lecting meaningful and responsive quality of life instruments for use in clinical trials and other evaluative studies.

Health outcomes and quality of life assessment is becoming increasingly important in the evaluation of pharmaceutical products, in terms of labeling claims and product promotion as well as in terms of formulary decisions. Each of these uses requires an assessment strategy that provides information relevant for decision-making. What are the components of a successful strategy? How is a given strategy evaluated to select the best for the given evaluative study? This workshop will address these questions and introduce an analytic framework that participants can apply in their daily experience.

SESSION 3

WPE7

SCHIZOPHRENIA: HELPING THE DECISION-MAKER TO UNDERSTAND THE IMPACTS OF ATYPICAL ANTIPSYCHOTICS

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WORKSHOP OBJECTIVE: The purpose of this workshop is to demonstrate, using a schizophrenia case study, how prevalence-based drug value information can be presented in a format that is understandable and useful for decision-makers.
PARTICIPANTS WHO WOULD BENEFIT: Those who want to learn a process that will increase the likelihood that prevalence-based drug value analyses are used by decision-makers.

Although many drug value analyses have been completed in recent years, it is not clear to what extent these analyses have been used to inform decisions. In a recent paper, Mauskopf (VH 1998) has suggested that prevalence-based annual estimates of population and cost outcomes would be of value to decision-makers. In this workshop, we will take the participants through a series of activities designed to ensure that decision-makers can understand and use the results of prevalence-based drug value analyses. We will illustrate these activities using a project that we recently completed for schizophrenia. In this project, we developed an interactive computer model to estimate the impacts of the atypical anti-psychotics on patient and family outcomes and healthcare costs for a population of schizophrenia patients. The project included three main activities: 1) develop a preliminary model; 2) present the model to decision-makes to determine its value to them; and 3) revise the model based on decision-maker comments and create an interactive computer version of the model. We will show the workshop participants how we presented our model to the decision-makers. We will summarize the decision-makers responses to the presentation. We will then lead the workshop participants in a discussion about the range of possible responses to these comments and the trade-offs between 1) keeping a model well grounded in published literature; and 2) extrapolating information to address outcomes that are important to decision-makers, but not well researched. We will conclude the workshop by describing how we modified the preliminary model in response to the decision-makers' comments and by showing the final interactive computer model.

WPE8

DESIGNING NATURALISTIC OUTCOMES TRIALS THAT ARE APPLICABLE TO THE "REAL WORLD" OF CLINICAL PRACTICE

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WORKSHOP OBJECTIVE: To highlight design features that characterize state-of-the-art studies evaluating outcomes of competing pharmacotherapies, balancing the need to maintain internal validity with the goal of providing information that can be applied to the "real world" of clinical practices.
PARTICIPANTS WHO WOULD BENEFIT: 1) Outcomes researchers, statisticians, health economists, and others who wish to expand beyond the traditional clinical trial design; and 2) clinicians, healthcare organizations, and others who wish to learn more about how to make informed decisions based on comparative cost and effectiveness claims.

Various methodological issues are critical in the design of naturalistic outcomes trials. These include how narrowly (or broadly) to define the patient population, whether or not to "blind" the study, how much physician discretion to allow in treating patients, and how to obtain and analyze data on patients who switch from their originally-assigned medication (or on patients who discontinue medication). Additionally, the definition of comparator(s) and the appropriate time horizon of the study are important. These and other issues will be discussed and illustrated through examples of two randomized naturalistic trials designed by the workshop leaders and colleagues. One study is designed to answer the question of whether using an atypical antipsychotic agent as first-line therapy is more effective and less costly than requiring a patient to first fail on conventional medications. The other study is designed to determine how three different selective serotonin reuptake inhibitors compare in terms of various outcome measures including patient adherence, quality of life, and resource utilization. The authors will discuss the decisions made in designing these trials and the implications of these decisions for data analysis and interpretation of findings.

WPE10

GUIDELINES FOR THE ECONOMIC EVALUATION OF PHARMACEUTICALS: CURRENT USE AND EMERGING TRENDS

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