tual equivalence to ‘hassled’. CONCLUSIONS: Though not always possible to translate an English word exactly into the target language, a full translation and linguistic validation process, including creation of a concept elaboration document followed by an in-depth discussion at back-translation review stage, enables a conceptually equivalent translation to be produced. However, numerous experiential and practical problems limit the usefulness of ICERs for decision making.

PM46 IS IT TIME TO ELIMINATE THE ICER? USING NET BENEFITS TO REPORT THE RESULTS OF DETERMINISTIC COST-EFFECTIVENESS ANALYSES
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BACKGROUND: Incremental cost-effectiveness ratios (ICERs) are used to report the results of cost-effectiveness (CE) analyses and represent the cost per unit of effectiveness of a more expensive and more effective option. However, numerous practical and theoretical problems limit the usefulness of ICERs for decision making. These problems include, but are not limited to, negative ICERs, one-way sensitivity analyses, complexity of multiple comparator analyses, and statistical limitations with ratios. The net benefits approach was developed to address the statistical limitations of ICERs and is now an accepted methodology used in probabilistic sensitivity analysis to estimate CE confidence intervals and plot acceptability curves. However, despite the remaining challenges and limitations the use of ICERs persists, raising the question: Is it time to eliminate the use of ICERS in the reporting of CE analyses?

METHODS: We propose expanding the net benefit method to present deterministic CE analysis results using a net monetary benefit (NMB) chart or table. A NMB chart is plotted with the x-axis representing the WTP threshold and the y-axis representing the NMB. The NMB of each option is a line with the intercept representing the cost and the slope representing the effectiveness across a specified range of WTP values. The line with the greatest NMB at a given WTP represents the most cost-effective option at that WTP. The vertical distance between the two lines represents the incremental NMB. Dominance, extended dominance, and the frontier are captured graphically and intuitively. Multiple comparator analyses are simplified and one-way sensitivity analyses are enhanced due to the elimination of negative ICERs.

CONCLUSIONS: A net benefits approach provides a more intuitive, informative, and useful method to present CE results, compared to the use of ICERS. Moreover, it has the benefit of facilitating a uniform and consistent approach to presenting the results of deterministic and probabilistic CE analyses.

PM42 VISUALLY EVALUATING THE MEASUREMENT COMPARABILITY BETWEEN PAPER-BASED AND ELECTRONIC VERSIONS OF ADMINISTRATION OF THE LUNG FUNCTION QUESTIONNAIRE
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In randomized crossover designs, intraclass correlation coefficients (ICCs) are often used to assess the concordance between scores on different administration versions of patient-reported outcome (PRO) measures. An ICC and its associated criterion for “adequate” concordance enable analysts to simplify information and provide a quick, easily interpreted output. Our objective is to assess this tool’s ability to translate and adapt a lung function questionnaire from English into a different language. We compare the concordance between versions of a lung function questionnaire using ICCs. This strength of the ICC—its simplicity—may also be a weakness. Analysts may over-look important information (e.g., biases, outliers) when ICCs are used as the primary method for assessing concordance. One way to avoid overlooking important information is to use scatter plots. However, the interpretation of Bland-Altman plots when assessing concordance is more complicated. Bland-Altman plots allow one to visually determine whether two measures produce similar scores, therefore, supplementing the concordance information gained from theICC evaluation. ICCs and Bland-Altman plots complement each other’s strengths. ICCs provide an efficient and concise estimate to determine the comparability of versions, while Bland-Altman plots provide a greater level of detail that incorporates a broader view of the analyzed distributions. The use of the two methods together provides a more holistic view of concordance. We present Bland-Altman plots and corresponding ICCs under a randomized crossover design, using the Lung Function Questionnaire, a PRO instrument originally designed to be administered via paper, and later via three alternate administration versions (Web, interactive voice response system, and interview). We provide examples to illustrate instances in which ICCs and Bland-Altman plots agree and disagree. GSK study number: ADC001HO.

PM43 BIOSIMILARS: DEMONSTRATING SIMILARITY THROUGH EVIDENCE
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OBJECTIVES: The differences in the active substance of biosimilars compared to their originator reference product can cause risks that are unique to biologics, mainly: immunogenicity, long-term safety risks, and lack of efficacy. These risks are unknown at the launch of a biosimilar and can lead to unexpected costs for payers. The aim of this abstract is to describe a methodology for evaluating the unknown risks of biosimilars. METHODS: A structured literature review revealed that for many biologics, post-marketing observational studies have been set up to identify long-term safety and efficacy outcomes. These studies are a useful source of information to quantify the unknown risks of biosimilars and define methods of minimizing those risks. The information required is product- and population-specific. This information first includes potential safety issues such as immunogenicity (all biologics), serious infections and autoimmune disorders (anti-TNFs, interferons), and increased mortality and cardiovascular events (epoetin). Second, information is available on long-term benefits such as clinical outcomes that improve overall survival (e.g., reduced recurrence of malignancies through interferon use and reduced cardiovascular events through insulin use), reduction in healthcare resource utilization (epoetin, somatropin), and proportion of long-term reponsiveness (anti-TNF, anti-IFN, anti-IL-12/23) and proportion of patients with two different effective options. Ideally, observational data can be used to optimize treatment regimens to achieve maximum treatment benefit (epoetin, insulin, somatropin). All these data can be used in an economic evaluation where the unknown risks for biosimilars are quantified through worst- and best-case scenarios. CONCLUSIONS: Often, patients are attracted to biosimilars that have the lowest acquisition costs. However, the risks of unknown information for these biosimilars should be valued against the lower price of these drugs. Observational data for the originator biologic product can be leveraged to quantify these risks. This will help determine for which populations the unknown risks outweigh the reduction in acquisition costs.