Faulty Design Resulting in Temporary Pacemaker Failure*

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A 77-year-old man became asystolic 3 days after aortic valve replacement and coronary artery bypass surgery. A dual-chamber temporary pacemaker generator was turned on but failed to discharge; instead, an obscure error message appeared on the liquid crystal display of the pacemaker. The intensive-care nurses and physicians were unable to activate the pacemaker. We describe the pacemaker design that led to this instance of pacemaker failure. This case is important because it illustrates how a medical equipment design flaw can turn a human error into a potentially catastrophic event.

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Pacemakers, both permanent and temporary, are complex pieces of medical equipment. Although generally reliable, pacemakers do fail for a variety of reasons. For instance, failure to pace does occur with temporary pacemakers. Most commonly, this is due to displacement of the lead, accidental removal of the lead, or a loose cable connection. In light of publicity generated from reports citing patient mortality and morbidity related to practitioners and hospital error, proper system design of medical equipment is very important.

Poorly designed processes and systems lead to latent errors or errors “waiting to happen.” We describe what we believe is a latent design error in a temporary pacemaker that led to temporary pacemaker failure during a cardiopulmonary arrest.

CASE REPORT

A 77-year-old man patient became bradycardic and then asystolic while sitting in an ICU chair 3 days after aortic valve replacement and coronary artery bypass for severe aortic insufficiency and obstructive coronary artery disease. The nurse turned on the temporary pacemaker (Medtronic 5388 Dual Chamber Temporary Pacemaker; Medtronic Inc.; Minneapolis, MN), but rather than appropriate pacing and capture, an error message appeared on the liquid crystal display of the pacemaker.

The error message persisted despite attempts to turn the pacemaker off and then on again, as well as attempts to switch to the emergency asynchronous mode. Cardiopulmonary resuscitation was initiated. Quickly, another pacemaker was obtained (same model) and turned on, and successful pacing (DOO) was achieved. After a complicated hospital course, the patient was discharged home with no apparent ill effects from the episode.

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DISCUSSION

The Medtronic 5388 Dual Chamber Temporary Pacemaker may become inactive if while it is in the “self-test” mode another key is pressed along with the “on” key (model 5388 technical manual; section 3–35; Medtronic Inc.). If this occurs, the pacemaker will not work, temporary pacemaker failure results, and an error code—0004—is displayed. The pacemaker cannot be turned off, nor can it be “reset.” In order to correct the situation, the battery drawer must be opened and then the drawer must be reinserted. This clears the error code and turns the pacemaker off. It can then be restarted by pressing the “on” key.

It might be unusual and unique for a clinician or nurse to press another key as well as the “on” key, as happened in our case. But in a stressful situation such as a cardiac arrest, it can happen. Therefore, the inherent design in this dual-chamber temporary pacemaker necessarily leads to a pathway that creates operational pacemaker failure. Once operational pacemaker failure occurs, it is not intuitively clear to the practitioner what to do. As a matter of fact, the trouble-shooting checklist distributed by the manufacturer does not include the solution for this dilemma (although the large technical manual designed for the biomedical engineering department does). When the manufacturer was informed of this incident, the company agreed to design a sticker to be affixed to the pacemaker that would inform those using the pacemaker the steps that must be taken to clear the error code.

The events described are classic examples of human error. There are two approaches used in describing the causes and management of human error. One approach focuses on the errors of individuals, blaming them for forgetfulness, inattention, or carelessness. For instance, in this case, a patient who was already at risk for postoperative bradycardia and heart block (given the patient’s aortic valve surgery), why was the pacemaker turned off and not in a standard VVI or DVI backup mode? This was a major clinical error. On the other hand, the systems approach focuses on the conditions under which individuals work. The basic premise in the systems approach to human error is that humans are fallible and errors are to be expected, even in the best of organizations.

The systems approach to error management tries to erect defenses to avert errors or mitigate their effects. For instance, in this case, a systems approach would take into account the following: the high-stress environment of an arrest situation; the closeness of pacemaker key pad buttons to each other; and the baseline human error rate in high-stress situations (approximately 25%). Therefore, a systems-error approach acknowledges a probability of two keys being activated at once. The manufacturer obviously realized this, since this possibility was addressed in the detailed manual designed for the biomedical department. More importantly, the systems approach would permit an easy intuitive escape pathway once the error message occurred, or utilize one of the main principles of good design—forcing functions—to prevent a practitioner from taking a pathway leading to pacemaker failure.

Systems should be designed as much as possible to avert
or mitigate errors. However, there are many cases of device design flaws that are often not readily apparent to the manufacturer and are found after the device is marketed. Some of the reasons that design flaws are found after rather than before devices are marketed include increasing sophistication and complexity of medical devices, as well as greater postmarketing surveillance efforts by the manufacturers themselves. Classic examples of serious flaws in devices leading to recall or warnings include faulty pacemaker leads, prosthetic cardiac valves, and drug infusion devices.

In terms of error-management concepts, the intrinsic design of the temporary pacemaker generator described in this case can be designated a latent threat, in that it increases or predisposes the risk of error in a high-stress situation, but in and of itself lies dormant or latent until an active failure (human error) occurs. This case is important because it serves as a classic example of how intrinsic equipment design flaws can amplify human error into potentially catastrophic outcomes. Analyzing cases such as these and using the lessons, particularly from aviation, may not only improve pacemaker design but the design of all complex medical devices.

REFERENCES