

Understanding

Health Outcomes and Pharmacoeconomics

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Dedication

To my wife and children who have endured the countless hours taken from them by me overseeing the research and production of this work—not to mention “the dinners” which have included a healthy serving of pharmaceuticals, a side of health care, and a dash of politics on any given evening.

To my parents who inspired the drive in me to always do my best professionally and personally.

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I would like to recognize the students who over the years have inspired and challenged me in the classroom, in practice, and in life. Likewise there have been colleagues within higher education, the health sciences and clinical practice communities, the health insurance industry, as well as the pharmaceutical industry that have provided sage knowledge and guidance to me.

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Foreword

Following my pharmacy clinical residency, I chose a path very different from many of my pharmacy peers—I pursued a fellowship in Pharmacoeconomics. I was driven by my clinical research demonstrating the benefits of a newly marketed product, Epogen, on patients’ quality of life. Witnessing positive changes in physical and emotional endpoints in conjunction with the improvements seen in the traditional clinical markers for these patients receiving dialysis, I knew immediately the cost of this drug was worth every penny. From this experience, I was determined to pursue a research career demonstrating the value of effectiveness, safety, health, and economic endpoints together in order to drive more informed decisions regarding the allocation of healthcare dollars.

The educational tools at the time were limited to a primer, which provided the definitions and analytical basis for conducting pharmacoeconomic research. What was missing from the literature was the application of these theories and equations for pharmacists. To bridge theory to practice, I published an article, “Guidelines for Performing a Pharmacoeconomic Analysis,” in an attempt to encourage pharmacists and other medical providers to conduct their own research in this area. This was a good start, but I was unaware that this research field was about to take off—and it did. Almost every pharmaceutical company and payer organization added a research arm responsible for demonstrating value, and pharmacy schools began to add the topic of pharmacoeconomics to the curriculum.

Over the last 20 years, the study and importance of pharmacoeconomics, health outcomes, health economics, and epidemiology have grown along with the increased demand for evidence beyond the traditional safety and efficacy endpoints. The true tipping point in the United States came with the signing of the American Recovery and Reinvestment Act of 2009 (ARRA) where the term comparative effectiveness research (CER) became known by all healthcare researchers and providers. This milestone elevated the importance for all healthcare providers and payers to better understand the techniques and tools for comparing not only pharmaceutical products but all interventions in relation to conventional treatment.

This textbook is intended to provide pharmacists and other healthcare providers with a comprehensive overview and applicable tools in order to conduct research demonstrating value to both the patient and the healthcare system. As pharmacists, we have the opportunity to lead this research as we practice across the various care settings. We are consulted and relied on to recommend and distribute biopharmaceuticals—where spending on medicines can lead to decreased hospitalization costs and extended life expectancy—but only if we have the evidence that can be applied at point of care. Therefore, we should call upon ourselves as healthcare providers to learn how to best assess new interventions and treatments. Dr. MacKinnon and the contributing authors have prepared a premier textbook that will be your foundation for conducting new and applicable health outcomes and pharmacoeconomic research.

Lynn Jolicoeur Okamoto, PharmD
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Lynn J. Okamoto, PharmD is Senior Vice President of Health Economics and a Senior Research Scientist at United BioSource Corporation (UBC) in Bethesda, Maryland. Dr. Okamoto leads the health economic and policy efforts in the United States and interfaces with UBC's European operations on global issues. She has extensive experience in global management, as well as advanced leadership skills and command of strategic planning and implementation.

Dr. Okamoto has well over a decade of experience conducting health outcomes and pharmacoeconomic research and has held senior-level positions at NDCHealth and Glaxo Wellcome. She assisted in developing domestic and international pharmacoeconomic research strategy for various pharmaceutical products.

During her tenure at Glaxo Wellcome, Dr. Okamoto took an active role in pharmacoeconomic research at many levels, including decision modeling, strategic health outcomes research in support of new products, and regulatory strategy. Bringing this expertise to NDCHealth, she created and directed the company's Outcomes Research department. In her most recent position at NDCHealth, Dr. Okamoto served as Vice President and General Manager of the Intelligent Health Repository.

Dr. Okamoto received her Doctor of Pharmacy from the University of Michigan, and her work in pharmacoeconomics has led to publication in healthcare journals, including *Clinical Therapeutics*, the *Journal of Asthma*, *Pharmacotherapy*, the *American Journal of Managed Care*, and the *Annals of Allergy, Asthma & Immunology*. Her research covers a wide variety of therapeutic areas and perspectives, from cost-of-illness analyses in respiratory care and influenza management, to quality-of-life studies in asthma. Dr. Okamoto's research has been exhibited internationally at conferences such as the International Society of Pharmacoeconomic and Outcomes Research Annual & European Conferences, and the European Respiratory Society Annual Congress.

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About the Author

A native of northern Wisconsin, Dr. George E. MacKinnon III received both his BS (Pharmacy) and MS (Hospital Pharmacy) from the University of Wisconsin–Madison. He completed two years of postgraduate clinical pharmacy residency training at the University of Wisconsin Hospital and Clinics. He obtained his PhD in Educational Leadership and Policy Studies from Loyola University Chicago. Over the past 20 years, he has held joint academic appointments in medicine and pharmacy at various educational institutions engaging in clinical practice, research, teaching, and academic administration. His previous appointments include Vice President of Academic Affairs with the American Association of Colleges of Pharmacy in Alexandria, Virginia, and Director of Global Health Economics and Outcomes Research of Abbott Laboratories.

Dr. MacKinnon has been involved in a leadership capacity in the establishment and subsequent accreditation of three new colleges of pharmacy in the United States (Chicago and Phoenix). Dr. MacKinnon has engaged in significant curricular innovation (accelerated graduation and nontraditional pathways; integrated curriculum of biological, clinical, and pharmaceutical sciences; and use of student annual academic assessments) with respect to the professional doctor of pharmacy degree (PharmD). He taught one of the first required courses in pharmacoeconomics, health economics, and outcomes assessment at an academic pharmacy program in the early 1990s.

Dr. MacKinnon has assisted in the development of numerous pharmacist–medical practice initiatives as well as several postgraduate residency training programs in various practice settings over the years. He led the development of academic–practice partnerships that have been modeled across the United States. Dr. MacKinnon’s personal research interests and developed products relate to documenting the value of pharmacists’ and students’ interventions with patients and other healthcare providers, and demonstrating the overall clinical and economic impact of such encounters to stakeholders. He has secured extramural funding in excess of \$1.2 million to support various educational programs and research projects.

Dr. MacKinnon served as the Founding Editor of *InetCESM*, one of the first Internet-based continuing education publications, from 1996–2006. Dr. MacKinnon has delivered over 220 presentations, written over 60 publications, and authored several book chapters in pharmacy and the health sciences arena. He received the Clinical Faculty Award for Teaching from the 1992 graduating PharmD class of the St. Louis College of Pharmacy. In 2000, he was recognized by peers as a Fellow of the American Society of Health–System Pharmacists (FASHP), and in 2003, he was the recipient of the Service to Pharmacy Award from the Arizona Pharmacists Association.