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ties encountered and offer recommendations for using such databases to examine provider prescribing practices, patient compliance, and outcomes of ADHD-related care. The following methodological issues will be discussed: 1) determining the presence of specific psychiatric disorders and their comorbidities from pharmacy benefits databases; 2) using pharmacy benefits databases and patient telephone and mail surveys to distinguish discontinued psychotropic treatment from patient noncompliance and medication switching; 3) applying health services utilization and pharmacy databases to determine small area variation in ADHD care; 4) examining the impact of behavioral health care carve-outs on analyses of patient outcomes; 5) employing findings to benchmark existing quality of care, calculate rates of provider adherence to guidelines, identify best practices, and evaluate impact of interventions on outcomes of patients with ADHD.

wwa

USING LINKABLE CLINICAL AND ADMINISTRATIVE CLAIMS DATA TO IMPROVE OUTCOMES RESEARCH: SELECTED CASE STUDIES FROM ONCOLOGY AND DIABETES MELLITUS

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OBJECTIVES: The objectives of this workshop are to describe various types of linkable clinical and administrative claims data, review selected case studies, and highlight the strengths and limitations of these databases.

PARTICIPANTS WHO WOULD BENEFIT: Those involved in planning, designing, implementing, and using data from retrospective database studies would benefit from this workshop.

Administrative claims are increasingly used for outcomes research studies, despite known limitations associated with data reliability and validity, and a lack of clinical content. In recent years, efforts have been made to link claims to other sources, such as disease registries and clinical laboratory files, to create richer databases for research purposes. These linked data sources offer the potential for improved accuracy in case identification and outcomes ascertainment. For example, study patients can be selected based on their presence in a disease registry instead of relying on diagnoses reported on medical claim forms, and clinical laboratory files can be used to evaluate the success or failure of therapy. In this workshop, we will review, via case studies from oncology and diabetes, the content of linkable clinical and claims databases, the specific ways in which such data have been used in published outcomes studies, and the remaining limitations of this record linkage approach. Participants will learn how clinical data can be applied to strengthen studies of treatment costs and the burden of illness, and they will gain an appreciation of the improvements that linked data sources can make to the pharmacoeconomics and outcomes research fields. One case study will review applications of the SEER-Medicare database, which includes a linkage between cancer registry data and Medicare administrative claims for approximately 14% of U.S. cancer cases across 17 diverse regions. The other illustration will describe published studies of the economic benefits of improving glycemic control among diabetes patients, in which claims data from several managed-care organizations were linked to glycosylated hemoglobin test results.

WW3

ISSUES AND PROBLEMS ENCOUNTERED IN MODELS ON PREVENTION OF DEEP VENOUS THROMBOSIS (DVT)

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OBJECTIVES: The purposes of the workshop are to demonstrate a systematic method to compare published models developed for a same disease and to point out the importance of validation of model structure, data input and outcomes.

PARTICIPANTS WHO WOULD BENEFIT: Pharmacoeconomic and outcomes researchers involved in modeling and/or in the area of DVT.

In the clinical and health economic literature, 11 different models from different researchers are published in the area of DVT prevention with heparins. These models generally compare standard heparin with one of the low molecular weight heparins in order to assess the health economic consequences of better prevention at a higher price. All models differ in many aspects of study design and methodology: perspective, target audience, patient population, patient subpopulations, choice of comparator(s) and justification of this choice, medical management patterns and corresponding decision trees, clinical data input and reporting, economic data input and reporting, dealing with uncertainties, validation, conclusions and extrapolations. This lack of uniformity in design and methods within a same research topic leads to incomparable outcomes and conclusions. The workshop is designed to discuss with the audience the strengths and weaknesses of all models, and to have the audience suggest solutions for better design, reporting and communications of results in this area and for decision models in general. A novel consensus method, leading to a new model, attempting to bring together the best elements of existing models, is proposed for discussion with the audience.

WW4

A NEW APPROACH TO DISEASE MODELING WITH NUMEROUS COMPARATORS AND MULTIPLE DECISION TREES

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OBJECTIVES: The objective of this workshop is to describe the approach used in developing a comprehensive, multi-national breast cancer treatment model. This disease model was developed for six international markets—U.S., U.K., Germany, Japan, France, and Italy—and includes over 70 treatment comparators used in 24 unique decision trees. The model's flexibility, with nearly 350 variable cost components related to the diagnosis, treatment, and outcomes of breast cancer, allows for an examination of the effect of varying cost and probability scenarios to reflect a multitude of country-specific treatment practices and international practice variations.

PARTICIPANTS WHO WOULD BENEFIT: Researchers involved in the development of international clinical and economic decision analysis models.

A disease treatment model can be a useful tool for comprehensively evaluating the clinical and economic aspects of a specific disease. This workshop will explain the steps involved in building the model, including: Use of accepted clinical guidelines to develop treatment pathways and the use of expert-opinion to reflect variations in actual current practice Probability data collection for over 144 million decision nodes Cost data collection for all treatments and cost components. Computer software used to program the model. Interaction of clinical endpoint, cost, and clinical pathway modules. Type of results generated (e.g., database queries, sequence queries, costeffectiveness analysis). Limitations and possible applications to other diseases Participants in this workshop will have an opportunity to suggest customized queries to be answered by the model.

WW5

CREATIVE APPROACHES TO MODELING LIFE EXPECTANCY GAINS FOR ECONOMIC EVALUATION USING PUBLISHED DATA

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OBJECTIVES: Cost-effectiveness analysis requires estimating gains in life expectancy from effective treatments. Survival is not an endpoint in many clinical trials, because of limited follow-up intervals or statistical power. If databases linking survival to the surrogate markers used in the trials are not available, fragmentary published data based on follow-up studies may suffice. This workshop illustrates methods for using limited published data to estimate life expectancy gains. Participants will be encouraged to share their own experiences in modeling life expectancy.

PARTICIPANTS WHO WOULD BENEFIT: Analysts who want to estimate cost-effectiveness based on limited published data.

This workshop illustrates methods for using limited published data to estimate life expectancy gains. The exam-

ple concerns AIDS wasting, in which patients with HIV infection experience significant weight loss. Treatments such as human growth hormone (HGH) and anabolic steroids have been found effective in retarding weight loss or even restoring body weight in patients with AIDS wasting. Published survival curves stratified by weight change from baseline (in ranges such as -10% to -5%) and CD4 cell count were found in the literature. A clinical trial of HGH reported means and standard deviations of weight change from baseline with drug and with placebo. Our task was to use these data to estimate the life expectancy gain with HGH in patients stratified by CD4 cell count. The presenters will demonstrate the following analytic steps: (1) estimating probability distributions of weight change from the clinical trial and using these to estimate the probability that patients would experience each range of weight change; (2) estimating areas under the published survival curves to estimate truncated life expectancies by range of weight change; (3) using the DEALE method to extrapolate survival and life expectancy beyond the trial follow-up period; (4) combining steps (1)-(3) to estimate the gain in life expectancy attributable to treatment; and (5) applying discounting to the survival analysis and life expectancy calculations. As with all life expectancy estimates mediated by surrogate markers, there is no "proof" that weight change caused by treatment will translate into life expectancy gains. In the absence of direct evidence of a survival benefit, however, these methods can be used to estimate potential life expectancy gains.

ww6

CONDUCTING COST-BENEFIT AND COST-UTILITY ANALYSES: A CONJOINT ANALYSIS APPROACH

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OBJECTIVES: The objective of this workshop will be to develop an understanding of conjoint analysis methodology, and how it can be used to conduct cost-utility analysis and cost-benefit analysis by capturing patient preferences.

PARTICIPANTS WHO WOULD BENEFIT: Analysts involved in the conduct of pharmacoeconomic studies, particularly those interested in the patient's perspective.

Cost-utility analysis (CUA) and cost-benefit analysis (CBA) are alternate analytical frameworks that can be used to evaluate health interventions. CUA uses a non-monetary metric, such as quality-adjusted life years (QALYs), to value health benefits. In CBA, both costs and benefits are measured in monetary terms. Conjoint analysis can be used to estimate the benefits of an intervention in either monetary or non-monetary terms and can be used in both CUA and CBA. In this workshop, we