

Introduction

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New medical device technologies have the potential to revolutionize health care delivery in the United States. With device technologies as diverse as the artificial lumbar disc, fecal DNA testing, cardiac resynchronization therapy, and coronary artery calcium measurements, the promise of new medical devices is great, but the risks of misuse and overuse are substantial. In spite of the ubiquity and impact of medical technology, many physicians do not understand the process by which these technologies appear in the marketplace and how this differs from that for new pharmaceuticals. Indeed, the level of evidence required for FDA approval of new devices is, in most cases, far less stringent than for pharmaceuticals. Most generalists do not know where to turn for evidence-based information when a patient asks about the latest device advertised in the local newspaper or when a specialist recommends a high-tech solution to a common problem.

The impetus for this *JGIM* supplement grew out of a special symposium on Medical Technology sponsored by the California Technology Assessment Forum of the Blue Shield of California Foundation that was held at the 2006 Society of General Internal Medicine Annual Meeting. The goal of the session was to educate general internists about how to evaluate the effectiveness of new medical device technology and where to turn for unbiased information. New technologies in colon cancer screening, such as virtual colonoscopy and fecal DNA testing, were discussed to explore broader issues surrounding the policy and practice of medical device technology. The main message of the symposium was the need for objective, evidence-based assessments of new and emerging medical device technology that can inform patients, clinicians, and policymakers.

The articles published in this supplement are representative of the spectrum of issues surrounding new technologies. Dr. Conrad describes the tremendous potential of the biotechnology revolution to improve cancer screening through proteomics. Dr. Feldman details the issues of FDA regulation and technology assessment initially explored at the SGIM Symposium. A series of articles further explores these issues in the

context of implantable cardiac devices. Dr. Zhan carefully describes the remarkable increase in the use of these devices over the past decade, and considers some of the risks associated with device implantation. Dr. Goldstein provides insights into both the physician and patient perspectives on deactivating the devices. Finally, Dr. Sulmasy argues that the fundamental differences between implantable devices and drugs require a new framework to adequately address the ethical issues that arise when considering use of such devices.

Dr. Sim discusses additional differences between devices and drugs in the context of clinical trials registration for medical devices. Dr. Pateinaude studied the differences in interpreting the use of new technologies by key thought leaders; the issues identified raise important questions about oversight and human subjects review. Finally, a series of articles investigate the impact of medical information technology on medical student education, physician prescribing behavior, diagnosis, and the doctor-patient relationship.

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We hope that this Supplement gives readers a sense of the many issues raised by our society's embrace of new medical device and information technologies and stimulates them to learn more about this important aspect of modern medicine.

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