Clinical Trials: Issues and Controversies (340.635.11)
Monday, June 30, 2014 to Thursday, July 3, 2014

Course Director: Lawrence J. Appel, M.D., M.P.H.
Professor of Medicine, Epidemiology and International Health

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Lecturers

Lawrence Appel, MD, MPH is Professor of Medicine, Epidemiology, and International Health (Human Nutrition) at the Johns Hopkins Medical Institutions and is Director of the Welch Center for Prevention, Epidemiology and Clinical Research. The focus of Dr. Appel’s investigative career is the conduct of clinical, epidemiologic and translational research pertaining to the prevention of hypertension, cardiovascular disease, and kidney disease, through both non-pharmacologic (lifestyle) and pharmacologic approaches. Over the course of his career, he has designed and/or conducted numerous (> 50) trials. He has been Principal Investigator of several trials, many of which have influenced health care policy. These studies include the DASH (Dietary Approaches to Stop Hypertension) trial, DASH-Sodium trial, the Optimal Macronutrient Intake Trial to Prevent Heart Disease (OmniHeart), the African-American Study of Kidney Disease and Hypertension (AASK), PREMIER, Weight Loss Maintenance (WLM) Trial, and the recently completed, NHLBI-supported, comparative effectiveness trial, the Practice-Based Opportunities to Reduce Weight (POWER) trial. Currently, he is Principal Investigator of Chronic Renal Insufficiency Cohort Study (CRIC). Dr. Appel has also been actively involved in policy-making committees that synthesis evidence, including the Nutrition Committee of the American Heart Association (Chair, 2006-2008), the 2005 and 2010 U.S. Dietary Guidelines Scientific Advisory Committees, and several Institute of Medicine Committees (Committee on Evaluating Coverage of Nutrition Services for the Medicare Population; Committee on Evaluation of the Evolving Science in Dietary Supplements; Committee on Dietary Reference Intakes for Electrolytes and Water, which he chaired; and Committee on Strategies to Reduce Sodium Intake). Also, he has chaired several data and safety monitoring boards.

Eliseo Guallar, MD DrPH MPH is a Professor of Epidemiology in the Bloomberg School of Public Health. Dr. Guallar’s work focuses on the epidemiology and prevention of cardiovascular diseases, with a special emphasis on environmental exposures such as heavy metals. He is particularly interested in the role of mercury, arsenic, lead, and cadmium in the development of cardiovascular disease. His methodological interests include the determination of threshold effects in epidemiological studies and the application of statistical methods in epidemiological problems. Dr. Guallar is an Associate Editor of Annals of Internal Medicine, American Journal of Epidemiology, Nutrition Journal, and Environmental Health Perspectives.

Brent G. Petty, M.D., is an Associate Professor in the Division of Clinical Pharmacology and the Division of General Internal Medicine in the Department of Medicine, and is an Associate Professor in the Department of Pharmacology & Molecular Sciences. He holds the position of Hospital Pharmacologist at the Johns Hopkins Hospital, chairs the Pharmacy & Therapeutics Committee for the Hospital, and serves on the Institutional Review Board for reviewing and approving human experimentation. Dr. Petty has a keen understanding of early phase trials and has designed and implemented several such studies. He received several teaching awards from the graduating medical students, and has received the Professors’ Award for Excellence in Teaching in the clinical sciences. Dr. Petty has published in journals such as the New England Journal of Medicine, Annals of Internal Medicine, Journal of General Internal Medicine, and Neurology.

Jodi B. Segal, MD MPH is an Associate Professor of Medicine in the Division of General Internal Medicine at Johns Hopkins University, with joint appointments in the Departments of Epidemiology and Health Policy and Management in the Bloomberg School of Public Health. She is the principal investigator of the FDA-PACES Initiative, which aims to advance comparative effectiveness methodology at the Food and Drug Administration.
She has been the Associate Director of the Johns Hopkins Evidence Based Practice Center during EPC III. Additionally, she co-directs the DEcIDE Network Center at Johns Hopkins, funded by the Agency for Healthcare Research and Quality, which performs comparative effectiveness research (CER). She is the principal investigator on two post-doctoral training grants at Johns Hopkins including one for Comparative Effectiveness Research. She is a past co-chair of the committee leading the CER efforts for the Clinical and Translational Science Awards consortium. Her research interests include developing methodology to use observational data to understand the use of new drugs, particularly drugs for treatment of diabetes, blood disorders, and osteoporosis. She is an experienced clinical epidemiologist and health services researcher and in collaboration with her colleagues in biostatistics, has developed new methodologies for observational research and methods to account for competing risks and heterogeneity of treatment effects in analyses. She is a practicing internist.

Claire Snyder, PhD is an Associate Professor of Medicine, Division of General Internal Medicine, at the Johns Hopkins School of Medicine with joint appointments in Oncology and Health Policy & Management (Bloomberg School of Public Health). Her research focuses on the quality of cancer care, with emphasis in two areas: quality of life for cancer patients undergoing treatment and coordination of care for cancer survivors. She has conducted studies to investigate preventive and comorbid condition care in cancer survivors and has also applied her research to developing survivorship care strategies at Johns Hopkins. In other research, she is investigating whether having cancer patients complete questionnaires about their quality-of-life and supportive care needs, and providing that information to their clinicians, improves care quality. She also collaborated on a project to develop a framework for evaluating the quality of end-of-life care.

Jill Marsteller, PhD is an Associate Professor of Health Policy and Management in the Bloomberg School of Public Health. Her research has included a national evaluation of the Chronic Care Model and the organizational traits related to successful implementation of the CCM. Among other things she led a social network study of interaction among collaborative teams as well as an analysis of the relationship between diversity on health care teams and their creativity and fidelity to the Chronic Care Model (a framework for improving chronic illness provision). She currently works to improve the measurement of group psychosocial traits and processes within quality improvement teams in intensive care units. She is also adapting a model of organizational readiness for change to aid dissemination of the "Hospital at Home" intervention. Her research is conducted with a view to providing actionable advice and behavioral tools to teams and organizations seeking to implement quality improvement innovations.

Michael Rosenblum, PhD is an Assistant Professor of Biostatistics at JHSPH. His research focuses on developing improved methods for the design and analysis of randomized trials. Specific goals include (i) addressing the FDA's Critical Path Opportunities to streamline clinical trials by conducting methods research on innovative trial designs, (ii) developing new trial design methods to determine which subpopulations benefit from and are harmed by different treatments, which is in the area of patient centered outcomes research, (iii) developing software tools to make new, proven design and analysis methods widely available and easy to implement. His work includes the development of the covariate adaptive randomized trial design currently implemented in the CLEAR Phase III trial of a novel treatment for intraventricular hemorrhage. He is currently involved in the Partnership for Applied Comparative Effectiveness Science (PACES) with the FDA to constructing new adaptive trial designs for endpoints that are observed soon after patient enrollment.

Curtis Meinert, PhD is a Professor of Epidemiology and was the founding director of the Center for Clinical Trials at the Bloomberg School of Public Health. The Center for Clinical Trials, a joint initiative of the Bloomberg School of Public Health and the School of Medicine, supports the conduct of clinical trials for investigators throughout the Johns Hopkins medical institutions. Its faculty, based in many departments, collectively works to advance the methodology and conduct of clinical trials. Under his leadership, the center has become a model venue for carrying out clinical trials and for improving the methodology of trials. Dr. Meinert also holds a joint appointment in the Department of Biostatistics.
<table>
<thead>
<tr>
<th>Session 1</th>
<th>Session 2</th>
<th>Session 3</th>
<th>Article for Discussion</th>
</tr>
</thead>
<tbody>
<tr>
<td>(8:30am - 9:30am)</td>
<td>(9:45am - 10:45am)</td>
<td>(11:00am - 12:00pm)</td>
<td>(12:00pm - 12:30pm)</td>
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<tr>
<td><strong>Monday (June 30th)</strong></td>
<td><strong>Tuesday (July 1st)</strong></td>
<td><strong>Wednesday (July 2nd)</strong></td>
<td><strong>Thursday (July 3rd)</strong></td>
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