work-related activities consisting of nurse, pharmacist, and/or patient medication dispensing, preparation, administration and/or storage. Projects consisted of time and cost differences related to 1) three proton pump inhibitor dosage forms and seven administration methods, and 2) seven recombinant human growth hormone administration methods. Performance-based time data were then used to determine personnel/patient opportunity time and supply costs associated with different forms of medications and delivery devices. Simulations were developed and used to hold independent variables constant so only observed differences between medications and/or administration methods could be assessed. Statistical and micro-economic cost analysis were conducted specific to each type of medication and/or device. RESULTS: Processes and results show two detailed examples as case studies of how simulation-based research may be used to assess health care processes at the micro level. The advantages of isolating processes from the day-to-day complexity of patient care are demonstrated. Simulations may also represent an efficient assessment alternative of health care processes at the micro level with potential for projection to the macro level as compared to live, direct observation, cost-intensive, patient-centered care practice evaluations. CONCLUSIONS: Simulation-based time and motion and activity-based cost analyses allowed detailed micro-level time, workload, and supply evaluations that may be projected to the macro level. Professional schools’ simulation laboratories offer appropriate settings for such studies.

ESTIMATING TIME-PROFILED ECONOMIC BURDEN OF ILLNESS
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OBJECTIVES: Demonstrate a technique to characterize the economic burden of illness over time, correcting for censoring bias and controlling for differences in baseline characteristics between comparison groups. A sample of patients with diagnosis of disease A in 2004–2008 were extracted from MarketScan databases and followed to death, disenrollment, or December 31, 2008 (cases). The first diagnosis date was the index date. Enrollees without disease A were extracted as controls. Their index dates were assigned based on the distribution of index dates of cases. METHODS: First, Kaplan-Meier estimates for the probability of remaining in the data were calculated by month and disease status. Failure event was death or disenrollment. Censoring event was termination of MarketScan contract or end of study period. Next, total health care costs were estimated using generalized linear models (GLM) on the sub-sample of survivors/enrollees in each month, controlling for disease status, patient demographic and clinical characteristics. Adjusted costs were calculated by month and disease status using the regression estimates and average characteristics. Estimated total costs during the whole follow-up period were the sum of probability of remaining in the data multiplied by regression-adjusted costs in each month. RESULTS: At the end of year 1, 40.5% of cases deceased or disenrolled from unpaid/uninsured and to 13.6% of controls (p < 0.001); at the end of year 4 these figures were 76.4% and 30.5%, respectively (p < 0.001). GLM results indicated significantly higher cost among the group with disease A in each month during follow-up. The adjusted costs based on average characteristics was $86,592 for cases vs. $6,178 for controls in the first year and $151,077 vs $21,890 in the first 4 years. CONCLUSIONS: In studies with variable-length follow-up, an estimator combining the survivor probability and regression-adjusted cost is more robust to censoring bias, and better depicts the economic burden of illness over time.

CONCEPTUAL PAPERS & RESEARCH ON METHODS – Databases & Management Methods
PMC7
THE EFFECT OF LENGTH OF OBSERVATION AND CLAIMS DATA ON ESTIMATES OF COMORBIDITIES AMONG MEDICAID BENEFICIARIES
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OBJECTIVES: Researchers frequently use claims data to create comorbidity measures. The objective of this project was to examine how the number of months of observation data and the type of claims data can affect identification of comorbidities. METHODS: Inpatient (IP) and outpatient (OT) claims data were used to identify comorbidities for beneficiaries enrolled in a state Medicaid program. Beneficiaries were included if they were enrolled for continuous 24-month period between January 2002 and December 2004. Data were used to identify the first month in which an ICD-9 code appeared for each of the 17 comorbidities included in the Charlson Comorbidity Index. The D’Hoore scoring system was used to identify ICD-9 codes associated with each comorbid condition. Results from the IP and OT claims were combined to create overall comorbidity measures. RESULTS: The study included a total of 618,337 unique patients. The OT claims could identify almost all comorbidities (low of 88.0% for myocardial infarctions, high of 99.7% for diabetes). IP claims were much less likely to recognize comorbid conditions (low of 11.5% for chronic respiratory disease, high for myocardial infarction). At 12 months, less than half of the beneficiaries with comorbid events during the 24-month period had been identified for dementia (43.9%), cerebrovascular disease (45.6%), peripheral vascular disease (45.6%), and myocardial infarction (48.4%). In contrast, 78.1% of patients with dementia, and 69.0% of patients with chronic pulmonary disease had been identified at 12 months. CONCLUSIONS: The percentage of patients ascribed comorbidities will vary significantly depending on the number of observation months. Obviously, the incidence rate for new events/diagnoses contributes to the increase over time. However, researchers must be careful since some comorbidities may not be associated with frequent enough physician office visits to accurately detect existing comorbidities when the number of observation months is short.

DATA SCAFFOLDING: A PRAGMATIC APPROACH TO STRUCTURING A LITERATURE REVIEW SPREADSHEET TO MAXIMIZE INFORMATION, RATIONALE & DEVELOPMENT OF AN ONLINE DIRECTORY OF DATABASE PROFILES FOR PHARMACOEPIEMIOLOGY, OUTCOMES, & POPULATION RESEARCH
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OBJECTIVES: Large epidemiology studies using population databases are in high demand in the current health care environment. Simultaneously, the number of health care databases available for research has risen considerably. Increasingly complex research questions require population researchers to be more aware of the availability and details of databases worldwide. To address this growing need, a web-based directory with detailed profiles of population research databases was developed. METHODS: R.L.D.G.E. TO DATABASES (Risk:Information for Drug Evaluations) is an advanced version of the original R.A.D.A.R. (Risk:Assessment of Drugs Analysis & Response) books (1990s; 200+ database profiles), and the subsequent R.L.D.G.E. On-Line version (1999–2003). Over a 20-month period, we convened an advisory board, re-branded the website, and updated content. A web development firm built the infrastructure of bridgedata.org. Content was developed by assessing existing database profiles and performing extensive literature reviews. A database profile template was created with 75 common fields covering the following categories: population type, demographics, physician, drug, diagnosis, procedure, economic, validation, linkage, and administrative data. We received advisory board feedback at multiple stages, and database managers were contacted for listing authorization and content approval. A quality assurance process involved systematic review of each profile by the primary editor, DGI staff, and database managers. RESULTS: The site was launched in November 2009 with 50 database profiles from USA, Europe, and Asia. It features a web interface designed to perform database searches by field type and to allow side-by-side comparison of multiple databases. Limitations included a short timeline and budgetary constraints. CONCLUSIONS: Development of a web-based directory of population research database profiles will enable the identification of appropriate databases for pharmacoepidemiologic, economic, and health services research. Other applications may include serving as an educational tool and as a model for developing new health care databases.
a pilot project to collect this data and make it available for evaluation and planning processes in a standardized language according to CAP (Catalog for ambulatory procedures). METHODS: The data will be transferred into a new database in two data streams to ensure data protection. Data about the patient containing sex, age and other characteristics will be sent in a pseudonymized way in one data stream. Another will contain data about the procedures according to CAP and information about contract physicians, outpatient clinics and ambulatories. RESULTS: The new database will offer information about what until now has been more or less a black spot. It will give information about procedures performed in the ambulatory and outpatient sector for all stakeholders participating in this pilot project. CONCLUSIONS: Data about outpatient clinics and ambulatories have not been made accessible in one database for all participating stakeholders in a standardized language until now. The initiated pilot project and the database created therewith offer an opportunity to cover this lack of information.

CONCEPTUAL PAPERS & RESEARCH ON METHODS – Modeling Methods

RULING OUT EXTENDLY DOMINATED OPTIONS USING AN ICER MATRIX

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BACKGROUND: Incremental cost-effectiveness ratios (ICERs) represent the cost per unit of effectiveness of switching to a more costly and more effective option. In reporting results for cost-effectiveness (CE) analyses, options that are strictly dominated are ruled out and no ICERs should be reported. Additionally, some options may be ruled out by extended dominance, i.e., there is a linear combination of two options that dominates an option not otherwise excluded by strict dominance. In order to plot the CE efficiency frontier both strictly and extendedly dominated options must be excluded. Calculating strict dominance (e.g., in Excel) is straightforward. However, calculating extended dominance is more complex. METHODS: We present a method to exclude extendedly dominated options using an ICER matrix. To form an ICER matrix all options are ranked ordered by cost. For a CE analysis with N options, the ICER matrix is an N x N-1 sized table, where the first column represents the ICER from the least costly option to each more costly option, the second column represents the ICER from the second least costly option to each more costly option, etc. Negative ICERs, representing strictly dominated options, are excluded from the table. Extended dominance is established by calculating whether the ICER for a non-strictly dominated option is greater than the ICER for at least one more costly option. If so, the option is ruled out by extended dominance, otherwise not. We show how to perform the required calculations in Excel and how to graphically plot the CE efficiency frontier once all dominated and extendedly dominated options have been excluded. CONCLUSIONS: Strictly dominated and extendedly dominated options must be ruled out in order to plot the CE efficiency frontier. The ICER matrix is a systematic method to rule out strictly and extendedly dominated options.

THE COST-EFFECTIVENESS SENSITIVITY CURVE: QUANTIFYING THE EFFECT OF INDIVIDUAL PARAMETER UNCERTAINTY IN A PROBABILISTIC MODEL

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BACKGROUND: The cost-effectiveness acceptability curve (CEAC) graphically depicts the joint uncertainty in a probabilistic model by transforming the incremental cost-effectiveness ratio (ICER) into a net-benefit framework to represent the probability that a strategy is cost-effective over a range of willingness-to-pay (WTP) thresholds. By defining a new variable age was statistically significant. This model validated that knowledge significantly causes attitude towards product produce an improved fit, producing a chi-square value of 4679 (df < 902, p < 0.0001). This model validated that knowledge significantly causes attitude towards product purchase intention. Further research is needed to evaluate variables that can improve the understanding of consumer’s purchase intention.

Synchronization of random number streams greatly enhances efficiency of probabilistic models

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The inclusion of probabilistic components in health care models requires the implementation of random number sampling. Many microsimulation models use a simple random number generator without concern for its properties. This limits the user’s ability to use the identical set of random numbers across different model runs to compare study results or to analyze consumer’s OTC medication purchase intention. The model validated that knowledge significantly causes attitude towards product purchase intention. Further research is needed to evaluate variables that can improve the understanding of consumer’s purchase intention.

REVIEW OF COST EFFECTIVENESS STUDIES OF HIGH BUDGET IMPACT DRUGS

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OBJECTIVES: The recently made coverage decisions by UK’s NICE, Scotland’s SMC and the allocation of $1.8 Billion for comparative effectiveness research by the United States, are strong indicators of trends in pricing and reimbursement that are likely to be observed in the future. To gain an additional insight into these trends, we analyzed the cost effectiveness studies for the top ten highest selling drugs (>$80–95B worldwide sales). METHODS: The Top 10 drugs were selected based on their worldwide sales. For this analysis, we segmented these drugs into categories as primary care, specialty, small molecules, biologics, therapy areas and availability of generic alternatives. We analyzed the cost effectiveness studies that were published in peer-reviewed journals. Search was conducted using generic names of the drugs and the phrase “cost effectiveness” in abstract of the published study. RESULTS: During 2003–2008, the number of published studies on “cost effectiveness” have increased by more than 30%. Almost half of the published studies belong to—Remicade, Plaxiv and Enbrel. There is a large