



Adaptive Treatment Strategies in Practice: Planning Trials and Analyzing Data for Personalized Medicine (ASA-SIAM Series on Statistics and Applied Probability)

By Michael R. Kosorok, Erica E. M. Moodie

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Personalized medicine is a medical paradigm that emphasizes systematic use of individual patient information to optimize that patient's health care, particularly in managing chronic conditions and treating cancer. In the statistical literature, sequential decision making is known as an adaptive treatment strategy (ATS) or a dynamic treatment regime (DTR). The field of DTRs emerges at the interface of statistics, machine learning, and biomedical science to provide a data-driven framework for precision medicine.

The authors provide a learning-by-seeing approach to the development of ATSs, aimed at a broad audience of health researchers. All estimation procedures used are described in sufficient heuristic and technical detail so that less quantitative readers can understand the broad principles underlying the approaches. At the same time, more quantitative readers can implement these practices.

Adaptive Treatment Strategies in Practice: Planning Trials and Analyzing Data for Personalized Medicine provides the most up-to-date summary of the current state of the statistical research in personalized medicine; contains chapters by leaders in the area from both the statistics and computer sciences fields; and also contains a range of practical advice, introductory and expository materials, and case studies.

The authors multidisciplinary approach unifies the subject for practicing statisticians, medical and public health researchers, and computer scientists interested in medical applications. Graduate students in all these fields will find both theory and practice in the book, including real-world case studies.

Contents: Chapter 1: Introduction; Part I: Design of Trials for Estimating Dynamic Treatment Regimes; Chapter 2: DTRs and SMARTs: Definitions,

designs, and applications; Chapter 3: Efficient design for clinically relevant intent-to-treat comparisons; Chapter 4: SMART design, conduct, and analysis in oncology; Chapter 5: Sample size calculations for clustered SMART designs; Part II: Practical Challenges in Dynamic Treatment Regime Analyses; Chapter 6: Analysis in the single-stage setting: An overview of estimation approaches for dynamic treatment regimes; Chapter 7: G-estimation for dynamic treatment regimes in the longitudinal setting; Chapter 8: Outcome weighted learning methods for optimal dynamic treatment regimes; Chapter 9: Value search estimators for optimal dynamic treatment regimes; Chapter 10: Evaluation of longitudinal dynamics with and without marginal structural working models; Chapter 11: Imputation strategy for SMARTs; Chapter 12: Clinical trials for personalized dose finding; Chapter 13: Methods for analyzing DTRs with censored survival data; Chapter 14: Outcome weighted learning with a reject option; Chapter 15: Estimation of dynamic treatment regimes for complex outcomes: Balancing benefits and risks; Chapter 16: Practical reinforcement learning in dynamic treatment regimes; Chapter 17: Reinforcement learning applications in clinical trials; Bibliography; Index.

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Editorial Review

About the Author

Michael R. Kosorok is W. R. Kenan, Jr. Distinguished Professor and Chair of Biostatistics and Professor of Statistics and Operations Research at the University of North Carolina at Chapel Hill. He is an honorary fellow of both the American Statistical Association and the Institute of Mathematical Statistics and an Associate Editor of *The Annals of Statistics*, *Journal of the American Statistical Association*, and *Journal of the Royal Statistical Society, Series B*. He is the contact principal investigator for a program project (P01) from the US National Cancer Institute entitled "Statistical Methods for Cancer Clinical Trials." His main research interests are in precision medicine, clinical trials, machine learning, and related areas.

Erica E. M. Moodie is a William Dawson Scholar and an Associate Professor of Biostatistics in the Department of Epidemiology, Biostatistics, and Occupational Health at McGill University. She is an Elected Member of the International Statistical Institute, an Associate Editor of *Biometrics* and *Journal of the American Statistical Association*. She holds a Chercheur-Boursier Junior 2 career award from the Fonds de Recherche du Québec-Santé. Her main research interests are in causal inference and longitudinal data with a focus on dynamic treatment regimes.

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