

Have a heart, FDA: Let the recycling of pacemakers proceed

By ACSH Staff — October 27, 2011

Used pacemakers may be a [safe option](#) ^[1] for poor patients in developing countries, a new study suggests.

Currently, people who live in developing nations may have essentially no chance of obtaining an expensive new pacemaker to treat life-threatening arrhythmias, which are disturbances in the rhythm and rate of the heart that can lead to breathlessness, fatigue, fainting, and even death. An estimated 1 to 2 million people around the world die each year because they have no access to a pacemaker. Considering that the cost of a pacemaker in India, at \$2,200 to \$6,600, is more than most poor or middle-class individuals earn in a year, their scarcity there is not surprising.

A recent study, however, explored a much more cost-effective, resourceful means of getting pacemakers to this low-income population. Researchers examined whether used pacemakers, donated from funeral homes with the approval of the deceased individual's family, would be safe for re-use. Fifty-three patients in India with heart difficulties who received such donated pacemakers were followed for an average of two years after implantation. No infections or pacemaker malfunctions occurred. All of the patients survived the surgery, and all but two among those who were followed reported a significant improvement of symptoms. While the study was small, the results seem hopeful in suggesting that used pacemakers may be safe.

Some questions remain, however, about the feasibility of actually providing used pacemakers to developing regions. Even within this small study, it was not possible to follow up with a quarter of the patients since they lived in remote areas. Considering the importance of regular follow-up to ensure the functionality of the pacemaker (and since pacemaker batteries die after several years) the difficulty of providing regular care for patients in resource-poor settings may prove to be a significant obstacle.

Further complicating the matter, FDA regulations specify that pacemakers cannot be reused in the U.S., but a group of doctors are attempting to circumvent this regulation by sterilizing the pacemakers abroad. ACSH's Dr. Gilbert Ross remarks, It would be a shame if these FDA regulations got in the way of providing this important medical device to impoverished patients around the world.

ACSH's Dr. Josh Bloom adds, Although the program is small and there are some problems to overcome, it's good to see that a simple but clever idea can be used to benefit people who otherwise would have no access to such a product.

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[1] <http://www.reuters.com/article/2011/10/27/us-heart-pacemakers-idUSTRE79Q0CI20111027>