The Twin Pillars—Knowledge and Trust

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Recent events have raised important questions about current systems for post-market surveillance and analysis of pacemaker and implantable cardioverter defibrillator (ICD) performance and the communication of that performance to physicians and patients. The Policy Conference on Pacemaker and Implantable Cardioverter Defibrillator Performance, convened on September 16, 2005 by the Heart Rhythm Society and the United States Food and Drug Administration (FDA), provided an unprecedented opportunity for the major stakeholders—industry, the FDA, cardiac electrophysiologists, nurses, and patients—to discuss challenges, concerns, and opportunities for improvement. Several issues related to communication of device performance to physicians and to patients were addressed during the conference. Many of these issues involved one of two unifying themes: knowledge and trust. Physicians and patients need to receive timely, accurate, and understandable information regarding device performance in order to make appropriate decisions regarding medical care. Furthermore, patients need to trust that physicians, industry, and the FDA will always act with the best interests of patients in mind.

The benefit of pacemakers and implantable defibrillators has been demonstrated and confirmed by countless clinical trials. Thousands of lives have been saved and many more lives have been improved by these devices. But like all manmade devices, malfunctions in pacemakers and implantable defibrillators can occur. Timely detection and communication of malfunctions that have the potential to recur are critical to patient safety and necessary to improve these devices.

The conference addressed postmarket surveillance, analysis, and reporting of device performance information to

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FDA, physicians, and patients. If one is to identify a device malfunction, one must first know the expected performance of the device. It is generally understood that pacemakers and ICDs, which are powered by lithium batteries, have a certain "life expectancy" (usually a few years) due to battery depletion; patients do not expect their devices to function forever. What may not be well-understood is that these devices, like all electronic devices, are subject to so-called "random component failure." Random component failure is an event that occurs usually due to chance and is thought to have little or no likelihood to occur in other devices. The random component failure rate for pacemakers and ICDs is very low, but it is not zero.

During the conference, patients clearly expressed that they desire to understand before implantation the expected performance and "life expectancy" of their devices, including the likelihood that components might fail. Prior to implantation, physicians routinely counsel their patients on the risks and potential benefits of the procedure and the therapy and often discuss expected battery longevity. Additional information regarding device longevity and performance could be provided in written form by the manufacturer and could be conveyed to the patient as part of the pre-procedure consent process.

Postmarket surveillance is critical to timely identification of potential device malfunctions and precise reporting of device performance. FDA uses passive surveillance (including mandatory and voluntary event reporting and annual reports), enhanced surveillance (through the Medical Product Surveillance Network (MedSun)), and observational studies (both required and discretionary) to accomplish this task. Passive surveillance relies on the return of devices after explantation or death for analysis, particularly when a malfunction is known or suspected. However, industry reports that only a fraction of pacemakers and ICDs are returned. Increasing the fraction and absolute number of devices that are returned for analysis would enhance the surveillance process significantly and would have beneficial effects downstream in the process.

Physicians, nurses, morticians, manufacturer representatives, and patients and their families play an important role in returning devices that provide useful information. Some may be unaware of the importance of

returning the device even when it appears that it has performed very well. Others may not be aware of what must be done to return a device properly. The handling of a device after it is removed can affect the quality of the data available for analysis. Removing an active device or cutting the leads when a device is active can corrupt the stored data and make it difficult to assess device performance.

Educational programs may improve the rate of return and the quality of the information that is available for analysis. All of the relevant parties should understand the importance of returning these devices and the process for doing so. Those who remove devices (physicians and morticians) should understand how to do so properly in order to retain as much data as possible.

Additional options to enhance surveillance include the use of current and new databases, new electronic remote monitoring capabilities, and incentives or regulatory requirements. Countries with some of the highest return rates, like Denmark, provide financial incentives to physicians and patients to return devices; payment of medical bills depends on return of the device. Providing similar incentives or requirements for return of devices in the United States would constitute a major change in public policy.

The current system for surveillance and analysis of pacemaker and ICD performance relies to a significant extent on the manufacturers who receive and analyze information and devices from the field and report findings to the FDA, physicians, and patients. Although FDA has some ability to discover findings independently, the system depends on the manufacturer acting in the best interest of all to identify and report significant device problems accurately and in a timely fashion. As was pointed out in the policy conference, it is in the manufacturer's best long-term interest to do so. However, it was also noted that manufacturers could encounter disincentives, primarily short-term financial ones, to disclose such information. For instance, it was noted that the discovery of a significant problem in a device with considerable unsold inventory could affect a manufacturer's expected revenue dramatically. Furthermore, disclosure of potential malfunctions is not welcome news to investors and can affect stock prices adversely.

Industry has used certain practices that limit these potential conflicts and other practices might be considered.

When a potential device malfunction is identified, manufacturers often convene a group of physician experts to discuss the implications, suggest the best approach to mitigation, and communicate information to physicians and patients. Some have suggested that an independent group of experts could serve industry and the FDA for all such circumstances. Others have suggested that an independent body, such as the underwriters' laboratory, might be best-suited to collect, analyze, and report information on device performance. However, some believe that such an approach would be costly, burdensome, and problematic, given, among other things, the proprietary information associated with many devices. They believe that the manufacturer is best-positioned to analyze and make adjustments in devices and that only minor, if any, adjustments to the current system are required.

Patients and physicians have expressed the desire for certainty which might be achieved by standardizing certain communication processes. Several expressed the desirability of identifying triggers for notifying physicians and patients of a potential for device malfunction. These triggers could be based on the objective risk level (for example, 1/1000 or 1/5000 incidence) or the subjective risk level (such as the potential impact of the malfunction on the patient's health). One problem with triggers based on objective risk level is that people do not agree on what likelihood of event occurrence constitutes an acceptable risk; neither physicians nor patients appear to agree on the risk level at which notification should occur. Furthermore, basing the trigger on objective risk alone does not account for the variable impact on health of different device malfunctions. Another approach is to base triggers for notification on the potential impact of the malfunction on patients' health. Such a trigger would need to account for the variable impact that some malfunctions may have between patients. It seems clear that both the objective and subjective risks must be considerations in any system, and that some uncertainty will exist for individual patients. In the end, patients may be willing to accept some uncertainty if they can trust that under certain circumstances they, and their physicians, will be notified of a potential device malfunction.

Patients and physicians have also expressed the desire for standardized device performance reports. Opportunities exist for standardization among manufacturers of annual reports and notifications of device malfunction that could enhance the

interpretation of the information. Reports could include similar information and display that information in a common format. It has been recognized however, that differences in devices and potential malfunctions make standardized reporting a challenging goal.

Furthermore, patients and physicians have expressed the desire to better understand the terms that are used when notified of a potential device malfunction. Many patients do not understand medical device recall terminology, the different types of recalls, or the implications of these terms for medical care. The term "recall" can cause unnecessary concern and confusion because the implications of the term when used for non-medical products can be significantly different than when the term is used for a pacemaker or implantable defibrillator. Moreover, it is not clear that patients thoroughly understand the differences in recall classification: class I for potential malfunctions that are life-threatening and class II for potential malfunctions that are not life-threatening. Revision of the current terminology is no simple task because it is stipulated in the federal code. In the short term, patients may benefit from education regarding the meaning and medical implications of these terms.

Patients want to hear from their physicians when a potential malfunction in their device is reported. Physicians would prefer that their patients heard from them first. FDA and industry have traditionally communicated with patients through their physicians. However, in an environment where information can be shared "real time" through the media and the Internet, and publicly traded companies are required to share information quickly with investors, patients often do not learn of a potential device malfunction from their physicians. This situation is not likely to change unless medical electronic information systems and communication systems become much more robust. New remote monitoring technology might provide opportunities for rapid patient communication in the future. Until then, patients and physicians should expect that they may sometimes learn of device problems through sources other than the FDA or industry. Nonetheless, patients should consult their physicians to understand the implications of any potential malfunction for their medical care.

Indeed, the implications of a potential device malfunction may vary greatly among patients. For instance, sudden loss of pacing could be life-threatening in a patient without an

underlying heart rhythm but completely inconsequential in a patient with an ICD who has no risk for a slow heart rhythm. The recommended actions for these two patients might be quite different. Furthermore, patients need to understand the potential consequences (risks and benefits) of the actions that they might take to mitigate the risk of a potential device malfunction. Replacing a pacemaker or defibrillator lead or pulse generator can entail risk and in some cases that risk may be greater than the risk associated with the potential malfunction. Here too, the risk associated with device replacement may vary significantly between patients. A patient's physician is best qualified to understand these issues and provide appropriate advice.

But the physician is not the only source of information from which patients wish to hear. Patients have stated that they want to receive information from the manufacturer and from FDA. Some patients value the opportunity to talk directly with their physician and the device manufacturer representative simultaneously. In certain cases, some physicians have invited their patients to meet with them and an industry representative in an open forum. Patients, physicians, and the industry representatives have found that this open dialogue enhances communication and helps to maintain trust.

The Device Performance Policy Conference provided an opportunity for open dialogue among patients, physicians, industry, and government that was unprecedented. The conference provided a clearer understanding of the complex surveillance, analysis, and communication processes and the opportunities for improvement. The knowledge that was shared benefited all involved and provided a basis for next steps. Perhaps the most crucial lesson learned during the conference was the importance that the FDA, device manufacturers, and physicians collaborate to improve the system. Patients are depending on us to continue to work together and to place their interests first. Only by doing so will patients trust their devices and those of us who are responsible for their medical care.