The North Carolina Automated External Defibrillator Location Project: Recommendations for Use of Automated External Defibrillators in the Resuscitation of Victims of Out-of-Hospital Sudden Cardiac Death

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ABSTRACT

Purpose: The study was undertaken to determine the current level of Automated External Defibrillator (AED) preparedness in North Carolina and to evaluate potential alternatives for future actions in the area of AED deployment and Public Access Defibrillation (PAD).

Methods: A literature review was conducted to evaluate the efficacy and cost-effectiveness of treatment options for out-of-hospital sudden cardiac death (SCD). Primary data were obtained via phone and electronic mail surveys of state and county EMS officials, commercial AED vendors, and American Heart Association Training Centers.

Results: Review of the literature indicates successful defibrillatory treatment of SCD must be accomplished within 10 minutes of collapse. With few exceptions, most communities cannot achieve such a prompt response with traditional EMS service. Communities with AED-equipped first responders accomplish such a prompt response with greater frequency than those without such responders. PAD allows for prompt defibrillation and a markedly increased probability of survival for SCD victims in public places; only 3% of all SCDs occur in such public places.

In North Carolina, in addition to 282 EMS agencies and Fire Departments, 600 locations were found to have at least 1 AED, many of which have the possibility of PAD. None of the 9-1-1 centers in the state had the locations of AEDs entered into Computer Automated Dispatch (CAD), 33% percent of counties did not have an AED or other defibrillator on all first-responding fire or

EMS vehicles, and 45% of counties are unable to provide instructions for use of an AED over the phone.

Conclusions: All first-responding EMS units and fire engines need to be equipped with AEDs. Those AEDs located in areas for potential PAD need to have their location registered with 9-1-1 dispatch in order to ensure they are used in the event of a near-by SCD. Emergency Medical Dispatchers must be prepared to provide instructions for use of an AED to the untrained bystander. More research is needed before recommendations regarding placement of additional AEDs for PAD can be made.

INTRODUCTION

Treatment for out-of-hospital sudden cardiac death (SCD) is an active area of prehospital research. There are multiple factors that contribute to the popularity of this topic, including the large number of subjects affected each year as well as the immediate gratification that can be associated with a "save". Paul Pepe, one of the major academicians in this area, is known to clearly summarize this sentiment during lectures with the Biblical reference "And the Dead Shall Rise" (personal communication).

On the forefront of research in this area is the concept of Public Access Defibrillation (PAD). Automated External Defibrillators (AEDs) are devices capable of recognizing life-threatening cardiac rhythms that are most commonly responsible for SCD, namely ventricular fibrillation/pulseless ventricular tachycardia (VF/VT). Additionally, the device is capable of recommending electrical countershocks to treat VF/VT, all without the assistance of trained medical personnel.

The purpose of the North Carolina AED Location Project is to provide descriptive statistics regarding the state of PAD in North Carolina. By way of background, the burden of disease for out-of-hospital SCD as well as the treatment history for this disease in the United States is reviewed. Following the review, the details of the North Carolina AED Location Project are summarized. Finally, future directions and goals of AED research are discussed.

BACKGROUND

Burden of Suffering

Sudden cardiac death (SCD) is a leading cause of morbidity and mortality in the United States, resulting in approximately 300,000 deaths each year (1). The lack of a uniform reporting system prevents precise estimates of incidence although what estimates are available have remained constant over the past several years. In the mid-1980s, a complete 5-year review of data from the National Center for Health Statistics from forty states revealed a total of 223,864 SCDs (2). The population in these forty states represented 71% of the entire US population; assuming this population is a representative sample, the annual incidence of SCD for the entire US population would be 315,000. A 1998 review estimated the annual incidence of SCD to be 0.1% to 0.2% of the US adult population. Given a current adult population of 202,252,210, these more recent estimates are similar to those reported 15 year ago, ranging from 208,000 to 416,000 annual cases, or an annual incidence rate of 1 SCD per every 486 to 972 adults (3). In all cases, a majority of SCDs occurred outside the hospital, with as many of 50% of patients having no symptoms of cardiac disease prior to their SCD (1,2). By way of comparison, only cardiac death (all cause other than SCD) and all cause cancer deaths claim more lives per year in the United States (4).

Research Challenges

Given this enormous burden of suffering, it is not surprising that research evaluating treatment for SCD was a dominating force in early Emergency Medical Services (EMS) research. Unfortunately, much of this initial research was of poor design. Additionally, there was lack of consensus regarding not only case definition but also what constituted a successfully treated patient. In 1980, a review of all published articles relating to out-of-hospital SCD for the previous ten years revealed 21 total studies. In these studies, 4 separate case definitions were used, and only one study was a prospective randomized controlled trial (5). Indeed, the difficulties in determining what constitutes a "save" (e.g., any return of spontaneous circulation versus survival to hospital discharge) led some to call for measurement of discrete, easily definable endpoints. For example, it has been advocated that AEDs be judged solely upon their ability to recognize and advise a countershock for patients with VF/VT rather than upon their ability to result in an increased proportion of "saves" (6). In other words, the efficacy of AEDs is easier to measure than the effectiveness, yet it is questions of effectiveness that are most in need of evaluation.

Given these early difficulties with basic concepts of case definitions and which outcomes to measure, an international panel was convened in the early 1990s to provide a standard reporting template. Named after the abby where the meeting was held, the Utstein Style for reporting research in the area of out-of-hospital SCD was rapidly adopted by the American Heart Association, the European Resuscitation Council, and many other members of the international medical community (7). This style provides uniform definitions as well as a template by which data can be reported in a consistent manner. Unfortunately, many of the studies relating to SCD, and particularly the use of AEDs, are not reported in this style, so comparison remains problematic.

The difficulties with comparison are quite pronounced when one attempts to compare the Seattle/King County system with other systems. As is analyzed in detail below, some studies from this area demonstrate a cardiac arrest survival rate as high as thirty percent with most other systems in the United States achieving a survival rate of less than ten percent. It appears these differences relate primarily to reporting style and definitions, particularly as it relates to the population at risk and the possibilities of selection bias. For example, in some Seattle studies only patients with witnessed arrest, bystander CPR, and/or initial rhythm of ventricular fibrillation are included. In others, only patients with autopsy-proven primary cardiac etiology of the SCD are included. When compared with patients without these characteristics, these patients have a far greater chance of survival. Thus, the entire population at risk for cardiac arrest is not considered, as it is in many other studies. Such a selection bias would overestimate the proportion of survivors for all victims of cardiac arrest. Most other studies include the entire population at risk and, where the above criteria are considered, they are considered in a stratified analysis. Additionally, the inclusion and exclusion criteria for patients in the Seattle studies are often difficult to determine, again introducing the possibility of selection bias. Given these limitations, the evidence from the Seattle/King County system must be interpreted with caution. The attention to the Seattle data is of paramount importance, for this system has contributed a large amount of research to the area of out-of-hospital cardiac arrest.

It is hoped that future research will more consistently follow the Ustein style, for items such as the population at risk as well as uniform definitions of survival must be clearly provided. Unfortunately, unless otherwise noted, the studies in this review do not conform to the Ustein style. Where available, the definitions used in each study are presented.

Development of the Model for SCD Treatment

Historical Perspectives

The American experience with defibrillation for victims suffering SCD began in Baltimore in the 1950s. Executives from Edison Electric Company were concerned about the number of linemen experiencing SCD after unintentional electric shock. The Edison Electric Company offered funding to Dr. Kouwenhoven and his colleagues at Johns Hopkins University to develop a method of treatment. As most victims of electrocution were experiencing VF/VT, electrical defibrillation was the treatment method upon which research efforts focused. Open chest defibrillation was successful in animal models, yet rather impractical for humans in the out-of-hospital setting. Soon an external defibrillator was developed that was also efficacious in the treatment of VF/VT; the first in-hospital VF/VT arrest was successfully treated at Johns Hopkins with external defibrillation in 1957 (8).

Interestingly, the weight of the defibrillating paddles also led to findings concerning external chest compressions. The weight of the paddles that delivered the countershock was so great that transient increases in femoral pulse were noted as the paddles were applied. This quickly led to the development of closed-chest cardiac compressions. Indeed, in what may be the earliest out-of-hospital save of a cardiac arrest victim in the US, on January 6, 1960, two paramedics that were assisting in Kouwenhoven's lab responded to an ambulance call. After finding a breathless and pulseless victim, chest compressions were initiated and the victim was rapidly transported to hospital where he was successfully defibrillated. The patient was subsequently discharged with no apparent sequalae (8).

By the end of the decade, the external defibrillator became mobile enough to allow defibrillation in the out-of-hospital setting. From Belfast to New York, "Mobile Coronary Care Units" were developed, dispatching defibrillator-equipped physicians to the side of patients in the community, often with anecdotal success (9,10).

Over the next several years, it became apparent that rapid defibrillation was an important treatment modality for victims of SCD. Questions were raised concerning the ability of non-physician or paramedical providers to deliver defibrillation in the out-of-hospital setting. Although somewhat limited by a study design that incorporates historical controls, results from the Seattle/King County system reveal initial data concerning paramedics. In that system, a trial compared the proportion of survivors from out-of-hospital SCD treated by paramedics capable of advanced cardiac care (defibrillation, intubation, and medication administration) versus those treated by basic EMTs. An overall increase in the proportion of patients surviving out-of-hospital SCD increased in the group of patients treated by paramedics. The proportion of out-of-hospital SCD patients that survived to admission increased from 19% to 34% ($p < 0.01$), with an increase in survival to discharge from 7% to 17% ($p < 0.01$) (11). As is discussed above, this study represents one in which there is potential for selection bias, for 20% of subjects suffering out-of-hospital SCD were excluded after autopsy revealed a non-cardiac etiology for sudden death (11). Certainly, successful defibrillation is more likely to occur if a victim's sudden death is from a cardiac origin. Clinically, then, this exclusion criterion is appropriate. Practically, however, it is often not possible to determine the cause of sudden death in the field with the certainty one obtains at autopsy. Most studies from other systems use clinical criteria to exclude non-cardiac patients, thus providing the ability to reproduce results in the field. It is clear from this study that paramedic-level intervention improved the odds of survival to admission and to discharge; the absolute benefit, however, must be viewed with caution, especially as one attempts to compare the overall percentage of survivors to other studies with less opportunity for selection bias.

The same investigators compared two communities, one with and one without advanced paramedic services, again demonstrating a significant improvement in the paramedic-equipped areas (6% vs 22% of out-of-hospital SCD patients discharged alive ($p<0.01$)) (12). In this study, similar exclusion criteria were applied to those with a non-cardiac cause of sudden death, with the inherent risk of over-estimating the benefit of the intervention. In this study, only victims that received CPR from responding medical personnel were included. Although not specifically discussed, certainly those with "obvious death" would not have received CPR, again introducing the possibility of selection bias.

Finally, in this study, it is not clear whether "paramedic level service" implied one or two responding paramedics. This is an important distinction, for communities wishing to use this data to make changes in their own system need to know the level of response needed to achieve similar results.

In both of these studies, it is not possible to determine the relative benefit of defibrillation versus other advanced interventions such as airway management or medication administration. There were no strata of patients that received defibrillation alone. In an effort to investigate the incremental benefit of defibrillation alone, EMTs in the Seattle/King County system were trained only in the recognition of ventricular fibrillation and use of a defibrillator – no other advanced skills were employed. Using historical controls, the addition of defibrillation alone increased survival to hospital discharge from 4% to 18% ($p<0.01$) (13). Additionally, a retrospective analysis of a defibrillation-first versus an intubation/drug-first strategy clearly favored the former, with long-term survival rates of 12.3% vs 3.6% ($p=0.03$) (14).

Importance of defibrillation

Given this early evidence regarding the importance of defibrillation in the treatment of out-of-hospital SCD, communities began evaluating the possibility of training basic EMS personnel in the recognition of VF/VT and the appropriate use of defibrillation. In the Seattle/King County system, a three-year comparison of EMT response with defibrillation capability (EMT-D) vs basic EMT (EMT-B) response yielded an overall survival rate of 38% vs 18 %, respectively (15). Similarly, a prospective trial in which communities in Iowa with EMT-Ds were compared to communities with only EMT-Bs demonstrated a 19% survival rate for patients found in VF/VT in the EMT-D group versus 3% in the EMT-B group (16). Both of these studies are limited by a lack of true randomization as well as the possibilities of selection bias; yet even given these limitations, the evidence still appears to support EMT-D level care over EMT-B level care.

One of the difficulties with the EMT-D strategy involved the need for additional education and skills maintenance. While paramedics undergo extensive education regarding cardiac rhythm assessment and treatment, the basic EMT curriculum includes no such education. In order to function as an EMT-D, each EMT-B had to undergo extensive rhythm recognition training as well as annual refresher courses in order to accurately interpret rhythms and provide countershock when appropriate. In the mid-1980s the advent of the Automated External Defibrillator (AED) provided a potential alternative treatment modality that did not require such extensive education. These devices required no rhythm interpretation on the part of the operator; the entire process was automated. Not surprisingly, the Seattle/King County system led the way in the evaluation of this new device.

Benefits of AEDs

In one of the first randomized clinical trials to evaluate out-of-hospital interventions in the treatment of cardiac arrest, EMT-Ds using standard defibrillators were compared with EMT-Ds using AEDs. There were no significant differences between the two groups with respect to survival rates to hospital admission or hospital discharge, accurate recognition of VF, or success of defibrillation attempt (17). The researchers conclude that AEDs are an acceptable alternative to standard defibrillators when used by EMT-Ds, and may have some advantage with regard to training and ease of operation (17).

Subsequent to this equivalence study, many communities in the United States as well as worldwide began investigations regarding the use of AEDs by trained EMS providers. Unfortunately, many of these studies were limited by lack of appropriate controls. A non-randomized trial from the Seattle/King County system demonstrated an overall survival rate for victims in VF/VT of 27% with the use of AEDs by EMT-Ds; historical control data, however, demonstrated a 25% survival rate when only EMT-B level service was provided, so the benefit appeared to be modest (18). A Belgian study presents quite possibly the most convincing evidence regarding AED effectiveness, with an improvement in survival from 7% to 19% after the introduction of AED level response. These conclusions, however, must be observed with caution as 3 years expired between the data obtained for historical controls and that obtained for the experimental group; there is no attempt to statistically control for possible confounding variables (19).

In a convincing publication regarding the use of AEDs by first responding personnel, the Seattle/King County system evaluated 1287 consecutive reports of cardiac arrest. While not randomized, this retrospective study did incorporate contemporaneous controls, thus eliminating many potential confounders. Firefighters were trained in the use of AEDs and instructed to use them on victim found in cardiac arrest. Data for patients in which the firefighters arrived on-scene more than 3 minutes prior to paramedics were included in the study (the authors note than any smaller difference in response times is unlikely to provide an opportunity to use the AED prior to paramedic arrival). Firefighters in 22 of 40 firehouses underwent AED training. Based on multivariate analysis, the use of the AED by firefighters demonstrated an odds ratio of 1.8 (95% CI 1.1-2.9) for survival to hospital discharge as compared to patients treated by a firefighter without an AED (20).

Two rural AED studies are also worthy of mention. The first, a study from rural Wisconsin, demonstrated an overall improvement in survival for victims of out-of-hospital SCD from 3.6% to 6.4% with the addition of AEDs in first responding units. Again, historical controls were utilized. Also of note are the markedly lower survival rates for both groups. Citing previous studies, the authors emphasize the importance of timeliness of response to cardiac arrest; their study indicates time to arrival on scene as an important indicator of the probability of survival (21). Unfortunately, in their study, all response times were prolonged, with a mean time of 7.1 +/- 5.8 minutes. The mean time for the small portion of survivors, however, was 3.7 +/- 2.0 minutes (21).

A similarly modest effect was demonstrated in a case series report from rural Kentucky. Overall, the survival rate to discharge for victims of out-of-hospital SCD was 3.2 %, with an 11% survival for those in VF/VT (22). Given the limitations of a case series, it is nonetheless interesting to note that after analysis relating to response times, age, size of the EMS agency, and initial rhythm, the only predictor of survival was defibrillation by an AED (22).

While limited by study design, review of the studies reveals a trend in which several factors are important in the treatment of out-of-hospital cardiac arrest. The timeliness of response appears quite important, with very rapid response necessary for the greatest chance of survival. Additionally, first responding personnel should be capable of providing defibrillation, although the incremental benefit of such response may be modest if response times are prolonged. Finally, additional resources provided by paramedics are beneficial. The data from these studies are too limited to determine the incremental benefit of paramedic level interventions versus the benefits from defibrillation alone.

Lack of AED benefit

Not all studies, however, demonstrated a positive benefit after the addition of AEDs to treatment protocols. Perhaps the most striking of these is a study involving the addition of AEDs in rural Minnesota. With sound statistical analysis to control for variables, this prospective non-randomized trial evaluated the outcome for patients treated by EMT-Ds with AEDs versus EMT-Bs. The former group had a 5% survival rate while the latter group had a 2.5% survival rate; the difference was not statistically significant (p=.154) (23). Statistical analysis reveals the mean response time (6.5 minutes) to be longer than for the Seattle/King County (4 minutes) or previous rural studies (5.5 minutes) (23). The authors call the results "sobering" and emphasize that the addition of AEDs alone is insufficient to result in a significant increase in survival to hospital discharge.

Similar results are noted in some metropolitan environments as well. A well-designed non-randomized cross-over trial from Memphis clearly demonstrates the limitations of AEDs. In this trial, 20 of 40 fire companies were provided with an AED and told to use it immediately upon arrival to any cardiac arrest. The other 20 companies provided CPR only while awaiting EMS arrival. The roles of the fire companies were rotated on a periodic basis. The mean response difference from fire to EMS/paramedic arrival was only 2.5 minutes (recall the Seattle/King County study excluded firehouses with a response difference of less than 3 minutes). Additionally, the mean response interval for firefighters was only 3.5 minutes and 6.0 minutes for paramedics. In this case, there was no difference between the AED and the CPR group with regard to successful initial resuscitation (32% versus 34%), survival to hospital admission (31% versus 29%), or survival to hospital discharge (14% versus 10%) (24). The authors conclude that in an efficient urban EMS response system, the addition of AEDs to initial responders may have little benefit (24).

In metropolitan systems with longer response times, the addition of AEDs may not result in improved patient outcomes. In the Charlotte/Mecklenburg EMS system, for example, the 24 firehouses with the longest response difference between firefighters and paramedics were chosen for analysis. AEDs were placed with one-half of these fire companies with the other one-half providing CPR alone. Data were collected and groups were rotated in a design similar to the Memphis study. There was no difference in the proportion of patients that experienced successful resuscitation in the field, were admitted to hospital, or were discharged alive (25). Notably, however, the overall proportion of patients surviving was much lower than for some other metropolitan areas: 4.6 to 5.3%.

Taking only those patients in VF/VT does not result in any substantial improvement, with survival to discharge rates of 6.5 to 7.6% (25).

Two factors are important in analyzing this difference. First, the response time for Charlotte/Mecklenburg firefighters averaged 4.3 to 4.4 minutes, almost 60 seconds greater than for Memphis Fire Department. Also, the mean time for paramedic arrival was 9.9 to 11.1 minutes, markedly longer than the 6.0 minutes in the Memphis study[1]. Finally, the call processing time for the Charlotte/Mecklenburg 9-1-1 centers was unacceptably long, with calls requiring an average of 2.5 minutes to undergo processing and some calls not being dispatched for over 4 minutes (25). As the study authors note, the addition of AEDs alone in a system with prolonged response times and inefficient dispatch is unlikely to result in benefit (25).

Finally, a study of the London ambulance service supports the conclusions from the Memphis and the Charlotte/Mecklenburg studies. The addition of AEDs to the 8 ambulance stations in South London resulted in a modest increase in the proportion of survivors from 2% to 4%, using contemporaneous non-randomized controls. The numbers were small, however, and study only enrolled 1/6 the number of patients that would be required to determine a statistically significant difference between the control and the experimental groups. While exact response time data are not included, it is clear that more than 8 minutes elapsed from call to first unit on the scene in more than 60% of cases, likely a major contributing factor to the overall poor resuscitation rate (26).

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[1] It should be noted that the Charlotte/Mecklenburg EMS agency (MEDIC) now responds to over 90% of emergency calls in less than 10 minutes 59 seconds.

These individual studies demonstrated wide variation in the treatment success of out-of-hospital SCD; the key findings of each study are summarized in Table A. While factors such as time to treatment as well as accuracy of dispatch appear to be important factors in a successful treatment strategy, the quantification of the importance of these various factors is difficult to surmise from these individual studies. Several predictive models as well as meta-analyses have been completed in an attempt to provide a clear understanding of the factors associated with successful resuscitation of out-of-hospital SCD.

Data Synthesis

In an attempt to further describe the relative importance of the various factors relating to treatment of out-of-hospital SCD, predictive models were developed. The first of these, the "ACLS score" was developed based on simple descriptive statistics and probabilities. The data used for this model were obtained from a prospective observational study known as Project Restart that was conducted from 1976 to 1979 in the Seattle/King County system. In this model, factors that increased the probability of survival included experiencing a witnessed SCD, receiving bystander CPR, experiencing an initial rhythm of VF/VT, and having a response time for paramedics (capable of defibrillation) of less than 4 minutes (27).

Several years later, a more sophisticated logistic regression model was evaluated. The study is limited by its retrospective nature as well as by missing data from a significant number (33%) of out-of-hospital SCD victims. Given these limitations, however, it is reasonable to evaluate the model for the proportion of patients for whom data were available. Factors such as age, medical history, and medication history as well as the emergency response information were included in the model. The only statistically significant factors related to survival were the period from collapse until initiation of CPR and the period from initiation of CPR until defibrillation (28).

More recently, a regression model containing data obtained in a controlled, prospective manner also demonstrated the importance of early defibrillation. Importantly, all SCDs evaluated in this study occurred in-hospital rather than out-of-hospital. While the underlying cause of SCD is presumably similar regardless of where an arrest occurs, certainly hospitalized patients may have a different overall state of health as compared with victims of SCD from the community. With this caveat in mind, the data from this study support the benefits of early advanced treatment for SCD. In this model, prompt defibrillation as well as type of initial rhythm, performance of intubation, and patient age were important predictors of survival from SCD (29).

In perhaps the most popular work regarding out-of-hospital SCD, the Seattle/King County group reviewed treatment methods and outcomes for twenty-nine cities. In this review, five possible response configurations were evaluated: EMT-B (only), EMT-D (only), Paramedic (only), EMT-B first-tier response with paramedic second-tier response, and EMT-D first-tier response with paramedic second-tier response. This study is limited by its retrospective nature as well as lack of uniform definitions and reporting guidelines. Additionally, a majority of the two-tiered data came from the Seattle/King County system, so the review essentially compared that system to other systems in the country. Given these limitations, it is noteworthy that systems with only EMT-basic level response achieved a 11% discharge to home rate for out-of-hospital SCD victims while those with a two-tiered EMT-D/Paramedic response achieved a 30% discharge to home rate. The authors speculate that earlier CPR and earlier defibrillation associated with the two-tiered response were major factors associated with the increased survival. The study design prohibited formal evaluation of this hypothesis (30).

By 1991, based on these and similar studies, the American Heart Association adopted the Chain of Survival concept, emphasizing the importance of prompt activation of Emergency Medical Services, Early CPR, Early Defibrillation, and Early Advanced Cardiac Care (31). Over the past decade, this model has become popular not only in the medical arena but also in the commercial arena as is evidenced by its use in public advocacy campaigns.

Meta-analyses

During the 1990s, four meta-analyses were completed; for the first time, the observational studies and descriptive statistics found in the early studies were subjected to rigorous review rather anecdotal reporting and basic statistical modeling. The first of these studies included very strict inclusion/exclusion criteria with only seven studies of sufficient strength for analysis. In this well-designed analysis, there was an absolute 8.5% (95% CI 7-17%) overall increase in the odds of survival with EMT-D versus EMT response. As was noted in the twenty-nine cities study above, those with a two-tiered response experienced a greater benefit, with an absolute 16% (95% CI 8-24%) reduction in risk versus a 6.3% (95% CI 4-16%) reduction for those in a single tier system (32).

A subsequent meta-analysis with slightly different inclusion criteria reviewed ten studies, six that were evaluated in the previous analysis as well as four unique to this study. As with the previous report, this study was well designed with reasonable inclusion and exclusion criteria. All included studies demonstrated some benefit regarding the use of AEDs by EMT-Ds. Although the confidence intervals are broader, a similar pooled affect is noted, with a 9.2 % (95% CI 2.7 – 15%) absolute improvement in the probability of survival if victims of out-of-hospital SCD were treated by EMT-Ds versus EMT-Bs (33). There was no stratified analysis based on single- versus double-tiered response.

Two other meta-analyses focused more particularly on the timeliness of response rather than on the response configuration. The first of these studies incorporated broad inclusion criteria and reviewed 37 articles. In this analysis, it was noted that no significant changes in the probability of survival to hospital discharge were noted so long as the defibrillation-capable responder reached the victim in the first six minutes, no matter what the response configuration. There was a 0.72 (95% CI 0.61 to 0.84) decrease in the odds of survival for each minute that passed without defibrillation from 7 to 11 minutes; no interventions were found to be helpful after 11 minutes. Finally, as has been noted in the other analyses, for all patients the odds of survival to discharge was highest in a tiered response system. The odds ratio for survival in a two-tier EMT-D/Paramedic system versus a Paramedic single tier system was 2.31 (95% CI 1.47-3.62) (34).

This meta-analysis indicates a tiered-response is best if the paramedics are not capable of reaching a victim in six minutes or less, with EMT-D level response in the first tier.

Another analysis reviewed 36 articles, many of which were identical to the articles included in meta-analysis just reviewed. In this case, the overall survival in a one-tiered system was 5.2% versus 10.5% in a two-tiered system. For each one-minute decrease in response interval, there was an associated increase in survival of 0.4% for one-tiered systems and 0.7% for two-tiered systems. As the authors state, the studies available for the analysis were of only average quality, with no randomized controlled trials meeting inclusion criteria. The authors caution that the modest improvement in survival as it relates to response times in this study needs further evaluation before change in response policy is adopted (35).

The authors of the latter two meta-analysis mentioned above are also members of the OPALS (Ontario Prehospital Advanced Life Support) study group. This group is conducting a large, randomized EMS trial now ongoing in Canada. The first phase of this trial investigated the potential survival benefit associated with improving response times in a large EMS system. Using historical controls, the authors tested that hypothesis that increasing the proportion of EMS units arriving to patients in less than 8 minutes would increase the proportion of survivors of out-of-hospital SCD. In their study, increasing the proportion of victims reached in 8-minutes from 76.7% to 92.5% resulted in an absolute increase in the proportion of survivors of out-of-hospital SCD from 3.9 to 5.2% (p=0.03) (36).

The overall survival rate in this study is clearly much lower than that reported from the Seattle/King County system. While there are multiple possibilities for this difference, one is particularly noteworthy. As is discussed above, retrospective exclusion criteria were often applied in the Seattle studies. In the OPALS study, all victims of sudden death were included except those with clinically obvious non-cardiac cause of death or those with obvious signs of non-recent death for whom resuscitation was not attempted. Thus, the OPALS study includes the entirety of patients likely to be encountered by EMS personnel, while the Seattle study retrospectively excludes many patients upon whom resuscitation would be attempted in the field.

These meta-analyses provide the first rigorous evidence in the development of a model for the treatment of cardiac arrest; the key results are summarized in Table B. All studies consistently indicate the two-tiered response system is superior to a single-tiered response. The rapidity with which defibrillation is provided is an independent factor associated with survival; the magnitude of its impact is difficult to conclude based on the available data. Given these findings, the most logical treatment algorithm for the treatment of out-of-hospital SCD includes a two-tiered response configuration with defibrillation capable first-tier responders. It appears that improved outcomes can be achieved based on the rapidity with which both tiers respond. Additionally, it appears the response time for the defibrillation-capable first tier is most critical. The data are not sufficient to determine the relative importance of a timely response by the advanced life support second tier. Nevertheless, the preponderance of the evidence suggests that with optimal response, a survival rate of five to ten percent can be anticipated for victims of out-of-hospital SCD.

Public Access Defibrillation

Failures of the Model

As noted above, a model for the treatment of out-of-hospital SCD began with the AHA Chain of Survival concept and was strengthened initially by observational studies and then by more rigorous meta-analyses. In many locations in the US, both rural and urban, the implementation of this model has proved quite difficult.

In Chicago, a retrospective analysis of over 3,000 cardiac arrest victims demonstrated that only 2% were discharged alive from the hospital. Given there is paramedic level response, this is an usually low survival rate. In attempts to explain this apparent exception to the model, the authors analyzed the actual time to defibrillation for victims of SCD. Given the complexities of navigating high-rise structures and other difficulties encountered in this urban setting, it was estimated that it took paramedics an average of eight minutes to reach a patient and perform defibrillation after they had already arrived on the scene, for an average defibrillation time (from dispatch to defibrillation) of 16 minutes. As the authors note: "The single factor that most likely contributed to the poor overall survival was the relatively long interval between collapse and defibrillation" (37).

Similar difficulties were noted in New York City. In the 1994 Pre-Hospital Arrest Survival Evaluation (PHASE) study, 2329 out-of-hospital SCDs were evaluated in a prospective manner. The overall survival rate was 1.4%. Again, a prolonged time to first defibrillatory shock was noted, with a mean of 12.4 minutes (interquartile range 11.7 to 16.4 minutes). Again, lengthy response times as well as other "factors that may predispose residents of large cities to higher cardiac arrest mortality" were cited as possible explanations for the low observed survival rate (38).

Policy Statements

Recognizing the difficulties inherent in allowing a 9-1-1 dispatched medical responder to reach a victim in a timely manner, attention has become focused on the possibility of public access defibrillation (PAD) by minimally trained or untrained bystanders. It is hypothesized that such bystanders will be able to provide defibrillation in a timely manner, certainly in less than the 12 to 16 minutes experienced in two of America's largest cities. In 1994, the American Heart Association's Public Access Defibrillation Conference recommended an expanded role for bystander use of AEDs as well as emphasized the need for well-designed studies to substantiate the benefits of such treatment (39). The PAD trial that is now underway in many communities in the United States is the first prospective study to evaluate the benefits of PAD. No results are currently available, but the design was described at the 1999 Turtle Creek Consensus Conference on Prehospital Care (40). Additionally, nomenclature for the various types of providers that might use an AED is included in this consensus statement (40):

Level I – traditional first responders such as fire and police
Level II – non-traditional first responders such as security guards and flight attendants
Level III – citizens trained in the use of AEDs through a nationally recognized course
Level IV – untrained bystanders that have access to an AED

In perhaps the most exhaustive work on the subject of AED use, Marenco and colleagues reviewed 101 publications. Clearly, the move to PAD from Level II to Level IV responders was the area of greatest interest and most in need of additional research (41).

Initial successes

The only evidence currently available regarding PAD involves Level II personnel (40). This evidence, however, is quite remarkable in that extraordinarily high survival rates have been reported. The use of AEDs by flight attendants and casino security guards is reviewed.

An observational study evaluated the effects of placing AEDs on all Quantas Airlines aircraft as well as in major airport terminals served by the airline. The survival rate to hospital discharge for all patients that presented in VF/VT was 26%, rivaling the reported successes of the Seattle/King County system. Unlike previous studies that evaluated only Level I personnel, airline employees trained in AED use made up the Level II responders in this trial, making the comparison with Seattle/King County all the more impressive. Although this study was strictly observational in nature, the ability of Level II responders to achieve success on the order of the best Level I responders was nonetheless suggested by these results (42).

In a small study of 14 patients that suffered VF/VT arrest while in the aircraft or in the terminal, excellent results from the use of the AED by Level II airline responders were also noted. All patients undergoing treatment were successfully converted to a stable rhythm with a pulse on the first countershock. Of these, 40% survived to hospital discharge (43).

Security guards in casinos have achieved possibly the highest survival rate for victims of out-of-hospital SCD ever reported. These Level II responders used the extensive surveillance system already in place in casinos to not only rapidly notice a potential victim of cardiac arrest but also to assist in recording response and defibrillation times. One hundred five victims were found initially to be in VF/VT; of these, 53% survived to hospital discharge. Moreover, stratified analysis revealed that of victims receiving a countershock in less than 3 minutes, 74% survived to hospital discharge, as opposed a 49% survival for victims receiving their first countershock after 3 minutes (44). The ability of minimally trained Level II responders to deliver effective treatment was established, and the importance of timely response reaffirmed.

Future Directions

It is now hoped that Level III and Level IV responders can achieve successes similar to those of Level II responders. The issues involved in the initiation of such a program include determining the optimum placement of AEDs in the community, the cost-effectiveness of any plan, and the level of expertise to which an operator should be trained in order to operate a AED safely and effectively. Where available, most of the evidence concerning any of these issues is preliminary at best. Given the emphasis placed upon rapid defibrillation by a preponderance of the evidence, it seems that Level III and Level IV PAD is the next logical step to take in order to provide this life-saving treatment to the greatest number of individuals. As is noted in the Chicago and New York, as well as by simple observation of American geography and traffic patterns, it is not possible to maximally benefit victims of out-of-hospital SCD from Level I and Level II AED response alone.

Placement

There is little in the way of randomized data to guide one in placement of AEDs in the community. In all placement studies, the majority of cardiac arrests occurred in private homes or some other non-public place (45,46,47). A review of all out-of-hospital SCDs in Kansas City for an entire year revealed only five public locations in which more than one cardiac arrest occurred. These included the airport, an airline maintenance facility, a casino, and two hotels, leading the authors to conclude, "it may be difficult to identify high-yield public places in which to place an AED" (45). Similar difficulties were noted in Pittsburgh, where over a three-year period, only 27 locations had two or more cardiac arrests, 94% of which were nursing homes and dialysis centers. These authors concluded that it "was not possible to identify other public locations as high risk for out-of-hospital SCD in our city" (46). Data presented in abstract from Canada has also indicated the difficulties with effective placement of AEDs in the community setting (47).

As has been their pattern in all cardiac arrest research, the Seattle/King County group again provides a unique perspective on the issue of PAD and AED placement. In a review of cardiac arrest locations over a four-year period, locations of arrest were characterized by type rather than by unique address. In other words, if an arrest occurred in a health club, this was counted as one health club arrest rather than an isolated arrest at a particular address. By this method, higher risk location types were established. In the next phase of the project, the total number of locations within each category was totaled. By this manner, the total number of AEDs needed to provide service for the ten highest risk location types was calculated. In these top ten areas of cardiac arrest, there were a total of 134 cardiac arrests over a four-year period, all of which could have been reached with 276 AEDs (48).

It is useful to view these potential placement sites from an epidemiological perspective. As is mentioned in the review of the meta-analyses above, a ten percent theoretical survival with standard EMS response is possible; the most recent data, however, indicates the national average of survival for out-of-hospital SCD is seven percent (49). Given the overall lack of data regarding the effectiveness of Level III and Level IV responders, one can conservatively assume they would be as effective as the least effective Level II responders. Based on data to date, there appears to be at least a twenty-six percent survival for those treated by Level II response (42). In the Kansas City study, placement of

AEDs in the sixteen locations with more than one cardiac arrest on an annual basis would have reached eleven percent of all cardiac arrests, totaling 38 victims. Twenty-eight of these victims were in nursing homes; if these patients are excluded, only 10 victims (or 3.2% of all cardiac arrest victims) would have been reached by AEDs placed in the five locations with more than one cardiac arrest. Given the assumptions above, only 6 patients need to be treated to save additional one life, meaning placement in Kansas City would save one to two additional lives per year. If one assumes two AEDs would be needed for each location, a total of 20 AEDs would be needed to save one additional life per year. As most AEDs have a five-year life span, these twenty AEDs would be expected to save 8 lives over their lifetime.

In Pittsburgh, only 17% of all cardiac arrests would have been reached by AEDs placed in the fifteen locations having more than two cardiac arrests over a three-year period. If nursing homes and dialysis centers are excluded (for they presumably are eligible for Level I response to SCD), only Three Rivers Stadium had more than more than one out-of-hospital cardiac arrest. Only 3 cardiac arrests (0.3% of the total for Pittsburgh) occurred here over the 3-year period. Using the same assumptions from above, one must treat 6 victims to provide one additional life saved, making this option not epidemiologically sound, as one would treat only 5 victims over the 5-year life-span of the AED.

Finally, the Seattle data are examined. Over 5 years, placement of 276 AEDs in high-risk public locations would have provided treatment for one percent of all cardiac arrests, or 134 victims. It is anticipated twenty additional lives would be saved by the placement of these 276 AEDs.

Cost-effectiveness

There is little data available regarding the costs of AED programs that provide Level III or Level IV care for victims of out-of-hospital SCD. Two studies, however, provide cost-effectiveness data in relation to defibrillation and other ACLS care for Level I or Level II response. These studies, as well as the only cost-effectiveness study that deals directly with AED placement, are reviewed.

A 1986 review evaluated the cost per life saved for response by EMT-Bs, EMT-Ds, and paramedics. Costs for training were tabulated based on data from all 50 states as well as the District of Columbia. Review of the literature estimated the proportion of victims with VF/VT arrests saved to be 6%, 25%, and 28% for each type of responding personnel, respectively. Even given that these calculations may be over-estimates (given the review of the literature above), it remains noteworthy that the cost-per-life saved for an EMT is $7687 while for an EMT-D it is $2126 and for an EMT-P it is $2289. Given the incremental cost for training an EMT to the EMT-D level is only $27.00, there is no economic disincentive to train, even if the improved survival rate falls short of the estimated 25% (50). Training EMT-Bs to provide defibrillation, then, makes not only for good medicine but also for good economic policy.

An excellent cost-effectiveness analysis was completed in the mid-1990s. In this study, a meta-analysis was performed to determine the effectiveness of the various types of EMS systems in the resuscitation of out-of-hospital SCD. Additionally, the cost for each component of the EMS response as well as QALYs (Quality Adjusted Life Year) saved based on the different response characteristics and response times were calculated. For each 48 seconds of improved response time, the costs were as follows: $368,000 per additional QALY for a single-tier response but only $40,000 per additional QALY for a two-tier response using firefighters trained to the EMT-D level. The costs per additional QALY for other tiered options feel in between these extremes (51). As with training of basic EMTs to the EMT-D level, development of a two-tiered response system makes good medical as well as economic sense.

Finally, a late 1990s study evaluated the potential cost-effectiveness of true Level III and Level IV PAD. It is interesting that in this study the incremental effects of PAD were estimated to be quite low, with a 7.9% survival for victims served by standard Level I and Level II response versus 8.7% for those served by Level III and Level IV response. Given the recent successes noted with airlines and casinos, this low incremental benefit may under-represent the potential benefit of Level III and Level IV PAD. In this cost-effectiveness model, however, such under-representation is desirable, for it allows one to examine the worst-case scenario. Even with this low incremental benefit, the median incremental cost per additional QALY was $44,000 for the Level III and Level IV PAD, consistent with the generally referenced $50,000 value per QALY and similar to costs for improving response times in two-tiered EMS systems (52).

Rather than evaluating QALYs, one can simply examine the potential cost per life saved based on the three cities' placement studies above. The following assumptions are made. First, the initial cost of the AED is $3,000, with a 3% discount rate for each year of service, giving an initial capital cost of $3,450. Batteries would have to be replaced once over the lifetime of the device, at a cost of approximately $200, for a total 5-year cost of $3,650. Most devices are now equipped with a self-test mechanism that will alert owners of impending difficulties with batteries, etc., keeping maintenance costs to a minimum (53). Using this model, the Kansas City scenario would cost $14,600 per life saved while the Seattle solution would cost $50,370 per life saved. The quality of life after the save is obviously an important factor that is not considered in this calculation, although it is noteworthy that both of these studies only counted a "save" as a discharge alive from the hospital.

Safety and Education

In addition to medical effectiveness and cost considerations, the ability of Level III or Level IV responders to safely and effectively operate an AED must be considered. An important component of safety involves the sensitivity and specificity of the AED rhythm analysis. In this case, the specificity is of paramount importance for poor specificity may result in inappropriate delivery of a countershock. Ideally, the device would also be highly sensitive, advising a shock in all patients that could benefit from such treatment. In an effort to first do no harm, however, the AED algorithms place emphasis on specificity over sensitivity. Several studies have evaluated the diagnostic algorithms of AEDs, consistently noting the specificity to be 99 to 100% with sensitivities ranging from 71-83% (54,55,56).

A case report of inappropriate countershock provided by an AED deserves analysis. In 1992, there was a report of a 79 year-old gentlemen inappropriately shocked by an AED. The gentleman had a palpable pulse and was being monitored by an AED while in transport to hospital in an EMS vehicle. A shock was inappropriately advised, possibly due to electrical interference from the vehicle. A second inappropriate shock was advised, with resultant ventricular fibrillation. Fortunately, an appropriate shock was advised for this rhythm and the gentleman's heart was converted back to a sinus rhythm. In the final analysis, two factors were determined crucial in this misadventure. First, motion artifacts as well as the patient's underlying tall T-waves likely led the AED to incorrectly interpret the rhythm as ventricular tachycardia (57). Level III and Level IV first responders will likely not be evaluating patients in moving vehicles (as indeed this particular ambulance crew should not have been), so the probability of this type of difficulty is remote. Additionally, this patient had spontaneous respirations at the time of the inappropriate defibrillation. While it remains possible that an AED would be applied to such an individual by a Level III or Level IV responder, it is hoped this would be a rare occurrence.

Recent evidence has made it clear that Level III responders with no medical background can be trained in the safe and effective use of AEDs; early reports indicate Level IV responders can operate the device in a similar manner. A randomized controlled trial evaluated the performance of EMT-Ds on both written and practical examinations one week and 18 months after two types of training. An abbreviated four-hour course was compared with the standard ten-hour curriculum. In this case, EMT-Ds from the four-hour course performed with equal proficiency at both testing sessions when compared with those from the standard 10-hour course (58). Such an abbreviated course appeals to potential Level III responders; the AHA currently offers a 4-hour course to teach CPR and AED use to lay responders (59).

The ability of laypersons to retain skills from such a course was evaluated in observational study of family members of cardiac arrest survivors. Co-habitants of individuals with a history of cardiac arrest were offered training in CPR and AED use. Thirty-two of 34 homes had an individual with the mental and physical capabilities to undergo training. All 32 were successfully trained in an average of 4.1 hours. Although this was individualized training, the 4-hour training time is consistent with the time allotted for abbreviated EMT-D group training mentioned above. There was a marked skill decrement over time, implying refresher courses may be necessary (60).

While these studies focus on the ability to train lay responders, the effectiveness of true Level IV response is just beginning to undergo evaluation. A recent study of naïve six-grade children offers hope that the untrained bystander may successfully provide defibrillation with an AED. In a mock-cardiac arrest scenario using a mannequin, sixth-graders were told only how to remove the adhesive backing from the AED pads. No other AED instruction was given except that time was of the essence. In this situation, it only took an average of

23 second longer (95% CI –1 to 47 seconds) for the sixth graders to provide the first countershock than it took trained paramedics. In all situations, the electrodes were placed appropriately and the children were safely clear of the patient prior to delivering the shock, even in the absence of prior instruction (61). The National Academy of Emergency Medical Dispatch now advocates telephone instructions be provided for AED use, even for the non-trained provider. In fact, once the report of cardiac arrest has been confirmed, the next prompt instructs Emergency Medical Dispatchers to ask about the availability of an AED and provide instructions in its proper use (62).

Summary of Evidence

Out-of-hospital SCD affects approximately 300,000 citizens of the United States each year, making this one of the top 3 causes of death (1,2,3). Although initially only physicians were capable of providing treatment, it is now clear that a two-tiered EMS response offers the most medically and economically sound treatment method of out-of-hospital SCD in many communities (9,12,18,30,50,51). In some communities with prolonged response intervals, however, it is equally clear that no response configuration will result in the timely arrival of a defibrillator to a victim's side (25,26,37,38).

Given the overwhelming importance of time in response to SCD, alternative methods for the prompt provision of defibrillation have been explored, including Public Access Defibrillation with the use of AEDs (27,28,29,39,40,41). While the evidence remains preliminary, it appears that in high risk locations AEDs can dramatically improve the odds of survival from cardiac arrest, with only 6 cardiac arrest victims requiring treatment with an AED in order to save one additional life (42,43,44). The costs of such care are potentially acceptable, with estimates near the $50,000 per-life saved range. The precise methods by which these high-risk locations are evaluated remains an area in need of more research (45,46,47,48).

Based on current data, however, it appears that even with aggressive placement of AEDs in high-risk locations, only 3% (or 9000 of the 300,000 cases in the US each year) of out-of-hospital victims of SCD could be reached with such a strategy. Of those treated, it is anticipated 1 in 6 will survive due to treatment by the AED, resulting in 1500 lives saved per year, or 0.5% of all cardiac arrests in the United States. Even if the remarkable results found by the Level II response is casinos could be duplicated in all "high risk" public areas, 1 in 2 would survive due treatment by the AED, saving 4500 lives per year, or 1.5% of all victims of out-of-hospital SCD. Certainly when the outcome is death, even such small improvements are clinically significant. Indeed, using the accepted $50,000 per QALY, the "justified" costs per year for PAD would be on the order of $75,000,000 (1500 * $50,000) to $225,000,000 (4500 * 50,000). Yet, given available data, claims that PAD is the panacea for SCD must be viewed with skepticism, for only a very small proportion of cardiac arrest victims will be reached by such a strategy.

The North Carolina AED Location Project

There is insufficient evidence to establish an optimal plan for placement of AEDs in the community, and even greater doubt that a substantial proportion of victims would be saved even by the most optimal placement. Nevertheless, there is evidence that for the small proportion of victims treated with publicly placed AEDs, survival rates can be quite high. Indeed, the American Heart Association and other medical groups are advocating purchase and placement of AEDs in many community areas (63, 64). While the evidence is still inconclusive regarding placement for AEDs for use by Level III and Level IV responders, there is considerable evidence supporting the use of AEDs by Level I and Level II response personnel, especially in systems which have optimized other components of their response plan (13,15,16,17,18,25,26).

In North Carolina, the extent to which AEDs are incorporated into any level of response has not been compiled into a database. For example, each county may know which Level I and Level II responders are capable of providing defibrillation, yet from a statewide perspective, these data are not available. Moreover, although state statute requires AEDs placed in the community to be registered with the Office of Emergency Medical Services, lack of penalty for failure to register as well as reluctance on the part of private industry to reveal sales information has rendered this database incomplete (53,66).

The purpose of the North Carolina AED Location Project is to establish a database regarding AED use within the state. Specifically, those areas in the state without Level I and Level II defibrillation-ready response are identified. Additionally, those locations with AEDs placed for Level III and Level IV response are included. In the future, this database will be used to update the Computer Assisted Dispatch (CAD) algorithms at 9-1-1 centers in order to ensure the closest AED is used for out-of-hospital victims of SCD. This database will also be used as a statewide AED registry, with the hopes of providing quality data to guide future placement of AEDs in the community. Finally, this data will also be used to assist with funding applications for future AED research as well as for purchase of additional AEDs. In summary, it is hoped that Level I and Level II AED response will be accomplished statewide and that Level III and Level IV responses will be designed to ensure a maximum benefit for each AED placed.

Methods

The database of AED locations was compiled from four sources. First, the North Carolina Office of EMS list of registered AEDs was obtained via electronic mail and entered into the database (66). Secondly, a list of all vendors that sell AEDs in North Carolina was obtained (67). A sales representative from each vendor was contacted and asked to submit their list of sales for AEDs within North Carolina (53). Once confidentiality of sales information was assured, all vendors submitted sales lists via electronic mail to the research team. Thirdly, all American Heart Association training sites within the state were contacted. This was accomplished by electronic message to the listserv for all American Heart Association (AHA) training sites. The regional coordinator for the AHA training centers approved and circulated the message. Trainers were asked to submit records of training in the use of AEDs placed in private businesses or other possible public locations. Finally, the Emergency Medical Services (EMS) agency for each of the 100 counties in the state was contacted by phone. At the beginning of the phone interview, the research team member asked the individual if they were knowledgeable about AED placement and use in their EMS system. If the individual that answered the phone had such knowledge, the interview proceeded; otherwise, the research team member asked to be transferred to an individual with such knowledge. Data gathered from the EMS agencies included defibrillation capabilities of Level I and Level II responders, level of sophistication of local Computer Assisted Dispatch (CAD), and known locations of AEDs in the local community that might be used by Level III and Level IV responders.

Data were subsequently analyzed in a standard format by one of three members of the research team from September 2001 through June 2002. The North Carolina Office of EMS registry list, sales list data from vendors, and information from AHA training centers was sorted and the location type was characterized as Fire/EMS, Hospital, other Health Care Service (e.g., doctor's office), Government Building (including schools), Private Business, or Private Residence. The sorting was based on address and other contact information provided from these sources. Data from the county EMS agencies were obtained via phone interview through a standard questionnaire (Appendix A). The primary investigator (JBM) was available at all times via email for clarification of any points regarding data gathering during the phone interview process. All data were entered into a Microsoft Excel spreadsheet and duplicate entries were deleted.

Counties with 100% of first tier responders capable of defibrillation were determined to be Level I/Level II compliant. A county in which any first tier response agency did not have an AED or personnel trained in defibrillation with a standard defibrillator were determined to be non-compliant. Counties with Computer Assisted Dispatch, with the capability of providing standardized pre-arrival instructions over the phone via Emergency Medical Dispatch (EMD) protocols, and with more than one individual available in the dispatch center 24 hours a day (to allow one dispatcher to provide EMD instruction while the other dispatched the responding agencies) were determined to be Level III/Level IV prepared. Counties without any one of these three components were determined to be Level III/Level IV unprepared. Any county that had locations of AEDs already included in the Computer Assisted Dispatch were determined to be Level III/IV complaint; all others were considered to be Level III/IV non-compliant. The study was conducted under an approved exemption for human studies from the IRB of the University of North Carolina Hospitals.

Descriptive statistical analysis was performed using the STATA software package (STATA Corporation, College Station, Texas, Version 7.0). Mapping of AED locations was performed with MapPoint 2002 (Microsoft Corp, Seattle, Washington, 2002).

Results

All three AED vendors within North Carolina submitted their sales lists for review. Eleven of fifty-three individuals listed on the AHA training center list responded to the electronic email message. A repeat message yielded no additional responses. All 100 county EMS agencies provided complete information.

Eight hundred eighty-two unique locations with evidence of at least one AED from at least one of the four data sources were found. A summary of the location types is provided in Table C; these data are graphically represented in Appendix B. The preparedness level of counties is summarized in Table D. Given the large number of counties that are unprepared, Table E provides a breakdown of difficulties encountered by counties. A county-by-county list is included in Appendix C.

Several key components of this initial data deserve comment. First, there were no counties that achieved Level III/Level IV compliance. In other words, the location of AEDs in the community is not known to 9-1-1 dispatchers in any county. Secondly, 33% (39/99) of counties do not have an AED on every first tier-response vehicle. Additionally, 45% (45/99) of counties are unable to offer instructions over the phone regarding the use of an AED.

The outstanding preparedness level of one county in particular is not adequately reflected in the data. New Hanover County (in which the city of Wilmington is located) has achieved one of the most complete AED programs in the state. AEDs are located not only on every Level I response unit, they are also found on every Level II responder to include all local law enforcement agencies. Additionally, AEDs are located in every high school and many other public locations in the county, thus incorporating Level III/Level IV preparedness. The CEO of the only hospital system in New Hanover County has extensive EMS experience and it appears that his leadership contributed greatly to such a high level of AED preparedness.

Discussion

Several items from this initial phase of data gathering are worthy of comment. First, it was a surprise to the investigators that so many counties do not have defibrillation capabilities on all first-tier response units. This is especially troubling, given that first-tier rapid defibrillation is a treatment for SCD strongly supported by the literature. Given that the training can be obtained in 4 to 10 hours and that the current price of an AED is less than $3,000, this is certainly an area that deserves prompt attention. Perhaps there are political factors that relate to training or funding restrictions, or perhaps there is a simple lack of accurate information. This is a high priority area for future research and intervention.

Secondly, there is a general lack of coordination in the Level III and Level IV response with AEDs. Not only was the NC Office of EMS database incomplete, a relatively small proportion of county EMS agencies were aware of AED locations within their own county. Given the stress that must be endured by an untrained bystander witnessing a cardiac arrest, we cannot expect these individuals to recall the location of an AED and use it on a consistent basis. For Level III and Level IV response to have a major impact, AED use must be incorporated into all phases of the emergency response. This is particularly true in the area of Emergency Medical Dispatch (EMD). Given the large proportion of counties that are Level III/Level IV unprepared, another area of priority must be the accurate representation of AED locations in the Computer Assisted Dispatch.

Finally, the degree to which AEDs have been located in private businesses was noteworthy. In most (if not all) of these circumstances, these AEDs were placed on the direction of businesses or sales representatives from the AED manufacturers. There is no evidence that EMS Medical Directors or other public health officials have been involved in these decisions to any extent. Given the lack of data to guide placement decisions, this likely has not resulted in any significant misplacement that could have been avoided by medical direction. As the evidence becomes stronger, however, medical direction will be a necessary component of an AED placement program. A third priority area relating to AED use involves active participation by local EMS Medical Directors.

The results of this study offer the first statewide database for the location of AEDs in North Carolina. There are weaknesses, however, that must be considered. First, only a small proportion of AHA training centers responded to the survey. In private conversation, several instructors stated they simply had not taught any Level III responders and did not respond for that reason. This is obviously anecdotal and does not substitute for a higher response. Second, it has taken over 10 months to gather all of the data, so some of the sales data may be outdated. Third, due to the methods by which the data were compiled, it is not possible to determine the source of duplicate entries (e.g., one site is listed twice because it was both on a sales list and from a EMS agency list versus the vendor simply listed the device twice twice). Fourth, the accuracy of the data has yet to be verified (see below).

Future directions

The next phase of the North Carolina AED location project is already underway. In this phase, each of the unique address locations will be contacted via telephone to confirm the location of the AED as well as gather other pertinent information necessary to incorporate the AED into Computer Assisted Dispatch. The questionnaire for this process has already been pilot tested for ten locations; the questionnaire is include in Appendix D.

Subsequently, two avenues of action will be pursued. First, a mechanism for evaluating the AEDs placed in the community will be employed. It is hoped victims of out-of-hospital SCD treated by Level III and Level IV responders can be compared with contemporaneous controls from a geographically similar location. It will be necessary to match cases and controls in such a nested fashion, as the time required to collect a sufficient sample size will likely be on the order of several years, thus eliminating the possibility of using historical controls. Indeed, even if AEDs demonstrated a 20% improvement in survival over another treatment strategy, 72 out-of-hospital SCDs would be needed in each group to demonstrate a statistically significant result (alpha 0.05, power 0.80); a more modest improvement of 5% with AED use increases this sample size to 726 in each group. Given the lack of information to predict this relative improvement with any precision, it is assumed a large sample size will be required.

It is also hoped that this data will be useful in the direct care of patients. Not only will the AED location information be helpful during an actual out-of-hospital SCD, but also communities that need improvements in their Level I and Level II response capabilities can use this data to gain political and financial support. In the past several weeks, the Community Access to Defibrillation Act of 2002 passed both houses of Congress and was signed into law by President

Bush. Over twenty million dollars for the purchase and placement of AEDs is provided by this federal legislation (68). It is hoped the data obtain from this study will be useful in determining optimum use of resources provided by this Act.

Conclusion

The North Carolina AED Location Project represents an important first step in accumulating evidence that may guide placement of AEDs in the community. Immediate benefits from use of this data include improved direct patient care via the incorporation of AEDs in an overall Emergency Response Plan directed by Computer Assisted Dispatch. Additionally, communities may use this information to improve their first-tier response capabilities where appropriate. Future projects will assist with verification of location information as well as with gathering data to guide future AED placement decisions.

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TABLES

Table A – Summary of Literature Review

Author(s) (ref #)	Year	Study-type	Results[1]
Eisenberg et al (11)	1989	Case-control	Paramedic treatment was superior to EMT treatment regarding both survival to hospital admission (34% vs 19%) and hospital discharge (17% vs 7%)
Eisenberg et al (12)	1980	Case-control	Paramedic treatment was superior to EMT treatment regarding discharge alive from the hospital (22% vs 6%)
Eisenberg et al (13)	1980	Case-control	EMT defibrillation treatment was superior to CPR alone regarding survival to hospital discharge for patients with VF/VT (26% vs 7%)
Martin et al (14) (abstract only)	1986	Retrospective	Defibrillation prior to airway management or drug therapy was superior to airway management or drug therapy prior to defibrillation regarding long term survival (12.3% vs 3.6%)
Eisenberg et al (15)	1984	Prospective RCT with pseudorandomization	First-tier defibrillation was superior to first-tier CPR only for witnessed VF arrests in victims receiving CPR when the interval from first-tier response to second-tier (paramedic) response was > 4 minutes with regard to survival to hospital discharge (38% vs 18%)
Stults et al (16)	1984	Case-control	In rural areas, proportion of survivors to hospital discharge for patients found in VF/VY by first responders is greater for those receiving defibrillation vs those receiving CPR alone (19% vs 3%)
Cummins et al (17)	1987	Prospective RCT with pseudorandomization	No difference in outcomes comparing standard defibrillator with EMT interpretation vs AED with automated interpretation in treatment of SCD
Weaver et al (18)	1986	Case series	Victims treated with AEDs demonstrated a 33% survival to hospital discharge

[1] All results are significant to at least the $p<0.05$ level unless otherwise stated

Table A – Summary of Literature Review (continued)

Author(s) (ref #)	Year	Study-type	Results[2]
Mols et al (19)	1994	Case-control with historical controls	Treatment with AEDs vs CPR only increased the percentage of victims of SCD surviving to hospital admission from 7% to 19%
Weaver et al (20)	1988	Prospective observational study	Use of AEDs in first-tier response increased the odds of survival to hospital discharge (OR 1.8, 95% CI 1.1 to 2.9)
Olson et al (21)	1989	Case-control with historical controls	Use of AEDS vs CPR alone increased the proportion of survivors to hospital discharge from 3.6% to 6.4%
Stapczynski et al (22)	1995	Prospective observational study	Use of AEDs resulted in a survival to discharge proportion of 11% for victims of SCD in VF/VT
Bachman et al (23)	1986	Prospective observational study	Used of AEDs increased the proportion of survivors to hospital admission but not to hospital discharge
Kellerman et al (24)	1993	RCT with Pseudorandomization	No difference in survival for AED vs CPR-only treatment
Sweeney et al (25)	1998	RCT with Pseudorandomization	No difference in survival for AED vs CPR-only treatment
Walters et al (26)	1990	RCT with Pseudorandomization	No difference in survival for AED vs CPR-only treatment (sample size insufficient)
Stiell et al (36)	1999	Case-control with historical controls	Improving timeliness of response (from 76.7% arriving in less than 8 minutes to 92.5% arriving in less than 8 minutes) improved survival to hospital discharge from 3.9% to 5.2%
Becker et al (37)	1991	Prospective observational study	Overall survival to hospital discharge in Chicago for all victims of out-of-hospital SCD 2%
Lombardi et al (38)	1994	Prospective observational study	Overall survival to hospital discharge in New York City for all victims is 1.4%; 5.3% for victims initially in VF/VT

[2] All results are significant to at least the $p<0.05$ level unless otherwise stated

Table A – Summary of Literature Review (continued)

Author(s) (ref #)	Year	Study-type	Results[3]
O'Rourke et al (42)	1997	Prospective observational study	AED use by trained flight personnel resulted in 91% initial resuscitation rate for victims of SCD on airplanes and in terminals; 26% of these victims were discharged home alive
Page et al (43)	2000	Prospective observational study	AED use by trained flight personnel resulted resulted in 100% initial resuscitation rate for victims of SCD on airplanes with a 40% survival rate of survival to discharge from the hospital
Valenzuela et al (44)	2000	Prospective observational study	AED use by trained security guards in casinos resulted in an overall survival to discharge rate of 53% for victims of out-of-hospital SCD; 74% of victims defibrillated in less than 3 minutes survived (49% of those defibrillated after 3 minutes)

[3] All results are significant to at least the $p<0.05$ level unless otherwise stated

Table B – Summary of Meta-analyses

Author(s) (ref #)	Year	Conclusions
Auble et al (32)	1995	BLS defibrillation risk of death was 0.915 (p=0.003) as compared with BLS without defibrillation for out-of-hospital SCD victims
Watts DD (33)	1995	Victims of out-of-hospital SCD treated with EMT defibrillation were 9.2% more likely to survive to hospital discharge as compared with those treated by EMTs without defibrillation
Nichol et al (34)	1999	Victims of SCD defibrillated in less than 6 minutes had no difference in proportion of survivors; each minute from 6 to 11 minutes resulted in a decreased probability of survival; no benefit of defibrillation was noted after 11 minutes. BLS-defibrillation backed by ALS response demonstrated an OR of survival to hospital discharge of 2.31 (95% CI 1.47 to 3.62) as compared with BLS-defibrillation alone
Nichol et al (35)	1996	Survival to hospital discharge was 5.2% for single-tier response vs 10.5% for two-tier response. Each one minute decrease in response resulted in a 0.4% and 0.7% increase in survival to discharge for single-tier and two-tier response, respectively

TABLE C – AED Locations by Type

Location Type	Number	Percent of Total
Pvt Business	336	38%
Fire/EMS	282	32%
Health Service	109	12%
Gov't Bldg	63	7%
Hospital	37	4%
Private home	35	4%
Other	15	2%
Police Dept	5	1%
TOTAL	**882**	**100%**

Table D – County Characteristics

Characteristic	% Complaint or prepared	% Noncompliant or unprepared
Level I/Level II	61	37
Level III/Level IV Prepared	33	67

Table E – Preparedness Needs for Counties

Reason Not Prepared	# of counties
No EMD Instructions Available	45
Lack of AEDs on all first-tier response agencies	37
9-1-1 staffing < 2 dispatchers	26

APPENDIX A: Sample Phone Questionnaire for County EMS Agencies

County ______________________
Contact #1 ______________________
Contact #2 ______________________

Call back info ______________________

Questionnaire for County EMS Offices:

1) Which agencies, if any, in your county carry Automatic External Defibrillators?

____ BLS Ambulance
____ ALS Ambulance
____ Paid Fire Dept. First Responders
____ Volunteer Fire Dept. First Responders
____ City/Town Police
____ Sheriff/County Law Enforcement
____ Other (please specify: ______________)
____ No agencies carry AEDs

2) Does your county dispatch first responders with AEDs on 9-1-1 calls?

YES ("Which agency is dispatched?" ______________________)
NO

3) Which department operates your 9-1-1 dispatch center?

___ Fire
___ EMS
___ Law Enforcement
___ Independent dispatch center activates all agencies
___ Other Agency (specify)
___ There is a central call receiving center that "routes" calls to each agency for dispatch

4) Do the dispatchers responsible for dispatching medical emergencies do the following?

___ Provide instructions to callers (e.g., choking, CPR) with a pre-determined set of instructions (e.g., EMD)
___ Provide instructions to callers (e.g., choking, CPR) without a pre-determined set of instructions
___ Dispatch resources "hot" or "cold" (lights and sirens vs no lights and sirens) based on a pre-determined set of criteria

___ Have CAD or similar device that displays caller address, phone, etc.
___ Have CAD (or similar device) display information such as nearest fire hydrant, etc.
___ Have pre-determined instructions for assisting callers with CPR
___ Have pre-determined instructions for assisting callers with the use of an AED

5) Are there at least two employees available to assist with dispatching high-priority (e.g., cardiac arrest) medical calls? In other words, can instructions be provided to the caller by one individual while resources are dispatched by another?

___ Yes, 24 hours a day
___ Yes, <24 but >12 hours a day
___ Yes, <12 but > 0 hours a day
___ No, there is only one call-taker/dispatcher for medical emergencies on a 24-hour basis

6) Have any AEDs located in public places or private homes/businesses (that is, any location not associated with fire/police/EMS) been registered with you or your medical director?

YES (follow script below)   NO (proceed to question #7)

"The Department of Emergency Medicine at UNC Chapel Hill in conjunction with the American Heart Association and the North Carolina College of Emergency Physicians is conducting a multi-phase study to improve the use of AEDs in North Carolina. We are currently completing the final part of the first phase that involves locating as many AEDs within the state as possible. Manufacturers of AEDs and training centers have submitted their lists to the research team; we are now calling every county in the state to make certain as many AEDs as possible are located. Once all of the data has been gathered, each county will be notified of the known locations of AEDs in their county. Could you fax the information for any "public" AEDs to us. Please be assured that this information will be used for study purposes only."

FAX Number: 919-966-3049   email: bmyers@unc.edu

If asked,

"The second phase of the trial involves contacting all public/private owners of AEDs to determine their training/maintenance preparedness as well as to invite them to join in the third phase of the study (next question)."

7) "The third phase of the study involves incorporation of AED use into dispatch protocols. The details are still being determined, but in essence we hope to

achieve the following. First, the location of each AED within the county will be added to the CAD (Computer Automated Dispatch) such that the "nearest AED" is displayed, just as the "nearest fire hydrant" is currently displayed in many dispatch centers. Second, part of EMD will include instructions for callers to obtain the nearest AED (when appropriate). Third, instructions will be provided for the caller for AED use. This phase of the study is still in the planning stages; once we enter into this phase of the study, may we re-contact you to tell you more about it?"

YES NO Needs additional information

APPENDIX B: Mapping of AED Locations by Type

Summary Data for Appendix B

Title[4]	Page	Total #[5]	City/County[6]	ZIP[7]
Private Business	B-1	336	14	28
Health Services	B-2	109	0	13
Government Buildings	B-3	63	0	4
Hospitals	B-4	37	3	2
Private Homes	B-5	35	1	7
Other	B-6	15	0	1
Police	B-7	5	0	0

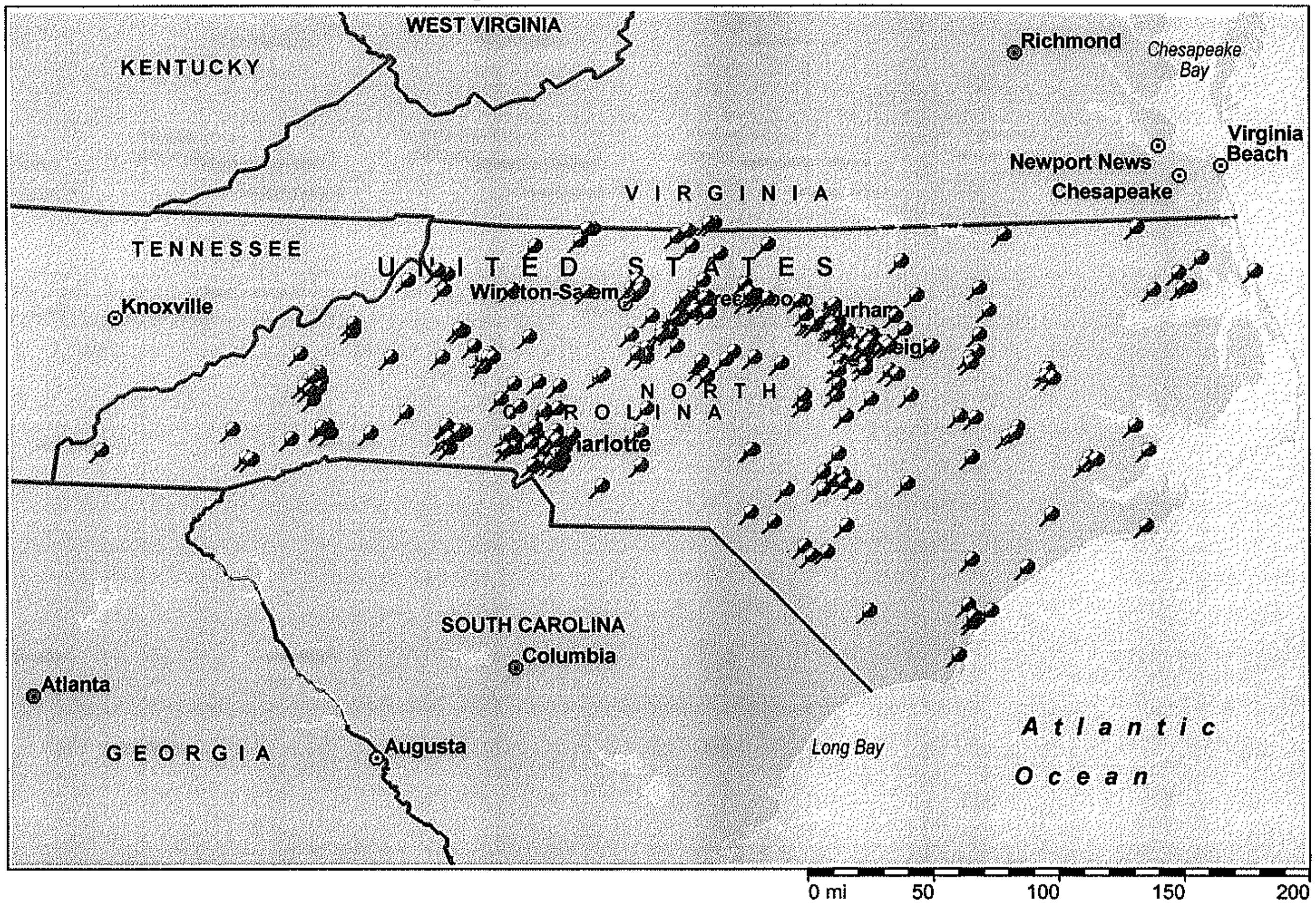
[4] The title of the map corresponds to the location type described in the text

[5] This represents the total number of AEDs mapped for a particular category. The total number mapped to an exact street address can be determined by subtracting the "city/county" and the "zip" columns from the "total" column

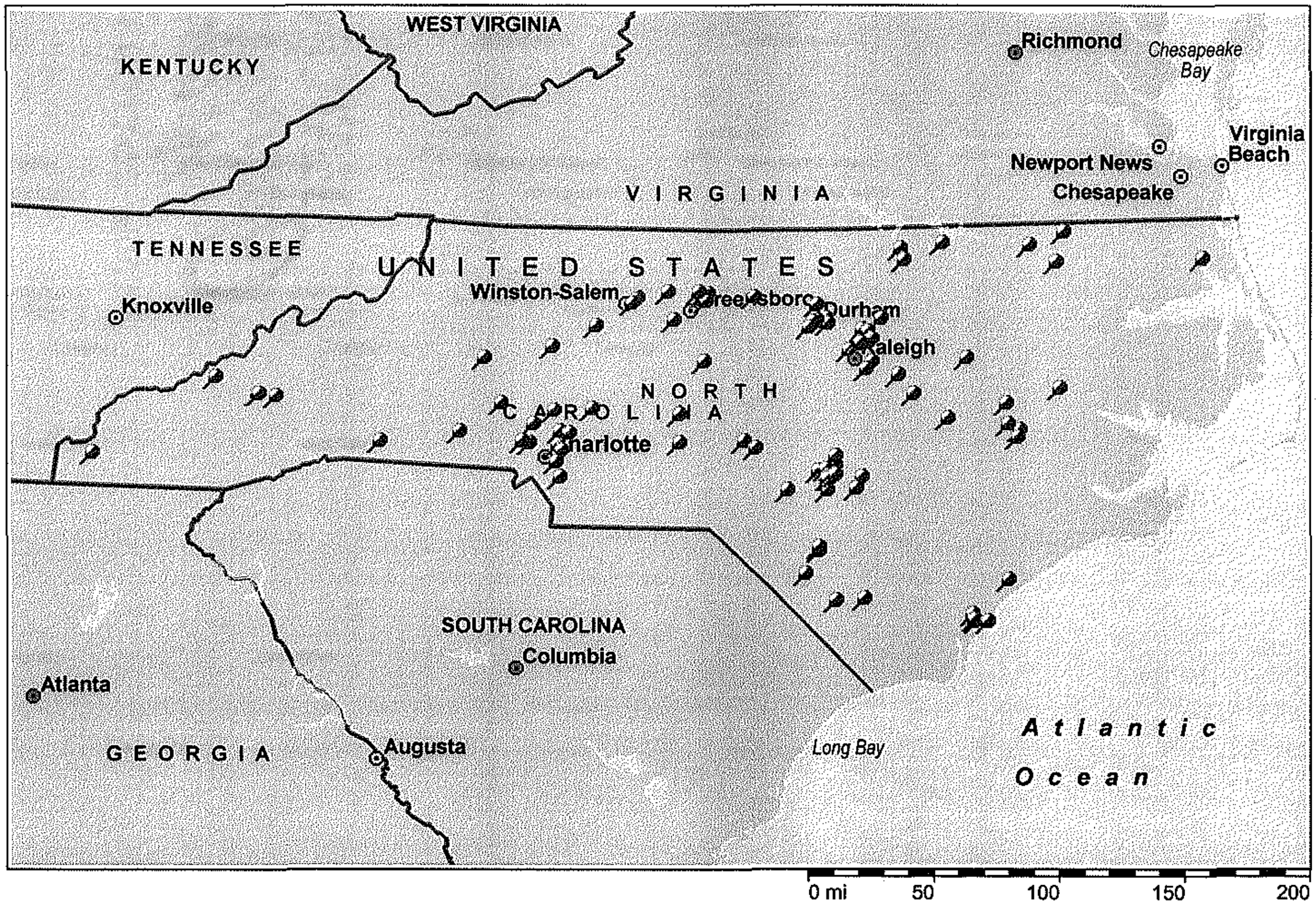
[6] Where exact street address information did not match MapPoint database, the city or county in which the AED was located was substituted on the map

[7] Where exact street address information did not match MapPoint database, the ZIP code in which the AED was located was substituted on the map

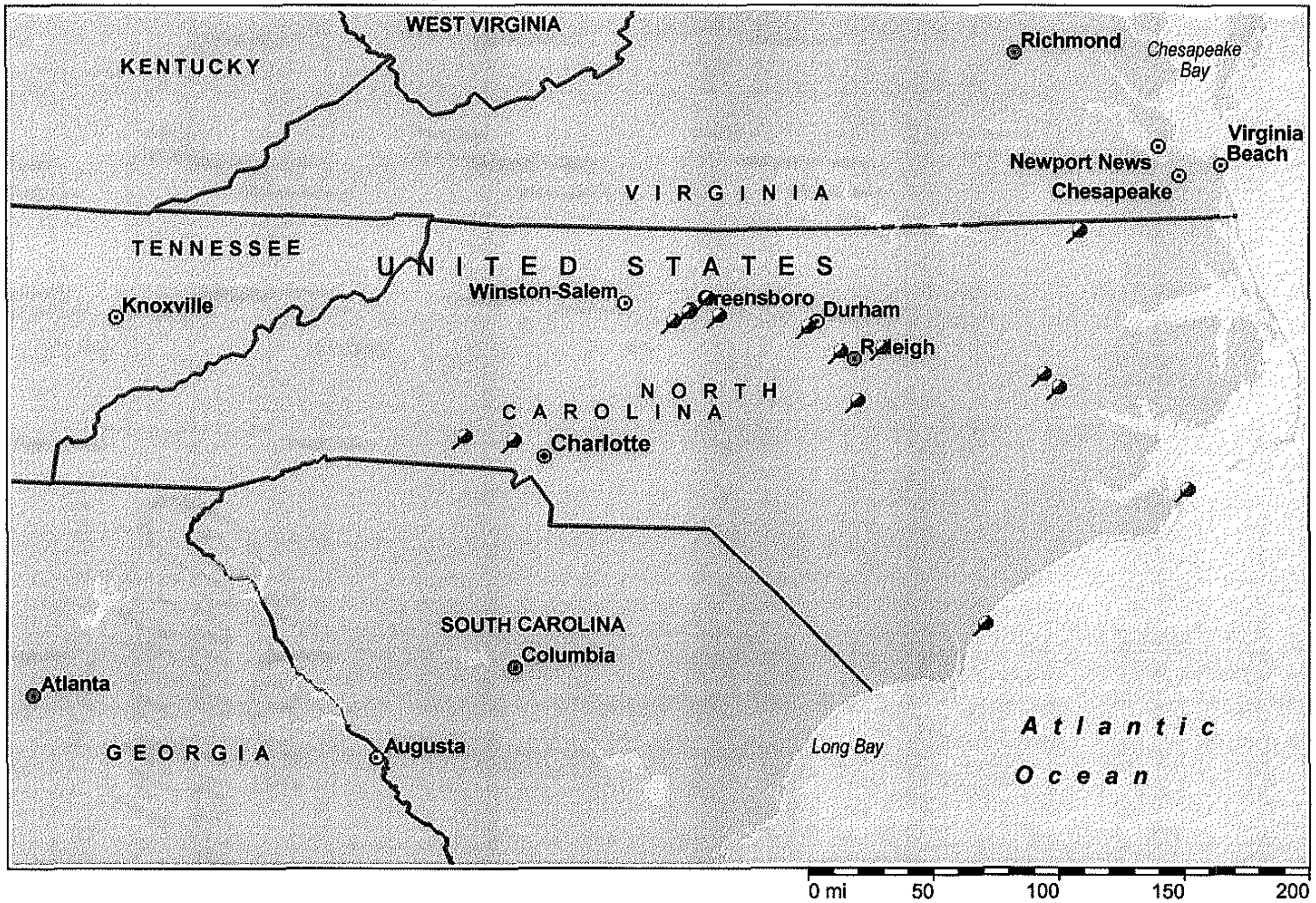
Page B-1 Private Business



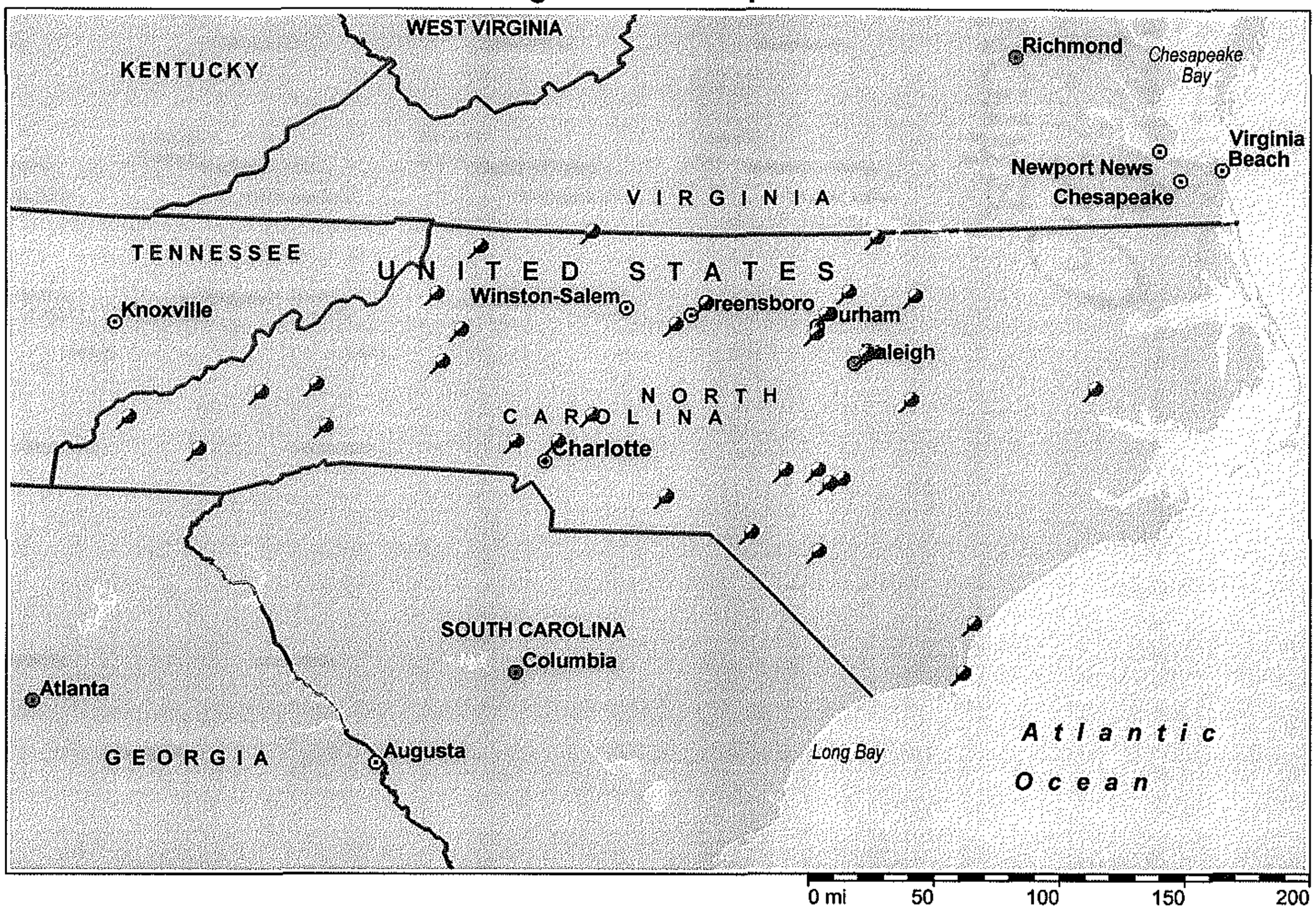
Page B-2 Health Services



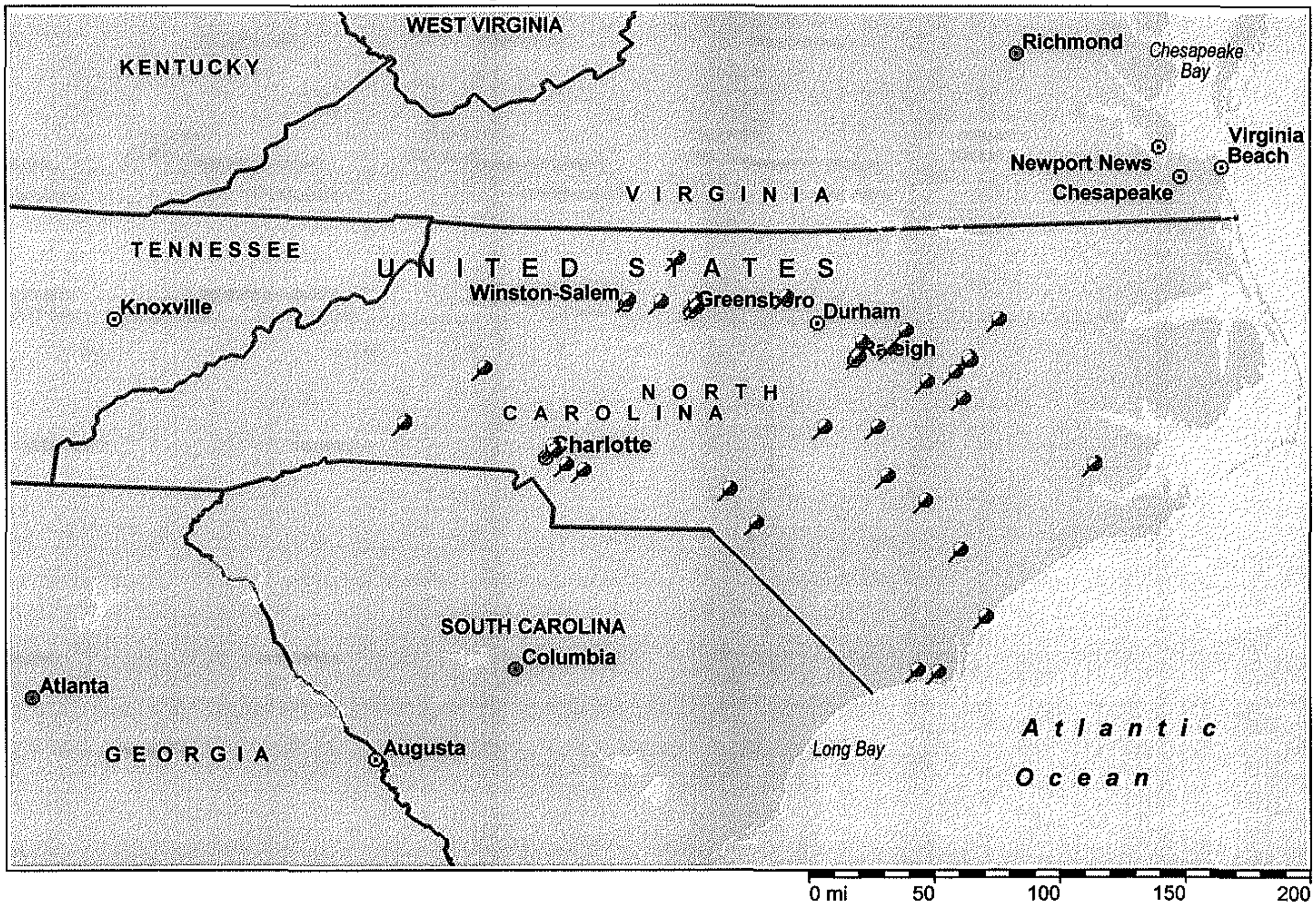
Page B-3 Government Buildings



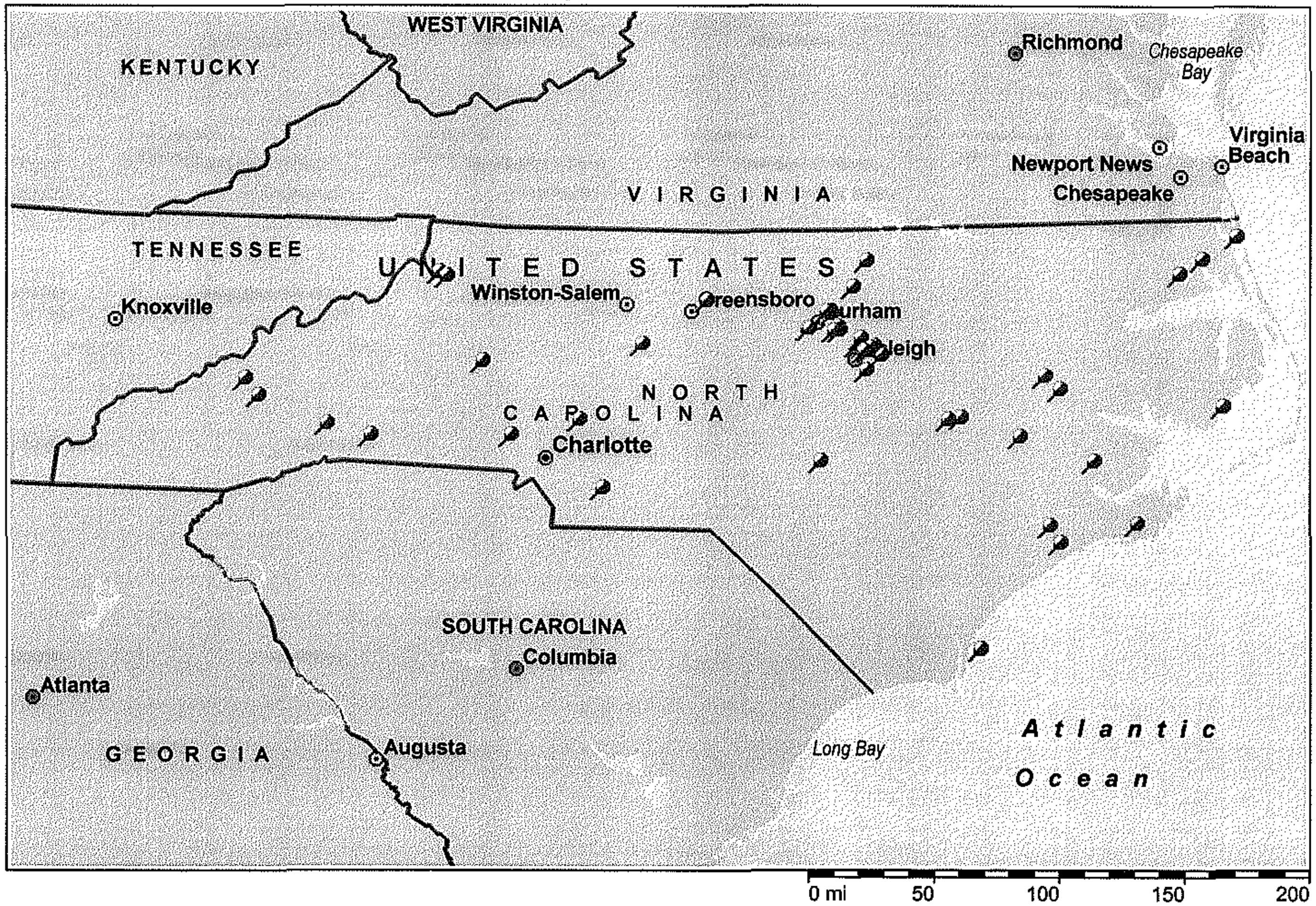
Page B-4 Hospitals



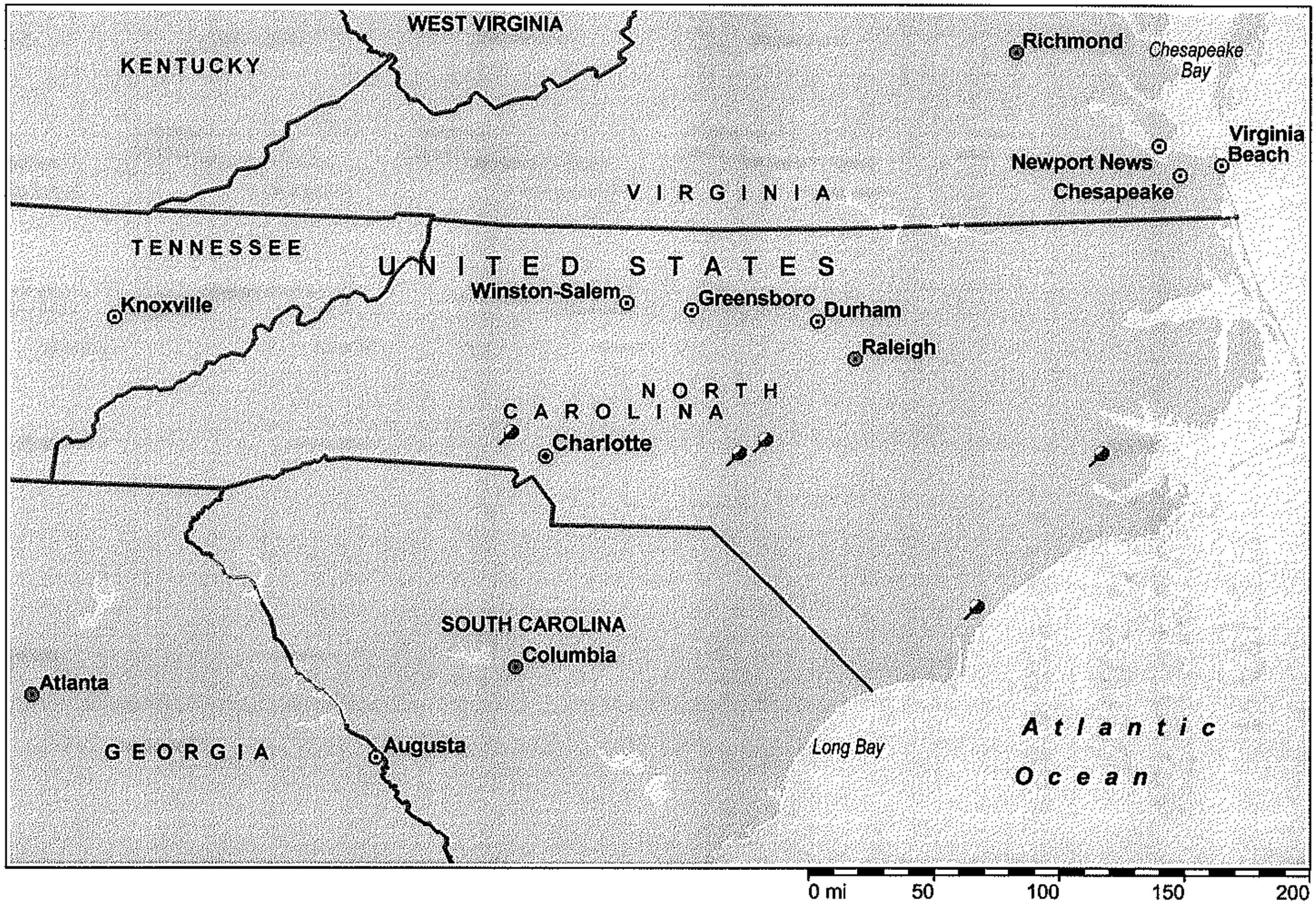
Page B-5 Private Homes



Page B-6 Other



Page B-7   Police



APPENDIX C: County Listing of Key Preparedness Characteristics

County	AED on All 1st Responding Units	Provide Emergency Instructions Over the Phone
Alamance	No	Yes
Alexander	Yes	Yes
Alleghany	No	No
Anson	No	No
Ashe	No	No
Avery	Yes	No
Beaufort	Yes	No
Bertie	Yes	No
Bladen	Yes	Yes
Brunswick	Yes	Yes
Buncombe	Yes	Yes
Burke	Yes	Yes
Cabarrus	Yes	Yes
Caldwell	Yes	No
Camden	No	Yes
Carteret	Yes	No
Caswell	No	No
Catawba	Yes	Yes
Chatham	Yes	Yes
Cherokee	No	No
Chowan	No	No
Clay	No	No
Cleveland	Yes	Yes
Columbus	Yes	Yes
Craven	Yes	No
Cumberland	Yes	Yes
Currituck	No	No
Dare	Yes	No
Davidson	Yes	Yes
Davie	Yes	Yes
Duplin	Yes	No
Durham	Yes	No
Edgecombe	Yes	Yes
Forsyth	Yes	Yes
Franklin	Yes	Yes
Gaston	No	Yes
Gates	Yes	Yes
Graham	Yes	Yes
Granville	No	No
Greene	No	No
Guilford	Yes	Yes
Halifax	Yes	Yes
Harnett	No	Yes
Haywood	Yes	Yes
Henderson	Yes	Yes
Hertford	No	No
Hoke	No	No
Hyde	No	No
Iredell	Yes	Yes

County	AED on All 1st Responding Units	Provide Emergency Instructions Over the Phone
Jackson	Yes	Yes
Johnston	Yes	Yes
Jones	No	No
Lee	No	No
Lenoir	No	Yes
Lincoln	Yes	No
Macon	Yes	Yes
Madison	Yes	No
Martin	No	No
McDowell	Yes	Yes
Mecklenburg	Yes	Yes
Mitchell	No	Yes
Montgomery	No	No
Moore	No	Yes
Nash	No	Yes
New Hanover	Yes	Yes
Northampton	No	No
Onslow	Yes	Yes
Orange	No	Yes
Pamlico	No	No
Pasquotank	No	Yes
Pender	No	No
Perquimans	No	No
Person	Yes	No
Pitt	No	Yes
Polk	Yes	No
Randolph	No	Yes
Richmond	Yes	Yes
Robeson	Yes	Yes
Rockingham	Yes	No
Rowan	Yes	Yes
Rutherford	Yes	No
Sampson	Yes	Yes
Scotland	Yes	Yes
Stanly	Yes	Yes
Stokes	Yes	No
Surry	Yes	Yes
Swain	Yes	Yes
Transylvania	Yes	No
Tyrrell	No	No
Union	Yes	Yes
Vance	Yes	No
Wake	Yes	Yes
Warren	Yes	No
Washington	No	No
Watuga	No	Yes
Wayne	No	No
Wilkes	No	No
Wilson	Yes	Yes

County	AED on All 1st Responding Units	Provide Emergency Instructions Over the Phone
Yadkin	Yes	No
Yancey	Yes	No

APPENDIX D: Field-tested Phone Questionnaire for Owners of AEDs

LOCATION:
PHONE NUMBER:

Questionnaire for Owner's of AEDs

Good morning/afternoon. I am calling from the American Heart Association on behalf of the North Carolina AED Location project. Our records indicate there is an AED (Automated External Defibrillator) at your location. May I speak with the individual responsible for your AED? (If the call-taker does not know to whom you should be referred, say: "In many instances, the individual responsible for the AED may be the safety officer, the person in charge of first aid, or anyone responsible for medical care.")

Once you have reached the appropriate individual:

Good morning/afternoon. I am calling from the American Heart Association on behalf of the North Carolina AED Location project. Our records indicate there is an AED (Automated External Defibrillator) at your location. I have some simple questions regarding the training, maintenance, and placement of your AED. Are you familiar with the basic facts about your AED? (If yes, proceed – if no, return to list above for additional referral).

I have some basic contact information-type questions first.

1) What is the name and position of the contact person with responsibility for your AED Program?

2) How many AEDs are on site?

3) What is the address of the building in which the AED is actually located?

4) Please provide directions to the actual location of the AED from the front entrance of your building. In other words, assume the person looking for your AED has not been in the building before.

I have some training and maintenance-type questions now:

5) Are there individuals at your location that have undergone formal training in the use of the AED? (if no, go to question 6)

6) Is there at least one individual trained in the use of the AED in your location during all hours that the building is occupied (e.g., during business hours for a factory, etc.)?

7) In the event of an emergency requiring the AED, how are responders notified (e.g., is there an internal emergency phone number, intercom, etc.)?

8) In the event on an emergency requiring the AED, who is responsible for contacting 9-1-1?

9) If the 9-1-1 center were to be notified of an emergency at your location requiring the use of an AED, is there a number to call to activate the AED "response team"? If so, what is that number?

10) How often are refresher training classes scheduled?

11) How often is the AED tested to ensure it is operational?

Finally, I have some general questions?

12) If you know, what lead to the decision to purchase the AED in the first place (e.g., an emergency at your location, public pressure, OSHA recommendation, etc.)?

13) How many times has your AED been used in an emergency? If you know, has it ever delivered a shock?

14) Which of the following best characterizes your location?

- ____ Large business (> 50 employees)
- ____ Small business (< 50 employees)
- ____ Retail business (e.g., WalMart, other shop/store)
- ____ Sporting facility (Golf course, gym, etc.)
- ____ Government Bldg (e.g., Court house, etc.) JAIL.
- ____ School
- ____ Religious Blg (church, mosque, etc.)
- ____ Other (____________________)

15) Finally, does your business operate in other locations in North Carolina that might have an AED? If so, how can I contact them?

In the final stages of our project, we hope to provide 9-1-1 centers with locations of AEDs in their response districts. If legal liability were not a concern, would you or your business be willing to allow use of your AED to assist a patient in a near-by location? In other words, if someone next door needed the AED and there were a method by which you could be notified, could the AED be used in that situation? (If the individual is not authorized to make this decision, please attempt to determine how to contact the person that is authorized to make the decision).

Thank you so much for your help. Have a great day.