Disease Questionnaire (IBDQ). Over the years a standardized document was developed to help the authors to clarify the concepts and intent of each item of their questionnaire(s). This document and examples will be presented. CONCLUSIONS: This review demonstrates the lack of a formal, written concept lists for PRO questionnaires developed before the publication of the FDA guidance and the need to develop standardized documents. Involvement of the developer(s) is crucial at this step.

Research on Methods – Statistical Methods

PRM36 NONPARAMETRIC ESTIMATION OF INCREMENTAL COST EFFECTIVENESS RATIO ACCOUNTING FOR SKEWNESS

Blough DK

University of Washington, Seattle, WA, USA

OBJECTIVES: Typically, mean costs and mean measures of effectiveness are used in the estimation of the incremental cost effectiveness ratio (ICER). Cost and effectiveness distributions, however, are often skewed. The goal of this work is to use a nonparametric generalization of location to obtain a location region in the cost effectiveness plane. The region accounts for uncertainty and all points in the region are appropriate estimates of the ICER that account for skewness in the marginal distributions. METHODS: First, analogous to Mann-Whitney, all pairwise cost and effectiveness treatment differences are computed. Univariate methods, an estimate of a location rectangle is obtained as the Cartesian product of marginal distributions.

RESULTS: By comparing the location region with the usual bootstrap estimates for the ICER, it was found that the location region approach produced confidence intervals that were considerably larger for both skewed and symmetric distributions of costs and effectiveness. CONCLUSIONS: This work provides estimates of the ICER that appropriately accounting for skewness. In such cases, the mean is not the best measure of location. In spite of the use of the nonparametric bootstrap to obtain confidence intervals, skewness introduces an extra element of variability that should be accounted for.

PRM37 THE DISCRETE MODELLING OF INTERVENTIONS WITH CONTINUOUSLY VARYING COSTS AND EFFECTS: IMPLICATIONS FOR ICERS, CEACs AND EVPi

O'Mahony J, van Rosmalen J

Erasmus University Medical Center, Rotterdam, The Netherlands

OBJECTIVES: To show how the discrete modeling of continuously varying dose-response analysis (CEA) influences incremental cost-effectiveness ratios (ICERs), cost-effectiveness acceptability curves (CEACs) and the expected value of perfect information (EVPi). In particular, to show that each of these metrics is contingent on the discrete conversions chosen within a CEA. METHODS: The cost-effectiveness of hypothetical interventions with continuous dose-response relationship is simulated. The cost-effectiveness of a small number of possible dose levels is simulated first. The analysis is then repeated a number of times, progressively increasing the number of possible doses and resulting combinations of costs and effects. For each run of the analysis ICERS are calculated for each dose level, a probabilistic sensitivity analysis is simulated, and CEACs and the EVPi are plotted. RESULTS: As the number of potential cost and effect combinations increases, the ICERs for each dose level increase, the CEACs fall towards zero and the EVPi both rise and changes from having sharp inflection points to being a smooth, downward-sloping curve. CONCLUSIONS: Many interventions demonstrate dose-response relationships, most of which are in principle continuous, even if doses are typically varied discretely. The continuously increasing intensity of interventions means the number of possible alternatives is infinite. The general conclusion from the analysis is that each of the metrics presented here are contingent on the discrete conversions chosen within the analysis. The significance for EVPi is that while it has previously been recognised that excluding relevant comparators can reduce the EVPi, including all theoretically possible interventions may be impossible. Further work may be needed to understand this constraint on measuring the upper bound of the value of further research.

PRM38 THE EXTENSION OF THE COST-EFFECTIVENESS ACCEPTABILITY CURVE: HOW TO MAKE IT MORE INFORMATIVE?

Kamal A, Ari S, Kontopantelis E

Kojo University Graduate School of Health Management, Fujisawa, Japan, 2Meji University of Integrative Medicine School of Nursing Science, Nantan-shi, Kyoto, Japan, 3Tufts Medical Center, Boston, MA, USA

OBJECTIVES: To develop new schemes which can make the cost-effectiveness acceptability curve (CEAC) augmented to be more informative regarding the types of acceptance and statistical inference. METHODS: Theoretical approaches have been undertaken to address two questions: how the area under the curve (AUC) can be zoned by the types of acceptance, and how the accepted dataset of incremental cost-effectiveness ratios (ICERs), which are generated by computer runs, can be statistically associated with a standard threshold of ICER. RESULTS: The AUC of a typical sigmoid-shaped CEAC was divided into three zones, each of which represents the different confidence regions of the ICER. The number of ICERs that were accepted for the threshold $t$, the confidence region of the ICER for $t$, and the probability of acceptance for the threshold $t$ are the mean ICER of all the plots accepted for the threshold $t$. Also, statistical validity of the CEAC was inferred by the confidence interval of the mean $m_t$ using $t$-test. Furthermore, the series of confidence intervals defined for one threshold $t_0$ corresponding to different size of computer runs were summarized as a diagram for showing the progression of the confidence intervals, which looks similar to the forest plot in meta-analysis. All those schemes were graphically illustrated based on examples.

CONCLUSIONS: Visualizing the component types of acceptance in the AUC, drawing the MCEAC, and the progression diagram of confidence intervals will provide us with more useful information on cost-effectiveness decisions.

Research on Methods – Study Design

PRM39 LITERATURE REVIEW OF RANDOMIZED, CONTROLLED STUDIES OF THE IMPACT OF PHARMACISTS’ INTERVENTIONS TO IMPROVE PATIENT OUTCOMES

Khazaat AA1, Borrego M2, Rauch DW3

1University of New Mexico, NM, USA, 2University of New Mexico College of Pharmacy, Albuquerque, NM, USA

OBJECTIVES: The objective was to summarize the impact of pharmacists’ interventions on patient outcomes as reported in studies utilizing a randomized controlled trial (RCT) design. METHODS: A comprehensive literature search was conducted utilizing PubMed and International Pharmaceutical Abstracts for the years 1979-2009. Studies were included if they evaluated pharmacist-provided interventions, utilized RCT designs with control groups, and were conducted in the United States. Studies were summarized by 1) publication year; 2) study setting; 3) disease/health condition; 4) type of intervention provided and whether performed by a pharmacist alone or a pharmacist with other health care professionals, 5) primary outcome variables and 6) study findings. Patient outcome results were categorized as positive if they found a statistically significant improvement in the patient outcome compared to the control group, or to no change (i.e., no difference). Chronic conditions were studied in 56% of the studies. Studies of interventions delivered by pharmacists alone comprised 64%, while 36% involved pharmacists working with other health care providers. Overall, ‘positive’ patient outcomes were demonstrated in 73% of the studies. When interventions were delivered by pharmacists working with other health care providers, however, 97.2% had positive outcomes. CONCLUSIONS: ‘Positive’ patient outcomes were demonstrated in the majority of the studies, supporting increased pharmacists’ roles in the health care system to improve patient outcomes. When working alongside other health care providers, the positive impact was most likely.

Research on Methods – Conceptual Papers

PRM40 ISSUES CONCERNING THE TRANSLATION OF THE WORD ‘HASSED’ IN THE MORISKY MEDICATION ADHERENCE SCALE (MMAS-8)

Griffin A1, Wild D2, Morisky DE2

1Oakford Outcomes Ltd, Oxford, Oxfordshire, UK, 2UCLA School of Public Health, Los Angeles, CA, USA

OBJECTIVES: The word ‘hasseled’ is commonly used in PRO measures including the Morisky Medication Adherence Scale (MMAS-8). The translation of the word ‘hassle’ is used as an example of how creation of a concept elaboration and a full face validity and linguistic validation process can result in a translation that is conceptually equivalent to the source text and to aid in the future translation of ambiguous words. METHODS: The MMAS-8 was translated into 29 languages using the standard methodology of two forward translations, reconciliation, two back translations, back-translation review, developer review and proofreading. Examples of translation issues of the word ‘hasseled’ in the following statement were assessed. Do you ever feel hassled about sticking to your anti-rejection treatment plan?

RESULTS: A ‘hassle’ is defined in the Oxford English Dictionary as an ‘irritating inconvenience’. In the above question, this word encompasses several concepts – bother, disturbed, frustrated, agitated, inability to tolerate or adjust to a situation. Therefore, this question was translated to ‘souffrant/bothered/overwhelmed’, with French speaking patients, who agreed that this was the best translation in this context. For other languages, ‘hassled’ was translated variously as: a nuisance, cumbersome, difficult, bothersome, troubling, tiresome, irksome, burdensome and complicating. These were queried with translator and the developer to confirm concept.

A152 VALU E IN HEALTH 14 (2011) A1-A214