compare guideline-adherent and routine clinical practice. Value of information analysis will be employed to identify areas for future research. We are applying this translational approach to various current and developing examples of PM in cancer: 1) trastuzumab for human-epidermal growth factor receptor-2 positive BC; 2) gene-expression profiling to identify patients who will benefit most from adjuvant treatment in BC; 3) cytochrome P450 2D6 testing to select patients for adjuvant tamoxifen therapy in BC; and 4) testing for Lynch Syndrome in CRC patients and their family members to inform treatment and preventative interventions. This research will develop evidence-based information for patients, providers, industry, researchers and policymakers to objectively assess how PM can be beneficial and efficient in improving cancer outcomes.

PODIUM SESSION III: RESEARCH ON THE USE OF UTILITY MEASUREMENT

UT1

ASSOCIATION BETWEEN UTILITY AND TREATMENT AMONG PROSTATE CANCER PATIENTS

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OBJECTIVES: To analyze the association between utility, treatment and generic and prostate-specific health related quality of life (HRQoL) among prostate cancer patients. **METHODS:** In this longitudinal cohort study we recruited 201 (≥45 yrs) newly diagnosed prostate cancer patients from urology clinics of an urban academic hospital. Participants completed Quality of Wellbeing (QWB-SA), generic (SF-36) and prostate-specific (UCLA-PCI) HRQoL surveys prior to treatment and up to 24 months post-treatment. Clinical and demographic data were obtained via medical chart review and utility scores were computed using QWB-SA. To analyze the relationship between treatment and utility we used linear mixed effects models, after adjusting for covariates. Similar models were used to examine association between generic and prostate-specific HRQoL and utility. **RESULTS:** Mean baseline utility was comparable between radical prostatectomy (RP) and external beam radiation therapy (EBRT) groups (0.73 vs. 0.69, p = 0.1750). Mixed effects models indicated that RP was associated with higher utility at 24 month (OR = 1.12, p = 0.027), after controlling for covariates. RP was associated with improved functioning for role physical, role emotional, vitality, mental health and bodily pain and impaired urinary function. Higher scores on generic health subscales were indicative of higher utility. Also, for prostate-specific HRQoL, higher scores on bowl function, sexual function, urinary bother and bowel bother were associated higher utility. **CONCLUSIONS:** Treatment appears to have significant association with post-treatment utility. Thus, utility assessment provides an important quantitative tool to support patient and physician clinical treatment decision making process of prostate cancer care.

UT2

COMPARISON OF HEALTH STATE UTILITY ESTIMATES IN COST-EFFECTIVENESS ANALYSIS

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OBJECTIVES: This study examined the effect of different utility instruments and tariffs on chronic condition utility scores and incremental cost-effectiveness ratios (ICERs). **METHODS:** Postponement of diabetes was modeled in a high-risk population receiving a hypothetical intervention, as compared to a similar control group. Utility estimates for the general population, diabetes, hypertension, stroke, myocardial infarction (MI) and congestive heart failure (CHF) were taken from catalogues developed by Sullivan et al. for United States and United Kingdom EuroQOL-5D tariffs (EQ-5DUS and EQ-5DUK) and SF-6D, using the Medical Expenditure Panel Survey. Quality-adjusted life-years (QALYs) were modeled for 20 years using a 3% discount rate. The discounted cost of the intervention was assumed to be $150,000. **RESULTS:** The initial health state utility was lowest using the SF-6D(.709), and highest using EQ-5DUS(.800). The highest estimates for diabetes(.708), hypertension(.761) and MI(.575) were found using EQ-5DUS, but the highest stroke(.534) and CHF(.503) estimates were found with the SF-6D. The lowest estimates for stroke(.189), MI(.516) and CHF(.189) were from the EQ-5DUK, but the lowest estimates for hypertension(.583) and diabetes(.618) were from the SF-6D. The EQ-5DUK resulted in the largest marginal utility decrement for all conditions. The smallest decrement for hypertension(–.002) and diabetes(–.022) resulted from the SF-6D, but from the EQ-5DUS for stroke(–.069) and CHF(–.055). When these estimates were applied to the model, the resulting QALYs gained from the intervention were greatest from the EQ-5DUS(11.32) and least from the EQ-5DUK(9.77). Incremental QALYs gained were greatest for EQ-5DUK(3.278) and least for the SF-6D(2.880). The ICER varied from $46,000–$52,000 depending on the instrument/tariff. **CONCLUSIONS:** Different utility instruments/tariffs resulted in unsystematic differences in chronic condition utilities, but the marginal decrement in each of these conditions was systematically lower for the EQ-5DUK and may be a trend across all conditions. Incremental QALYs gained differed by instrument/tariff and the ICER varied from $46,000–$52,000.

UT3

RELIABILITY OF HEALTH UTILITIES INDEX (HUI) SCORES: PATIENT AND PARENT INTER-RATER AGREEMENT ACROSS TWO CLINICAL TRIALS OF TREATMENT FOR ACUTE LYMPHOBLASTIC LEUKEMIA (ALL) IN CHILDHOOD

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OBJECTIVES: To assess differences in the reliability of HUI Mark 3 (HUI3) health-related quality of life (HRQL) utility scores for patients between self and parent assessments across two Dana-Farber Cancer Institute (DFCI) clinical trials for treatment of ALL during childhood. **METHODS:** Patients were enrolled in either the DFCI 95-001 or 00-001trial, and were ≥12 years of age at the time of HUI survey. Patients and parents, blind to each other, completed HUI questionnaires at each of 5 trial phases: induction; CNS prophylaxis; intensification; continuation; and post-treatment. Reliability was assessed in terms of inter-rater agreement of individual scores and differences in mean scores. Agreement was quantified using the single-measure two-way mixed model intra-class correlation coefficient (ICC). An ICC of 0.41–0.60 represents moderate reliability, 0.61–0.80 good reliability, and 0.81–1.00 very good reliability. Mean differences of >0.03 are clinically important. Statistical significance was set at $p < 0.05$. **RESULTS:** The number of patient and parent paired assessments varied by assessment phase for both the 95-001 (minimum = 29, maximum = 50) and the 00-001 (minimum = 28, maximum = 54) trials. ICCs in the two trials ranged from 0.49 ($p < 0.05$) to 0.88 ($p < 0.05$). There was substantial overlap of ICC 95% confidence bounds across the two trials at each of the five assessment phases. There was no significant difference ($p > 0.06$) between patient-parent pairs of scores at any assessment phase in either trial. The difference between trials in mean patient-parent scores was ≤0.03 and insignificant ($p > 0.08$) for each of the 5 assessment phases. **CONCLUSIONS:** Agreement between patient and parent scores was moderate or better for all assessment phases in both trials. There were no important differences in mean patient and parent scores for any of the assessment phases of the two trials. Inter-rater reliability of scores was similar across the two trials. Parental assessments provide acceptable and consistent estimates of HRQL for children.

UT4

EVALUATING WILLINGNESS TO PAY THRESHOLDS FOR A DEMENTIA CAREGIVING INTERVENTION

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OBJECTIVES:—Assess the methodological challenges of evaluating appropriate willingness to pay thresholds (WTP) in cost-effectiveness studies which do not use a societal perspective or a QALY outcome measure. **METHODS:**—Tailored Activity Program (TAP), an intervention designed to reduce caregiver burden for dementia patients, served as a case study. Caregiver interventions such as TAP employ an individual perspective and non-QALY outcome measures such that standard societal WTP thresholds are not applicable. Two outcome measures related to caregiver burden were used 1) reduction in hours "on duty," and 2) reduction in hours "doing things." To estimate appropriate WTP values for each TAP outcome measure, we identified three studies which met these inclusion criteria: 1) published studies in the past 5 years using contingent valuation methodology to identify WTP, 2) assessed WTP for a dementia-related intervention that required an out-of-pocket expenditure, and 3) asked caregivers what they would be willing to pay for an outcome of reducing caregiver burden. We also assessed WTP based on the potential financial savings caregivers could achieve from purchasing TAP. To assess proportion of time TAP was cost-effective, we built a Monte Carlo simulation to test the four WTP values identified. **RESULTS:**—For the outcome measure "on duty" WTP varied between $1.06/hr–$4.58/hr. WTP for the outcome measure "doing things" varied between $2.21/hr–$9.57/hr. Applying WTP values to TAP indicates TAP cost-effectiveness varies between 50%-80% for both outcome measures. **CONCLUSIONS:**—If WTP data can not be collected prospectively or societal values can not be applied, evaluating WTP using comparable studies appears to be an acceptable method for informing decisions makers of potential cost-effectiveness. Application of WTP to TAP shows potential cost-effectiveness that can be expected under different WTP scenarios.

POSTER SESSION I

CONCEPTUAL PAPERS & RESEARCH ON METHODS – Clinical Outcomes Methods

PMC1

EVALUATING CLINICIAN REPORTED OUTCOME (CRO) ENDPOINTS FOR FDA REGULATORY APPROVALS

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OBJECTIVES: Clinician reported outcomes (CROs) are the most commonly observed endpoint in FDA approved product labels (Wilke et al, 2004) but few have been adequately scrutinized in terms of their suitability as endpoints. This study evaluates four widely used CROs in order to assess their suitability as endpoints for regulatory approvals. **METHODS:** Published evidence on the Karnofsky Performance Status

Scale (KPS), Spitzer QOL-Index, Expanded Disability Status Scale (EDSS), and the Hamilton Rating Scale for Depression (HAM-D) were evaluated in terms of: conceptual framework; patient, literature and clinician contribution to development; process for deriving items; content validity; item reduction; linguistic and cultural adaptation; scoring; and reliability, validity, and ability to detect change. **RESULTS:** The FDA discourages the use of CROs for symptoms that can only be known to the patient, whereas clinical signs are usually observed and interpreted by the clinician. Despite the widespread use of the KPS as a classification of functional status in patients with cancer, there is little data supporting the development, content validity, and statistical measurement properties of the scale. Among other critiques, the EDSS has questionable inter-rater reliability. Although the Spitzer QOL-index was developed with patient input and has documented measurement properties, the use of proxy for QOL/HRQL evaluations is widely discouraged. The HAM-D is considered the 'gold standard' of depression rating scales with good psychometric properties, but with questionable content validity. **CONCLUSIONS:** The suitability of the selected CROs as endpoints for regulatory approvals varied widely. CROs are essential and complimentary primary and secondary endpoints for drug evaluations for the purpose of FDA regulatory submissions, it is likely that sponsors will face increasing FDA scrutiny of CRO endpoints for the purpose of label claims.

CONCEPTUAL PAPERS & RESEARCH ON METHODS – Cost Methods

PMC2

REVIEW OF PHARMACOECONOMIC RECOMMENDATIONS FOR THE DEFINITION OF A SOCIETAL PERSPECTIVE

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OBJECTIVES: To compare the ways pharmacoeconomic (PE) guidelines in European and North American countries define the societal perspective for economic evaluations. **METHODS:** Full-text country-specific PE guidelines were obtained via the ISPOR website and where possible cross-referenced with Health Technology Assessment (HTA) agency recommendations. The following countries were selected for comparison: Belgium, Canada, Finland, France, Italy, Norway, the The Netherlands, Portugal and Sweden. The cost categories considered for the societal perspective were assessed and compared between country guidelines. **RESULTS:** PE guidelines from eight of the selected countries identified specific cost categories for the societal perspective. Guidelines agreed that the direct costs associated with this perspective included costs to the health service, costs to other publicly funded services and costs to patients/family. Costs of time lost by family/unpaid carers was considered by 6/8 guidelines, which differed in assigning the cost as direct or indirect. There were differences in the indirect costs considered; costs of time lost by patients was only considered by 2/8 guidelines. Intangible costs were considered by 4/8 guidelines, although it was generally accepted that these should be accounted for in the outcome measurement rather than through costs. Productivity loss was considered as an indirect cost by nine guidelines; however the preferred method of derivation differed between guidelines: 2/9 guidelines preferred the Friction Cost Method (FCM) and 3/9 guidelines preferred the Human Capital Method (HCM). Moreover, there were differing views regarding the types of productivity loss to include: Portugal recommended consideration of employee-related loss only, whereas Canada also included loss to the employer associated with hiring new staff. **CONCLUSIONS:** There are subtle differences between the ways the societal perspective is defined by PE guidelines in Europe and North America. This should be considered when devising evidence generation activities to support economic modelling, and may ultimately impact the outcome of HTA decisions.

PMC3

REVIEW OF COST EFFECTIVENESS ANALYSES THAT INCORPORATE NUMBER NEEDED TO TREAT/HARM VALUES

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INTRODUCTION: Number needed to treat/harm (NNT/NNH) values are universally understood and applied by clinical decision makers. Therefore providing these values alongside cost effectiveness analysis (CEA) results may increase the relevance and clarify clinical implications of CEAs to decision makers. **OBJECTIVES:** To review the literature of CEA studies that incorporate NNT/NNH values. **METHODS:** We searched Pub Med using the Mesh term "cost-benefit analysis" and "number needed to treat ", "number needed to harm", "NNT", or "NNH". We included CEA studies and studies describing relationships between NNT/NNH and quality adjusted life years (QALYs) published in English. **RESULTS:** There were 102 publications identified. Of these 47 provided both CEA and NNT/NNH results. There were 43 (91.5%) studies published in clinician-focused practice journals, 2 (4.3%) in policy journals, and 2 (4.3%) in economic journals. The CEA incorporated NNT/NNH directly as part of the CEA ratio in 23 (48.9%) studies and CEA was separately stated from NNT/NNH in 14 (29.8%) studies. The CEA was expressed as cost per QALY distinctly from NNT/NNH in 10 (21.3%). The focuses of the articles were disease treatments in 28 (59.5%) studies, disease prevention in 15 (31.9%), and patient education or disease management in 2 (4.3%) each. Also, there were 4 studies regarding relationships between NNT/NNH and QALYs. **CONCLUSIONS:** We found that the majority of articles incorporating NNT/NNH into CEA were published in clinical practice journals and most involved comparisons of specific disease treatments. Incorporating NNT/NNH into CEA results may improve relevance to clinical decision-making, but further research is needed regarding how they are best integrated. One alternative may include weighting NNT/NNH values for different outcomes in terms of QALYs.

PMC4

THE DERIVATION OF TRICARE SPECIFIC CONSUMER PRICE INDICES FOR PRESCRIPTION DRUGS

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OBJECTIVES: One of the chronic issues in pharmaceutical utilization management is the dearth of accurate price benchmarks available to establish pharmacy-pricing performance. This paucity of appropriate benchmarks is further complicated for organizations, such as TRICARE, who have reason to believe that their demographics and hence disease profiles yield atypical prescription drug market baskets. Thus, to obtain an accurate assessment of organizational performance, organization-specific indices need to be developed. **METHODS:** A unique approach to developing organization specific benchmarks is underway in a joint venture between the TRICARE Pharmaceutical Operations Directorate (POD) and the US Bureau of Labor Statistics (BLS). The primary method is to match retail pricing information provided by BLS and portfolio information provided by TRICARE to construct organization specific benchmarks that can be tracked over time. Variables from the Consumer Price Index for Prescription Drugs (CPI-Rx) are transferred to the POD as specified in an intergovernmental memorandum of understanding. To form an overall TRICARE-Rx index for a specific month, all TRICARE prescription data are aggregated by specific drug and the number of prescriptions is computed for each drug for specific month using a file extracted from the Pharmacy Data Transaction Service (PDTS). CPI-Rx prices are then aggregated by same list of unique drugs used in the TRICARE sample then averaged in a separate file. The files are then merged using NDC codes as the key. The index is computed using the average CPI-Rx price for each specific drug multiplied by the TRICARE N for the corresponding drugs then averaged. **CONCLUSIONS:** TRICARE spends roughly $7.5 Billion annually for prescription drugs. With the development of these indices, we can better gauge our cost containment priorities and efforts. This will help us determine if increases in costs are due to general drug price inflation specific to our unique market basket of drugs.

PMC5

VALIDATING A WEB-BASED INCREMENTAL COST-EFFECTIVENESS SOFTWARE PROGRAM THAT USES A MARKOV TRANSITION PROBABILITY MATRIX ANALYSIS MODEL

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OBJECTIVES: Commercial software can be expensive when conducting pharmacoeconomic analyses. We developed a free web-based software program, which incorporates Markov transition probabilities to compare the cost-effectiveness of any two treatments. The web-based software program was based on the model described in a decision modeling for health economic evaluation textbook, edited by A. Briggs. This Markov web-based software program calculates the incremental cost-effectiveness based on Markov matrices using multi-state transition probabilities, along with corresponding Markov state costs and utilities and graphically displays the results, using JavaScript algorithms and is available free at www.healthstrategy.com. The variable inputs for two treatment options include state transition probabilities, number of cycles, cost per state, and utility per state. The software creates a plot of incremental costs versus incremental utilities in cost-effectiveness quadrants; and with death as an absorbing state, also graphs life expectancy curves for two treatment comparisons. The objective of this study was to validate this free web-based software. **METHODS:** The Excel spreadsheet structure and data downloaded from the web for the specific example described in the modeling textbook were used as the reference case. **RESULTS:** For the example used, considering four transition states for each therapy option, and 20 cycles with no discounting, the MS Excel spreadsheet model versus the web-based JavaScript software compared as follows: average incremental US dollar costs: ($67701 vs. $67853), average incremental utility: (5.89 vs. 5.90) and average incremental cost-effectiveness ratio:($11500 vs. $11494). **CONCLUSIONS:** This free web-based Markov matrix JavaScript program gives similar results as the MS Excel spreadsheet model. With this free software, the user can input their own therapy parameters, and generate incremental costs, incremental utilities, life expectancy curves, and incremental cost effectiveness ratios. This free web-based software has potential benefit as an educational tool for students and health professionals interested in exploring these analytical approaches.

PMC6

USE OF CLINICAL SIMULATION CENTERS TO CONDUCT PATIENT-CENTERED TIME-AND-MOTION SIMULATIONS AS A BASIS FOR ECONOMIC ANALYSIS

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BACKGROUND: Patient-centered professional practice and technology assessment research performed in health professional schools' clinical simulation centers is a novel concept. Opportunities can be created for multidisciplinary collaboration relative to evaluation of medication regimen and device complexity. Micro-level costs can then be assigned and economic analysis conducted in a more precise fashion than in traditional clinical trials or database outcomes analysis. **METHODS:** One university's pharmacy and nursing schools' clinical simulation centers were used in two separate projects to conduct time-and-motion and activity-based costing analyses specific to