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Comments on Thomas C. Chalmers's Address: Evaluating Clinical Trials

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Those ERN/ENet members who remained for Saturday morning's featured speaker were richly rewarded by Dr. Thomas C. Chalmers's

discussion of his research program pertaining to the quality of clinical trials. During this 15-20-year period, Dr. Chalmers has been an outspoken champion of the need for randomized controlled trials (RCTs) in medicine while serving as President and Dean of Mt. Sinai Medical Center.

Dr. Chalmers's presentation was particularly relevant to members of the evaluation community in dealing with many issues germane to non-medical settings. In fact, to those familiar with the Campbell and Stanley threats to validity framework, the problems confronted are strikingly similar to those encountered in our own research during the past couple of decades. However, the analyses conducted and the solutions suggested offer a unique perspective for understanding the pattern of research results in our own fields of inquiry.

The presentation itself was heavily data-based and centered on two themes: the role of study quality in the particular inferences that are made, and the use of data synthesis techniques to assess what is known about a particular treatment. Numerous slides of tables and graphs taken from previous studies were utilized to illustrate these two themes.

A critical shortcoming of many clinical studies has been the failure to establish proper control groups that use randomization to assign patients to the conditions of an experiment. Instead, medical researchers have utilized historical controls (groups of patients who have not received the treatment of interest whose data are taken from a previous time period) to argue for the effectiveness of treatment. Chalmers and his colleagues have demonstrated quite cogently across a number of examples that the result of this practice of using historical rather than randomized controls has been to *overestimate* consistently the benefit of treatment. In this context it is easy to understand another interesting finding of Chalmers's research—that authors express much more enthusiasm for study results that have used poorer controls while expressing less enthusiasm for studies that have used better controls. For these and other reasons Dr. Chalmers has urged medical researchers to employ RCTs, arguing that randomization should proceed with the first patient that could potentially receive treatment.

The second major theme of Dr. Chalmers's presentation centered on the utility of research synthesis in medical research. Since innovations in the medical field are characterized by small benefits and individual studies typically involve small sample sizes, Dr. Chalmers argued that synthesis efforts are necessary to identify effective interventions. This strategy

would minimize the risk of labeling as useless treatments that appear to be ineffective due to the lack of statistical power. In a particularly provocative application of research synthesis, Dr. Chalmers demonstrated graphically how the results of studies could be cumulated across time to identify the precise period needed before a decision regarding treatment effectiveness could be made. Thus, effective medical technologies can be disseminated more widely and potentially harmful technologies abandoned without undue delay.

The invited address provided the evaluation community the opportunity to acknowledge the pioneering efforts of Dr. Chalmers to enhance research quality by arguing for randomized controls in medical research. It also made quite clear his early role in developing data synthesis procedures as well as the potential value of research synthesis techniques in evaluation research, an area also plagued by small benefits and small samples. Most remarkable of all is the fact that this novel and important research work was conducted while Dr. Chalmers served as President and Dean of Mt. Sinai Medical Center. And given that Dr. Chalmers is spending a portion of his sabbatical year with Dr. Frederick Mosteller at Harvard, we can look forward to still other influential contributions to the evaluation of clinical trials.

Themes of Evaluation '83

Business/Higher Education Forum on Evaluation Training

Alan Nowakowski
Arthur Andersen & Co.

Jeri R. Nowakowski
Northern Illinois University

Arthur Andersen & Co. and Northwestern University co-hosted an invitational forum on human resource evaluation on October 19, 1983 at the Arthur Andersen & Co.'s (AA&Co.) Center for Professional Education