Increasing Patient Safety and Orthopaedic Device Quality via Adverse Event Reporting Mechanisms

BY MICHAEL TANNER, MS, AND GLORIA BRADLEY, BSN, RN

Introduction

Recent advances in orthopaedic implant development have increased the expected in vivo longevity of such devices and are the result of extensive research and development activities, including the evaluation of orthopaedic implants retrieved at the time of revision surgery. Therefore, to help to ensure continued innovation, it is important for the hospital to appropriately notify the device manufacturer of adverse events such as implant revisions. In fact, the United States Food and Drug Administration’s (FDA) Safe Medical Device Act (SMDA) requires the hospital to notify the device manufacturer of adverse events, and an implant revision meets the definition of an adverse event. There is generally perceived to be a low level of provider compliance with adverse event reporting requirements, which may negatively impact patient safety. For example, higher reporting rates could lead to implant recalls being issued earlier, saving patients from an unnecessary procedure. While physicians generally agree with the importance of adverse event reporting activities, many are unaware of the reporting tools available to them. This paper will demonstrate how adverse event reporting can affect patient safety and will identify reporting tools that are readily available to members of the health-care industry.

FDA regulations require hospitals to report adverse events that result in patient death to the FDA as well as to the medical device manufacturer. Hospitals also are required to report to the medical device manufacturer any adverse events that result in serious injury. Serious injuries include those that are life-threatening, those that require initial or prolonged hospitalization, and those that require medical intervention to prevent permanent damage, disability, or congenital anomaly.

Materials and Methods

We reviewed adverse event reports by accessing the FDA’s MAUDE (Manufacturer and User Facility Device Experience) Database. The number of reported revisions of the Sulzer Inter-Op acetabular implant was compared with the number of revisions of this implant as well as the number of components affected by the recall reported in the popular press during the same time-period.

Results

The earliest domestic report of an adverse event involving the Inter-Op implant was filed in 1999, at least a year before Sulzer issued its voluntary recall in December 2000. The number of reports filed with the FDA through March 2001 was 104 (Table I). At least forty-five of these reports were filed with the FDA before the recall. However, through April 2001, Sulzer disclosed that at least 1700 revision procedures had been performed, more than a sixteenfold increase over the number of revisions reported as adverse events.

<table>
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<th>Table I Data on Inter-Op Acetabular Revisions*</th>
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<td>Number of domestic Inter-Op revisions through April 2001</td>
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<td>Number of domestic Inter-Op medical device reports filed with the FDA through March 2001</td>
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<td>Affected products implanted</td>
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*The number of domestic revisions of the Inter-Op acetabular implant substantially exceeded the number that was reported to the FDA.

The number of components affected by the recall (and therefore at risk for revision) was disclosed to be 17,500. However, many of those devices may have been implanted with bone cement and therefore would not have been subject to the loosening phenomena associated with the press-fit construct.

Discussion

The reporting results for the Inter-Op implant clearly demonstrate a trend toward underreporting of revision as an adverse event. Errors such as the misspelling of the manufacturer’s name (“Silzer”) by the individual who filed the report for the hospital often make it difficult to search for products, firm names, and other important information in the adverse event database (Fig. 1).
Adverse event reporting is a simple process. Information and forms are readily available at www.fda.gov/cdrh. One may also complete and submit the forms online. In addition, third-party entities (in partnership with the FDA and at no cost to the hospital) exist to enhance the quality of hospitals’ adverse event reporting. One such example is the Medical Product Surveillance Network (MedSun) (https://www.medsun.net), which is a pilot program that was begun in 2002 as a means of facilitating the electronic sharing of adverse event information between hospitals and the FDA. Currently, approximately 180 hospitals participate in this no-cost program, and additional hospitals are being sought to participate.

Conclusion

The results of the present review suggest that revisions of the Sulzer Inter-Op acetabular implant were underreported as adverse events. Had hospitals been more compliant with the reporting requirements, Sulzer may have recognized this problem and issued a recall earlier, thereby keeping some patients from undergoing the procedure with this implant and thus saving them from an unnecessary revision. Patient safety may be optimized by educating hospital stakeholders in the recognition of adverse events and the value of communicating these events appropriately to the FDA, the device manufacturer, or the local institutional review board. It is also important to recognize events that may not be defined as reportable adverse events in order to prevent dilution of valuable information.

References