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Newly OK'd defibrillator could save 100,000 lives

By Doug Levy
USA TODAY

A lightweight, less expensive and easier-to-use device to start the heart beating again has been approved by the Food and Drug Administration.

Seattle-based Heartstream announced the approval Thursday, saying its ForeRunner automatic defibrillator now can be available to the people most likely to reach a cardiac

arrest victim first, such as police or office security guards.

Less than 25% of emergency vehicles carry defibrillators, but using one within four minutes of a cardiac arrest increases survival rates to 30%, from less than 5%.

Defibrillators, which shock a heart into normal rhythm, have long been carried by paramedics.

But their use has been limited by the cost, size and need

for maintenance. Even automated versions, in use by some fire and police departments, cost \$5,000 or more.

ForeRunner "has some very definite advantages," says Dr. Roger White of the Mayo Clinic, who urged defibrillators be put in police cars in the clinic's hometown of Rochester, Minn.

It now has the USA's highest cardiac arrest survival rate.

The American Heart Association estimates 100,000 lives

could be saved if defibrillators were more widely used.

Heartstream plans to sell ForeRunner for \$3,000 to \$4,000. A recording provides instructions, and there are only two buttons to use. Powered by a long-life battery, the four-pound device is about the size of a large paperback.

ForeRunner was not approved for use on airplanes because its ability to function at high altitude is unstudied.



By Robert Scott

New model: Smallest, che

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HEALTH -
DEFIBRILLATORS

The New York Times

WEDNESDAY, APRIL 16, 1997

Cardiologists Say Portable Defibrillators Can Save Time and Lives

By JANE FRITSCH

When Tony Cox's heart stopped beating, he was working out on a treadmill at the Reebok Club on the Upper West Side.

Theoretically, his odds of survival were as high as 60 percent or 70 percent. A doctor was exercising nearby and a club employee was a trainee paramedic; they began working on him immediately. Others called 911. And the club was only 10 blocks from St. Luke's-Roosevelt Hospital, whose ambulances respond to 911 calls.

But Winston Hill (Tony) Cox, a 55-year-old father of four and the former chairman of Showtime, died that Saturday afternoon last September.

He might have had a chance, doctors said, if emergency medical workers had arrived sooner with a defibrillator, a machine that delivers

RACING THE AMBULANCE

A special report.

an electric shock to restart the heart. But it took 16 excruciating minutes for the ambulance to arrive that day, far more than the 5- or 6-minute window of hope.

In New York City, in fact, the likelihood of being revived after cardiac arrest is only about one percent. The congealed traffic in New York — and in most American cities — and the vast distances ambulances must travel in rural areas mean that emergency workers simply cannot reach most cardiac arrest victims in time.

Cardiologists estimate that a half or more of the 350,000 people who die of cardiac arrest in the United States each year could have been saved.

Cardiologists now argue that it is time to give up on emergency medi-

cal squads as the chief means of reviving heart patients. In the last year, the American Heart Association has begun to push for much wider availability of defibrillators. The devices should be placed just about everywhere, the association contends — in factories, health clubs, apartment buildings, and even in private homes, and available for use by a variety of nonmedical people, like security guards and doormen. Within a decade, the association hopes, the devices should become as common as fire extinguishers.

While the heart association's proposal may seem simple, state laws and Federal regulations are in the way.

The Food and Drug Administration, which regulates the machines, has not considered whether they are safe and effective for use by the general public.

State emergency medical directors have joined together to oppose the widespread use of defibrillators, saying that the matter needs more study.

Still, the heart specialists plan to



Librado Romero/The New York Times

The Lifepak 500 is made by Physio-Control, one of four companies offering a new defibrillator.

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fight aggressively for their plan, kicking it off at a meeting this week in Washington.

Not too long ago, defibrillators were so complicated that the operators had to be specially trained to the screens and interpret the waves. But the heart association says a new generation of automatic, easy-to-use machines has been developed that can be operated by almost anyone. The new lightweight machines analyze heart rhythms, decide whether a shock is needed, and give simple voice instructions. The machines will not shock a person who does not need it, the manufacturers say.

What this means is that the machines are practical, the association says. They have five-year lithium batteries that eliminate the need for regular maintenance. The Food and Drug Administration approved several of the new lightweight models last fall, but only for prescription use.

The average cost is about \$3,000, but the price is expected to drop significantly if the market is opened to all who want to buy them.

The collection of data on deaths from cardiac arrest is haphazard, making the rates difficult to compare. But experts generally agree that dismal survival rates apply to all but a few American cities and most suburban and rural areas.

"This is an area that has been hidebound by rules and laws and regulations," said Dr. Myron J. I. Weisfeld, the chairman of the Department of Medicine at Columbia Presbyterian Medical Center and the head of the heart association's task force on defibrillators.

"If the defibrillators aren't there, and the survival rate is less than 5 percent, then you'd better find a way to get them there," Dr. Weisfeld said.

The Condition

The Heart And Its Problems

Like Mr. Cox, about half of all those who die of heart disease die suddenly and unexpectedly, without ever having shown any symptoms, the heart association says. Many are unaware that they have clogged arteries or other types of heart disease.

In Mr. Cox's case, an autopsy showed that three coronary arteries were blocked, but there was no sign of the muscle damage that would have been present if he had had a heart attack.

Mr. Cox's heart had been reorganized, the heart association says. It had been a candidate for cardiac bypass surgery, Dr. Nicholas J. Fortuin, a professor of medicine at Johns Hopkins, said. That procedure restores blood flow to the heart and can add decades to a life. But Mr. Cox might have died even with early defibrillation, Dr. Fortuin said.

Cardiac arrest does not necessarily mean a heart attack occurred. Arterial blockages alone can cause the heart's electrical impulses to become disorganized and incapable of coordinating the contractions that keep the heart beating normally.

The disorganized electrical activity, called ventricular fibrillation, can last for about five minutes. During that time, a shock from a defibrillator can reorganize the electrical impulses so that the heart resumes normal beating.

But with each passing minute, the likelihood of successful defibrillation drops significantly. Expertly done cardiopulmonary resuscitation can buy the victim a little more time, but it is useless unless a defibrillator arrives quickly, before all electrical activity in the heart has ceased.

It is a common notion suggested by television shows and movies that defibrillation is not done until a flat line appears on a heart monitor, but that is not so. A flat line indicates that there is no electrical activity in the heart at all, and therefore no

electrical impulses to be reorganized by a shock from a defibrillator.

Dr. John La Pook, a Manhattan internist and friend of Mr. Cox, was so disturbed by his friend's unexpected death that he has since purchased a defibrillator and keeps it at his apartment on Central Park West.

Sometimes, he even takes his defibrillator to his regular basketball game in Brooklyn, where he plays with an friends with ages ranging from the 30's into the 50's. At first they laughed at him, Dr. La Pook said, but they seem to have come to appreciate having the thing around.

The Newest Models Come on the Market

Use of defibrillators by the public is generally not covered by state "good samaritan" laws, which protect amateur rescuers from liability. But cardiologists are afraid that at some point, health clubs, office buildings and other public buildings, as well as airlines could be found negligent if they did not have defibrillators.

American Airlines recently became the first airline in this country to order defibrillators for its planes and other domestic airlines are considering it because it is all but impossible to land a plane and get a defibrillator to a victim in time. Metro North has ordered defibrillators to be placed on its cars of emergency medical supplies in Grand Central Station, and a few casinos in Las Vegas have also bought defibrillators.

Dr. La Pook can legally have his own defibrillator because he is a physician. Under current Federal regulations, and the law in most states, including New York, only doctors or people authorized by doctors may buy and operate defibrillators, even the simplest models.

Last fall, the National Association of State Emergency Services Directors became so concerned with the push for public access to defibrillators that it passed a resolution calling on the heart association to postpone its defibrillator campaign until data show that use by the public is effective and safe.

"They are potentially wonderful devices," said Dr. Robert R. Bass, the executive director of the Maryland Institute for Emergency Medical Services. "But we don't see any evidence that the devices are going to be effective in the hands of the public. Before we call for a national movement to place these devices everywhere, we need to know how safe they are and what the cost benefit is."

Manufacturers of the devices say they are completely safe, and the heart association says they are all but foolproof. And, they add, if the choice is between defibrillation by an amateur and no defibrillation at all, the answer is clear.

But Food and Drug Administration officials say some safety and ethical considerations have yet to be addressed.

"There's a question of whether you can do as much harm as you can do good," said Thomas J. Callahan, the Food and Drug Administration official who oversees the evaluation of such devices. "In the hands of a lay person, are there going to be more disasters than there are benefits?"

He said he was not certain that in all cases the new machines could distinguish a heart rhythm that should be shocked from those that should not. To evaluate fine distinctions, he said, trained technicians are necessary.

Late-stage resuscitation by amateurs, he said, might restore a heart beat and do little more, leaving the victim with little brain function and permanently dependent on life support systems.

Advocates of greater distribution of defibrillators say such results are rare and no more likely to happen when rescuers are amateur than when they are highly trained.

The reality is that none of us is that good at it," said Dr. Alex Koehl, the chairman of the New York City medical advisory committee on emergency services and the head of the city's emergency services agency.

"There's always a danger you're going to shock a living rhythm, but that brain is going to be dead," he said. "But if we can get the very few of us play God in who lives and who dies. We back the one thing that we back, which is the heart, and that the brain is intact."

And those who are brain not linger on life supports, he adding, "Two days later you're in the respirator."

York City was published in the Journal of the American Medical Association and was based on 1991 data.

Since then, the department has gradually equipped all fire engines in Brooklyn, Queens, the Bronx and Staten Island with defibrillators, on the theory that firetrucks are more likely to reach victims in time than are ambulances. Similar plans are under way in Manhattan.

The latest statistics show that the average response time for fire engines on cardiac arrest calls is only five minutes, according to Deputy Commissioner Edward M. Dolan. It takes another five minutes for an ambulance to arrive, he said.

Present Practice

A Few New Models But Most Are Old

For the near future, at least, New Yorkers must depend on the Fire Department's emergency services for help with cardiac arrests. The department has worked aggressively for the last three years to improve response time, and there are indications that the efforts are working. But no statistics have been compiled to show whether the survival rate has improved. The study that showed a one percent survival rate in New

The firefighters are using virtually the same models that the heart association is advocating for public use.

The Suffolk County Police Department has ordered the models for its police cars because the county is almost entirely served by volunteer ambulance squads, which have great difficulty reaching victims in time.

Four companies are now manufacturing the machines, and are in fierce competition for what they hope will be an exploding market over the next decade. They are Heartstream, of Seattle; Laerdal Medical Corporation, a Norwegian company with American headquar-

ters in Wappingers Falls, N.Y.; Physio-Control Corporation of Redmond, Wash., and Survivalink Corporation, of Minneapolis.

Their machines, all similar, weigh about five pounds and were designed in consultation with the heart association to be as simple as possible for amateurs to use. The recent advance that makes them practical, according to cardiologists, is the inclusion of a lithium battery with a five-year life. The batteries eliminate the need for constant maintenance or recharging, and computer chips perform complete tests of the operating systems each day.

When the machine is turned on, it gives a series of simple voice instructions, so that panicky users do not need to stop to read complex directions. The rescuer is told to attach two plastic leads to the victim's chest and then stand back.

The machine analyzes the heart rhythm and determines whether the victim's heart is in fibrillation. If so, it charges up, instructs the rescuer to stand clear, and then to push a red button that delivers a shock. The machine may call for a second or third shock if necessary, then a period of cardio-pulmonary resuscitation, followed by another cycle of shocks.

Defibrillators are a shocking success

Other airports encouraged by Chicago lifesaver

By Robert Davis
USA TODAY

A safety program in Chicago's airports — an effort being copied at airports across the nation — has paid off with surprisingly quick results: four lives saved in less than five weeks.

Chicago spent about \$500,000 to put emergency defibrillators — devices that deliver lifesaving shocks to some victims of cardiac arrest — within a minute's walk in airport terminals. The latest defibrillators require little training to use because they automatically detect erratic heartbeats and decide when a shock is needed.

Since Aug. 20, the devices have been used to shock four victims, the most recent one Wednesday, saving all of the victims of "sudden death."

"I can't even believe it," says Sherry Caffrey, director of Chicago's HeartSave program. "It worked, and it worked so well."

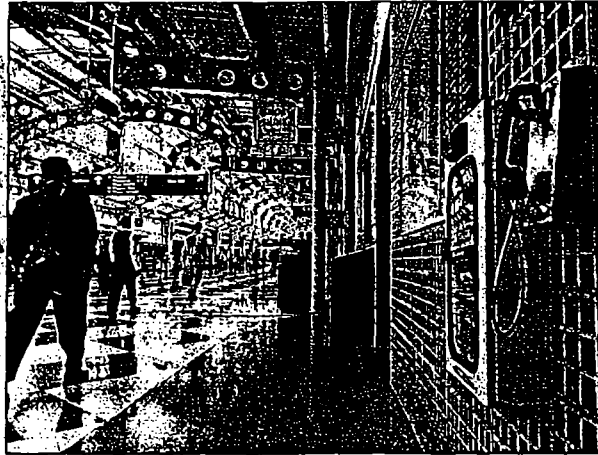
Airports are following fast. "It's a trend that is growing rapidly," says Bonnie Wilson of the Airports Council International, a trade group. "There are preliminary discussions about requiring them in airports."

The \$4,000 defibrillators are more common in public places because they have proved themselves in the hands of people with little training.

Some victims of cardiac arrest suffer from a deadly short-circuit of the heart called ventricular fibrillation, which leaves the body's blood pump quivering uselessly. Only a shock can save those people.

But the shock must come fast. After 10 minutes of the quivering, doctors say, there is no chance of restoring a normal rhythm to the heart.

"We feel it is imperative with cardiac arrest to have defibrillation occur as quickly as possible," says San Francisco International Airport spokesman Ron Wilson.



Rescued: Lou Caccia, below with wife Laura, was saved by a defibrillator at O'Hare.



The San Francisco airport unveils a similar program Oct. 4.

"Having these and training a vast number of airport employees to use them will go a long way to save more lives," Wilson says.

Some airports are resisting. The world's busiest, Atlanta's Hartsfield International, has rejected the idea.

"We feel they should be in the

hands of trained professionals," says spokeswoman Lanli Thomas. "We have 911 emergency units at the airport."

But it can take more than 10 minutes for paramedics with defibrillators to travel from a station on the airport grounds, across busy runways or roadways, to reach a victim of cardiac arrest.

Caffrey, a paramedic who was involved by coincidence in the first rescue using an airport defibrillator in Chicago, restored a normal heartbeat to a 77-year-old Seattle man within the 10 minutes it took the airport ambulance to arrive.

The ambulance crew had to navigate rush-hour traffic snarled by construction outside Midway Airport.

The defibrillators are mounted in cases much like fire extinguishers. When the door holding the device is opened, an alarm sounds at the airport's emergency center, and paramedics are dispatched.

At the same time, a light begins to flash above the case's door, and a horn sounds for 30 seconds, alerting airport workers that there is an emergency.

The airport offers training to all who work there, from airline employees to food-cart vendors. But Caffrey says the number of air travelers who have learned to use the devices is surprising.

John Aranza, a 59-year-old tutor at a boys and girls club in Chicago, says he signed up for training after hearing about the airport program so he could grab a defibrillator and help somebody.

"They should be in all public buildings," Aranza says.

He recalls the death of a neighbor and wonders whether his new training or a closer defibrillator could have made a difference. "The wife is crying, just hysterical," he says. "Nobody is doing anything. Maybe the man's life could have been prolonged."

Lou Caccia's life was.

The 73-year-old retired truck driver from Newtonville, Mass., feels lucky that he was connecting through Chicago's O'Hare on Sept. 13.

Returning from a cribbage tournament in Las Vegas, he went to the wrong terminal for his connecting flight to Boston.

When he realized his mistake, he had less than 10 minutes to make his flight. He was rushing to catch the plane when his heart gave out.

"I was dead," he says from the Chicago hospital bed where he is recovering from heart bypass surgery.

Airline and Federal Aviation Administration employees in the airport used a defibrillator to save him.

"I'm not glad that it happened," he says, "but I'm glad that it happened here."

Reducing the risk of hospital infection stopping the spread of flu in the family

By Anita Manning
and Steve Sternberg
USA TODAY

The first drug in a class of antibiotics shows promise in fighting the most common cause of hospital-acquired infections, researchers reported Sunday.

Research on the latest antibiotics and antiviral drugs is being presented this week at the American Society for Microbiology's 39th Interscience Conference on Antimicrobial Agents and Chemotherapy in San Francisco.

Scientists from Harvard Medical School, Stanford University and the VA Ann Arbor Medical Center showed in research involving more than 2,200 patients that the experimental antibiotic linezolid effectively fights bacteria that cause pneumonia, blood poisoning and surgical wound infections.

It proved 77% effective in patients suffering from the hard-to-kill microbe known as methicillin-resistant *Staphylococcus aureus*, which accounts for 40% of the *Staphylococcus aureus* found in hospitals.

A separate study suggests that zanamivir can prevent flu from spreading within families. The drug reduced the risk of acquiring the flu by 79%. Out of 337 families, 4% in the zanamivir group got the flu, compared with 19% in the placebo group.

AIDS drug protects cells

A new type of AIDS drug, the front-runner in a class that prevents HIV, the AIDS virus, from fusing with white blood cells, is safe and helps clear the virus from the bloodstream, doctors will report today at the in-

terscience conference.

Known as T-20 and made by Merck, the drug must be injected twice a day.

Research indicates that T-20 seems to be safe and well tolerated except for mild to moderate irritation at the injection site, says Ja Lalezari, director of Quest Clinical Research in San Francisco.

The study of 71 patients also found that the drug seems to work in people who are infected with viruses that are no longer susceptible to other classes of antiviral AIDS drugs.

HIV attacks white blood cells, mainly of the body's immune system. T-20 keeps the virus out of and fusion inhibitors represent most important advance in the treatment of AIDS since the advent of protease inhibitors, Lalezari says.

Earaches resistant to cure

Scientists at Kentucky Pediatric Research reported Sunday that infections, which send more to the doctor than any other illness, are becoming harder to cure.

Researcher Stan Block says drug-resistant strains of two of the most common bacteria that cause ear infections have doubled.

Researchers studied the rate of resistant bacteria in more than 1,000 children having ear infections between 1994 and 1998. They compared that with the rate found in 1989 and 1993. For the first time, strains of *haemophilus* were resistant to standard antibiotics, and the rate of moderately resistant *pneumococcus* had doubled.

"Over one-third of children with ear infections have some type of drug-resistant bacteria," Block says.

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DEFIBRILLATORS IN PUBLIC PLACES
BYLINE: David Brown
CREDIT: Washington Post Staff Writer
DATELINE: LAS VEGAS

The man in the white baseball cap had just finished playing poker when he cashed in his chips in a very big way.

The grainy videotape, taken from a surveillance camera at the Boulder Station Casino, shows him lying on the floor next to a roulette table. He's in full cardiac arrest. A security officer, by chance walking by, calls for help on a radio and then starts working on him. A woman shoots a look over her right shoulder, but keeps playing.

Two minutes and 32 seconds after the man's collapse, two other guards arrive, one carrying a box about the size of a briefcase. From it they take two large plastic patches attached to wires, which they paste to his chest. The man's left hand, all of him that's now visible, jumps off the floor, the effect of 200 joules of electricity delivered in less than a tenth of a second.

By the time the county emergency medical technicians arrive nine minutes and 35 seconds into the drama, the man is sitting up and protesting. Within two hours, in fact, he's checked himself out of the hospital against medical advice. Since that day 20 months ago, he's been seen more than once back at the tables, trying his luck again.

Scenes like this have occurred dozens of times in the last two years, since casinos here began training security guards in the use of portable heart-shocking devices, known as "automated external defibrillators."

Today, Las Vegas's gambling halls are about the safest public places in the world, at least in terms of their preparation for cardiac disaster. They're leading a movement in the United States to make automated defibrillators what life jackets and seat belts once were -- pieces of technology that our risk-averse society can't imagine ever having lived without.

"Someday, these things may be as common as fire extinguishers," said Richard Hardman, training coordinator for the Clark County Fire Department, and the person largely responsible for bringing defibrillators to Las Vegas's entertainment industry.

A bill before Congress, the Cardiac Arrest Survival Act, would direct

the secretary of health and human services to promote the outfitting of all federal buildings with the devices, and the training of people to use them.

The American Heart Association and the American Red Cross are the driving forces behind the bill, which has been offered twice before. This bill's sponsors are Sen. Slade Gorton (R-Wash.), whose state is home to two of the three makers of the devices, Medtronic Physio-Control and Heartstream, and Rep. Cliff Stearns (R-Fla.).

Even without the bill, the devices are proliferating in federal offices. Congress and the Supreme Court have them, and the Washington headquarters of HHS, Labor, EPA and several other agencies are getting them. The Internal Revenue Service and the Federal Deposit Insurance Corp. are putting them in "selected buildings" nationwide.

About 40,000 of the devices will be sold this year, with the market doubling about every 18 months. More than a dozen airlines carry them on all planes. American Airlines, the first domestic carrier to acquire them, reports eight "saves" out of 17 uses in two years.

USX Corp. recently got automated defibrillators for two steel mills near Pittsburgh, and over the next year will outfit four more plants, as well as four oil refineries run by its subsidiary, Marathon Oil. John Hancock Mutual Life Insurance Co. has them in five office buildings at its Boston headquarters. R&B Falcon Corp., an oil drilling contractor in Houston, bought 88 for its rigs and offices.

"We want to make certain that we give our employees the best possible care. The defibrillator is as important to us on a rig as any other safety equipment," said Robert B. Carvell, the company's director of risk management.

Nationwide, about 250,000 people die each year of sudden cardiac arrest, which is sometimes also called "sudden death." Although regional variations in medical care have been widely documented in recent years, few are as dramatic as those seen in the treatment of this condition.

Seattle and its suburbs in King County, Wash., have among the highest save rates, 14 percent and 18 percent, respectively, with a save defined as a resuscitated person leaving the hospital alive. New York's, however, is only 1.4 percent, and Chicago's is 2 percent.

By some estimates, one-quarter to one-third of people in sudden cardiac arrest might be saved with optimal emergency care, including faster defibrillation. To achieve that, however, lots of ordinary people will have to be willing to do something they've only seen on "ER."

Contrary to popular impression, electricity isn't a general tonic capable of jolting errant hearts back to work. There are rhythms that don't benefit from shocking, and ones made worse by it. A heart in electrical standstill, for example, can't be restarted with a defibrillator.

However, shock is the treatment of choice for ventricular fibrillation, the heart rhythm found in about 80 percent of cardiac arrest victims in the first minutes after collapse.

Of 127 people who have collapsed, pulseless and not breathing, in a casino equipped with a defibrillator, 51 have been revived and have gone home alive. This "save rate" of 40 percent is roughly five times that of the rest of the country.

Automated defibrillators cost about \$3,000 apiece. Although it is possible to operate one without training, most places give security guards or other employees three to five hours of instruction.

Current models require only that a person place two electrode patches as instructed on the victim's chest and press a start button. The machine takes an EKG and analyzes it, and a voice prompts if the rhythm is one that can be shocked. (If it isn't, the device doesn't charge up, so ill-advised shocks are impossible.) The machine even shouts "Stand clear!" although the operator has to deliver the shock with a button.

Public access to automated defibrillators is getting its biggest test in Chicago's airports, where 33 were installed at O'Hare and seven at Midway in June. They are in plain view, rigged to dial 911 when removed from the wall.

"The wider use of defibrillation is not a new wish," said Peter Safar, a longtime resuscitation researcher. "The technology has now caught up with the wish."

Their notable success in reviving Las Vegas's downed gamblers is attributable to two things -- access and speed.

Although not every person in cardiac arrest can be saved by electricity, those who can need to be shocked within five minutes of collapse to have a reasonable chance of survival. There are now about 350 automated defibrillators in 59 Las Vegas casinos. As a rule, security guards can get one to any place on a property in less than three minutes.

On a recent morning, Paul Ready, medical training officer for Sam's Town, dropped a mannequin on the floor of the sprawling casino's sports bar, which was closed for cleaning. It was time for the monthly defibrillator drill. An assistant called the casino operator to say that a member of the janitorial crew was down.

First officer on the scene: 1:05 minutes. Equipment arrival: 1:35. Rhythm analysis: 2:38. First Shock: 2:52.

"I'm glad to have these. I might need one one day," said Henry McCallum, 56, red-faced and sweating, when the drill was over. He once was a police officer in Manchester, N.H., where, he says, "we ran the city ambulance with absolutely no training." He doesn't mind being better prepared now.

Some companies fear that training employees to operate an automated defibrillator may expose them to lawsuits if victims die. The Nevada legislature addressed this problem when it was raised by casino owners. It extended the state's Good Samaritan law to cover nonmedical workers, such as security guards, who defibrillate people on the job.

In recent years, 43 states have enacted laws protecting rescuers using defibrillators (and in some cases, the companies who own the devices) from

liability suits. The bill before Congress would extend protection to the rest. Maryland and Virginia each have such laws, but the District doesn't.

There have been no lawsuits over deaths following the use of a defibrillator by "lay" rescuers. Most experts, in fact, think risk to employers lies elsewhere.

"If there's any threat of litigation, it is more for not providing the device," said Richard Hamburg, director of government relations for the American Heart Association.

****END OF STORY REACHED****