It's My Heart

Why Not My Data?

Ira S. Nash, MD

I am a cardiologist. I am also a patient with a potentially life-threatening heart condition. Like millions of other patients, I cannot see the information about my own heart that is being recorded by a cardiac implantable electronic device. The reason I can't is not based on any technical limitation. It is the result of a choice by the device's manufacturer to reveal clinical data only to doctors, not to patients. That arrangement is typical, and it is also inappropriate, anachronistic, and dangerous.

In my own practice, I have learned the value of engaging patients in their own care. That comes in part from the humbling nature of clinical experience, in which some good outcomes have come from patients ignoring my advice, and some bad outcomes have followed their taking it, and with the recognition that I (and medicine in general) do not have all the answers to patients' questions. Maturing as a clinician means I recognize that there are few absolutely right or wrong care plans, and that patient preferences, informed by the best medical information available, ought to shape clinical decision making.

My journey as a patient started in 2008, when I learned that I have a relatively unusual variant of hypertrophic cardiomyopathy. Although I am asymptomatic, a recent article[1] challenged my sense of well-being. It reported that a cohort of patients with findings similar to mine had a prognosis worse than previously appreciated, with a relatively high risk of arrhythmic sudden cardiac death.

After considerable thought and broad consultation, I decided to try to get a better assessment of my personal risk by having a cardiac loop recorder implanted. It is programmed to detect asymptomatic episodes of nonsustained ventricular tachycardia, the presence of which would indicate a higher likelihood that I would benefit from an implantable cardioverter-defibrillator.

The implantation of the loop recorder was a quick outpatient procedure, and the device itself is unobtrusive. I was sent home with a bedside communication unit that establishes a wireless connection each night with my device, which uploads the information it collected. The bedside unit then sends the data via a cellular connection to a central facility operated by the device manufacturer, which then makes the information available to my physician on a Web-based portal, through which he can see and download information about his patients. I knew all about that going in. What I did not realize was that I would be kept totally in the dark about what my device was recording.

Short of waiting for the doctor to call and tell me all is well or that something worrisome was detected, I have no idea what, if anything, my device has detected. I cannot even tell if it has successfully uploaded its storehouse of data to the manufacturer. Keeping patients out of the information flow appears to be a deliberate design feature, suggested by the sticker on the bedside monitor that reads, "Do not push any buttons unless instructed."

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Why keep patients uninformed? I suspect it is because cardiac implantable electronic device manufacturers view doctors, not patients, as their customers. After all, doctors, not patients, choose which company's device to implant. I can state from personal (professional) experience that the manufacturers' sales representatives are keenly aware of that, and eager to provide service. In fact, a company representative was present during my implantation procedure, and relieved the implanting physician of the burden of registering my device and of establishing the initial wireless connection with the bedside monitor. When I asked him how I could see the same data my doctor was going to be sent, I was told that I could not, even though there is no legal, ethical, or insuperable technical barrier to providing patients with similar access.[2]

The reason why I and others cannot see the recorded data is just the outmoded business model that supports a paternalistic relationship between doctors and patients, in which doctors fear disintermediation by (or more phone calls from) better-informed patients, and device manufacturers fear upsetting their doctor-customers. Only bad doctors and shortsighted companies should harbor such fears. Instead, physicians should embrace the opportunity to educate their patients about the significance of any findings and partner with them in developing a care plan. Device manufacturers have an unrealized opportunity to provide educational materials and other support to make that connection between patients and physicians more effective.

Contemporary cardiac implantable electronic devices, including loop recorders, pacemakers, and implantable defibrillators, record a host of information about their operation and about the patients in whom they are implanted.[3] Depending on the complexity of the device, the indications for its implantation, and the programmed settings, the data may include the integrity of the device and associated leads, remaining battery life, heart rate trends, the device's interpretation of intracardiac electrograms, and the nature, frequency, and duration of a spectrum of rhythm disturbances (which the patient can correlate with his or her activity, medications, etc.) and more. These are not doctors' data about patients; they are the patients' data. Of course, not every patient will want direct access to all or even any of this, but it should not be up to physicians and device manufacturers to decide who gets to see what, any more than we should try to dictate which patients get to know their own blood pressure or cholesterol levels.

In a world where we take for granted that we can answer every question with a tap on a screen, it is unreasonable to continue to separate patients from the answers to questions they have about their own health. In recognition of this, many provider organizations now routinely provide patients with laboratory results, imaging reports, and physician office notes through patient portals that are mandated by federal meaningful-use criteria for electronic health records. Other organizations go further, supporting a model of care in which patients control their own health information.[4] In contrast, device manufacturers and implanting physicians are engaged in ongoing hoarding of data generated by cardiac implantable electronic devices, which is not likely to be tolerated by younger, more tech-savvy patients. This approach flies in the face of proclamations made by healthcare providers and device manufacturers about their commitment to patient-centeredness and their sensitivity to patients' emotional and physical needs, as well. Failing to provide patients with access to their own data also hamstrings the growing grassroots movement of patients sharing their own clinical information,[5] which may in turn delay or prevent important new insights into disease mechanisms and treatments. Finally, keeping patients ignorant of their results is a safety hazard, because a failure on the part of their physicians to communicate positive findings is likely to be misinterpreted by patients as a lack of detected arrhythmic episodes.

Patients like me should no longer be denied access to their own data that they can use to understand their conditions better, make better choices about how they live their lives, engage more effectively in decisions about future treatment, and gain a measure of autonomy and control that is all too often stripped by illness. Doctors like me would appreciate that too.

Postscript: Since I submitted this article, I have been granted special, physician-only access to my data, an option that remains closed to other patients.

DISCLOSURES

None.

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FOOTNOTES

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