increased 161.8%, and any oxycodone-containing compound increased 267.3%. Mentions of each of these three classes of opioids remained less than 2% of all total drug mentions per year for each year studied. Medical use of the selected opioid classes, as reported in the ARCOS database and measured by grams distributed, all increased substantially (fentanyl 151.2%, morphine 48.8%, oxycodone 347.9%). CONCLUSIONS: Using this method of analysis, the rates of drug abuse, and resultant morbidity secondary to the use of opioid analgesics, remains low in spite of the increase in medical use of these substances.

PPN8

PATTERNS AND TRENDS IN OPIOID USE AMONG INDIVIDUALS WITH BACK PAIN IN THE UNITED STATES
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Secondary analysis of the Medical Expenditure Panel Survey (MEPS) from 1996 to 1999. OBJECTIVE: To examine patterns in opioid use in 1996, 1997, 1998 and 1999 among individuals with back pain in the US, and to investigate trends in the use of overall and individual opioid category. No study has examined at a national level the patterns and trends of opioid use among individuals with back pain. METHODS: Individuals with back pain were stratified by socio-demographic characteristics and geographical regions. Rates of overall opioid use were compared among different strata. To investigate trends in opioid use, use rates of the overall and individual opioid category were calculated and compared. From 1996 to 1999, the use of opioid was not significantly different across different gender or racial/ethnic groups, but significantly higher among individuals who were publicly insured, had low or below low income and had education at or below 12th grade compared to their respective counterparts. During the 4-year period, significant variations in opioid use across different age groups or geographic regions were observed in early years, but the variations became non-significant in later years. RESULTS: Trend analysis indicated that the rates of overall opioid use increased slightly across the 4-year span. Among individual opioid categories, the use of oxycodone or hydrocodone increased whereas the use of propoxyphene decreased. CONCLUSIONS: The significantly higher use of opioids among individuals who were publicly insured, had low or below low income and had education at or below 12th grade raised serious concerns about drug safety in this patient population. The increase in the use of hydrocodone and oxycodone indicated a need to better assess the efficacy and safety associated with these drugs among individuals with back pain.

PPN9

PRESCRIPTION OF NON-STEROIDAL ANTI-INFLAMMATORY DRUGS AND MUSCLE RELAXANTS FOR BACK PAIN IN THE UNITED STATES
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Secondary analysis of the 2000 Medical Expenditure Panel Survey (MEPS). OBJECTIVE: To examine national prescription patterns of non-steroidal anti-inflammatory drugs (NSAIDs) and muscle relaxants among individuals with back pain in the United States. Summary of Background Data. There is a lack of information on national prescription patterns of NSAIDs and muscle relaxants among individuals with back pain in the US. METHODS: Traditional NSAIDs, cyclooxygenase-2-specific (COX-2) inhibitors and muscle relaxants were investigated. Individuals with back pain were stratified by socio-demographic characteristics and geographical regions. For each medication category, overall prescribing frequency was compared across different strata and individual drug prescription was analyzed. RESULTS: Traditional NSAIDs, COX-2 inhibitors and muscle relaxants respectively accounted for 16.3%, 10% and 18.5% of total prescriptions for back pain in 2000. Among individual drugs, ibuprofen and naproxen accounted for most of the prescriptions for traditional NSAIDs (60%), whereas two-thirds of the prescriptions for muscle relaxants were attributable to cyclobenzaprine, carisoprodol and methocarbamol. Prescription of COX-2 inhibitors or muscle relaxants demonstrated wide variations across different regions. Several individual characteristics including age, race and educational level were associated with the prescription of some of the medications. CONCLUSIONS: Neither traditional NSAIDs, nor COX-2 inhibitors, nor muscle relaxants dominated prescriptions for back pain. However, a small number of individual drugs were attributable to most of the prescriptions for traditional NSAIDs or muscle relaxants. The prescription of some of the medications demonstrated wide variations across different regions or different racial and educational groups. More studies are needed to understand why the variations occurred and how to standardize the prescriptions.
significant higher costs for cilostazol using a gamma GLM model. CONCLUSIONS: The gamma GLM technique is a powerful tool for modeling strictly positive skewed outcomes and should be more widely employed in pharmaceutical analyses.

**PMED**

**MONTE-CARLO VALIDATION OF DELTA-K METHOD FOR SAMPLE-SIZE CALCULATION IN A COST-EFFECTIVENESS TRIAL**

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To design a cost-effectiveness trial, the Delta-K method newly developed provides us with a new formula for sample-size calculation. The Delta-K utilizes the difference between two cost-effectiveness ratios, $q_A$ and $q_B$, respectively of control and experimental regimens (i.e., $K_0 = 1/q_A - 1/q_B$). The advantage of the method is simplicity for estimating the sample-size, naturally extending the conventional binomial formula, whereas under the assumption of “constant” cost for each regimen. OBJECTIVES: Using multivariate analysis with the Monte-Carlo simulation for “variable” costs, we assess the robustness of the Delta-K method in search of the probable range of sample-sizes calculated based on the formula. METHOD: A case study of cost-consequence analysis is employed to validate the design of a clinical trial, which evaluates herpes zoster treatment with Valaciclovir vs. Aciclovir. Our former investigation on this case illuminated that the sample-size for the RCT could be reduced from $n = 821$ to $n = 36$ in use of the Delta-K method regarding the average costs as constant. In the Monte-Carlo simulation, therefore, the three major factors of costs such as primary medication, treatment for post herpetic neuralgia (PHN), and outpatient care were assumed to have a normal distribution since each factor is quantified with the mean and the standard deviation (S.D.) (e.g., for PHN; US$1504.9 ± 6.1 in Valaciclovir, whereas US$2006.6 ± 6.6 in Aciclovir). Under these conditions Monte-Carlo simulation was run up to 10,000 times to assess the overall distribution of sample-sizes calculated from the formula. RESULTS: The runs of 10,000 times resulted in the distribution with the sample-size of 35.2 ± 0.8 (the mean ± 2 S.D.) and the range of (33.7, 37.0) = (min, max), which is far smaller than the original sample-size $n = 821$. CONCLUSION: We confirmed sufficient robustness of the Delta-K method in a case study even if medical costs vary against the assumption of constant cost. It suggests the usefulness of the new method.

**PMED3**

**INCREMENTAL COST EFFECTIVENESS RATIOS AND CONFIDENCE INTERVALS—RELATIONSHIP OF CALCULATIONS WITH NNT VERSUS BOOTSTRAP METHOD**

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The concept of incremental cost effectiveness ratios (ICERs) and confidence intervals (CIs) may seem complicated to many practitioners and decision makers. There is a growing body of literature regarding the use of NNT (number needed to treat) as a statistic that may be easier to understand in clinical practice. NNTs and ICERs are receiving increased attention in the interface of clinical and economic concepts. OBJECTIVE: To compare the ICER and CI results by using NNT-related calculations versus bootstrap analyses utilizing datasets from three published papers. METHODS: An NNT spreadsheet calculator was developed that generates NNT confidence intervals and incremental cost to treat calculations. Datasets with an aggregate total of over 2000 patients from three previously published pharmaco-economic studies were analyzed with both the NNT and bootstrap ICER approach. The NNT calculator used a two by two contingency table with additional cells for including cost of each treatment. Confidence intervals (95%) were calculated for NNT and the upper and lower values of the incremental cost per successfully treated patient. In contrast, the bootstrap software utilizes each individual patient case in the datasets to generate ICER ratios and ICER confidence intervals. RESULTS: The NNT results for the mean cost needed to treat for one successful outcome showed good agreement with the bootstrap generated ICER slopes. For NNT versus bootstrap, the anti-platelet study mean ICERs were $43,729 vs. $43,742, the antidepressant comparative study ICERs were $1647 vs. $1648 and the antidepressant combination study ICERs were $188,012 vs. $188,012. Using 5th and 95th percentiles for cost of treatment multiplied by corresponding NNT confidence intervals did not generate very close agreement with the bootstrapped CIs. CONCLUSIONS: NNT related calculations may be a method for initially analyzing local pilot data or explore the economic ramifications of a clinical publication when the full dataset is not available.

**PMED4**

**ISHIKAWA CAUSE AND EFFECT DIAGRAMS: A USEFUL TOOL IN DESIGNING ECONOMIC ANALYSES**

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OBJECTIVES: Cause and effect diagrams (also known as Ishikawa or fishbone diagrams) graphically depict the relationships between a particular outcome and all of the identified factors contributing to that outcome. The diagram’s structure includes a central “bone” with the topic of interest (the “head”) attached at the right-hand end. Branching out from the central line are “sub-bones” that represent primary causal factors, and each of these in turn has sub-bones representing subsidiary contributing factors. METHODS: Ishikawa diagrams were originally developed and have typically been used as a tool for root cause analyses, but they also can benefit the planning of economic analyses for a particular disease state, medical technology, or other health care intervention. Recent projects conducted by the Department of Health Policy of Jefferson Medical College illustrate the value of Ishikawa diagrams in planning economic analyses. One project involved the development of an economic model related to the diagnosis and management of Crohn’s disease. An Ishikawa diagram was used to organize the findings of an extensive literature review on this topic. The main categories, or “sub-bones” contributing to the cost of Crohn’s included: diagnostic work-up, medication therapy, administration, hospitalization, surgery, and adverse reactions/complications. RESULTS: Many of these categories were further broken down into appropriate subcategories. In another project, this tool was used to organize and graphically depict cost factors for allogeenic blood transfusions. Identified factors contributing to total costs were organized around four main sub-bones: Acquition, Administration, Preparation, and Adverse Events/Complications. CONCLUSIONS: In both of these projects, the constructed diagram facilitated the organization of large amounts of information, selection of key factors for inclusion in decision analytic economic models, and identification of unmeasured contributors to cost, which might influence the model’s assumptions or findings. Outcomes researchers therefore are