dominancy is a key to answer, we aimed to formulate an analytical criterion which judges the extended dominancy of a new technology in comparison with the SOC and placebo. **METHODS:** Assume the ICER of a new technology is evaluated with expected effectiveness Ex and cost Cx, compared to placebo or the SOC, respectively, with a pair of effectiveness and cost: (Ep, Cp) and (Es, Cs), where Ep < Es < Ex and Cp <Cs < Cx. Then, regarding an ICER as the slope between two points on the cost-effectiveness plane, the concept of extended dominancy was materialized through a geometric approach so that the slope of the line connecting between a new technology and the SOC should be shallower than that between the SOC to placebo. **RESULTS:** The analytical development resulted in the following criterion: if the expected cost Cx is smaller than the value of aEx + b, where a = (Cs - Cp) / (Es - Ep) and b = (CpEs - CsEp) / (Es - Ep), then the new technology can be judged as being extended dominant to the SOC. It implies the ICER of the new technology compared to the SOC must be smaller than that compared to placebo. If Cx is greater than aEx + b, the extended dominancy disappears with the ICER to the SOC greater than that to placebo. **CONCLUSIONS:** The criterion would be useful for decision makers to judge the extended dominancy and further to know the magnitude relationship between two ICERs of a new technology compared to the SOC or placebo.

PRM142

THE EXPANDED NUMBER NEEDED TO TREAT: APPLYING THE CONCEPT OF NNT TO CONTINUOUS HEALTH ECONOMIC OUTCOMES

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OBJECTIVE: To present the concept of the expanded number needed to treat (NNT) as a potential decision aid for continuous outcome measures, to show how the expanded NNT can be derived from results of health economic analyses, to review some examples, and to discuss potential benefits and limitations. METHOD: The NNT, calculated as the inverse of the absolute risk reduction, provides clinicians and patients with intuitive risk-benefit information based on natural frequencies as opposed to reporting statistics in terms of probabilities, such as relative and absolute risks. However, one significant limitation of the NNT is that it only applies to binary outcomes. Methods have been developed for estimating NNTs for continuous outcome measures, for example by dichotomizing outcomes according to whether a minimal clinically important difference is achieved. These methods may be appropriate for clinical decision making but may not be necessary for continuous outcomes, such as LYs and QALYs, when considered from the perspective of a health policy decision maker at the societal level. Accordingly, we propose the concept of the expanded NNT, calculated as the inverse of the difference in outcomes or, alternatively, as the incremental cost-effectiveness ratio divided by the incremental costs. The expanded NNT is a measure of clinical benefit, informing decision makers of how many people would need to be treated with one intervention versus another to achieve one additional unit of outcome (eg, LY or QALY). We review some differences between the NNT and expanded NNT, provide some worked examples, and discuss the potential benefits and limitations of the expanded NNT. CONCLUSION: The expanded NNT may provide policy makers with a more intuitive metric to compare the clinical benefit of population level interventions involving LYs and QALYs and is consistent with standard methods of health economic decision making.

PRM143

IMPORTANT STATISTICAL CONSIDERATIONS FOR DEVELOPING EQUATIONS FOR DISEASE SIMULATORS

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Disease simulators model the evolution of biomarkers or clinical events characterizing the disease in question over different time horizons, populations or treatment options. At the core of simulators are inter-connected equations that capture how patients' characteristics impact changes in biomarkers and events over time. Many considerations go into the derivation and validation of such equations. Using examples from the development of an Alzheimer's disease (AD) simulator, we call attention to a few specific issues and provide guidance on how to address these. The first issue concerns the parameterization of outcomes; for instance, predicting change from baseline versus previous visit, or determining whether a transformation is required. A practical consideration in choosing among formulations is the simplicity of the pattern of change over time for each option, which can both enhance the fit and facilitate interpretation. Furthermore, one must consider how the effect of treatments on these markers is typically reported, so that these can be easily studied in the simulator. A more intricate issue lies in correctly capturing the inter-dependence of the various outcomes in the simulation without amplifying co-linearity between predictors. For instance, in AD, functionality depends on cognitive ability; thus, various measures of cognition can be helpful in predicting change in functionality over time. These measures of cognitive ability may be highly correlated, but have complimentary associations with functionality. High co-linearity can limit the generalizability of the equations beyond the source data and over long projection windows, and yield illogical predictions. The optimal formulation must balance the relative importance of correlated predictors with the relative gain in fit. Finally, we address validation, more specifically, the clinical plausibility of individual equation forms and results when equations are integrated together, and the propagation of errors as predictions from one equation are used to predict other outcomes.

PRM144

PACE CONTINUOUS INNOVATION INDICATORSâ€"A NOVEL TOOL TO MEASURE PROGRESS IN CANCER TREATMENTS

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Cancer policymakers, researchers, and advocates have different priorities for cancer treatment research and may define 'value' of new treatments differently. Harmonizing the priorities and values of diverse stakeholders may be neither possible nor desirable. In November 2012, as part of its Patient Access to Cancer care Excellence (PACE) initiative, Lilly Oncology convened a Global Council of opinion leaders in cancer research, care, and policy to identify barriers to innovation in oncology research and develop strategies to improve cancer care. Participants concluded that the cancer policy field lacked tools to visualize these differences and to track progress in cancer treatments based on variable sets of values. Responding to this need, PACE developed the Continuous Innovation Indicators: novel, scientifically rigorous progress trackers designed to increase understanding of continuous innovation in cancer treatments among different stakeholders. The Indicators quantify progress in cancer treatments by: 1) mining the literature to determine the strength of the evidence supporting each treatment; 2) weighting the analysis according to the audience's priorities and values; and 3) calculating Evidence Scores (E-Scores), which are measures of progress based on the strength of the evidence weighted by the assigned value. We introduce a flexible model to illustrate differing values, show how the values from the model can be used to weight the evidence from the scientific literature to obtain E-Scores, and demonstrate how assigning different values influences E-Scores. Differentiated analyses based on values provided by various stakeholders will help the cancer policy field to obtain accurate representations of the complex, stepwise progress against different cancers over time. We envision partnerships and collaborations to support educational efforts, identification and illustration of policy goals, and work in the field of health technology assessments. We will not make this tool available to individuals or organizations for the purpose of deriving treatment recommendations.

PRM145

REVIEWING CLINICAL OUTCOME ASSESSMENT USAGE IN CLINICAL TRIALS: INTRODUCING THE COLA METHODOLOGY

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It is widely accepted that, as well as developing new Clinical Outcome Assessments (COAs) for clinical trials, using existing COAs to evaluate treatment benefit from the patient perspective is often a more pragmatic, time- and cost-effective strategy. However, the suitability of a COA (whether new or existing) is dependent on evidence of content and psychometric validity in a specific context and for specific concepts of interest. Determining which existing COA is most suitable based upon these criteria is particularly challenging when a large pool of instruments is available. For example, a recent MEDLINE search for COAs in head and neck cancer yielded more than 100 instruments. To shortlist from here, the logical next step is to review which COAs have been used (successfully and unsuccessfully) by sponsors in previous and ongoing trials. However, there is no clear guidance that explains how to identify relevant products or trials and what information to review to support measurement selection and ensure regulatory acceptance. Thus we outline an approach that is systematic, robust and pragmatic to support the selection of an existing COA for inclusion in upcoming studies. The Competitor Outcomes Landscape Analysis (COLA) methodology is a four-step approach: 1) identify relevant competitor drugs using a global clinical trial database, 2) review the Drugs@FDA database and the EMA's European Public Assessment Reports to establish approval status and identify COAs included in labelling, 3) review FDA's Drug Approval Packages to document regulatory decision-making and 4) identify COAs included in trial protocols for drugs in development. The COLA approach helps sponsors to select the most appropriate COA for studies in a specific population and disease area. We believe this framework allows for more confidence, transparency and credibility in the decision-making process and as such COLA is a systematic approach to support an optimal COA strategy.

PRM146

ADVANCING METHODS OF HTA: OPTIMISING MONITORING TESTS TO MEET VALUE TARGETS

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Optimising the value of monitoring tests is currently under-researched. Conventionally, tests are repeated at fixed intervals using a fixed test cut-point value. Theory however suggests that diagnostic test performance changes with repeated use in any given population. We hypothesize that conventional practice may be sub-optimal. A simulation model is built to determine the test cut-point and retest interval which maximize population health. A simulated experiment is carried out on a hypothetical population of 10,000 patients who are being monitored for disease progression or remission of some chronic disease for a period of 6months. a dichotomous test is applied on the population each month for the entire monitoring period. The patients are repeatedly stratified into diagnostic sub-populations (positive or negative) after each test, using a cut-point value between 0 and 1. The test performance and optimal cut-point in each sub-population is measured after each repetition. Patients are then allowed only two tests within a monitoring period. We allow the retest interval and cut-point value to vary simultaneously across sub-populations. Population net health benefit (in QALYs) is estimated for all possible intervals and cut-points, and the optimal cut-point and retest interval is determined. Preliminary results from our hypothetical simulation suggests that patients should be initially diagnosed using a cut-point of 0.25. Patients with a positive diagnosis should be re-tested after 4 months using a cut-point of 0.55, while those with a negative diagnosis should be re-tested after 2 months using a cut-point of 0.20. The most efficient conventional strategy is associated with an expected health loss of 50 QALYs across the population compared to the optimal strategy. Maximising the value of a monitoring test requires a dynamic test cut-off with respect to population characteristics based on previous test results, and the re-test interval.