OBJECTIVES: Personalized medicine is characterized by an increasing number of tests and payer scrutiny over their value. Depending on the use of a test, health care costs may increase in predictable ways depending on the type of test; we offer cut-off values that reflect the broader value of the product’s benefits and compare against the updated “basic threshold” value. CONCLUSIONS: There are general practical issues that might arise from using this MCDa approach in the HTA process and further research is needed to be performed on the issues identified in order to ensure the success of this MCDa technique in the appraisal process.

PRM58 TURNING THE IMPLAUSIBLE TO THE PLAUSIBLE: TOWARDS A BETTER CONTROL OF OVER THE COUNTER DISPENSING OF ANTIBIOTICS IN EGYPT
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As a developing country, Egypt has long suffered negative outcomes from irrational drug dispensing practices. This affected health economics adversely and increased the burden of many diseases. With limited resources, in Egypt, it becomes imperative to guide the researchers to potential adverse effects of over-the-counter dispensing on antibiotic resistance prevalence. This research aims to define the flaws in antibiotic dispensing in Egypt and its impact on the access to antibiotics. Specifically, focusing on pharmaceuticals in Egypt constitutes about 36% of the total health care spending. The Ministry of Health and Population has enforced several laws prohibiting over-the-counter dispensing of drugs. However, there is limited evidence on the effectiveness of these regulations on inappropriate dispensing. Literature review revealed that only one report that dates back to 1998 addressed over-the-counter dispensing of antibiotics. Section of analyzed data on pharmacists in 25 different districted pharmacies in Alexandria showed that 60% of medications dispensed were without a prescription or a pharmacist recommendation. Among those products, there were 98 different antibiotic products of which 42% were dispensed with a prescription. Over all, Egypt suffers high percentage of over-the-counter dispensing of drugs with little studies paying attention to this aspect in terms of antibiotic resistance patterns. Despite enforced laws prohibiting over-the-counter dispensing of drugs, further interventions are required. More strict laws must apply to pharmacists who do not comply with the official regulations of drug dispensing. The current practice of health technology appraisals is

PRM59 TRADE-OFF ANALYSIS: AN EXTENSION OF THRESHOLD PRICING ANALYSIS
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BACKGROUND: Investment decisions are made on the basis of whether a new drug is expected to meet certain criteria specified in a target product profile (TPP). Similarly, such decisions assume a target price, which is used in calculations of return-on-investment. Assuming a payer-cost-effectiveness threshold, threshold pricing models are used to estimate the maximum value-based price assuming a new drug achieves its TPP, and to estimate minimum value-based efficacy, safety, and tolerability required to support a target price. To assess the effects of uncertainty, one way to quantify variability analytically is to use probabilistic models that reflect the broader value of the product’s benefits and compare against the updated “basic threshold” value. CONCLUSIONS: There are general practical issues that might arise from using this MCDa approach in the HTA process and further research is needed to be performed on the issues identified in order to ensure the success of this MCDa technique in the appraisal process.

PRM60 OPERATIONALISING MULTIPLE CRITERIA DECISION ANALYSIS FOR HEALTH TECHNOLOGY ASSESSMENT
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OBJECTIVES: To discuss the different methods of multi criteria decision analysis (MCDA) that could be used in health technology assessment (HTA) and their relative merits. METHODS: The current practice of health technology appraisals is based on the incremental cost-effectiveness ratio (ICER) i.e. the incremental cost per quality adjusted life year (QALY). The ICER is the main determinant of treatment. Even though other factors (e.g. severity, saving-life, etc) are considered along with ICERs, there is concern that its approach may fail to capture other important sources of value. MCDA is aimed at supporting decision makers focused on evaluating alternatives taking into account multiple, and often conflicting, criteria in an explicit manner. This paper addresses a number of questions related to the most appropriate MCDA method that might be used to support decision making. For example, what criteria should be incorporated? Whose weights should be used and how should they be elicited? How to incorporate uncertainty into the MCDA process? How do we value the cost of displaced technologies? What should the ‘basic’ cost-effectiveness threshold be? How do we estimate it? This paper will discuss these questions, outline and assess methodological issues that would be raised by the use of MCDA in health technology assessment (HTA). RESULTS: A potential MCDa approach for HTA is to calculate “weighted” QALYs from the QALY weights which reflect the broader value of the product’s benefits and compare against the updated “basic threshold” value. CONCLUSIONS: There are general practical issues that might arise from using this MCDa approach in the HTA process and further research is needed to be performed on the issues identified in order to ensure the success of this MCDa technique in the appraisal process.

PRM61 IF YOU HAVE 2 WATCHES THEN WHAT TIME IS IT ? SELECTING A DEFINITIVE SOCIAL VALUE SET FOR MEASURING HEALTH GAINS
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Regulatory authorities in many countries require that societal preferences are used when health (dis)benefits are reported in terms of quality-adjusted life-years (QALYs). In the United Kingdom the NICE reference case, as set out in its published technical guidance, cites EQ-5D as the requisite health-related quality of life (HRQoL) system and Time Trade-Off (TTO) as the preferred method for eliciting societal values. This stipulation is simple to assert, but virtually impossible to implement. There is operationalisation in which TTO and QALYs are used to calculate incremental cost-effectiveness ratios (ICERs). Nevertheless, a more refined position for many years and has established a de facto national “norm”. These issues, however, are global in nature and common to economic evaluation of healthcare in all countries. The UK “preference for TTO is no more than that, for no scientific case has been made for rejecting Standard Gamble (SG), commonly acknowledged to yield systematically different estimates of utility. Both methods cannot be correct - one (at least) must be in error. It is patently absurd to consider them as commensurable equivalents in QALY calculations. In principle, a similar concern arises as new value sets are published, as will be the case in respect of the s-level version of EQ-5D. Cost-utility analysis reported in the literature reveals a 10-fold difference in incremental benefits (change from baseline) when EQ-5D/HRQoL system and Time Trade-Off (TTO) are used to compute QALYs, sufficient to reverse the location of an ICER with respect to any threshold. Nevertheless, the fundamental issue is that of updating the choice of a definitive value set for reference case analysis. This paper argues for a decision-centric approach in which a new metric may only be adopted if its use in measuring incremental effectiveness yields results that are consistent with those based on the existing reference standard. The argument is exemplified through the analysis of EQ-5D in published studies.

PRM62 VISUAL ASSESSMENT OF FIT OF EQUATIONS TO PREDICT TIME-TO-EVENT OUTCOMES
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Graphical tests are very useful for assessing the fit of statistical models. In linear regression models, for instance, a plot of predicted means against observed values can reveal systematic over- or under-prediction. Similar graphical tests are not necessarily straightforward for other types of regression models like those based on parametric survival distributions (e.g., to predict life-expectancy, time to progression of disease), particularly when multiple predictors are included in the model. The first complicating issue is censoring, which makes a scatter plot of observed and predicted values difficult to interpret. A better approach is to plot the empirical distributions (i.e., Kaplan-Meier curves) derived from the observed and predicted values, which inherently accounts for censoring in observed times. The second and more intricate issue is the definition of the predicted values. In linear regression models, the predicted value is simply the mean of the underlying normal distribution that produced the observation. Since the normal distribution is symmetric, it is reasonable to expect half of the observations to fall below their means, and the rest to fall above. Parametric survival distributions are highly skewed, however, so that the mean would generally be the most observed values. Similar problems arise if one uses the median (or any one particular percentile) as a reference, or plots the overall predicted curve at the mean predicted value of the regression parameter (i.e., the scale of the distribution). An accurate depiction of the overall predicted curve can be obtained instead by generating multiple random event times from each individual’s predicted distribution, and using these to derive the overall predicted curve. The approach will be illus-
trated with an example that highlights pitfalls involved with more simplistic approaches.

PRM63 CLOSING THE GAP BETWEEN THE FORMULATION AND IMPLEMENTATION OF CLINICAL PRACTICE GUIDELINES BASED ON EVIDENCE
gordillo AM, esava-Schmalbach J, Amaya Arias AC Universidad Nacional de Colombia, Bogota, Colombia OBJECTIVES: To describe the theoretical approach suggested to close the gap between recommendations and implementation of clinical practice guidelines (CPG’s) in Colombia, called harmonization of CPG’s with Public Policy. METHODS: Perspective paper. A theoretical approach is suggested to harmonize CPG’s recommendations with public policy. RESULTS: Public policies often don’t get the desired results, because there is a gap between the decision and the reality. There is a conceptual and temporal separation between policy formulation and implementation of decisions, CPG’s are tools to improve quality in the delivery of health services. However a process of harmonization between recommendations and implementation with public policy is requested. For this a process of three phases should be developed: 1) To do a review of existing regulations on health and on the specific issue of the CPG to harmonize the current policy with recommendations and identify barriers to the implementation process, 2) To adjust recommendations of CPG’s to eliminate the barriers encountered with the standards, 3) To state a negotiation process with all actors involved in the implementation of the CPG’s at different levels of care, to generate commitment with them, proposals for changes in policy and/or administrative, and if it is necessary, to remove barriers. CONCLUSIONS: Process of harmonization of CPG’s with public policy is a fundamental tool to improve their implementation. Three phases are proposed. Negotiation could be the most important one.

PRM64 SOCIETAL PERSPECTIVE IN ECONOMIC EVALUATION: CONFUSIONS AND HIRA’S RECOMMENDATION
Lee S, Lee S, You MY Health Insurance Review & Assessment Service, Seoul, South Korea BACKGROUND: Current HIRA’s guideline recommends that economic evaluation (EE) analysis should take societal perspective, yet the inconsistency in current guideline has been noted by the industry side. The purpose of this study is to review current theoretical trends and discuss the needs of updating HIRA’s current recommendations. METHODS: To identify the needs of EE guideline revision, HIRA has reviewed currently updated foreign EE guidelines, and discussed recent theoretical trends. In addition, survey results from pharmaceutical companies as well as discussion on current recommendation were considered. Expert meetings and working group meetings with industry people were held to share party’s perspectives. RESULTS: Pharmaceutical industry suggested that current recommendation of taking societal perspective while submitting indirect cost was not satisfactory. Inconsistencies in societal perspective have also discussed in previous studies and ISPOR consensus updated its perspective as “publicly funded health care system”, and UK (NICE) has recommended to take payer(NHS and PSS)’s perspective. Inconsistencies in societal perspective have also discussed in previous studies and ISPOR consensus paper on how the EE guidelines should provide detailed minimum standards for submission parties, a need to clarify current “societal” perspective has been argued by relevant parties. “Limited” societal perspective has been proposed to reduce unnecessary confusions while reflecting current practice patterns.

PRM65 PREVALENCE-BASED VERSUS INCIDENCE-BASED ECONOMIC EVALUATIONS FOR THE ASSESSMENT OF NEW HEALTH CARE INTERVENTIONS
Mauskopf JA RTI Health Solutions, Research Triangle Park, NC, USA OBJECTIVES: To compare the usefulness of decision makers of prevalence-based versus incidence-based economic evaluations of new health care interventions. METHODS: Comparison of evaluation methods by: population included, time horizon, outcomes measured, adherence to economic principles, and usefulness to decision makers. RESULTS: Incidence-based economic evaluation follows a disease cohort for the duration of the disease and estimates discounted costs and health gains with alternative interventions. The cost-effectiveness ratio is based on individual utility maximization and provides information to decision makers about the efficiency of a new healthcare intervention compared to societal willingness to pay for health gains. It does not estimate annual budget impacts. It generates thresholds for ratios generated using the prevalence-based approach.

DISEASE-SPECIFIC STUDIES

DIABETES-ENDOCRINE DISORDERS – Clinical Outcomes Studies

PDB1 COMPARING HYPOGLYCEMIA RATES FOR TYPE 2 DIABETES PATIENTS TREATED WITH SAXAagliptIN VERSUS SULFONYLUREA: USING CLAIMS DATA TO REPLICATE A CLINICAL TRIAL
Jankowski DA1, Zhang B, Lenhardt G2, Thomson EE1, Bell EP2, Graham JP2 Thomson Reuters, Washington, DC, USA, Bristol-Myers Squibb Company, Plainsboro, NJ, USA, Thomson Reuters, Cambridge, MA, USA OBJECTIVES: A lower rate of hypoglycemia occurred in a Phase 3 trial in T2DM patients receiving saxagliptin compared to glimepiride (sulfonylureas (SU)) added to metformin. The clinical trial included patient-reported and physician-reported hypoglycemia events. The objective of this study was to compare the rates of hypoglycemia events that required medical attention in actual clinical practice. METHODS: Retrospective claims data for patients who initiated saxagliptin or SU. During the 6 months prior to initiation, patients were required to have a prescription (Rx) for metformin and no saxagliptin, SU, or other diabetes Rx. Patients were followed for 4 months to assess the rates of hypoglycemia. During follow-up, patients were required to have at least one more metformin Rx. Adverse events Additional saxagliptin/SU Rx and no other diabetes Rx. A hypoglycemia event was defined as a diagnosis of hypoglycemia on an outpatient or emergency room claim or principal diagnosis on a hospital claim or an outpatient glucagon injection. SU patients were matched to saxagliptin patients (1:5) using propensity scoring. The rate ratio was further adjusted for covariates that were not balanced between the matched cohorts using a Poisson regression model. RESULTS: There were 1,557 saxagliptin, 21,025 SU, and 7,835 propensity-matched SU patients. The rate of hypoglycemia in the saxagliptin cohort was 1.74 per 100 person years (PY) in the SU cohort (rate ratio 0.31, 95% CI: 0.14 – 0.60) and 4.45 per 100 PY in the matched SU sub-group (rate ratio 0.39, 95% CI: 0.17 – 0.77). After multivariable adjustment, the rate ratio was 0.37 (95% CI: 0.19 – 0.74). CONCLUSIONS: In real world practice, as was demonstrated in a randomized controlled trial, saxagliptin patients had a lower risk of hypoglycemia than SU when added to metformin.

PDB2 VITAMIN B AND/OR ITS DERIVATIVES FOR DIABETIC KIDNEY DISEASE: A SYSTEMATIC REVIEW AND META-ANALYSIS
Raval A1, Thakker D2, Rangonwalla A2, Gor DM11 West Virginia University, Morgantown, WV, USA, 2Vitamins Research Institute at the University of Alberta, Edmonton, Alberta, Canada OBJECTIVES: To assess the benefits and harms of vitamin B and/or its derivatives in patients with diabetic kidney disease (DKD). METHODS: We searched the Cochrane Renal Group’s Specialized Register CENTRAL, MEDLINE OVID SP, Hand searching of renal journals and conference proceedings; EMBASE OVID SP; the International Clinical Trials Register (ICTRP) Search Portal & ClinicalTrials.gov. Randomized controlled trials (RCTs) comparing vitamin B and/or its derivatives with placebo, no active treatment, in patients with DKD were included. RESULTS: Out of 56 identified studies, four studies were found to be suitable for inclusion. A total of 745 participants were randomized to either vitamin B derivatives (benfotiamine (300 mg TI), thiamine (300 mg OD), vitamin B12 (500 mg OD)) or placebo. A total of 745 patients with diabetic kidney disease (DKD). Patients were followed for 4 months to assess the rates of hypoglycemia events that required medical attention in actual clinical practice. Threshold values based on economic principles, however, are not applicable for ratios generated using the prevalence-based approach.

PDB3 RISK OF COMPLICATIONS IN TYPE 2 DIABETIC PATIENTS WITH RENAL IMPAIRMENT: AN ANALYSIS OF THE RAMQ DATABASE
Lachaine J1, Beauchemin C1, Flavin J2 Université de Montréal, Montreal, QC, Canada, 1BupaHealth Insurance Company Ltd, Burlington, Ontario, Canada OBJECTIVES: Chronic kidney disease is often associated with type 2 diabetes mellitus (T2DM). Patients with T2DM and chronic renal failure are at higher risk of developing hypoglycemia or other metabolic acidosis. The purpose of this study was to identify treatment patterns in T2DM patients with chronic renal failure and to estimate the risk of developing complications. METHODS: This study examined data on patients covered by the Quebec provincial drug reimbursement program (RAMQ). The RAMQ database was used to identify patients with a diagnosis of chronic renal disease in the period from January 2005 to December 2010. A 1:1 control group of patients with diabetes and without renal failure, matched for age and gender, was also created. Patients’ characteristics and drug utilization patterns were analyzed and the risks of experiencing hypoglycemia or other metabolic acidosis were estimated. RESULTS: A total of 4889 patients who had a diagnosis of chronic kidney failure were included in this cohort. Aver-