tency was observed in the out-of-pocket questionnaire($p < 0.05$). Component analysis showed a few epidemiological variables are responsible for 80% of instrument's variability. **CONCLUSIONS:** Validated resource-use questionnaires are needed to homogenize costs and EE in developing countries. These validated questionnaires in Mexican population could be used by authorities to enhance cost-containment policies.

PMC13

A QALY ALTERNATIVE FOR COST–EFFECTIVENESS ANALYSIS IN HEALTH CARE

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The cost-effectiveness of health care interventions is often evaluated using quality-adjusted life years (QALYs) as a measure of outcome. However, QALYs are valid only under several restrictive assumptions. Furthermore, QALYs are ethically controversial, as they receive their strongest support from utilitarian theory, which is often considered an unacceptable ethical theory. The purpose of this work is to present a non-utilitarian approach to cost-effectiveness analysis, which avoids calculating QALYs, but still is able to aggregate and compare different clinical outcomes. By capturing benefits in terms of adverse events (AEs) avoided, the approach is based on one of the fundamental metrics of clinical epidemiology and thus moves the assessment of cost-effectiveness closer to that of clinical outcomes in clinical trials. Furthermore, it directly incorporates the two most important ethical values with regard to setting priorities in health care, ie, a concern for health gain as well as for health without treatment. The approach aggregates the different types of AEs avoided, by introducing weights that reflect their value. In order to project weights on an interval scale, ranking data, the time trade-off, or the standard gamble method can be used.

PMC14

DETERMINING COSTS OF CONCOMITANT MEDICATIONS IN RANDOMIZED CLINICAL TRIALS: A CASE STUDY

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OBJECTIVES: Determining costs of concomitant medications (CONMEDs) is a challenging but critical component of cost-effectiveness analysis. In clinical trials, CONMEDs are typically recorded using broad medication terms, with approximate costs linked to the entire category. In a recent phase III oncology clinical trial, we determined costs with an alternative approach based on the individual CONMEDs used by patients, using a combination of WHO preferred medication term codings, the NDC-HCPCS Crosswalk (CW), and Payment Allowance Limits (PAL) for Medicare Drugs Part. **METHODS:** The CONMED database was obtained from the clinical trial, and the CW and the PAL were obtained from CMS. Preferred medication terms of individual CONMEDs were coded according to the WHODrug version 2003 Q2 dictionary. The CW was used to map preferred medication terms to appropriate HCPCS codes, and the PAL was used to determine unit costs of the HCPCS coded medications. For medications with multiple HCPCs codes, the average payment limit per dosage unit was assigned. Total CONMED costs were computed by adding all cost information. **RESULTS:** The CONMED database comprised approximately 400 patients and 3,588 CONMED records. There were 562 unique HCPCS codes and 497 unique preferred medication terms in the CW and the PAL. In addition, there were 519 unique combinations of preferred medication terms and dose units, of which 78% (407/519) had multiple NDC codes. However, only 17% (70/407) of these had different unit payment limits across products within the combination. In these cases the average cost was used. Overall we were able to assign costs to 22% (780/3588) of CONMED records, consistent with the proportion of CONMEDs covered by Medicare. **CONCLUSIONS:** From third party payer perspective, this micro-costing method for CONMEDs was a feasible approach to pharmacoeconomic assessment with a clinical trial.

PMC15

EVALUATING AN ONLINE FREEWARE CALCULATOR FOR A COST EFFECTIVENESS MODEL TO ASSESS THE IMPACT OF MEDICATION COMPLIANCE

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OBJECTIVES: To evaluate an online freeware, cost-effectiveness calculator that generates and plots estimations related to the impact of medication compliance on life years gained, drug expenditures, and total health care cost. **METHODS:** An online calculator and plotter were developed that estimates the impact of patient compliance on the cost-effectiveness of therapy. This model was based on a more complex compliance model description published by Hughes D. et al. The online data calculations were compared with an MS Excel spreadsheet model. The cost effectiveness calculator is freely available through www.healthstrategy.com. Data inputs that can be modified include (for compliant and non-compliant separately): utility (QoL), annual drug costs, annual non-drug costs, percent deaths per year, total number of study years, and number of initial patients. **RESULTS:** The online calculator runs on most personal computer operating systems with javascript enabled browsers such as Internet Explorer, Firefox, Opera, or Safari. For twenty different levels compliance (from 0 to 100 percent) this Internet tool outputs and plots results for: total QALYs, life years, total health care costs, non-drug expenditures and total health care expenditures. For 100 patients over 5 years, the MS Excel spreadsheet data versus the online calculated values compared as follows for 50% compliance: QALYs (372 vs. 375), Life Years:(451 vs. 450), drug costs:($23,750 vs. $23,750), non-drug costs:($228,750 vs. $225,000), total health care costs:($252,500 vs. $248,750). **CONCLUSIONS:** With this online compliance and cost-effectiveness software, the user can enter their own data to calculate and graph estimated QALYs, Life Years, drug costs, non-drug costs and total health expenditures. This web-based calculator has potential benefit as a basic tool for students, health professionals, and decision-makers.

PMC16

EVALUATING AN ONLINE FREEWARE CALCULATOR AND PLOTTER FOR POWER ANALYSIS AND SAMPLE SIZE ESTIMATION FOR COST EFFECTIVENESS STUDIES

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OBJECTIVES: To evaluate an online, freeware calculator that generates and plots sample size estimations and power analyses for cost effectiveness studies. **METHODS:** Online software was developed and results were compared with a published analytical formula for power analysis and sample size calculations for cost and effectiveness data. The web-based, cost effectiveness calculator formulas, data and evaluation were based on published articles by Briggs A, Gray AM and Tambour M. The online calculator required data inputs include: probability of Type I and Type II error, standard deviation of costs and effects, mean cost and effect differences, correlation between differences in cost and effects, as well as willingness to pay (WTP) for additional health effects. This Internet tool outputs results for sample size in each study arm that would be required versus WTP threshold ranges, and power versus sample size. **RESULTS:** Compared to the published manuscripts for a power of 0.90 and effectiveness only, the online calculated sample size results were identical (N = 536). For the published examples with correlation differences in effect and cost of minus 1.0, the estimated sample sizes based on WTP compared as follows: WTP = $7500:(1400 vs 1387), WTP = $10,000:(1150 vs 1096), WTP = $15,000:(850 vs 865), WTP = $20,000:(790 vs 769), WTP = $30,000:(700 vs 682). The Briggs et al articles include additional results and sensitivity analyses based on additional correlations and power, which have to be run one at a time with the online software. **CONCLUSIONS:** With this online freeware calculator, the user can enter their own data to estimate sample size and power in planned or published cost effectiveness studies. This web-based software has potential benefit as a basic tool for students, health professionals, and decision makers.

PMC19

COST–EFFECTIVENESS OF PREVENTIVE CARE AND MEDICINES: DO AGING DISEASES OFFSET SAVINGS FROM MORBIDITY REDUCTION?

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OBJECTIVES: A major concern about the economic impact of preventive care and medicines is that savings from avoiding morbidity may be more than offset by the costs of prolonging life, resulting in a net expenditure increase. The purpose of this work is to examine this hypothesis. **METHODS:** A theoretical model is developed which determines the net outcome when savings from preventing morbidity are weighed against expenditures for added life years. The model is based on a single assumption, which is that costs and mortality are linearly correlated. This assumption holds for preventing the average disease because preventing all disease reduces mortality and costs by 100%. The model is validated based on long-term studies from the U.S. and Netherlands that model the economic impact of chronic-disease prevention. **RESULTS:** The model shows that for the average preventive measure savings from preventing morbidity are somewhat larger than expenditures in added life years. The ratio of savings to expenditures is approximately 1/(1 – relative reduction in all-cause mortality). The model is able to explain why some studies show that preventing chronic disease leads to savings while others do not. **CONCLUSIONS:** This work provides new insight into the cost consequences of preventive care and medicines. Results have implications for the economic evaluation of preventive medicines. For the average drug the long-term cost driver is not the additional life span, as expenditures during added life years roughly equal savings from morbidity reduction. Instead, increases in long-term costs are, on average, mainly driven by the medication itself.

PMC20

ESTIMATION OF HETEROGENOUS AVERAGE TREATMENT EFFECT OF BIOLOGIC DMARDS– PANEL DATA CORRELATED RANDOM COEFFICIENTS MODEL WITH POLYCHOTOMOUS ENDOGENOUS TREATMENT

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OBJECTIVES: To estimate the treatment effects of biologic disease modifying anti-rheumatoid drugs (DMARDs) on quarterly total health care expenditure, while controlling endogeneity in treatment choice and allowing heterogeneity in treatment effects. The structural parameters, heterogeneous (ATE), and homogeneous (ATE1) average treatment effects were defined as the impact of treatment on quarterly expenditure, if patients are randomly assigned to biologic DMARDs. **METHODS:** Retrospective cohorts were constructed from California Medicaid paid claims between January 1, 1999 to December 31, 2005. Non-overlapping quarters were created from pharmacy claims for biologic (adalimumab and etanercept) and standard (lefluonomide, hydroxychloroquine and sulfasalazine) DMARDs. Final sample included 24504 episodes on 5510 patients. In the two-stage estimation, the treatment selection model was varied between multinomial and nested-logit, to avoid independence of irrelevant alternatives. The outcome equation was panel data fixed-effects correlated random coefficients model (Wooldridge-2005), allowing heterogeneity in parameters.