

Technology Assessment of Medical Devices

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Whether it involves a technology as simple as a stethoscope or as complex as a magnetic resonance imaging scanner, almost every encounter between a healthcare provider and a patient involves some sort of medical device. Thus, even though the market for medical devices is smaller in dollar terms than that for pharmaceuticals, the sheer pervasiveness of devices suggests that their impact on healthcare costs and outcomes may be as great. Yet despite the prevalence and importance of medical devices in healthcare, technology assessments of medical devices are much less common than those for pharmaceuticals. Why is this so? The answer is complex but certainly involves the culture of the device industry, federal regulatory policy, the nature of devices themselves, and market demand for such information. Although there are many apparent barriers to device assessment (several are identified in this issue),

there is reason to believe that decision makers are not happy with the current state of affairs. Managed care organizations and academic-based researchers have decried the poor state of medical device assessment.^{1,2} The FDA Modernization Act of 1997 and the European Community's Medical Device Directive are both in part responses to the recognition that many devices have reached the market without adequate evaluations of their safety and effectiveness.^{3,4} On the other hand, device manufacturers argue that blindly following the drug model of evaluation is not appropriate for medical devices because their industries and products are fundamentally different.⁵

The impetus for this special issue was the convening of the Task Force on Technology Assessment of Medical Devices in March 1997. The task force, which met at the University of Washington and was sponsored by the Washington State Department of Labor and Industries, had three objectives: (1) to describe the principal factors that have limited the amount and quality of technology assessment of medical devices; (2) to develop a set of guidelines that could be used by device manufacturers, purchasers, and providers to improve the assessment and utilization of medical devices; and (3) to identify strategies that would improve the state of technology assessment of medical devices in the long run. Task force members included representatives from the device industry, managed care, the Food and Drug Administration, the Health Care Financing Administration, the Centers for Disease Control, and leading academic centers.

This special issue provides a forum for discussing the issues surrounding the evaluation, regulation, and adoption of medical devices and includes the perspectives of several major stakeholders in the device industry. In the first two articles, Drs. Sheingold, Kessler, and Richter provide views from the Health Care Financing Administration and the Food and Drug Administration—the two most influential federal agencies involved with technology assessment of medical devices. In the next article, Dr. Braslow and

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colleagues describe one large managed care organization's approach to device assessment as part of its decision-making process for health benefits coverage. A "typical" example of a device assessment is described by Dr. Cummings and associates, who are affiliated with a provider group (University Health-System Consortium) that is a recognized leader in technology assessments of medical devices. Dr. Shaw and coworkers describe the process of device evaluation conducted at multiple academic medical centers

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under the direction of researchers at Emory University. Next, Dr. Franklin and colleagues summarize the experiences—and frustrations—of the administrators of the Washington State workers' compensation insurance program, an organization that by nature is heavily involved in designing coverage policies for injuries and illnesses where medical devices are commonly used. In our article, we provide both a summary and a critique of the regulatory and market characteristics of the device industry. Although much of this information will be familiar to those intimately involved with the process of producing and regulating medical devices, it is our experience that these issues are not common knowledge to many purchasers and end users. Our article also contains two new practice guidelines, both developed by the Task Force on

Technology Assessment of Medical Devices. The first guideline was created to establish high standards for future technology assessments of medical devices. The second was designed to improve information exchange between manufacturers and managed care organizations for formulary decision making. This special issue concludes with Dr. Goodman's continuing medical education article on the general principles of technology assessment.

Unfortunately, this issue does not include perspectives from device manufacturers or manufacturers' representatives. This may be because technology assessment is fairly new to the industry, and there are few "internal experts" in the field. If so, we expect this will change. Only a decade ago, experts in technology assessment were rare in the pharmaceutical industry. Today, many highly trained people are working for pharmaceutical manufacturers and their "internal" assessments of pharmaceutical products are often published in peer-reviewed journals.

We hope the articles and guidelines in this issue will stimulate further discussion of the state of technology assessment of medical devices and serve as a template and reference for those who wish to do further work in this important area of the healthcare industry.

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