Automated External Defibrillators (AEDs) and Pediatric Patients:
Background, Costs, and Implications for Healthcare Policy

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Introduction

There have been two recent events involving automated external defibrillators (AEDs) that have brought these medical devices to the attention of the public. The first of these events involved a technical advance in AED manufacturing that led to the approval of AEDs for use in children. In early May 2001, the United States Food and Drug Administration (FDA) cleared the marketing of specially modified AEDs for use on infants and children younger than 8 years of age.¹ The second of these events involved the initiation of public access defibrillation programs involving schools. In May 2001, shortly after the FDA granted marketing clearance, legislation was passed in Pennsylvania (Act 4 of 2001, Section 1423) that provided funding for two Medtronic PhysioControl LifePak 500 AEDs to every public school district in the state. One year later, in May 2002, Governor George Pataki signed legislation requiring schools in the state of New York to have AEDs available for use no later than December 2002. The passage of this legislation in New York has been followed by the introduction of proposed state legislation regarding AED placement in schools in several other state legislatures including: California, Delaware, Georgia, Illinois, Maine Massachusetts, New Jersey, Rhode Island, and Virginia.² This widespread interest in mandatory public access defibrillation (PAD) programs in schools developed so soon after FDA clearance, it seems unlikely that interest in these school-based programs is based on published outcome data.

We have two main objectives in developing this information paper. First, we wanted to develop a better understanding of the technical advances that led up to FDA clearance of AEDs for treating children. Second, we wanted to assess the available evidence regarding the potential benefits, the overall costs, and the relative cost-utility of school-based PAD programs compared to other health initiatives. We hoped to develop the background information needed to make an informed decision regarding school-based PAD programs.
Part I – Background and Technical Advances

1. What is an AED?

*An AED is an electronic device used to treat people experiencing sudden cardiac arrest*

An AED is an electronic device about the size of a large telephone book that is used to treat someone who has collapsed, is unconscious, has no pulse, and is not breathing (cardiac arrest). When an AED is used, two pads stored along with the AED are placed on the chest, capturing the electrical activity of the unconscious person’s heart (heart rhythm). A computer chip within the AED analyzes this heart rhythm and advises the rescuer on whether or not to push a button and deliver an electrical shock to the unconscious person (defibrillate them). Minimal training is required to effectively operate an AED.\(^3\) Because only limited training is needed, AEDs can be placed in public locations where members of the public who have medical training (physicians, nurses, paramedics, etc.) or who have attended a short training course in AED use can pull these devices out of their storage areas (often in a well marked wall mounted cabinet) and use them to try to help someone who has suffered cardiac arrest.\(^4\)

2. What have been the concerns about using “adult” AEDs to treat children?

*Inappropriate pediatric rhythm analysis and excessive voltage*

Concerns about using the exact same AEDs to treat both adults and children have primarily centered on rhythm detection and voltage. Because the hearts of children typically beat faster than adults, there was concern that the computer within an AED may not be able to appropriately differentiate fast adult heart rhythms requiring an electrical shock (defibrillation) from fast, but otherwise unremarkable pediatric heart rhythms that should not prompt the delivery of a shock. There was concern that children who did not need defibrillation would be harmed by inappropriate shocks while other children who might benefit from defibrillation would not receive a potentially life-saving shock. Defibrillators that are not automated allow the health care provider to pick the level of energy delivered to the patient. Children, given their smaller size and thinner chest walls are usually given a lower level of energy (measured in Joules) than adults. This energy selection is done to provide sufficient energy to defibrillate the heart without delivering so much electricity that the heart muscle is damaged by the defibrillation.
3. Can AEDs reliably identify which pediatric rhythms to shock?

Yes, the available evidence suggests that AEDs can reliably identify these rhythms.

The main concern about the computer within AEDs interpreting arrhythmias in children involves the differentiation of perfusing, rapid tachycardias (which do not get shocked) and ventricular fibrillation (which does get shocked). Relatively common, unassuming heart rates for children overlap with heart rates that are often seen with shockable rhythms for adults. It is conceivable that AEDs could harm children if the devices interpreted rapid sinus tachycardia as ventricular fibrillation and inappropriately instructed users to push the button to defibrillate these children. Acceptable rhythm analysis is necessary if AEDs are to be safely used to treat children.

Three studies have assessed the use of adult oriented rhythm analysis for the decision to shock children. Atkins and colleagues found a sensitivity of 88% and a specificity of 100% for the analysis of 67 arrhythmias recorded for 18 children 5 – 15 years old, who underwent out-of-hospital cardiac resuscitation. However, this was a retrospective study, most children were more than 8 years old (mean 12.1 ± 3.7 years) and the AEDs used were older versions of the AEDs used today. Cecchin and colleagues analyzed 696 five-second rhythm strips from children younger than 12 years of age and found 100% specificity and 96% sensitivity for non-shockable rhythms. The criterion standard for this study was physician rhythm analysis. Only 19 of the children in this study were under one year of age. In this study, the sensitivity for identifying ventricular tachycardia was somewhat lower at 71%. Atkinson and colleagues recorded 1561 rhythm strips from 203 children up to 7 years of age (median age 11 months) and analyzed them with a LIFEPAK 500 AED (Medtronic Physio-Control Corporation). For the 73 rhythm strips from the 25 children who exhibited coarse ventricular fibrillation, the AED correctly advised shocking the patient in all but one case (sensitivity 99%, 95% CI [93% to 100%]). The AED correctly advised a shock for the three cases of shockable ventricular tachycardia. For the 1472 nonshockable rhythms, the AED recommended "no shock" for 1465 of these rhythms (sensitivity 99.5%, 95% CI [99.0% to 99.8%]). These authors also performed subgroup analyses for the neonates up to 28 days of age, infants from 29 days to one year of age, and children 1 through 7 years of age. The AED performed well in all age groups. There were, however, only 3 neonatal shockable rhythms in this study population.

Available evidence suggests that AEDs can reliably identify shockable rhythms in children and adequately differentiate these rhythms from nonshockable rhythms.
4. Can AEDs deliver safe and effective voltages to children?

Yes, when pediatric specific pads are used for children 1 to 8 years of age.

Most AEDs used for adults are programmed to deliver shocks with energies ranging from 150 to 360 Joules (J). This level of energy might cause myocardial (heart muscle) damage when delivered to a child. The most frequently cited threshold energy level considered injurious to the myocardium is 10 J/kg. This threshold is primarily supported by small animal studies. Since children older than 8 years-of-age tend to be heavier than 15 to 36 kg, it has been assumed that adult AEDs can be safely used in most children 8 years of age and older. New pediatric cables and pads have been designed and are now available for pediatric specific AEDs. These new AEDs divert some of the delivered current away from the patient so that the energy level administered is between 50-75 J. For a 10kg one-year-old, this would result in the delivery of between 5 and 7.5 J/kg, less than the presumed injury threshold of 10 J/kg.
Part II – Public Access Defibrillation Programs for Children

1. What is public access defibrillation?

A strategic plan for placing AEDs in communities to shorten the time to defibrillation

Public access defibrillation is the term given to programs that place AEDs in strategic locations within communities, make AEDs available for members of the public and non-medical personnel (e.g., security officers) to operate, and have a main goal of bringing prompt defibrillation to the people who experience cardiac arrest in public places.10-12

2. Why is it important to deliver a shock soon after cardiac arrest?

Once cardiac arrest has occurred, each minute defibrillation is delayed decreases the likelihood of meaningful survival

The most common rhythm encountered when adults suffer sudden cardiac arrest is ventricular fibrillation. Because adults suffer sudden cardiac arrest more commonly than children do, more is known about sudden cardiac arrest in adults. It is clear that the sooner an electrical shock can be delivered, the higher the likelihood of the return of spontaneous circulation and a good clinical outcome.13 Rapid defibrillation of ventricular fibrillation after witnessed cardiac arrest results in survival rates greater than 67%.14 However, the survival rate steadily declines as time passes. The chances of long-term survival for patients defibrillated more than 10 minutes after the onset of ventricular fibrillation are very low.15 For the past few decades, rapid defibrillation has been a central goal of emergency medical services. Arrival of trained personnel (typically paramedics) with a defibrillator has been the standard care. Obviously, the dispatch of trained personnel to the site of a cardiac arrest can take several minutes. In an effort to decrease the time from the onset of ventricular fibrillation to defibrillation, automated external defibrillators (AEDs) have been developed that can be used by a wider range of individuals including police, firefighters, basic emergency medical technicians (EMTs)16,17 and minimally trained members of the public.3,4
3. How common is pediatric sudden death in school-aged children?

Accurate data is not available, but one reasonable estimate is about 1 to 2 sudden deaths per million students per year.

Since there is not a federally mandated system of reporting pediatric sudden death, the true incidence is unknown. One source of data is the National Center for Catastrophic Sports Injury Research (NCCSIR). In 1995, Van Camp and colleagues reported on nontraumatic deaths in organized high school and college athletics in the United States as compiled in the NCCSIR. Over a 10-yr period from July 1983-June 1993, nontraumatic sports deaths were reported in 126 high school athletes (115 males and 11 females). Cardiovascular conditions such as hypertrophic cardiomyopathy and congenital coronary artery anomalies were more common causes of death than noncardiovascular conditions. In 2000, the NCCSIR identified 15 deaths of high school athletes in the United States. Twelve of these deaths were due to nontraumatic cardiac arrest, two deaths were attributable to direct trauma to the chest resulting in cardiac arrest (i.e., commotion cordis) and one death resulted from a head injury. Although sudden cardiac arrest has been reported in non-athletic adolescents during sedentary activities, the risk of sudden cardiac arrest appears to be lower in high school students who do not play competitive sports than in athletes. From these studies, it appears that an approximate number of high school aged athletes who die each year from conditions that might benefit from the use of an AED is 12 to 14.

It has been suggested that in 1999 there were about 13,400,000 high school-aged children in the United States. If the number of cardiac arrests in high school students is approximately 13 per year in athletes and perhaps a few more in non-athletes, the odds that any particular high school student would experience cardiac arrest is 1 to 2 per million students per year.

The incidence of sudden cardiac arrest among elementary students is probably very low. For example, in 2004, Young and colleagues reported on a prospectively derived, population-based study of pediatric cardiac arrest. In this study, the authors report on 601 pediatric cardiac arrests. Of these, most (54%) were younger than one year of age. There were 92 (15%) between 5 and 12 years of age. In a similarly designed study, Sirbaugh and colleagues reported on 300 pediatric cardiac arrests. Of these, 213 were considered to be due to nontraumatic causes and of these, 171 (80%) occurred in children younger than 3 years of age. Because most pediatric cardiac arrests occur in infants and preschool-aged children, “pediatric cardiac arrest” data that does not separate out these younger children should not be used in epidemiological analyses when the only group of interest is the school-aged population.
4. Where do pediatric sudden deaths occur?

Most pediatric sudden deaths occur in private residences. Death at school is rare.

De Maio and colleagues reported on the pediatric (age < 16 years) cardiac arrests from the Ontario Prehospital Advanced Life Support (OPALS) study covering years 1994 to 2001. In this study there were 268 pediatric cardiac arrests identified. Almost 90% of these occurred in private residences (236 of 268 (88%)). Other cases included 8 cases on streets/roads/highways (3%), 5 cases around water/boat/marinas (2%), 5 cases in stores or malls (2%), 4 cases in hotels or office buildings (1.5%), 3 cases in schools (1%), 2 cases in stadiums/fairgrounds, 2 cases on farms, and one case each for a daycare, a recreation/community facility, and a sports field or park. Young and colleagues reported that of 543 pediatric cardiac arrests, 363 occurred in homes and residences (67%), 73 occurred around water (13%), 50 involved roads and streets (9%), 21 involved vehicles (4%), 15 occurred at school or daycare (3%), 11 occurred at public areas or recreation sites (2%), 10 occurred at work (2%). In 2004, De Maio and colleagues reported on the epidemiology of cardiac arrest in schools based on data from the 21 communities included in the Ontario Prehospital Advanced Life Support (OPALS) study. From 1995 to 1999, of the 8,731 cardiac arrests in these 21 communities, 23 cardiac arrests occurred in elementary or secondary schools. Of these 23 cardiac arrests, two occurred in children. An 11-year-old and a 15-year-old experienced cardiac arrest during exercise.

Most pediatric sudden deaths occur in private residences. Schools are the location of pediatric cardiac arrest in approximately 1–3% of cases.

5. If a school purchased an AED, how often would the AED be used to treat a child in cardiac arrest?

Less frequently than once every 4,000 years.

There were 1,641 elementary and secondary schools included in the Ontario Prehospital Advanced Life Support (OPALS) study. In an 8 year period, there were 3 cardiac arrests identified in children < 16 years of age. This indicates that in 1,641 schools there were 3/8 or 0.375 pediatric cardiac arrests per year. Each of the schools should then expect that a pediatric cardiac arrest would occur at their facility every 4,376 years (1,641/0.375) on average if the frequency of pediatric cardiac arrests and number of schools remains constant.
6. If a school purchased an AED, how often would the AED be used to treat either an adult or a child?

*Approximately once every 350 years.*

From the available data, it appears that 94% of cardiac arrests in schools occur in adults. In the OPALS study, during a 5-year period there were 23 cardiac arrests in 1,641 elementary and secondary schools. This represents 4.6 cardiac arrests per year (23/5). For the 1,641 elementary and secondary schools, each school should expect to use their AED once every 357 years (1,641/4.6). There were two school aged children in this group.
Part III – Costs and Healthcare Policy implications

1. What are the direct and indirect costs of putting AEDs in schools?

*Initial costs are approximately $7500 with ongoing costs of $3000 per year.*

The direct costs of an AED are relatively straightforward. The first AED approved by the FDA for use in children less than 8 years of age (or < 25 kilograms) was the HeartStart defibrillator, currently marketed by Philips Medical Systems, Andover, Massachusetts.\(^1\)\(^,\)\(^2\) The cost of the HeartStart OnSite Defibrillator model M5066A, as of November 19, 2003, is $2,295.00. (Cost quote obtained by calling the company at 1-800-772-7900) Additional equipment needed to use this HeartStart includes a child/infant SMART pads cartridge for $84 and battery for $125. Additional accessories such as a wall-mounted cabinet would add to the direct costs. Specific pads for children are required with the HeartStart defibrillators. These pads will not work with other AEDs. The base direct cost associated with purchasing a pediatric approved AED is approximately $2500 - $3000 depending on the accessories purchased and the frequency with which the pads are replaced.

The indirect costs of purchasing an AED are unknown. Potential costs include initial and ongoing staff training, lost worker productivity due to training obligations, equipment maintenance and replacement, and the physical installation of the equipment. Hazinski and colleagues estimated that first year costs totaled $7000 to $8000 depending on whether substitute teachers would be required to cover teachers who are out of the classroom during life support training.\(^2\)\(^3\) Ongoing yearly costs were estimated to be between $2500 and $3100 depending on the need for substitute teachers.

One estimate of the number of high schools in the United States is 35,000.\(^2\)\(^3\) This number does not include elementary or middle schools. If a nationwide program were established to require AEDs to be purchased for every high school in the United States, the estimated start up cost for the first year is $262,500,000 (35,000 x $7500) with an ongoing annual cost of $105,000,000 (35,000 x $3000). If we estimate that there are 4 elementary schools and 2 middle schools for every high school, this yields an estimate of 245,000 schools in the United States. If all schools in the United States were required to purchase one AED each, the estimated start up cost for the first year is $1,837,500,000 (245,000 x $7500). The ongoing yearly cost is estimated at $735,000,000 (245,000 x $3000).

The data from the OPALS study reported by De Maio and colleagues can also be used to estimate cost.\(^2\)\(^7\) In this study, 1641 schools were included. If AEDs were required in each of these schools, the start up costs would be $12,307,500 (1641 x $7500). Estimated yearly costs would be $4,923,000 (1641 x $3000). Over the eight years covered by this study, total costs would be estimated to be $17,230,500. During this time period, 3 children experienced cardiac arrest at school. If 67% survival\(^1\)\(^4\) were achieved using AEDs, the cost could be expressed as $8,615,250 per life saved.

These estimates would need to be adjusted by changes over time. If schools purchased more than one AED per site, the direct costs for the AED and related equipment would multiply by the number of AEDs purchased, but the indirect costs (e.g., training for teachers) would remain relatively fixed. If the cost of the AED equipment
decreased over time - in a fashion similar to other common electronic devices (e.g., computers) - the estimated cost would be adjusted down. If litigation arises due to the presence of AEDs in schools (i.e., the trained teachers are not present on the day of the cardiac arrest, the equipment fails to function properly when needed, etc.) the cost could rise substantially.

2. Compared to other locations, what is the relative cost-utility of requiring AED’s in schools?

Widespread implementation of pediatric PAD programs in low volume, low risk areas such as schools may be associated with an unusually high cost that is 100 times higher than most traditionally accepted public health interventions.

In addition to the actual costs associated with AED acquisition, it is important to develop an understanding of the overall costs and benefits associated with this new program development from a societal standpoint. Cost-utility analysis is a specific type of cost-effectiveness analysis in which the results are expressed in terms of cost per quality-adjusted life year ($/QALY), and is the preferred method recommended by the U.S. Public Health Service to analyze and compare the costs and consequences associated with healthcare interventions, particularly when making decisions regarding the allocation of healthcare resources. As a means of comparison, these results then allow for the development of a “league table” to compare AED costs to those of other interventions. League tables serve as an important guide in making informed policy decisions. Interventions with an estimated cost/QALY less than $50,000 are generally recommended as being worthy of societal investment, while those with proportionally higher ratios are generally less favorably viewed.

Development of an accurate estimate of the cost-utility of pediatric PAD programs is difficult due to the paucity of reliable population-based information on the incidence of VF cardiopulmonary arrest in children, prevalence and risk estimates for those children most at risk, and relative percentages of the school-based subpopulation. In addition, there are no true estimates regarding the effectiveness of pediatric PAD programs. Extrapolating from the best evidence currently available, we calculate the annual incidence of VF arrest in children ages 5-16 years occurring at school to be 0.4-0.6/100,000. This results in a baseline incidence that is 100 times lower than that observed in the general adult population (40-60/100,000).

As with many public health interventions, PAD programs are deemed a good value when the incidence of the disease is high in the targeted population. For that reason, placement of AED’s in high volume, high risk areas such as airports, casinos, and large sporting events have favorable cost-utility ratios ($20-60,000/QALY). Placement in low volume, low risk areas such as schools or athletic fields that are 100 times less likely to have a cardiac arrest occur are expected to have a proportionally higher cost-utility (millions of dollars/QALY). An overall comparison can be performed. (Table 1) In an era of limited healthcare resources, decisions to legislate or mandate pediatric PAD programs with exponentially high cost-utility ratios should be reconsidered.
<table>
<thead>
<tr>
<th>Location</th>
<th>Average Annual Site Incidence (%) (if applicable)</th>
<th>Defibrillators required to maximize effectiveness</th>
<th>Cost-utility ($/QALY)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Folic acid suppl in cereals to prevent birth defects</td>
<td></td>
<td></td>
<td>Cost-saving*</td>
</tr>
<tr>
<td>Immunizations</td>
<td></td>
<td></td>
<td>Cost-saving* - $13,000/QALY</td>
</tr>
<tr>
<td>Health screening, public education, counseling</td>
<td></td>
<td></td>
<td>$3,000-74,000/QALY</td>
</tr>
<tr>
<td>PAD Program International airport</td>
<td>7</td>
<td>15</td>
<td>$55,000/QALY</td>
</tr>
<tr>
<td>PAD Program Large shopping mall or sports venue</td>
<td>0.4-0.6</td>
<td>20-30</td>
<td>$400,000-500,000/QALY</td>
</tr>
<tr>
<td>PAD Program Golf course, health club, gym</td>
<td>0.08-0.1</td>
<td>40-50</td>
<td>$4-5 million/QALY</td>
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<tr>
<td>PAD Program Community center</td>
<td>0.03</td>
<td>35</td>
<td>$10 million/QALY</td>
</tr>
<tr>
<td>PAD Program General adult population in targeted locations (as above)</td>
<td>40-60 per 100,000/yr</td>
<td>Vary with site location</td>
<td>$20,000-60,000/QALY</td>
</tr>
<tr>
<td>Pediatric PAD Program Estimate†</td>
<td>0.4-0.6 per 100,000/yr</td>
<td>Vary with site location</td>
<td>$2-6 million/QALY</td>
</tr>
</tbody>
</table>

*Cost-saving indicates that the future benefits of performing the intervention are greater than the cost of the intervention itself.
†Pediatric PAD estimate is based on population-based pediatric arrest data as described in text.\textsuperscript{25,26,28,32}
Conclusions

There is reasonably good evidence that AEDs, when properly equipped for pediatric patients, are safe and accurate for the treatment of children between 1 and 8 years of age who are experiencing cardiac arrest. However, according to our analysis of the best available evidence, for all practical purposes, any individual group of teachers at a particular school will never save the life of a child using the AED they purchase today. We currently do not have adequate outcome data on pediatric public access defibrillation (PAD) programs to recommend widespread development of new pediatric PAD programs. It is very unlikely that mandating AEDs in schools would be an effective public health measure. From a public health perspective, it is likely that funds used to place AEDs in schools could have a much greater impact on the lives of children if directed toward other health or educational initiatives.
References


