Aim and METHODS: The aim of this health technology assessment was to analyse the current scientific and genetic counselling situation about predictive genetic testing for hereditary breast and colorectal cancer. This report is based on a systematic literature research and on a specific health technology assessment (COHTA) resp. review (American Gastroenterological Ass.). Background: Breast and colorectal cancer are counted among the most frequently cancer diseases. 5–10% show a familial determination. A hereditary modified gen is responsible for the increased cancer risk. Results and CONCLUSION: The identification of the responsible gen defect in an affected family member is important. If the test result is positive there is an uncertainty about if the disease will occur, when and in which degree founded in the geno-/phenotype correlation. The individual risk estimation is based upon empirical evidences. The so-called preventive medical check ups are early detection examinations. For colorectal cancer the evidence about early detection methods is better than for breast cancer. Prophylactic mastectomy (PM) reduces the relative breast cancer risk by approximately 90%. Colectomy can be used as a prophylactic (FAP) and therapeutic method. After operations the cancer risk remains high and so detection examinations are still necessary. The evidence is often fragmentary and from limited qualit. New identifications of mutations and demand creation will result in an increase of predictive genetic counselling and testing. There is a gap between predictive genetic diagnosis and the prediction, prevention, early detection and surgical interventions. Since predictive genetic diagnosis is a very sensitive issue it is important to deal carefully with it in order to avoid inappropriate hopes.

SELF-REPORTED PATIENT EXPERIENCE DATA, PROVIDED TO PHYSICIANS AT THE POINT-OF-CARE, OFFER AN IMPORTANT COMPLEMENT TO TRADITIONAL EFFICACY DATA AND ENABLE THE DERIVATION OF PRACTICE-WIDE TREATMENT GUIDELINES
Schmeichel CJ1, Netherton DR2
1SMA, Munster, IN, USA; 2InfoMedics International, Inc, Woburn, MA, USA

OBJECTIVES: Prospective “real-world” patient experience data is a highly acceptable form of data that can be relevant to an individual clinician’s practice in determining the optimal patient profile to achieve the most efficacious results. This study was designed to assess the real-world effectiveness of a sleeping medication and provide the treating physician with self-reported data to profile optimal patients for treatment. METHODS: Self-reported data about symptoms of transient insomnia and symptom relief prior to and after using a sleeping medication were collected from patients via telephone or the Internet. Treating physicians enrolled all patients and received individual patient reports. RESULTS: A total of 1378 patients completed both surveys. Ages were 39% < 45 and 43% between 45 and 64, and 77% were female. At baseline, 62% of patients reported having difficulty sleeping ≥14 nights per month. Factors creating periods of insomnia included stress (59%), depression/anxiety (39%), travel (3%), and work-related issues (3%). The most important quality in a sleeping medication was reported to be absence of “grogginess” the following day (46%). The time required to get to sleep (15 to 60 minutes) improved for all study participants. With a statistical significance of p < 0.001, reported symptoms of trouble falling asleep, not feeling rested, feeling sleepy the next day, and trouble functioning the next day were improved by 3 to 5 points on a 10-point scale. CONCLUSIONS: Findings suggest that the use of the study medication offers considerable relief of key symptoms. The findings also provide the practicing clinician with insights into the factors that patients require in a sleeping medication and suggest that effectiveness endpoints complement and even synergize with efficacy endpoints.

COST SOURCE AND PERSPECTIVE IN ECONOMIC OUTCOMES STUDIES: FOCUS ON POSTERS PRESENTED AT THE 7TH ANNUAL INTERNATIONAL ISPOR MEETING
Kwon S, Taylor MD, Mayhew D, Hartzema AG
University of Florida, Gainesville, FL, USA

OBJECTIVE: Pharmacoeconomic studies evaluate medications in terms of financial consequences. Thus, the validity of the source of cost data influences study results. The primary objective of this study was to examine the sources of cost data used in studies presented as posters at the 7th Annual International ISPOR Meeting. Type of analysis and perspective of studies were also assessed. METHODS: The abstract of economic outcomes studies printed in Value in Health for each poster and a handout of the poster, when available, were used to assess the source of cost data, analysis type, and perspective. Three reviewers working together extracted and categorized the information for each poster presented. A 20% random sample of studies was reassessed to evaluate the reliability of data extraction and categorization. RESULTS: Of 127 studies sub-classified as economic within the various disease categories, 19 studies were excluded from the analysis due to not meeting inclusion and exclusion criteria. Sources of cost data were classified into 12 categories. The 4 most frequently used sources being literature (17%), commercial databases (13%), government databases (13%), and national statistics (11%). The distribution of study types was: cost-effectiveness (27%), cost-utility (3%), cost benefit (2%), cost minimization (2%), cost of illness (2%), cost assessment (62%), and multiple (3%). The analytic perspective was clearly stated in only 54% of studies. CONCLUSIONS: Pharmacoeconomic evaluations play an important role in Health care decision-making. The source and perspective of cost data,
the focus of this study, are key pieces of information necessary for decision-makers in evaluating economic outcomes study findings. This analysis suggests the need for continued emphasis of guidelines calling for clear identification of the source and perspective of cost data.

WILLINGNESS TO PAY, WILLINGNESS TO WAIT, AND SUPER QALYS: NARROWING THE CONCEPTUAL GAP BETWEEN CARDINAL AND ORDINAL HEALTH UTILITY MEASURES

OBJECTIVES: Using (SG) or time tradeoff (TTO) measures of QALY utility weights requires strong and generally unrealistic assumptions that effectively break the link between SG and TTO utilities and utility-theoretic preferences. In particular, QALY linearity assumptions violate the generally accepted law of diminishing marginal utility. This presentation derives general “super QALYs” from nonlinear, ordinal utility functions that incorporate wealth and non-health utility variables as well as time in specific health states. Thus super QALYs can incorporate patient satisfaction related to dosage or drug administration and other utility-relevant factors for both acute and chronic health outcomes.

METHODS: We illustrate comparisons between conventional QALY and super QALY measures using linear and Cobb-Douglas utility functions. Under general conditions, nonlinear super QALYs may rank health outcomes differently than QALYs, but linear super QALYs rank outcomes similarly. If preferences are nonlinear, marginal changes will be weighted differently with QALYs and super QALYs, thus affecting incremental cost-effectiveness ratios. When derived from consistent utility-theoretic preference relations, super QALYs, willingness to pay (WTP), and willingness to wait (WTW) represent alternative and equivalent rescaling of the same preference information.

RESULTS: We explore the empirical significance of these conceptual results using an empirical utility function from a recent choice-format conjoint study of acute respiratory and cardio-vascular symptoms. Setting utility to zero for the worst-observed outcome, quality-adjusted life days (QALDs) range from 0.066 for 5 days of pneumonia symptoms requiring hospitalization to 4.25 for 5 days of nasal congestion with some physical activity restrictions. Corresponding WTP, WTP per QALD, and WTW values for the same outcomes are $980 and $30, $199 and $40, and 4.93 and 0.75, respectively.

CONCLUSIONS: Although nonlinear ordinal utility functions sacrifice the simplicity of constant QALY weights and linearity over time, improved validity justifies the modest increase in analytical burden in many cases.

THE INTERNATIONAL COSTING SOURCES DATABASE: A TOOL FOR ENSURING CONSISTENT AND RIGOROUS INTERNATIONAL COSTING

WITHDRAWN