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Summary/Key Points:

1. Sudden cardiac arrest (SCA) kills more than 350,000 American per year, twice the number of those who die from breast cancer, lung cancer, and HIV/AIDS combined.

2. The key to survival is early treatment with an automated external defibrillator (AED). Every minute in delay to defibrillation results in a 7-10% decline in survival.

3. Survival rates for SCA are poor, varying regionally in the United States from 3.0% to 16.3%.

4. All 50 states and the District of Columbia have passed legislation concerning regulations for deploying AEDs and liability protections for AED owners and Good Samaritan rescuers. Unfortunately, the enacted AED laws differ from state-to-state creating a diverse patchwork of legislation that has produced an air of liability uncertainty for businesses wishing to deploy AEDs.

5. HR 4152 (The Cardiac Arrest Survival Act of 2015) will create a nationally uniform baseline of protection from civil liability for persons who use AEDs in perceived medical emergencies, who own or hold other property interests in AEDs, or who own, occupy, or manage premises in which an AED is used or from which an AED is taken for use in a perceived medical emergency.

6. Reducing the current uncertainty surrounding AED acquisition and use will encourage the deployment of additional AEDs, which will ultimately save lives that would otherwise have been lost to cardiac arrest.

Every year in the United States more than 350,000 people will die as a result of sudden cardiac arrest (SCA). The annual death toll from sudden cardiac arrest is about twice the number of those who die from breast cancer, lung cancer, and HIV/AIDS combined. Sudden cardiac arrest is a supremely lethal event that results in the death of 90% of those it afflicts.

Despite the manifold advances in cardiovascular medicine over the past 2 decades, survival from out-of-hospital SCA remains unlikely varying regionally in the United States from 3.0% to16.3%.[1] In 1991, in an effort to improve SCA outcomes, the American Heart Association introduced the "chain of survival" concept stressing 4 "links"; early activation of emergency medical services (EMS), early cardiopulmonary resuscitation (CPR), early defibrillation, and early advanced cardiovascular care.[2] The most crucial of these links appears to be prompt defibrillation. Every minute in delay to defibrillation results in a 7-10% decline in survival.[3] Although CPR can attenuate the severe survival penalty resulting from defibrillation delays, most patients with SCA do not receive bystander CPR prior to EMS arrival. In Gallagher's report of 2071 consecutive out of hospital cardiac arrests in New York, upon EMS arrival, only 32% of patients were receiving bystander CPR[4]. Survival for patients who were not receiving CPR was a near futile 0.8%, while those who did receive bystander CPR fared minimally better with a survival rate of only 2.9%.

In 1994 The American Heart Association's Public Access Defibrillation Conference noted that making AEDs more widely available should significantly improve SCA survival and recommended clinical trials to further evaluate AED use by first responders and the lay public.[5] Multiple studies followed, with a variety of responders

and venues, including Nevada casinos[6], commercial aircraft[7], community units[8], police cars[9, 10], and Chicago airports[11]. These experiences consistently demonstrated the positive impact on survival of early defibrillation using trained and untrained non-medical responders. In 2005 an advisory statement from the American Heart Association noted that lay rescuer AED programs will be most cost effective if they are instituted at high-density sites where at least 1 witnessed SCA is likely to occur every few years.[12] Data from Copenhagen refined this concept and suggested that a high proportion of cardiac arrests in public can be covered by strategic placement of AEDs in areas with the highest rates of cardiac arrest such as large shopping centers, train stations, high-density public areas, central bus terminals, and sports centers[13].

In 2006 the American Heart Association's Emergency Cardiovascular Care Committee, Council on Clinical Cardiology, and Office of State Advocacy noted that variations in state and federal legislation and regulations complicated efforts to promote lay rescuer AED programs[14]. Thirty-five states currently require the registration of AEDs with local authorities, a process that is different in each state and may be quite cumbersome. In New York[15], for example, to institute a public access defibrillation (PAD) program one must:

1. Identify a physician or hospital knowledgeable and experienced in emergency cardiac care to serve as "emergency health care provider" and participate in a collaborative agreement.

2. Develop a written collaborative agreement which includes written practice protocols for the use of the AED as well as written policies and procedures.

3. File with the Regional Emergency Medical Services Council serving the area a

copy of the "Notice of Intent to Provide PAD" along with a signed copy of the Collaborative Agreement.

4. Select and implement an approved PAD training course for AED users.

5. Provide written notice to 911 of the availability of AED service at the organization's location.

Although most states permit any rescuer to use an AED, 7 states still prohibit AED use by untrained operators. New York Law states: "No person may operate an AED unless the person has successfully completed a training course in the operation of an AED approved by a nationally-recognized organization or the state emergency medical services council."[15] Consequently, signage at AEDs in New York airports include the warning, "for emergency use by trained rescuers only". In contrast, in Virginia there is no specific training requirement and signage on AEDs in Virginia public places do not warn against use by novice rescuers.[16] The prohibition of the use of an AED by an untrained operator seems to suggest that it is preferable to wait for EMS arrival (which on average will take more than 7 minutes[1]) than it is to have a true first responder attempt defibrillation. In reality, AEDs are designed for effective and expeditious use by individuals with no prior medical experience. As the name implies, these devices are "automated", feature audio prompts, and require little more than the placement of 2 adhesive patches on an exposed chest. Rhythm analysis algorithms determine whether a shock is appropriate and will not allow delivery of a shock to a patient with a "non-shockable" rhythm. The intuitive nature of these devices was highlighted in a study comparing the performance of 15 AED naïve 6th grade children to 22 emergency medical technicians and paramedics using a mock cardiac arrest scenario[17].

In this study, the children placed the electrode patches correctly on all subjects and all operators remained clear of the "patient" during shock delivery. The children achieved a mean time to defibrillation of 90 seconds, only 23 seconds slower than the mean time achieved by the trained professionals. Data from the Resuscitation Outcomes Consortium, demonstrates the dramatic advantage in survival when an AED shock is delivered by a bystander.[18] In this study of 9867 patients with out of hospital cardiac arrest 249 (2.5%) had an AED placed by a bystander. Survival was 8% with bystander CPR but no AED, 33% when a shock was delivered by a bystander applied AED, and 15% with an EMS delivered shock.

Forty states and the District of Columbia require oversight of an AED program by a licensed physician. In New Jersey, oversight may be provided by any licensed physician[19], whereas in New York State, program monitoring must be provided by a physician or hospital knowledgeable and experienced in emergency cardiac care[15]. South Carolina allows program oversight by a physician, physician's assistant, nurse practitioner, or nurse[20]. Ten states have no requirement for program monitoring. The rationale for physician monitoring is, as Louisiana law states, "to ensure compliance with the requirements for training, emergency medical service notification, and maintenance".[21]

Although all 50 states and the District of Columbia have enacted some form of Good Samaritan protection for AED responders, these laws differ as to who, in particular, is eligible for liability protection. Nineteen states provide liability protection only to AED users who have been trained by a sanctioned organization. In Kansas, for instance, "any qualified person who gratuitously and in good faith renders emergency care or treatment

by the use of or provision of an AED shall not be held liable for any civil damages as a result of such care or treatment..."[22] The law defines a "qualified" person as one who received training or has demonstrated proficiency in the use of an AED. Thirty-two states and the District of Columbia offer Good Samaritan protection to all AED users. In Illinois only trained AED users are protected from civil damages arising out of the use of an AED but all entities providing the AED are protected from liability[23].

Federal laws addressing Good Samaritan AED protections have been limited. In 1998 President Clinton signed the Aviation Medical Assistance Act which directed the Federal Aviation Administration to determine whether AEDs should be mandated on passenger aircraft and established liability limitations to encourage air carriers and qualified passengers to provide in-flight assistance during medical emergencies.[24] This law did not provide liability protection for airlines deploying AEDs other than to shield the airline from any potential liability arising from the assistance of a passenger during an in-flight medical emergency. In 2000 Congress passed the Cardiac Arrest Survival Act which, in theory, provided Good Samaritan protection to both the users and acquirers of AEDs for damages occurring as a result of the emergency use of an AED in a public setting[25]. This federal law applied only to states without existing Good Samaritan AED protections and explicitly did not preempt existing state law. In practice, as all 50 states have enacted some form of Good Samaritan AED provision this federal statute adds no additional protection.

Collectively the varied state laws create a series of bureaucratic hurdles that must be crossed before an AED program can commence. While individual state laws make the process of instituting a single AED program cumbersome, state-to-state regulatory

heterogeneity creates a complex environment for national corporations considering enterprise-wide AED programs. Perhaps most importantly, state-to-state differences in Good Samaritan laws create an air of liability uncertainty for prospective AED providers and responders. The experience in the US hotel industry with more than 49,000 properties, 4.6 million guestrooms and 1.8 million workers, which has largely not pursued AED deployment, is illustrative. The American Hotel and Lodging Association has noted several issues with respect to widespread implementation of defibrillators in U.S. hotels, including "liability concerns for both individuals and businesses in the absence of strong national Good Samaritan protections"[26]. The Wall Street Journal noting that hotels around the United States have been reluctant to deploy defibrillators also raised the industry's concern about Good Samaritan protections and described the liability concerns "as the 'no good deed goes unpunished' exposure."[27] A representative for the hotel association was quoted as stating, "none of those arguments could be made if you had no AED at all." The hotel industry is far from alone in it its ambivalence toward AED technology. American retail stores have been similarly reluctant to deploy defibrillators. For example, a customer can purchase an AED from Walmart for $1,235 however, should that same customer experience a sudden cardiac arrest while shopping in the store, defibrillation will have to wait until the paramedics arrive.

To facilitate the placement of AEDs in public places across the United States and assuage concerns regarding liability risk there must be an unambiguous, nation-wide baseline of liability protections. To achieve this goal Congress should pass HR 4152, the Cardiac Arrest Survival Act of 2015. The bill will create a nationally uniform baseline of protection from civil liability for persons who use AEDs in perceived medical

emergencies, who own or hold other property interests in AEDs, or who own, occupy, or manage premises in which an AED is used or from which an AED is taken for use in a perceived medical emergency. Reducing the current uncertainty surrounding AED acquisition and use will encourage the deployment of additional AEDs, which will ultimately save lives that would otherwise have been lost to cardiac arrest.

Conclusions

Uncertainty regarding liability exposure is the unintended consequence of the current menagerie of state laws governing AED deployment and liability protection. The result is a virtual speed brake on the dissemination of this now mature technology. The current legislative melange of state AED provisions impedes the deployment of this simple, irreplaceable, decades-proven, therapy. Congress can remedy this problem with the passage of the Cardiac Arrest Survival Act of 2015, which will provide a nationwide baseline of liability protections for the owners of AEDs and the Good Samaritan rescuers.

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