The Defibrillator That Fails May Be the One You Need

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Everybody who has watched medical shows on TV has sooner or later witnessed a simulated attempt to start a heart going again with a defibrillator. The doctor in charge tells everybody else to get out of the way—he places electrodes on the patient's chest—then bang—the body arches upward and, depending on what the dramatic needs of the moment are, either starts breathing again or gets covered up for the last time. Used properly in real life, automated external defibrillators (AEDs) can be lifesavers.

For a variety of reasons including circulatory problems and electrical shock, a person's heart can go into an ineffective kind of twitching known as ventricular fibrillation, and blood basically ceases to flow. This is called sudden cardiac arrest. Invariably the person becomes unconscious and has no manually detectible pulse. It used to be the case that unless properly equipped emergency workers arrived with an AED within four to six minutes of sudden cardiac arrest, it meant curtains. Then it occurred to AED manufacturers to make their devices simple enough so even a sixth-grader could use one, as has been demonstrated in practice tests.

For the last fifteen years or so, easy-to-use AEDs have been showing up in public places such as airports, bus terminals, universities, and malls, and people have been rescued by quick-witted bystanders who grabbed an AED and used it in the right circumstances. But as reported in IEEE Spectrum last spring, a disturbing number of AEDs out there fail to do their job, or would fail if called upon to work.

About 300,000 people in the U. S. alone die from sudden cardiac arrest each year. Some of these folks would not benefit from application of an AED, but many of them—possibly as many as 40,000 a year—could be saved by a properly applied working AED. In Seattle, Washington, city authorities undertook to develop a

registry of the location of every publicly accessible AED in town, and then promoted a “citizen defibrillation program” with advertisements, public information publications, and training. The result is that as many as 45 percent of witnessed cardiac arrest cases (situations where the person is not alone) survive. Contrast this to the U. S. average of 4 percent, or the even more dismal figure of 0.5 percent for Detroit. The last thing anybody trying to use an AED expects is a little message on the machine’s display saying something like “BATTERY LOW” or “SELF-TEST ERROR 17.” But it happens.

AEDs are medical devices, aren’t they? And so they must go through the same rigorous Food and Drug Administration qualification and inspection tests as other medical devices, mustn’t they? Well, not quite, it turns out. AEDs are in a kind of legal gray area that allows manufacturers simply to say that their product is “substantially equivalent” to other AEDs, and then they can bypass the usual medical-equipment tests and qualifications. So it’s up to the manufacturers to ensure that the batteries will stay charged and the unit will be operational even after years of total neglect, and perhaps environmentally harsh conditions of high and low temperatures and humidity in outdoor locations.

This would be a hard trial for any piece of electronics, but for a unit that someone’s life may eventually depend on, it’s doubly difficult. The Spectrum report shows that an FDA investigation found over 90 percent of AED failures were not investigated sufficiently to identify the cause. Most of these failures showed up during routine tests, but 750 of the reports of failure between 2005 and 2009 followed a death in which the AED was involved. And at least one manufacturer maintained a “fix-on-fail” policy. That is, when the same design problem began to show up in a number of calls for repair of AEDs, you would think the firm would act like most auto manufacturers do and issue a recall to all owners of that model device. No—this outfit simply waited for the next failure to occur instead of notifying the owners of all potentially defective AEDs.

So what’s the answer? Changing the law to make AEDs qualify through the same rigorous process as other medical devices is one alternative. But the manufacturers claim, with some justification, that this will send prices (already in the $2,000 per unit range) through the roof. Ideally, an AED would be as cheap and reliable as a fire extinguisher so that people (for example, heart patients) could afford one at home. This isn’t going to happen if prices are north of two kilobucks a pop.

My libertarian streak makes me reluctant to say this, but the way we got fire extinguishers in every public building was by means of fire codes: laws that compel building owners to have so many fire extinguishers for a given square footage of space. It’s the owners’ responsibility to make sure those extinguishers are operational, too. Maybe the only way to make sure AEDs work and are widely accessible is to pass similar codes requiring AEDs, at least in places where the demographics indicate it would be helpful. Because people younger than 20 rarely go into ventricular fibrillation, for example, K-12 schools might not need more than one in a large building. Rest homes, for example, could use more.

This issue strikes close to home for me, because as a 58-year-old male I’m in the

prime demographic of those who might need an AED some day. Both my grandfathers died of circulatory problems, and while I try to eat right and exercise, there's only so much you can do. Let's hope the next time anyone you know needs a defibrillator, that one will be handy—and it will work, too.

Sources: The article "A Shocking Truth" by Mark Harris appeared in the March 2012 issue of IEEE Spectrum, the general-interest publication of the Institute of Electrical and Electronics Engineers, on pp. 30-34 and 57-59. I also consulted the Wikipedia article on defibrillators.

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