

Policy Recommendations:

Implantable Cardioverter Defibrillator and Pacemaker Performance

FAQs

Q: Why did HRS develop these recommendations?

- The Heart Rhythm Society is the international leader for cardiac arrhythmia professionals and patients. As part of our mission to improve the care of patients by promoting optimal health care policies and standards, we believed it was necessary to develop a set of recommendations and guidelines to address concerns that have been raised about the safety, effectiveness and post-market surveillance of cardiac devices.
 - Change to the current system is needed to ensure continued access to life-saving treatments and to enhance public knowledge, confidence and trust in these therapies.
 - ICD's are 99 percent effective stopping life-threatening arrhythmias and are the most successful therapy to treat ventricular fibrillation, the major cause of Sudden Cardiac Death (SCD).

Q: What do these guidelines recommend?

- The Heart Rhythm Society believes patient and physician knowledge, confidence, and trust can be enhanced and strengthened through:
 1. Greater transparency in post-market surveillance, analysis, and reporting of information;
 2. Enhanced systems to increase the return of devices to manufacturers and to improve the analysis and reporting of device performance and malfunction information;
 3. Cooperation among industry, the FDA, and physicians to make every effort to prevent injuries and deaths due to device malfunctions; and
 4. Standard notification and communication to physicians and patients from the manufacturer when a device malfunction is identified.
 5. Recognition that device performance issues are global in scope; cooperation among industry, physicians, government authorities and national health care systems are necessary to reduce the risk of injuries and deaths due to device malfunctions.
- The Report also provides specific guidance to physicians, industry, FDA and CMS officials and Members of Congress.

Q: Who was involved in developing the recommendations?

- In September, 2005, the Heart Rhythm Society convened a policy conference to discuss issues related to the performance of pacemakers and implantable cardioverter defibrillators (ICDs). As a result of that meeting, the Society assembled a fifteen-member task force of leading cardiac care providers and experts who were charged with the development of draft guideline recommendations.
 - Additionally, the Task Force worked with regulators from the FDA as well as representatives from industry and patient advocacy groups, to solicit feedback in the

initial phases of drafting the guidelines. It is the first such collaboration among these diverse groups.

Q: Do any task force members have connections with industry?

- Disclosures for each task member are included at the end of the report.

Q: How will these recommendations benefit patients?

- The recommendations will provide patients with clearer, timelier and more consistent information about recalls and advisories.
 - New systems have been recommended to identify malfunctioning devices more quickly and to return them to manufacturers for analysis.
 - These recommendations represent a renewed commitment by physicians, manufacturers and the FDA to provide patients with the safest, most effective devices possible.
 - The Heart Rhythm Society is recommending industry communicate with patients directly using a standard patient communication ‘form’ to notify patients regarding a potential malfunction with their device. The use of such a form will improve communication with patients.
 - HRS is also recommending FDA eliminate the term “recall” for implantable devices to remove the layperson’s expectation that these devices must be removed in all instances of a malfunction. In many cases, explantation of a device *is not* recommended after a device has been currently “recalled”.

Q: Has FDA’s recent decision to use outside experts to monitor these devices make your recommendations outdated?

- No. The final guideline recommendations are far broader and look at the surveillance and notification process for the entire industry.
 - The task force and the Society have met regularly with FDA officials since September 2005 to solicit their ideas and discuss the guideline recommendations for the regulation of these devices.
 - We are pleased that as a result of these dialogues, the FDA has decided that the use of outside experts will lead to providing patients with safer and more effective devices. Our recommendations compliment this decision.

Q: How does HRS plan to enforce these recommendations?

- Since the Society’s members are healthcare practitioners, it would be inappropriate for the organization to assume any role in enforcing or regulating the final recommendations that have been set forth. HRS is however, committed to advocating for changes to the post market surveillance system as we have outlined. We have pledged to continue our efforts to improve device surveillance and patient and physician communication regarding device performance.
 - HRS looks forward to continuing our collaborative efforts with FDA and industry to encourage adoption of these recommendations.
 - HRS will also be working with Congress to examine what, if any, legislation is needed to speed adoption of our recommendations and to ensure Congress provides

- the FDA the necessary resources to protect patient safety through the post market surveillance system.
- HRS is particularly interested in RECALL LANGUAGE

Q: Where are the final recommendations published?

- Final guidelines were published in the October issue of *Heart Rhythm* and are available on the Society's Web site on September 28 LINK.

Q: Can you explain in more detail the recommendation to physicians about considering risk and alternatives to re-implantation?

- When physicians are making potentially life-or-death decisions, any kind of guidance is helpful. These recommendations represent the first time specific physician guidelines have been developed to help clinicians make critical decisions about responding to recalls and advisories.
 - Each patient is unique and every device malfunction has unique characteristics, we could not offer "one size fits all" recommendations for every patient or malfunction.

Q: What are the central recommendations in each of the six areas?

Device Performance:

- We recommend that manufacturers establish standards of performance for their devices and develop standardized device performance reports twice a year.
- We suggest physicians should inform patients not only about the benefits and risks of devices, but also about the overall expected performance of devices, including potential malfunction rates.

Surveillance:

- We recommend that manufacturers use wireless and remote monitoring technologies to identify abnormal devices earlier and more quickly determine the cause of malfunctions.
- We suggest the FDA should enhance the Manufacturer and User Device Experience database to more readily identify devices that may pose a danger. And we recommend modifying the National Cardiovascular Data Registry, administered by The Heart Rhythm Society and the American College of Cardiology, to collect detailed data on device performance and adverse events, including the cause of patient deaths.
- We encourage Congress to determine what additional resources, funding or direction the FDA requires for post-market surveillance, analysis and reporting.
- We advise physicians to return malfunctioning devices to the manufacturer for analysis whether the replacement is routine or because of malfunction.

Analysis of Data:

- We suggest that manufacturers establish independent, standing committees of outside experts to analyze device performance reports and to recommend appropriate action.
- We recommend the FDA establish standing post-market advisory committees to analyze data on device performance and to suggest actions to address device malfunctions.

- We encourage Congress to ensure that FDA receives the resources and funding to establish and maintain these FDA advisory committees.

Format of Independent Standing Committees:

- “The words “independent standing committees” can understandably be interpreted in different ways by industry and the public. While it is entirely appropriate and expected that financial compensation be provided for service for non-employee experts on these Independent Industry Committees by the sponsoring industry corporation, the Heart Rhythm Society believes that members of the “Independent Committees” ideally should have no conflicts or financial relationships with industry.
- It is recognized, however, that these Committees may require participation of individuals with specific and required expertise who may in fact have other financial relationships with industry. The Heart Rhythm Society recommends that for these individuals, other financial compensation should not be significant (as defined by the Heart Rhythm Society, not in excess of \$10,000 per year from the company utilizing such experts). These individuals should also not have any stock or stock option ownership in the company in which they are consulting.
- It is further recommended that the individuals selected to serve on these independent committees be given a specific ‘term’ by industry to serve that is not affected or changed by industry based on any particular decision or recommendation of that committee member.”

Terminology

- First, we advise manufacturers and the FDA to use identical terminology when classifying device malfunctions.
- We recognize the threshold for activation of recalls and advisories may vary depending on the problem’s frequency and the clinical implications of the malfunction. We do not recommend attempting to classify the types of malfunctions that would automatically trigger a notification or advisory.
- We suggest that manufacturers continue to provide the FDA with semiannual product performance reports when problems are identified.
 - We strongly encourage the FDA to use simple language to communicate important information about device malfunctions. We recommend the FDA eliminate the term “recall” in public communications and change the term “Class I Recall” to “Class I Notification” or “Class I Safety Alert.” HRS is recommending FDA eliminate the term “recall” for implantable devices to remove the layperson’s expectation that these devices must be removed in all instances of a malfunction. In many cases, explantation of a device *is not* recommended after a device has been currently “recalled”.

Communication

- In addition to the physician advisory notification letters, we suggest manufacturers use a standardized Physician Device Advisory Notification format for all industry advisories to physicians regarding potential device malfunctions.

- Rather than the current regional system, we advise the FDA to use a centralized system to communicate device advisory notifications that will ensure a broader and more inclusive interpretation of issues.
- We encourage Congress to ensure that FDA receives the resources and funding to accomplish these recommendations related to post market surveillance.
- We recommend that physicians should use the standardized Physician Device Advisory Notification format to objectively assess and characterize FDA advisories.

Physician Recommendations

- We urge physicians to consider the risk of device removal and re-implantation when making clinical decisions and recommendations to patients who may have a malfunctioning device. Alternatives to re-implantation that may mitigate the consequences of device malfunction and decrease patient risk should be considered.
- We recommend that physicians seriously consider replacing the device or lead if failure of the device could result in patient death or serious harm, and if the risk of replacement is not substantially greater than the risk of device failure.