How to Respond to an Implantable Cardioverter-Defibrillator Recall

Kari B. Kirian, Samuel F. Sears and Julie B. Shea

Circulation. 2009;119:e189-e191
doi: 10.1161/CIRCULATIONAHA.108.810606
Circulation is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231

Print ISSN: 0009-7322. Online ISSN: 1524-4539

How to Respond to an Implantable Cardioverter-Defibrillator Recall

Kari B. Kirian, MA; Samuel F. Sears, PhD; Julie B. Shea, MS, RNCS, FHRS

The purpose of the implantable cardioverter-defibrillator (ICD) is to recognize and terminate abnormal heart rhythms and to provide protection from sudden cardiac death in at-risk patients. Ideally, the protection of the ICD can produce a feeling of safety for patients and families. The reliability and sustained performance of the ICD and its leads have become highly publicized issues with substantial media coverage and policy statements from medical societies.

ICD technology has evolved tremendously in the past 25 to 30 years. Despite these advances, "no complex device can be 100% free of design, manufacturing, and performance flaws."[1] ICDs, like cars, are designed, created, manufactured, and provided to consumers but require monitoring to optimize their benefit. Unfortunately, some errors can be found only after the products are in use. Although ICD malfunctions and recalls are inevitable, they are rare. In fact, out of more than 415 000 ICDs implanted in the United States between 1990 and 2002, only 2% were extracted because of confirmed malfunction.[2] ICDs are important life-extending devices that have saved many lives and will continue to save many more. The purpose of this article is to help ICD patients be prepared for and to decrease distress in the event of a recall.

Spectrum of Recall

The US Food and Drug Administration (FDA), which is responsible for the supervision and safety of all medical devices in the United States, defines a recall as "an action taken to address problems with a medical device that violates FDA law." Recalls occur when a medical device or a part of the device is defective, when it could be a risk to health, or when it is both defective and a risk to health (FDA). It is important to note that recall is a term coined by the FDA and does not mean that all devices included in the recall should be removed and returned to the manufacturer. A recall may often mean that the device simply needs to be monitored more closely. In fact, recalls rarely result in removal of the device.

The FDA classifies recalls into 1 of 3 classes according to the level of imminent danger involved (the Table).

How to Respond to ICD Recall: Your Actions and Emotional Reactions

Hearing the news of a recall can be an alarming event for an ICD patient. It is normal to experience some stress or uncertainty after a recall has been issued, but excessive worry may prevent you from managing your emotions appropriately and being proactive.

Behavioral Management Plan

Your best plan of action is to get all of the facts. Obtaining specific information about the recall will clear up confusion and will help make you feel more empowered. Determine the details of the recall by contacting your physician. Additional information can be obtained from your device manufacturer or from the FDA either by telephone or through their website.

First and foremost, you must find out if your device is included in the recall. To establish this, you will need to find out (1) the manufacturer, (2) the product (device or lead), and (3) the model and serial number of the device(s) included in the recall. Your device is included in the recall only if all of your device information matches

From East Carolina University, Departments of Psychology (K.B.K., S.F.S.,) and Cardiovascular Sciences (S.F.S.), Greenville, NC, and Brigham and Women's Hospital, Cardiac Arrhythmia Service, Department of Cardiology, Boston, Mass (J.B.S.).

Correspondence to Samuel F. Sears, PhD, East Carolina University, Department of Psychology, 215 Rawl Hall, Greenville, NC 27858. E-mail searss@ecu.edu

(*Circulation*. 2009;119:e189-e191.)

***Circulation* is available at http://circ.ahajournals.org** **DOI: 10.1161/CIRCULATIONAHA.108.810606**

Table. FDA Classes of Recall

Recall Classification	Implication
Class I	Use of the product has a reasonable probability of causing serious adverse health consequences or death
Class II	Use of the product may cause temporary or medically reversible adverse health consequences; remote probability of serious adverse health consequences
Class III	Use of the product is not likely to cause adverse health consequences
Market withdrawal	The product has a minor infraction (not subject to FDA action), and the manufacturer takes the product off the market
Medical device safety alert	Alerts, which may be considered recalls in some cases, are issued when a medical device presents an unjustifiable risk of considerable harm

From http://www.fda.gov/oc/po/firmrecalls/recall_defin.html Accessed June 23, 2008.

those devices that are included in the recall. Your device is not included in the recall if only the manufacturer is the same. Figure 1 is an example of what type of information you should obtain after an ICD recall.

Compare the specifics of the recall with your device information. This information may be found on your ICD identification card. Most patients receive a temporary card when they are discharged from the hospital, and a permanent card is mailed by the ICD manufacturer within 4 to 6 weeks of device registration. Typically, you will receive a notification of the recall from your implanting physician's office. However, you can always contact your physician if you are unsure about what type of ICD you have.

If your device is included in a recall, the next step is to determine the class of recall. The class of recall will help determine the level of risk involved and what action should be taken, if at all. You and your physician may decide to have the device or defective part removed and a new device or part implanted, but this depends on the chances of harm to you for the recall (eg, class I). Alternatively, you may decide that you are at low risk, such as with a Class III recall, and close monitoring of the device is all that is required (Figure 2).

Monitoring Recalled Devices

Many devices manufactured today have the ability to communicate wirelessly via radio wave and can communicate seamlessly via a monitor that is connected to a regular telephone line. If an alert condition is identified, the monitor will download the information from your device and transmit it to a secure website where your physician or device clinic nurse can access the information.

Many ICDs are built with the ability to signal a potential problem. Some devices will emit an alert tone (beeping) or will vibrate when an alert condition exists to notify about a change in the functioning of your device. You should contact your physician as soon as possible should you note an alert condition. Ask your provider to demonstrate this feature to you during your next office visit.

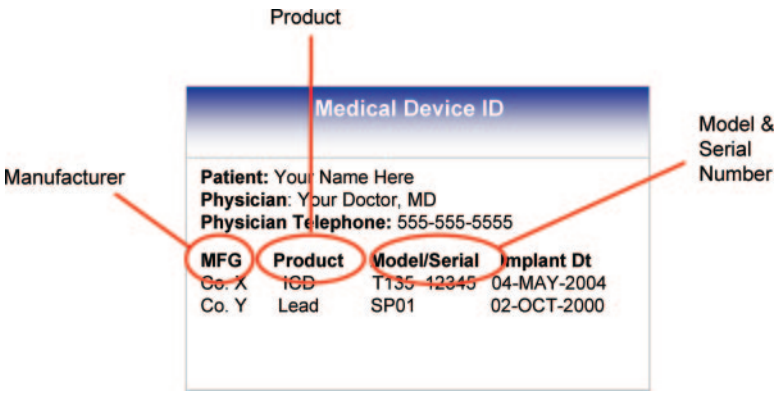

Figure 1. Example of an ICD identification card. Most patients are mailed a permanent ICD identification card from the manufacturer within 4 to 6 weeks after receiving their device. Identification cards are similar to the one pictured here and include specific details such as the device manufacturer, model, serial number, and the date that each product was implanted.

Managing Your Emotional Response

Certain uncomfortable feelings such as confusion, anger, or anxiety may arise after a recall. The psychological discomfort you may experience after a recall is often rooted in feelings of powerlessness over the situation. This scenario may lead you to feeling overwhelmed or even exaggerate the chances of the worst possible outcome related to your condition or device. Remember these 3 facts. First, a recall for 1 patient is not a recall for all patients. The recall of 1 brand of ICD does not mean that there is something wrong with all ICDs. Second, you are much safer with an ICD than without one. Your ICD will protect you from dangerous heart rhythms. Third, if you are affected by a recall, your team of medical professionals will help you manage the situation well.

Conclusions

Implanted medical devices such as ICDs have increased the quality of life and extended the life of many people. Unfortunately, the upsurge in ICD usage will be matched by increases in device malfunctions and recalls. Recalls happen and will continue to

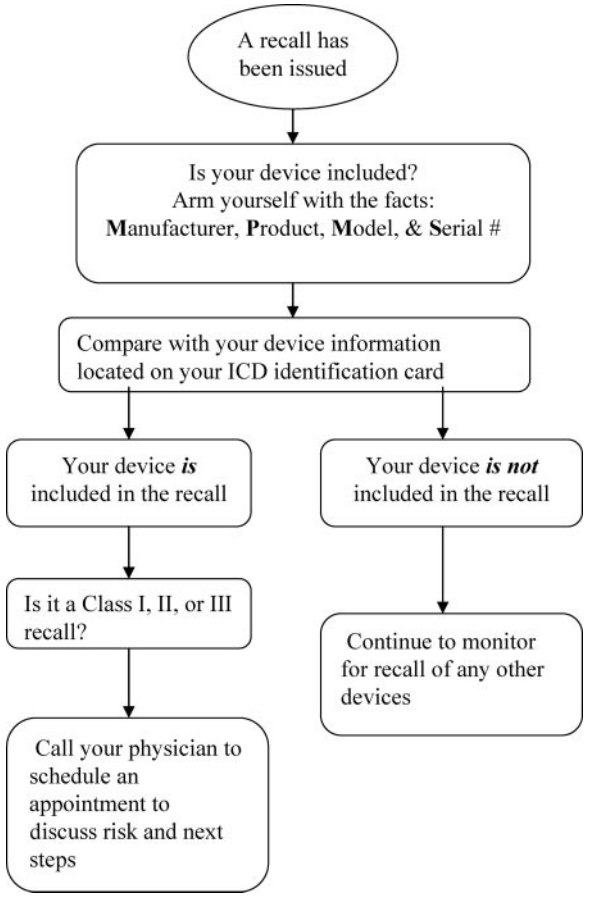

Figure 2. ICD recall behavioral management plan.

happen. This is the inherent limitation and the paradox of effective biotechnology; the more it is used, the more it is possible that problems can occur and may result in recall. Recalls may be unnerving, but if you are at risk of sudden cardiac death, you are much safer with an ICD than without one. Knowing the right steps to take after a recall has been issued will save you time and worry and keep you feeling safe.

Additional Resources

Food and Drug Administration website. Available at http://www.FDA.gov. Accessed June 25, 2008.

Medtronic website. Available at: http://www.Medtronic.com. Accessed June 25, 2008.

Boston Scientific http://www.Medtronic.com. Available at: http://www.BostonScientific.com. Accessed June 25, 2008.

St Jude Medical http://www.BostonScientific.com. Available at: http://www.sjm.com. Accessed June 25, 2008.

Disclosures

Dr Sears serves as a consultant to Medtronic and Boston Scientific and has or has had research grants from Medtronic and St Jude Medical. Dr Sears also has received speaker honorarium from Medtronic, Boston Scientific, St Jude Medical, and Biotronik. J.B. Shea serves as a consultant to Medtronic and has received honoraria from Medtronic. K.B. Kirian reports no conflicts.

References

1. Maisel WH. Semper fidelis: consumer protection for patients with implanted medical devices. *N Engl J Med*. 2008;358:985–987.
2. Maisel WH, Moynahan M, Zuckerman BD. Pacemaker and ICD generator malfunctions: analysis of Food and Drug Administration annual reports. *JAMA*. 2006;295:1901–1906.