intuitive to provide AEDs in out-of-hospital settings where the risk of cardiac arrest is high and a response plan involving trained first responders in the use of AEDs is in place.

Thus, the Medical Advisory Secretariat reviewed the literature and focused on the components of an AED program in out-of-hospital settings that maximize the effectiveness and cost-effectiveness of the program in the management of cardiac arrest. Search engines included MEDLINE, EMBASE, EconLit and Web sites of other agencies that assess health technologies. Any study that reported results of an AED program in an out-of-hospital setting was included. Studies that did not use AEDs, had a physician-assisted emergency response plan, did not have a program for the use of AEDs, or did not include cardiac arrest as an outcome were excluded.

## Summary of Findings

A total of 133 articles were identified; 62 were excluded after reviewing titles and abstracts. Of the 71 articles reviewed, 8 reported findings of 2 large studies, the Ontario Prehospital Advanced Life Support (OPALS) study and the Public Access Defibrillation (PAD) trial. These studies examined the effect of a community program to respond to cardiac arrest with and without the use of AEDs. Their authors had reported a significant reduction in overall mortality from cardiac arrest with the use of AEDs.

### Factors That Improve the Effectiveness of an AED Program

The PAD trial investigators reported a significant improvement in survival ( $P = .03$ ) after providing AEDs in public access areas and training volunteers in CPR compared with training volunteers in CPR only. The OPALS study investigators reported odds ratios (ORs) and 95% confidence intervals (CIs) for significant predictors of survival, which were age (OR [age per 10 year], 0.8; CI, 0.8–0.9), arrest witnessed by bystander (OR, 3.9; CI, 2.7–5.5), CPR initiated by bystander (OR, 3.7; CI, 2.6–5.1), CPR initiated by first responder (OR, 1.6; CI, 1.1–2.3), and emergency medical service response within 8 minutes (OR, 3.0; CI, 1.8–5.1). The last 3 variables are modifiable and thus may improve the effectiveness of an AED program. For example, the rate of bystander-initiated CPR was only 14% in the OPALS study, but it was 100% in the PAD trial. This was because PAD trial investigators trained community volunteers whereas the OPALS study investigators did not.

### Cost-Effectiveness

A systematic review of the literature suggests that cost-effectiveness varies from setting to setting. Most of the studies have estimated cost-effectiveness in American settings from a societal perspective; therefore, the results are not applicable to this report. However, results from this review suggest that the incidence of cardiac arrest in out-of-hospital setting in Ontario is 59 per 100,000 people. The mean age of cardiac arrest patients is 69 years. Eighty-five percent of these cardiac arrests occur in homes. Of all the cardiac arrests, 37% have heart rhythm abnormalities (ventricular tachycardia or ventricular fibrillation) that are correctable by delivering shock through an AED. Thus, in an out-of-hospital setting, general use of AEDs by laypersons would not be cost-effective. Special programs are needed in the out-of-hospital setting for cost-effective use of AEDs.

One model for the use of AEDs in out-of-hospital settings was examined in the OPALS study. Firefighters and police were trained and provided with AEDs. The total initial cost (in US dollars) of this program was estimated to be \$980,000. The survival rate was 3.9% before implementing the AED program and 5.2% after its implementation (OR, 1.33; 95% CI, 1.03–1.7;  $P = .03$ ). Applying these estimates to cardiac arrest rates in Ontario in 2002, one would expect 54 patients of the total 1,395 cardiac arrests to survive without AEDs compared with 73 patients with AEDs; thus, 19 additional lives might be saved each year with an AED program. It would initially cost \$51,579 to save each additional life. In subsequent years, however, total cost would be lower (about \$50,000 per year), when it would cost \$2,632 to save each additional life per year. One limitation of the OPALS study was that the authors combined emergency medical service response time and application of an AED into a single variable. Thus, it was not possible to tease out the independent effects of reduction in response time and application of an AED on the small improvement in survival. Nevertheless, the PAD study found that when response time was fixed, the application of AED improved survival.

There are other delivery models for AEDs in casinos, sports arenas, and airports. The proportion of cardiac arrest at these sites out of the total cardiac arrests in Ontario is between 0.05% and 0.4%. Thus, an AED placed at these sites would likely not be used at all.

Of the 85% cardiac arrests that occur in homes, 56% occur in single residential dwellings (houses), 23% occur in multi-residential dwellings (apartments/condominiums), and 6% occur in nursing homes. There is no program in place except the 911 system to reach these patients.

Accordingly, the Medical Advisory Secretariat examined the cost-effectiveness of providing AEDs in hospitals, office buildings, apartments/condominiums, and houses. The results suggested that deployment of AEDs in hospitals would be cost-effective in terms of cost per quality adjusted life year gained. Conversely, deployment of AEDs in office buildings, apartments, and houses was not cost-effective. An exception, however, was noted for people at high risk of sudden cardiac arrest; these were patients with a left ventricular ejection fraction less than or equal to 0.35.

## **Conclusions**

The OPALS study model appears cost-effective, and effectiveness can be further enhanced by training community volunteers to improve the bystander-initiated CPR rates. Deployment of AEDs in all public access areas and in houses and apartments is not cost-effective. Further research is needed to examine the benefit of in-home use of AEDs in patients at high risk of cardiac arrest.



# Abbreviations

<b>AED</b>	Automated external defibrillator
<b>CPR</b>	Cardiopulmonary resuscitation
<b>EMS</b>	Emergency Medical Service
<b>LVEF</b>	Left ventricular ejection fraction
<b>ICD</b>	Implantable cardioverter defibrillator
<b>OPALS</b>	Ontario Prehospital Advanced Life Support
<b>PAD</b>	Public Access Defibrillation
<b>QALY</b>	Quality adjusted life year
<b>RCT</b>	Randomized controlled trial

# Objectives

The objectives were to identify the components of a program to deliver early defibrillation that optimizes the effectiveness of automated external defibrillators (AEDs) in out-of-hospital and hospital settings, to determine whether AEDs are cost-effective, and if cost-effectiveness was determined, to advise on how they should be distributed in Ontario.

Within the context of a recent debate in a legislative committee over deployment of automated external defibrillators (AEDs) in public access areas, including government buildings, initiatives taken by a number of municipalities in installing AEDs in public access areas within their jurisdictions, and continuing media coverage on the importance of early cardiopulmonary resuscitation (CPR) and defibrillation, the Ontario Health Technology Assessment Committee asked the Medical Advisory Secretariat to review the literature on AEDs. Specifically, the Ontario Health Technology Assessment Committee asked the Medical Advisory Secretariat to identify the components of a program to deliver early defibrillation that optimize the effectiveness of AEDs in out-of-hospital and hospital settings, to determine whether AEDs are cost-effective and, if cost-effectiveness was determined, to advise them on how the devices should be distributed in Ontario.

## Background

### **Clinical Need: Target Population and Condition**

About 70% of cardiac arrests occur in out-of-hospital settings; of these, only 5% of these patients survive to be discharged home. (2-6) In the hospital setting, survival to discharge varies from 10% to 25%. Most of the cardiac arrests occur in elderly people; the mean age is 69 years. (4;5) Other specific risk factors are unknown. Given the lower survival rates in out-of-hospital settings compared with those in hospital settings, there is a need to improve response plans to reach people in time.

With each minute delay in defibrillation from the onset of cardiac arrest, the probability of survival decreases by 10%. (1) Early defibrillation (within 8 minutes of a cardiac arrest) has been shown to improve survival outcomes in these patients. (4) However, in out-of-hospital settings and in certain areas within a hospital, trained personnel and their equipment may not be available within 8 minutes. This implies that “first responders” should assume responsibility for delivering the shock. The first responders in out-of-hospital settings are usually bystanders, firefighters, police, and community volunteers. (3) In hospital settings, they are usually nurses. (7) These first responders are not trained in reading electrocardiograms and identifying abnormal heart rhythms restorable by defibrillation.

### **Existing Treatments Other Than Technology Being Reviewed**

The management of cardiac arrest requires initiation of a sequence of steps, often referred to as the chain of survival. (6) In the out-of-hospital setting, this includes prompt activation of the 911 telephone system, early CPR, rapid defibrillation, and timely advanced life support. The first link in the chain is generally activated by a witness, the second and third by firefighters, and the fourth by paramedics. The counterpart of this in the hospital setting is the code blue system. In the event of a cardiac arrest in a hospital, a code blue is announced using the hospital’s overhead paging system or by shouting to a colleague. (7) A code blue team trained in CPR, defibrillation, and advanced life support techniques takes over the management

of the person who has gone into cardiac arrest. Whether the arrest occurs in out-of-hospital setting or in hospital after initial resuscitation the patient is transferred to an intensive care unit for further management.

Cardiac patients who have a left ventricular ejection fraction less than or equal to 0.35 are at increased risk of sudden cardiac arrest. For these patients, implantable cardiac defibrillators (ICDs) are recommended. (8) An ICD is a battery-powered device that monitors heart rhythm and can deliver an electric shock to restore normal sinus rhythm when malignant arrhythmias are detected. Newer models are placed under the skin in the chest. If an ICD detects a minor arrhythmia, it activates a built-in conventional pacemaker to restabilize cardiac rhythm. If that fails, the ICD can deliver a small defibrillating electrical jolt to the heart. In the extreme, the device can deliver a stronger jolt to re-establish the normal heart rhythm. (9)

## **New Technology Being Reviewed**

An AED is a device that can analyze a patient's heart rhythm and deliver a shock if needed. The device is easy to use and usually provides voice instruction to lay users. Thus, AEDs may be used by first responders to a cardiac arrest to deliver early defibrillation in out-of-hospital and hospital settings. The use of AEDs requires developing and implementing a program at sites where the cardiac arrest rate is high, where a number of potential first responders are trained and retained, and where patients are transferred to an advanced care facility after initiating resuscitation. Obviously, placing an AED at a site where cardiac arrests are unlikely to occur would be futile, as would placing an AED at a site where no one knows how to use it. Moreover, abandoning patients after initial resuscitation by not transferring them to an advanced care facility would negate all earlier efforts.

### **Regulatory Status**

Health Canada has licensed the following devices for use in Canada:

HeartStart FRx automated external defibrillator (Licence 67991) is a Class 3 device from Philips Medical Systems (Seattle, Washington, United States).

LIFEPAK 500 3-D biphasic automated external defibrillator (Licence 14400) is a Class 4 device from Medtronic Emergency Response Systems (Redmond, Washington, United States).

Samaritan PAD automated external defibrillator (Licence 67532) is a Class 3 device from Heartsine Technologies Ltd. (Belfast, Ireland).

# Literature Review on Effectiveness

## Objectives

The objective of this review was to answer the question: What components of a program to deliver early defibrillation optimize the effectiveness of AEDs in out-of-hospital and hospital settings?

## Methods

The effectiveness and safety of AEDs in cardiac arrest is already established and thus not a subject of investigation in this report. One of the most important factors in the chain of survival is time to defibrillation. Thus, it is intuitive that AEDs should be provided in a hospital setting in areas that are not readily accessible to the traditional responders, the code blue team. However, owing to the diversity in out-of-hospital settings, there are several factors that may influence the effectiveness of an AED program. Therefore, this review focused on the components of an AED program in out-of-hospital settings that maximize the effectiveness of an AED program in the management of cardiac arrest.

## Search Engines

The Medical Advisory Secretariat searched MEDLINE, EMBASE and Web sites of other agencies that assess health technologies.

### Inclusion Criterion:

Any study that reported results of an AED program

### Exclusion Criteria:

Studies that did not use AEDs, had a physician-assisted emergency response plan, did not have a program for the use of AEDs, or did not include cardiac arrest as an outcome

## Results of Literature Review

The search employed a combination of key words: defibrillation, electric counter shock, pre-hospital, rapid, out of hospital, public access, emergency medical service (EMS); program evaluation; heart arrest; treatment outcome, survival analysis, survival rate, hospital discharge, mortality; Ontario Prehospital Advanced Life Support study, Public Access Defibrillation trial. The details are provided in Appendix 1.

A total of 133 articles were identified; 62 were excluded after reviewing titles and abstracts. Of the 71 articles reviewed, 8 reported findings of 2 large studies, the Public Access Defibrillation (PAD) Trial and the Ontario Prehospital Advanced Life Support (OPALS) study. There were 2 health technology assessments.

## Summary of Existing Health Technology Assessments

The nonprofit health services research agency ECRI (10) published an evaluation of 8 AED models from 5 suppliers in 2004. They rated the models for first-responder use and for PAD use as “preferred,” “acceptable,” and “not applicable;” their rating applies to the use of AEDs within and outside hospital settings. None of the 8 models was rated not applicable for use by first-responders; 2 were rated not

applicable for PAD use, but the suppliers had “acceptable” alternative models.

The Canadian Coordinating Office for Health Technology Assessment has published a narrative review of AEDs for home use. (11) The review focused on a single device, Philips Medical System’s HeartStart home defibrillator, which is approved for home use by untrained users. The review recognized that one barrier to widespread use of AEDs was lack of evidence supporting that the use of AEDs in the home by untrained persons would improve health outcomes. Other barriers were high cost (\$2,165/AED [Cdn]) and a general lack of awareness of this strategy.

## Summary of Medical Advisory Secretariat Review

Table 1 shows the levels of evidence of included studies based on the study design.

**Table 1: Quality of Evidence of Included Studies**

Study Design	Level of Evidence	Number of Eligible Studies
Large RCT, * systematic reviews of RCT	1	1
Large RCT unpublished but reported to an international scientific meeting	1(g)†	0
Small RCT	2	0
Small RCT unpublished but reported to an international scientific meeting	2(g)	0
Non-RCT with contemporaneous controls	3a	0
Non-RCT with historical controls	3b	1
Non-RCT presented at international conference	3(g)	0
Surveillance (database or register)	4a	0
Case series (multisite)	4b	0
Case series (single site)	4c	0
Retrospective review, modeling	4d	0
Case series presented at international conference	4(g)	0

\*RCT refers to randomized controlled trial.

†g indicates grey literature.

The PAD trial (12) was a cluster randomized trial conducted from 2000 to 2003. Its objective was to compare survival to hospital discharge rates in communities where trained volunteers were able to recognize cardiac arrest, telephone 911, and perform CPR, to communities where volunteers could also provide early defibrillation with an on-site AED. In the trial, 21 communities were randomized from the United States and 3 from Canada (from Vancouver, Calgary, and Edmonton). These communities were randomly assigned to CPR only or CPR plus AED. There were 16 (15%) survivors among 107 cardiac arrest patients in the CPR-only program compared with 31 (24%) survivors among 128 patients in the CPR plus AED program ( $P = .03$ ) (level 1 evidence).

The OPALS study had a multiphasic before-after clinical trial design to compare cardiac arrest rates among 3 distinct phases. (2) Its objective was to examine the effect of each link in the chain of survival in improving cardiac arrest outcomes. In this report, the Medical Advisory Secretariat reviewed results of the first 2 phases only – the third phase of OPALS relates to the introduction of advanced cardiac life support, which is not under investigation here. The OPALS study was implemented in 21 communities in Ontario within the response area of 11 EMS base hospital programs. All communities had 911 emergency telephone services.

The first phase (36 months) represented baseline status upon the introduction of the ambulance automatic defibrillation programs. Data collected for this phase included number and location of cardiac arrests, bystander witness rates, bystander-initiated CPR rates, first responder's time to arrival at the site, first responder-initiated CPR rates, time to defibrillation, patients' status (dead or alive) at the time of hospital discharge, and patients' neurological status following discharge. (3) By phase 2, firefighters were equipped and trained in the use of AEDs and EMS system was optimized to rapid defibrillation, defined as arrival at the scene with a defibrillator within 8 minutes of receiving the call in 90% of patients. (4) Data were prospectively collected for 1 year on the same variables, and results were compared to those obtained in phase 1. Out of 4,690 cardiac arrests in phase 1, 183 (3.9%) survived to hospital discharge, compared with 85 (5.2%) out of 1,641 in phase 2 ( $P = .03$ ). (4) The absolute increase in survival was 1.3% (95% confidence interval, 0.1%–2.5%), relative increase in survival was 33% (95% confidence interval, 3%–70%). In phase 1, EMS responded within 8 minutes in 76.7% of the calls, compared with 92.5% ( $P < .001$ ) in phase 2. It was found that age, bystander-witnessed arrest, bystander CPR, fire/police CPR, and EMS response less than or equal to 8 minutes were significant predictors of survival to hospital discharge (level of evidence = 3b). The OPALS study was funded by the Ontario Ministry of Health and Long-Term Care.

These results suggest that simply providing an AED would not likely improve survival outcomes. Rather, AEDs have a role in strengthening the chain of survival. Results of the PAD trial suggest that adding AED to a public access defibrillation program would improve survival in people who go into cardiac arrest. The OPALS study suggests that increasing rates of CPR by bystanders, firefighters, and police, and improving EMS response time would improve the effectiveness of an AED program. For example, the rate of bystander-initiated CPR could be improved. It was only 14% in the OPALS study, but it reached 100% in the PAD trial; PAD trial investigators trained community volunteers whereas OPALS study investigators did not.

## Economic Analysis

### Objective

The objective of this analysis was to ascertain if AEDs are cost-effective.

### Literature Review: Objectives and Methods

Adding the key words economics cost, cost analysis, cost benefit analysis and cost-effectiveness analysis to the previous key words, another search was executed for economic literature in the same databases; this search was re-executed in EconLit, but no additional articles were found. Details are provided in Appendix 2.

The Medical Advisory Secretariat found 79 articles; of these, 12 articles met the inclusion and exclusion criteria. Of the 12 articles, 8 estimated cost-effectiveness in public or community settings, 2 in airlines, and 1 each in home, and high-school athletic programs. All costs are expressed in US dollars.

## Results of Literature Review on Economics

### Public settings

Of the 8 cost-effectiveness studies, 1 (13) evaluated provision of different levels of prehospital care for cardiac arrest in Canada. The study began with a meta-analysis of effectiveness of the various EMS systems, followed by estimation of costs and quality of life for survivors. Finally a decision analysis was done. The most cost-effective system appeared to be the addition of first-responder firefighters to an ambulance system for a cost of \$40,000 per quality adjusted life year (QALY). This formed the basis for the OPALS study (3) in which first-responder firefighters were added to an ambulance system.

Although Stiell and colleagues (4) did not conduct a formal cost-effectiveness analysis, they estimated that the total initial cost for implementing the AED program in OPALS was \$980,000. The breakdown of the total cost was \$850,000 for purchasing equipment for the communities, \$65,000 for training firefighters at the base hospital programs, and \$65,000 for the administrative costs of policy revisions at the Ontario Ministry of Health and Long-Term Care. They estimated that these costs were equivalent to \$39,400 per 100,000 residents and about \$46,900 per life saved. However, the ongoing annual costs for continuing the program were lower. The total cost was equivalent to \$2,000 per 100,000 residents and \$2,400 per life saved.

Nichol and colleagues (14) used a Markov model to compare the cost-effectiveness of standard EMS system with that of EMS plus a PAD program (by lay responders or police) from a societal perspective. The median incremental cost of adding PAD by lay responders was \$44,000 per QALY gained, and of adding PAD by police was \$27,200 per QALY gained. However, from the perspective of municipal governments, who pay only for police services, the median cost per life saved for PAD by police was \$6,500.

In another study by Nichol et al., (15) they estimated the cost-effectiveness of defibrillation by trained targeted nontraditional responders in a variety of public settings including an international airport, county jail, shopping mall, health club, and community centre in the United States. The setting where PAD was most cost-effective was the international airport, where the median incremental cost was \$55,200 per QALY gained. The setting where PAD was least cost-effective was the community center, where the median incremental cost was about \$10.3 million per QALY gained. The authors concluded that rapid defibrillation by targeted nontraditional responders might be good value for money compared with standard EMS in settings where cardiac arrest is frequent and response time is short. The incidence of arrest should be considered when choosing locations to implement PAD.

Cram and colleagues (16) used a Markov model to compare PAD to EMS plus AED. They considered several public settings in the United States. The incremental cost per QALY gained for adopting PAD over EMS plus AED varied by site from \$13,000 (international airport) to \$12 million (retail store). The authors concluded that AED deployment is likely to be cost-effective in some public locations (but not retail stores).

Forrer and colleagues (17) estimated the cost-effectiveness of a police AED program in 4 suburban communities in Michigan, United States. They used a retrospective before-after quasi-experimental design. The estimated cost per life saved as a result of decreasing time to first shock with the police AED program was \$70,342. The authors concluded that a police AED program is a cost-effective intervention in those communities.

Groeneveld and Owens (18) compared the cost-effectiveness of 3 strategies for training unselected laypersons: CPR/defibrillation training alone, training combined with home defibrillator purchase, and no

training. They used a Markov model and adopted an American societal perspective. Cost per QALY gained for CPR/defibrillation was \$202,400 compared with about \$2.5 million for training laypersons in CPR/defibrillation with subsequent purchase of home defibrillator. However, the cost was less than \$75,000 per QALY gained if trainees lived with people aged over 75 years, or with those who have cardiac disease, or if total training costs were less than \$10 per person. The authors concluded that training unselected laypersons in CPR/defibrillation is costly compared with other public health initiatives. Conversely, training laypersons selected by occupation, low training costs, or having high-risk household companions is substantially more cost-effective.

Another study (19) estimated cost-effectiveness and cost utility of locating defibrillators in all major airports, railway stations, and bus stations throughout Scotland. The authors used data from Heartstart register, a database of the Scottish Ambulance Service and its base hospitals. The cost per life year gained was \$49,625 and cost per QALY gained was \$68,924. The authors concluded that PAD programs are not cost-effective and suggested alternative strategies such as the use of other trained first responders (firefighters/police).

### **Aircraft Setting**

Of the 2 studies on airlines, Groeneveld and colleagues (20) compared 6 strategies for the management of cardiac arrest in the US. These included training flight attendants in basic life support, or providing AEDs with BLS training, or providing AEDs without training flight attendants but relying on physician passengers to use AEDs. They varied the level of training and the passenger capacity of aircraft. They built a Markov model using literature-driven estimates of the effectiveness of AEDs, costs obtained from the Federal Aviation Administration and the Air Transport Association of America, long-term survival outcomes from the Heartstart Scotland Project, and quality of life from the published literature. It was estimated that 33 lives might be saved annually by the deployment of AEDs on all aircraft. From a societal perspective, they estimated that the cost of adding AEDs on aircraft with a capacity of more than 200 passengers would be \$35,300 per QALY gained. Incremental cost for adding AEDs to aircrafts with capacity for between 100 and 200 passengers would be \$40,800 per QALY gained, and the further incremental cost of full deployment of AEDs to all aircrafts would be \$94,700 per QALY gained. The authors concluded that placing AEDs on commercial aircrafts is cost-effective but dependent upon the capacity of the air craft; that is, it is more cost-effective in large capacity aircraft than aircraft with less capacity.

In the other study on airlines, Cram and colleagues (21) examined the cost-effectiveness of aircrafts with an AED compared to aircrafts without an AED. They estimated that 35 lives might be saved annually (similar to Groeneveld et al). (20) Their estimate of cost per QALY gained was \$34,000. However, when passive benefits (from the feeling of security while traveling in an AED-equipped air craft) were included, cost per QALY varied from \$17,000 to \$33,000, depending on the number of passengers who experienced passive benefits. The cost per QALY reduced because inclusion of passive benefits inflated the denominator. The authors concluded that AED deployment in aircraft is cost-effective and further research is needed to define the scope of these passive benefits.

### **Home Setting**

In a home setting, a recent study (22) compared the cost-effectiveness of the management of cardiac arrest by EMS equipped with AEDs to homes equipped with AEDs. The authors assumed that survival would double with in-home AED use compared to AED use by EMS, and they estimated from an American societal perspective that cost per QALY gained would be \$216,000 when all adults aged over 60 years are provided with AEDs in their homes. When adults at higher risk for cardiac arrest were considered, the cost per QALY gained was \$132,000 (multiple risk factors), \$104,000 (previous



myocardial infarction), and \$88,000 (ischemic cardiomyopathy with left ventricular ejection fraction < 0.30 and unwilling to get an ICD). The authors concluded that providing AEDs for in-home use to all adults aged over 60 years appeared relatively expensive.

### **High-School Setting**

Berger and colleagues (23) evaluated the cost-effectiveness of Project ADAM, a project to prevent sudden cardiac death in high school students in Milwaukee, Wisconsin, United States. Using a decision model, they estimated that Project ADAM could be cost-effective (cost per life year saved < \$100,000) when 5 to 8 people experience a cardiac arrest over 5 years in high-school settings.

In summary, the cost-effectiveness of AEDs depends upon where they are used. In settings where the rate of cardiac arrest is high and response interval is short, the evidence supports a conclusion that AEDs are cost-effective. In Ontario, the OPALS model is cost-effective.

### **Ontario-Based Economic Analysis**

#### **Notes & Disclaimer**

The Medical Advisory Secretariat uses a standardized costing methodology for all of its economic analyses of technologies. The main cost categories and the associated methodology from the province's perspective are as follows:

**Hospital:** Ontario Case Costing Initiative (OCCI) cost data is used for all program costs when there are 10 or more hospital separations, or one-third or more of hospital separations in the ministry's data warehouse are for the designated International Classification of Diseases-10 diagnosis codes and Canadian Classification of Health Interventions procedure codes. Where appropriate, costs are adjusted for hospital-specific or peer-specific effects. In cases where the technology under review falls outside the hospitals that report to the OCCI, PAC-10 weights converted into monetary units are used. Adjustments may need to be made to ensure the relevant case mix group is reflective of the diagnosis and procedures under consideration. Due to the difficulties of estimating indirect costs in hospitals associated with a particular diagnosis or procedure, the Medical Advisory Secretariat normally defaults to considering direct treatment costs only. Historical costs have been adjusted upward by 3% per annum, representing a 5% inflation rate assumption less a 2% implicit expectation of efficiency gains by hospitals. **Non-Hospital:** These include physician services costs obtained from the Provider Services Branch of the Ontario Ministry of Health and Long-Term Care, device costs from the perspective of local health care institutions, and drug costs from the Ontario Drug Benefit formulary list price. **Discounting:** For all cost-effective analyses, discount rates of 5% and 3% are used as per the Canadian Coordinating Office for Health Technology Assessment and the Washington Panel of Cost-Effectiveness, respectively. **Downstream cost savings:** All cost avoidance and cost savings are based on assumptions of utilization, care patterns, funding, and other factors. These may or may not be realized by the system or individual institutions.

In cases where a deviation from this standard is used, an explanation has been given as to the reasons, the assumptions and the revised approach.

The economic analysis represents an estimate only, based on assumptions and costing methods that have been explicitly stated above. These estimates will change if different assumptions and costing methods are applied for the purpose of developing implementation plans for the technology.

The objective of this analysis was to answer the question from a payer's perspective: If AEDs are cost-effective, how should they be distributed in Ontario? All costs are expressed in Canadian dollars.

#### **Hospital Settings**

The incidence of cardiac arrest in hospital settings and the associated survival rate is not known. The Medical Advisory Secretariat analyzed data from the Canadian Institute of Health Information and calculated that in 2004, 2,193 cardiac arrests occurred in hospitals in Ontario. Of these, 59% were in male patients whose mean (SD) age was 67 (17) years. The mean (SD) age was 69 (18) years in female patients. Of these 2,193 patients, 253 (12%) survived to hospital discharge.

For this review, the Medical Advisory Secretariat assumed the following: deploying AEDs in hospitals would reduce time to defibrillation by 2 minutes on average; the percentage of patients that have correctable rhythm out of the total patients would be 36%; (4) and each minute reduction in time to defibrillation would improve survival in patients who have correctable rhythm by 10%. (1)

On the basis of the above-noted population characteristics and assumed effect of AEDs, the Medical Advisory Secretariat estimated that 24 lives might be saved annually. Using a life table of Ontario, (24) this corresponds to an estimated 330 QALYs gained (utility, 0.8). (25) Thus, over 5 years, 120 additional lives might be saved which would correspond to 1,508 QALYs gained at a 3% annual discount rate and 1,422 QALYs gained at a 5% annual discount rate.

There are 135 hospitals in Ontario. The annual number of arrests is estimated to range from 0 to 119 per hospital. It is assumed that each hospital would require 10 to 100 AEDs (50–100 AEDs in Toronto hospitals). The cost of AEDs including training and maintenance is estimated to be in the range of \$2,000 to \$4,000. Thus, the cost of deploying AEDs in all hospitals in Ontario would be range from \$2.7 million to \$54 million.

Thus, the cost per QALY gained over 5 years would range from \$1,790 to \$37,975.

### **Out-of-Hospital Settings**

The annual cardiac arrest rate is estimated to be 59 per 100,000 in out-of-hospital settings. (6) The total population of Ontario is 12 million. This means every year 7,080 cardiac arrests are expected in Ontario. The mean (SD) age of arrest patients is 69 (13) years. (2) The OPALS model of distributing AEDs (to firefighters and police) is already in place and thus not a subject of further investigation in these analyses. However, it sets the baseline survival rate at 5.2%. (4)

For this analysis, the Medical Advisory Secretariat assumed that the following: on-site availability of AEDs would reduce time to defibrillation by 3 minutes on average in relation to current standards; the proportion of people that have correctable rhythm out of the total number of people would be 36%; (4) and each minute reduction in time to defibrillation would improve survival in patients who have correctable rhythm by 10%. (1)

On the basis of the above-noted population characteristics and assumed effect of AEDs, the Medical Advisory Secretariat simulated cardiac arrests in out-of-hospital setting and estimated that 47 additional lives might be saved annually. Using a life table of Ontario, (24) this corresponds to an estimated 815 QALYs gained (utility, 0.8). (25) Thus, over 5 years, 235 additional lives might be saved, which would correspond to 3,727 QALYs gained at a 3% annual discount rate and 3,516 QALYs gained at a 5% annual discount rate.

The OPALS study (6) reported that from 1995 to 2000, there were 7,707 cardiac arrests in the 21 participant communities in Ontario. Of these, 4324 (56.1%) were in single-unit residential dwellings (houses), 1,747 (22.7%) were in multi-unit residential dwellings (apartments/condominiums) and 457 (5.9%) were in nursing homes, comprising 85% of the total cardiac arrests. Of notable public sites out of the total sites, there were 96 (1.2%) cardiac arrests in office buildings, 77 (1%) in shopping malls, 28 (0.4%) in casinos, 14 (0.2%) in sports fields or parks, 4 (0.05%) in airport, bus or train stations, and 1 (0.01%) in a stadium.

Given that about 78% of all arrests occur in homes (single- or multi-unit residential dwellings) and 90% of patients are aged over 55 years, the Medical Advisory Secretariat considered deploying one AED per home for people aged over 55 years. About 23% of people in Ontario are over 55 years of age. (26)

Assuming each person has a spouse of similar age, we estimate that there would be at least 1.38 million homes where at least 1 person is over the age of 55 years. The cost of deploying AEDs after including the cost of training the spouse/partner would be \$2,300 (\$2165 for the device + \$160 for the training) per home; therefore, the total cost of deploying AEDs in all homes of people aged over 55 years would be \$3 billion.

Thus, cost per life saved would be \$16.3 million. This corresponds to about \$1 million per QALY gained.

The Medical Advisory Secretariat also considered deploying AEDs in multi-unit residential dwellings where the cost may be reduced by deploying 1 AED and training one person (for example, the building superintendent) per building rather than per home. It is estimated that there are 677,800 apartment buildings with 5 or more stories. (27) Thus, the cost of deploying AEDs in these buildings – giving 1 AED and training in its use to the building superintendent – would be \$1.5 billion.

Given that 23% of all arrests occur in multi-unit residential dwellings, 54 additional lives might be saved over 5 years. This would correspond to 808 to 857 QALYs gained. The cost per QALY gained would be in the range of \$1.8 million to \$1.9 million.

Nursing homes have the highest rates of cardiac arrest after single and multi-unit residential dwellings. However, most of the residents in nursing homes have advanced directives for “do not resuscitate.” (28) Thus, deployment of AEDs might not be an option in all nursing homes.

Only 1.2% of the total cardiac arrests occur in office buildings. Thus, deployment of AEDs in all the office buildings would save an estimated 3 additional lives in 5 years. This corresponds to 42 and 45 QALYs gained for 5% and 3% discount rates, respectively.

An estimate of the total number of office buildings in Ontario is not available at the current time. However, 3,000 government facilities are being considered for an AED program (Personal communication, Ministry of Government Services, Ontario Government, December 2, 2005). The number of AEDs required per facility varies, but is assumed to be in the range of 1 to 9. For these facilities, the mean cost per AED is estimated to be \$2,700. The cost of training is estimated to be \$67 per person. Thus, the total cost is estimated to range from \$8.3 million to \$74.7 million to deploy AEDs in all Ontario government buildings.

If at least a single life is saved in these government facilities out of the 3 expected lives saved in 5 years in all office buildings, then cost per QALY gained would range from \$184,467 to \$1.7 million.

Lastly, the Medical Advisory Secretariat considered the strategy of deploying AEDs in homes of patients at high risk. In an RCT by Bardy et al., (29) which compared mortality rates in patients at high-risk of sudden cardiac arrest (New York Heart Association class II or II chronic, stable chronic heart failure, and left ventricular ejection fraction  $\leq 0.35$ ) assigned to conventional therapy plus ICD, to mortality rates in similar patients assigned to conventional therapy plus amiodarone (a drug), or conventional therapy plus placebo. There were 829 patients in the ICD group. The median age in this group was 60.1 years and it was comprised primarily of males (77%). During follow-up (median, 3.8 years) there were 259 (31%) cardiac arrests. Of these 259 arrests, 177 (68%) were due to ventricular tachycardia or ventricular fibrillation. We have estimated that there are 23,000 patients in Ontario who are at high risk of sudden cardiac arrest based on the above-noted criteria. Ontario has the capacity to implant 1,600 ICDs annually. This means that over 5 years, 8,000 patients would receive ICDs, leaving 15,000 patients without the devices.

The Medical Advisory Secretariat assumed that placing AEDs in the homes of these 15,000 patients

would reduce time to defibrillation by 3 minutes on average given a cardiac arrest; the percentage of patients that have correctable rhythm out of the total patients would be 68%; (29) and each minute reduction in time to defibrillation would improve survival in patients who have correctable rhythm by 10%. (1)

On the basis of the above-noted population characteristics and assumed effect of AEDs, we simulated cardiac arrests in these patients and estimated that 15 additional lives might be saved annually. Using a life table of Ontario, this corresponds to 244 QALYs gained (utility, 0.8). Thus, over 5 years, 75 additional lives could be saved. This would correspond to 1,156 QALYs gained at a 3% annual discount rate and 1,052 QALYs gained at a 5% annual discount rate.

The total cost of placing AEDs and training one person per home would be \$34.5 million. Thus, the cost per QALY gained over 5 years would range from \$29,844 to \$32,794.

Note, these analyses are done from a payer's perspective. The payer could be the government, patients or a third party (insurance companies).

## **Existing Guidelines for Use of Technology**

### **The American Heart Association Guidelines (2005)**

Recently, the American Heart Association (30) has published new guidelines to integrate CPR and AED use in this sequence: activation of an EMS system or emergency medical response system, provision of CPR, and operation of an AED.

When 2 or more rescuers are present, activation of EMS and CPR can occur simultaneously.

When any rescuer witnesses an out-of-hospital arrest and an AED is immediately available on-site, the rescuer should use the AED as soon as possible.

Health care providers who treat cardiac arrest in hospitals and other facilities with AEDs on-site should provide immediate CPR and should use the AED or manual defibrillator as soon as possible.

When an out-of-hospital cardiac arrest is not witnessed by EMS personnel, upon arriving at the scene they may give about 5 cycles of CPR before checking the ECG rhythm and attempting defibrillation. One cycle of CPR consists of 30 compressions and 2 breaths; therefore, 5 cycles should take about 2 minutes.

When ventricular fibrillation or pulseless ventricular tachycardia is present, the rescuer should deliver one shock and should then immediately resume CPR, beginning with chest compressions. The rescuer should not delay resumption of chest compressions to recheck the rhythm or pulse. After 5 cycles of CPR, the AED should then analyze the cardiac rhythm and deliver another shock if indicated. If nonshockable rhythm is detected, the AED should instruct the rescuer to resume CPR immediately.

AEDs' voice prompts should not instruct the lay user to reassess the patient at any time.

Training materials for lay rescuers should emphasize the importance of continued CPR until basic or advanced life support personnel take over CPR or the patient begins to move.

Rescuers should place AED electrode pads on the patient's bare chest in the conventional sternal-apical position: The right chest pad is placed on the patient's right superior-anterior chest, and the apical pad is placed on the patient's inferior-lateral left chest, lateral to the left breast.

When an implantable medical device is located in an area where a pad would normally be placed, position the pad at least one inch away from the device.

If the patient has an ICD that is delivering shocks (i.e., the patient's muscles contract in a manner similar to that observed during external defibrillation), allow 30 to 60 seconds for the ICD to complete the treatment cycle before attaching an AED.

Do not place AED electrode pad directly on top of a transdermal medication patch. Remove the patch and wipe the area before attaching the electrode pad.

If the patient is lying in water or covered with water or extremely diaphoretic [sweaty] remove the patient from water and briskly wipe the chest before attaching electrode pads.

AEDs can be used when the patient is lying on snow or ice.

If the patient has a very hairy chest, it may be necessary to remove or shave some of the hair to attach electrode pads.

AEDs may be used in children in whom ventricular fibrillation is observed in 5% to 15% of the total arrests. For children aged 1 to 8 years, the rescuer should use a pediatric dose-attenuator system if available; otherwise, the rescuer may use the standard AED.

There is no recommendation for or against the use of AEDs in infants aged under 1 year. This is because there are insufficient data in the literature to make a recommendation.

### **Lay Rescuer Automated External Defibrillator Programs**

Programs that fail to reduce time to defibrillation will not be effective in improving survival outcomes in people who have a cardiac arrest. (30) The elements recommended for the lay rescuer program are a planned and practiced response – typically this requires oversight by a health care provider, training of

anticipated rescuers in CPR and use of the AED, link with the local EMS system, and a process of ongoing quality improvement.

AED programs are recommended in public locations where there is a relatively high likelihood of witnessed cardiac arrest (e.g., airports, casinos and sports facilities).

There is no recommendation for or against personal or home deployment of AEDs. This is because the reviewers found no studies that documented the effectiveness of home AED deployment, although 80% of out-of-hospital cardiac arrests occur in private or residential settings.

The AED rescuer should be trained not only to recognize emergencies and use the AED but also to support ventilation and circulation with CPR as needed. This is because AEDs are of no value for arrest not caused by ventricular fibrillation or ventricular tachycardia, and they are ineffective for the treatment of nonshockable rhythms that could develop after termination of ventricular fibrillation.

Quality improvement efforts should focus on routine inspections and postevent data collection to evaluate the following:

- Performance of the emergency response plan, including accurate time intervals for key interventions (such as collapse to shock or no shock advisory to initiation of CPR), and patient outcome
- Responder performance
- AED function, including accuracy of the ECG rhythm analysis
- Battery status and function
- Electrode pad function and readiness, including expiration date

### **Automated External Defibrillator Use in Hospitals**

AEDs should be considered for the hospital setting as a way to facilitate early defibrillation (a goal of < 3 minutes from collapse), especially in areas where staff members have no rhythm recognition skills or defibrillators are used infrequently.

An effective system for training and retraining should be in place.

### **Conclusions**

The OPALS model where AEDs are provided to EMS, firefighters, and police appears cost-effective, and effectiveness can be further enhanced by training community volunteers to improve the bystander-initiated CPR rates. Deployment of AEDs in all public access areas and in houses and apartments is not cost-effective. Further research is needed to examine the benefit of in-home use of AEDs in patients at high risk of cardiac arrest.

# Appendices

## Appendix 1: Literature Review Search Strategy

### Search Strategy AEDs Revised

Search date: September 1, 2005

Databases searched: OVID MEDLINE, MEDLINE In-Process and Other Non-Indexed Citations, EMBASE, Cochrane DSR and Cochrane CENTRAL

Database: Ovid MEDLINE <1966 to August Week 4 2005>

Search Strategy:

- 
- 1 \*Defibrillators/ (74)
  - 2 (automat\$ adj2 external adj2 defibrillat\$).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (507)
  - 3 exp electric countershock/ (8641)
  - 4 ((prehospital or pre-hospital or early or rapid or otc or over the counter or out of hospital or public access or semiautomatic) adj2 defibrillat\$).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (504)
  - 5 exp Emergency medical services/ or exp advanced cardiac life support/ (52145)
  - 6 or/1-5 (60233)
  - 7 exp Program Evaluation/ or program\$.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (337459)
  - 8 6 and 7 (4473)
  - 9 exp Heart Arrest/ (18469)
  - 10 8 and 9 (194)
  - 11 exp Treatment Outcome/ or exp survival analysis/ or exp Survival Rate/ or exp Hospital Discharge/ or exp Mortality/ (409440)
  - 12 10 and 11 (67)
  - 13 (Ontario Prehospital Advanced Life Support or OPALS or public access defibrillation trial or pad trial).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (26)
  - 14 12 or 13 (89)
  - 15 limit 14 to (humans and english language) (83)
  - 16 (systematic review\$ or systematic overview\$).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (7402)
  - 17 15 and 16 (0)
  - 18 15 (83)
  - 19 limit 18 to ("review" or "review literature" or review, multicase or "review of reported cases") (12)
  - 20 18 not 19 (71)

Database: EMBASE <1980 to 2005 Week 35>

Search Strategy:

- 
- 1 (automat\$ adj2 external adj2 defibrillat\$).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (455)
  - 2 exp resuscitation/ (17370)
  - 3 exp Emergency Health Service/ (8778)
  - 4 ((prehospital or pre-hospital or early or rapid or otc or over the counter or out of hospital or public access or semiautomatic) adj2 defibrillat\$).mp. [mp=title, abstract, subject headings, heading word, drug

trade name, original title, device manufacturer, drug manufacturer name] (458)

- 5 exp Cardioversion/ (4916)
- 6 or/1-5 (30320)
- 7 program\$.mp. (255277)
- 8 exp HEALTH PROGRAM/ or exp EDUCATION PROGRAM/ or exp VOLUNTARY PROGRAM/ (47980)
- 9 6 and (7 or 8) (1778)
- 10 exp Heart Arrest/ (11118)
- 11 9 and 10 (246)
- 12 exp SURVIVAL RATE/ or exp SURVIVAL TIME/ (49646)
- 13 exp Treatment Outcome/ (283778)
- 14 exp HOSPITAL DISCHARGE/ (13702)
- 15 exp MORTALITY/ (157940)
- 16 11 and (12 or 13 or 14 or 15) (103)
- 17 (Ontario Prehospital Advanced Life Support or OPALS or public access defibrillation trial or pad trial).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (39)
- 18 16 or 17 (138)
- 19 limit 18 to (human and english language) (109)
- 20 (systematic review\$ or systematic overview\$).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (11036)
- 21 19 and 20 (2)
- 22 19 (109)
- 23 limit 22 to "review" (17)
- 24 Case Report/ (850851)
- 25 22 not (23 or 24) (91)
- 26 from 25 keep 1-91 (91)



## Appendix 2: Literature Review and Search Strategy: 2

### AEDs and Emergency Cardiac Services – Costs/Economics

Database: Ovid MEDLINE <1966 to August Week 5 2005>

Search Strategy:

- 
- 1 \*Defibrillators/ (76)
  - 2 (automat\$ adj2 external adj2 defibrillat\$).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (508)
  - 3 exp electric countershock/ (8652)
  - 4 ((prehospital or pre-hospital or early or rapid or otc or over the counter or out of hospital or public access or semiautomatic) adj2 defibrillat\$).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (506)
  - 5 exp Emergency medical services/ or exp advanced cardiac life support/ (52218)
  - 6 or/1-5 (60317)
  - 7 exp Heart Arrest/ (18509)
  - 8 exp economics/ or exp "costs and cost analysis"/ (338728)
  - 9 6 and 7 and 8 (104)
  - 10 limit 9 to (humans and english language) (95)
  - 11 (systematic review\$ or systematic overview\$).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (7434)
  - 12 10 and 11 (0)
  - 13 10 (95)
  - 14 limit 13 to (case reports or "review" or "review literature" or review, multicase or "review of reported cases") (14)
  - 15 13 not 14 (81)

**Database: EMBASE <1980 to 2005 Week 36>**

**Search Strategy:**

- 
- 1 (automat\$ adj2 external adj2 defibrillat\$).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (457)
  - 2 exp resuscitation/ (17407)
  - 3 exp Emergency Health Service/ (8809)
  - 4 ((prehospital or pre-hospital or early or rapid or otc or over the counter or out of hospital or public access or semiautomatic) adj2 defibrillat\$).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (461)
  - 5 exp Cardioversion/ (4928)
  - 6 or/1-5 (30399)
  - 7 exp Heart Arrest/ (11150)
  - 8 exp health economics/ (160920)
  - 9 exp "cost benefit analysis"/ or exp "cost effectiveness analysis"/ (57849)
  - 10 6 and 7 and (8 or 9) (131)
  - 11 limit 10 to (human and english language) (116)
  - 12 (systematic review\$ or systematic overview\$).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (11151)
  - 13 11 and 12 (1)
  - 14 11 (116)
  - 15 limit 14 to "review" (36)
  - 16 Case Report/ (851870)
  - 17 14 not (15 or 16) (78)
  - 18 13 or 17 (79)

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