Drug-Induced Diseases

Prevention, Detection, and Management

Second Edition

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“The mediocre teacher tells. The good teacher explains. The superior teacher demonstrates. The great teacher inspires.”

—William Ward

This book is dedicated to the great teachers who inspire us.
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Societal expectations regarding medication safety have changed dramatically over the years. When I began my career in pharmacy, drug-induced diseases were rarely the subject of public concern. Patients typically had no knowledge of the potential dangers of their drug therapy, and health care practitioners did little to educate their patients regarding possible adverse effects and drug-induced diseases. Today, however, patients expect to be fully informed about the risks of prescribed drugs. They expect that regulatory agencies, pharmaceutical manufacturers, and their health care providers will protect them from drug-induced diseases. The standard of care for ensuring medication safety has clearly changed. And, importantly, change will continue. In the years ahead, society will insist on even better protection and at some point in the future it seems likely that we will look back to our practice today and ask why we accepted such low standards for drug safety.

But who will lead the next wave of progress in preventing drug-induced diseases? Will improvement be driven by health care professionals and scientists, using the best models of practice and science available? Or will it be necessary for society to use its political and economic power to achieve continuing improvement? The interest in the first edition of *Drug-Induced Diseases: Prevention, Detection and Management* (DID-1), published in 2005, suggests that the health professions are ready to lead. And the information included in this second edition (DID-2), when applied properly, will help health practitioners in their quest to continuously improve the standard of care as it relates to safe and effective medication use. This text will be useful to current practitioners and students alike.

Helping health care students develop the knowledge and skills needed to properly address drug-induced diseases will be critical to the mission of improving drug safety, and DID-2 provides much of the foundation for this instruction. Prevention, detection, and management of drug-induced diseases challenges the full scope of knowledge and skills for pharmacists, physicians, nurses, and other health care providers. It requires extensive knowledge of physiology, chemistry, genomics, and other biomedical sciences, as well as human behavior. To be most effective, health care practitioners must not only understand complex biomedical science but also must be skillful in patient consultation and education. Effectiveness in these roles requires lifelong learning to keep pace with rapidly changing information about drugs and their effects. In fact, the issue of drug safety in general is an excellent focus for interprofessional education in health care.

DID-2 will also serve as an essential resource for current health care practitioners. Prevention, detection, and management of drug-induced diseases requires a low-tech, personal approach in addition to the latest in biomedical science findings from patient consultation and education to pharmacogenomic assessment. It requires a careful, individualized approach to each patient, considering their overall health status, age, literacy, as well as population investigative tools of epidemiology. DID-2 helps organize this information in an easily retrievable format. The disease-oriented approach is useful and logical. The text pro-
vides needed structure to the identification and categorization of drug-induced diseases and it describes well the interactions of the many components of the health care system that influence drug-induced diseases. Tisdale and Miller, along with their many contributors, are to be commended for producing an extraordinary work that is the standard for understanding drug-induced diseases and the broader topic of drug safety.

Joseph T. DiPiro, PharmD, FCCP
Dean
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August 2009
Advances in pharmacotherapy have resulted in substantial improvement in patients’ outcomes and well-being. Specific examples can be found in virtually all therapeutic areas: angiotensin-converting enzyme inhibitors, adrenergic β-receptor blocking agents, aspirin, lipid-lowering and antihypertensive drug therapies, among others, for cardiovascular disease; antimicrobial agents for a variety of infectious diseases, including antiretroviral agents for management of acquired immunodeficiency syndrome; improved drug therapy for mental illness, cancer, neurologic disorders, diabetes, and many other diseases. These advances have prolonged and improved the quality of life for millions.

The effects of drugs, however, are not always entirely beneficial. Although they may cure or positively affect disease, drugs are also capable of causing new diseases or exacerbating those that already exist. Since the first edition of this book was published in 2005, numerous drugs have been withdrawn from the market in the United States as a result of morbidity or mortality associated with drug-induced diseases. Examples include pemoline (hepatotoxicity), pergolide (heart valve damage), tegaserod (stroke and myocardial infarction), aprotinin (increased risk of death, likely due to kidney and cardiovascular toxicity), and efalizumab (progressive focal leukoencephalopathy). Despite best efforts to ensure that all drugs are safe and effective, drug-induced diseases develop in millions of patients each year.

Pharmacists, physicians, nurses, and other health care professionals are on the front lines of patient care and pharmacotherapy and must be knowledgeable about the risk of drug-induced diseases and methods of detection, prevention, and management. Students in the health professions must learn that pharmacotherapy has both benefits and risks. And both practitioners and students must appreciate that simply knowing that a given drug can cause a particular disease may not be enough because, as Heraclitus suggested, unless one expects that a relatively unlikely event will occur, its occurrence may be overlooked. Every time a patient presents with a new disease or an exacerbation of an existing condition, someone needs to ask, “Could this be drug-induced?”

The purpose of this book is to provide a comprehensive source of information regarding the detection, prevention, and management of drug-induced diseases for current and future health care practitioners. Our hope is that it will also encourage practitioners to expect the unexpected.

As in the first edition of Drug-Induced Diseases: Prevention, Detection and Management (DID-1), we consider drug-induced diseases to be a specific subset of adverse effects caused by drugs a subset characterized by the severity of symptoms and outcomes. For the purposes of this book, we have defined a drug-induced disease as an unintended effect of a drug that results in mortality or morbidity with symptoms sufficient to prompt a patient to seek medical attention, require hospitalization, or both.

As with DID-1, DID-2 has been structured to facilitate readers’ ability to find specific information related to drug-induced diseases. The first section describes the changing regulatory, legal, and practice landscapes as they relate to drug-induced diseases, provides a general overview of the epidemiology and public health impact of these conditions, discusses factors that may contribute to the development of drug-induced diseases and
describes the structure and strategy of postmarketing surveillance for their detection and characterization, and provides a general approach to patient evaluation. The remainder is organized around specific diseases for which drugs have been implicated as causative agents or, in some cases, the organ system that is involved. Disease-related chapters follow a consistent structure: causative agents, epidemiology, mechanisms, clinical presentation and differential diagnosis, risk factors, morbidity and mortality, methods of prevention, management, and information for patients. Each chapter underwent blinded external review by one or more content experts.

Numerous changes and, we believe, significant improvements have been incorporated into DID-2. Two chapters have been added: “Drug Safety and Drug-Induced Disease: The Regulatory, Legal, and Practice Environments” and “Evaluating Patients for Drug-Induced Diseases.” Chapters from DID-1 have been expanded and, as would be expected, information throughout has been carefully updated by the contributors. “Diarrhea and Constipation” was a single chapter in DID-1, but has now been divided into two chapters. Similarly, the information regarding drug-induced arrhythmias now comprises two chapters: “Supraventricular Arrhythmias” and “Ventricular Arrhythmias.”

Each chapter includes a series of standard tables that are in a consistent format throughout. New drugs implicated as the cause of specific disease(s) have been added, as well as new information regarding epidemiology, mechanisms, risk factors, prevention, and management. DID-2 is more exhaustively referenced than DID-1 and the index has been expanded and improved.

Each of the “agents implicated” tables in DID-2 includes an indication of the strength of the evidence that links a listed drug to the specific drug-induced disease (thanks to Dr. Ross Tsuyuki for this suggestion). A “Level of Evidence” designation of “A” has been assigned when there is evidence of causality from one or more randomized, controlled clinical trials. A designation of “B” indicates that there is evidence of causality from non-randomized clinical trials, prospective observational studies, cohort studies, retrospective studies, case-control studies, meta-analyses, and/or postmarketing surveillance studies. A designation of “C” has been assigned when evidence of causality is from one or more published case reports or case series.

Undertaking a book such as this is not an easy task, and we gratefully acknowledge the work of the chapter authors and expert external content reviewers. Without their significant contributions, this book could not have been completed. We also gratefully acknowledge the support, guidance, and assistance of the staff at the American Society of Health-System Pharmacists. We sincerely hope that this work assists practitioners in their efforts to continually improve patient outcomes related to drug therapy.

JAMES E. TISDALE
DOUGLAS A. MILLER
September 2009

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