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Introduction

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Medical Device Epidemiology and Surveillance, as the name implies, is a book about the discipline of epidemiology as applied to medical devices. Epidemiology, known as the basic science of public health, aims to study the distribution and determinants of diseases in populations [1]. Epidemiologic methods have been successfully applied in a wide variety of public health arenas, including those involving both acute (infection, injury) and chronic (cancer, atherosclerosis) conditions. Surveillance, a key practice within epidemiology, involves not only the systematic collection, analysis, and interpretation of health data essential to public health, but also its dissemination and application [2]. Thus, for example, when applied to medical devices, epidemiology may describe patterns of use or factors associated with use or characterize the risk for certain outcomes in defined subgroups. Likewise, surveillance may identify unanticipated adverse events, related to medical device exposure, which may ultimately lead to product removal. Although both epidemiology and surveillance are essential to assuring the safe and effective use of marketed medical devices, as amply demonstrated throughout this book, their optimal application has yet to be fully realized. The ‘gap’ between current practice and future potential is magnified in importance when one considers the burgeoning field of medical device development and use, and the millions exposed daily to these products.

Medical devices, in short, are instruments, apparatus, implements, machines, contrivances, or in vitro reagents intended to diagnose, cure, mitigate, treat, or prevent disease, or intended to affect the structure or function of the body through means other than chemical action [3]. Given this definition, medical devices encompass a wide variety of products, from single-use disposable to short- and long-term implantable to multiple-use durable capital equipment, and are utilized throughout medical and surgical practice. Their very nature presents a degree of complexity not seen with other regulated
consumer products, such as drugs. Depending upon the device, a variety of factors, such as those related to biocompatibility, hardware or software design, or maintenance, may need to be taken into account in evaluating its initial and ongoing safety and effectiveness. In addition, accounting for both the user and the patient (at times the same) and venues for use (e.g. home vs. hospital care) are critical to a complete assessment of safe and effective use.

Although testing and evaluation of medical devices prior to marketing may be extensive, assurance of their continued safety and/or effectiveness is heavily dependent upon robust postmarket oversight, most importantly provided through the practice of epidemiology and surveillance. Their significant role assumes greater importance when considering well-known limitations of premarket testing and clinical trials (even those randomized) and the iterative nature of device development. Epidemiology, through the conduct of postmarket observational studies (significant examples of which are cited throughout this book), may assess several important device-related issues, including: (a) patterns of use (both on- and off-label); (b) long-term performance (including effects of re-treatment and product change); (c) ‘real-world’ performance (including effectiveness of training); (d) subgroup risk characterization; (e) general public health burden of adverse events; and (f) specific safety signals of significant potential public health impact. The latter are initially identified via device-related adverse event passive reporting systems, both US-based and international. These surveillance systems are key components for continuous postmarket monitoring and assessment of medical device safety.

Noting the importance of epidemiology and surveillance for assuring postmarket device safety and effectiveness, the US Congress called for a study to be conducted by the Institute of Medicine (IOM) to assess whether ‘the system under the Federal Food, Drug, and Cosmetic Act for the postmarket surveillance of medical devices provides adequate safeguards regarding the use of devices in pediatric populations’ [4]. ‘Postmarket surveillance’ was broadly defined to include observational studies. Although the focus of the study was pediatric, the IOM’s report, Safe Medical Devices for Children, made recommendations for improvements to ‘postmarket surveillance’ conduct and infrastructure generally applicable to all age groups and devices [5]. Among infrastructure improvement recommendations were development of device identification standards and enhanced outcome documentation in patient health records as a means to optimize epidemiologic use of healthcare-related databases. Others have noted similar database and related limitations [6,7]. Some have called for a more comprehensive and integrated approach, along with further database development and linking [8–12]. Partnering among relevant stakeholders, particularly the major government agencies overseeing device development and use, as well as professional medical societies, healthcare institutions, and product developers, has been another recent theme [7,11–14]. Major efforts to enhance postmarket epidemiology and surveillance via use of national registries have been recently initiated by the US Center for Medicare and Medicaid Services and the US National Institutes of Health, in conjunction with professional medical societies and the US Food and Drug Administration [15,16].
These recent developments are a testimony to the importance of epidemiology and surveillance in the postmarket oversight of medical devices. Much has already been achieved, as documented throughout this book. The tools and databases currently utilized are thoroughly described, in both their applications and their strengths and limitations, and the unique aspects of safe and effective device use and optimal postmarket assessment are highlighted via select medical specialty chapters.

Closing the ‘gap’ between current practice and future potential is what this book is all about. It provides a starting place to formally recognize medical device epidemiology and surveillance as a coherent field with enormous potential for growth, recognizing the vast and rapidly growing impact of medical devices in patient care and public health. To fully realize its potential, this field will require the concerted effort of both public and private parties.

References

4. Section 212 of the Medical Device User Fee and Modernization Act of 2002.