Medical Device Epidemiology and Surveillance

Editors

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Division of Postmarket Surveillance, Center for Devices and Radiological Health, Rockville, MD, USA
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Foreword

The problem of patient safety first leapt into the public conscience in 1999 with the publication of the Institute of Medicine’s landmark “To Err Is Human” report [1]. The report summarized a variety of studies which had been done in hospitalized patients and suggested that large numbers of patients were dying annually in the US as the result of care they were receiving, and many more patients were being injured. Two of the leading causes of injuries were surgical care and medications.

Since that time, medication safety has received a great deal of attention, and much more is known today about the epidemiology of medication-safety related issues, and how to prevent adverse drug events than in 1999. Similarly, monitoring of medication safety after drugs are released is relatively advanced. Surgical injuries are more diverse, and may be harder to address; in any event, they have received less attention.

Medical devices represent another extremely important type of medical intervention. While they are clearly beneficial in the aggregate, they also carry important risks. They represent an essential part of surgical and interventional care in particular, although they are used in all health care, and their importance is growing. The market capitalization for the device field was recently estimated to be $75 billion [2]. While this is not nearly as big as for drugs, it is still very large. Further complicating things, there appear to be approximately 8000 different companies in the medical device field and over 80% of these have fewer than 50 employees. These smaller enterprises in particular may find monitoring the safety of their devices challenging, especially as this monitoring competes for scarce resources with other parts of the company.

Monitoring of device safety is primarily the responsibility of the Food and Drug Administration, which works closely with industry to ensure public safety. Perhaps not surprisingly, many of the leading experts in the field of medical device epidemiology and surveillance work at the FDA. Thus, this authoritative book, edited by Drs Brown, Bright and Tavris from the FDA, is especially welcome. Many of the chapters are written by authors from the FDA, but there are also contributors from industry, academia, a consumer group, a consulting group, and a foreign government. The book attempts to describe the issue of device safety, and to begin to develop a theoretical framework for the study of problems with devices, much as pharmacoepidemiology did for pharmaceuticals.

Such a framework is badly needed, since many of the issues with devices are different from those with medications. For example, many devices are permanently inserted inside patients, and may have long-term consequences. Many other devices are not inserted into