OBJECTIVES: Generation of population cost estimates for event-time data requires a sophisticated approach to account for the probability of incurring the event over time. This research investigated the relationship of donor and recipient factors with all-cause renal graft failure and estimates of the cost of failure from a Medicare perspective.

METHODS: A two-part econometric approach was used to determine Medicare claims attributable to all-cause graft failure (including deaths). First, type-specific hazard functions were estimated with Cox proportional hazards models. Using data from USRDS for primary renal transplants in adults between 1993-1998, we developed separate predictive models for transplants from living and cadaveric donors after identifying covariates associated with graft loss. Models were stratified by transplant year and included donor and recipient characteristics plus clinical variables including immunosuppression therapies. Next, the log-transformed costs for patients who experienced the event were modeled against the covariates to estimate costs specifically associated with failure at a given time point. For patients who did not experience the event, predicted costs were generated based on the model coefficients and individual covariates. Retransformation of the log costs included an adjustment using residual smearing. The expected Medicare claims associated with graft failure were calculated by combining the estimated cumulative hazards of graft failure with the smeared estimate of the claims associated with the event.

RESULTS: For living donor transplants (N = 5831), expected Medicare claims attributable to renal transplant graft failure were approximately $13,073 (median $8,933; range $699–$214,184). For cadaveric donor transplants (N = 3 years post-transplant), the expected Medicare claims were approximately $13,149 (median $11,540; range $699–$214,184). CONCLUSIONS: These estimates provide groundwork for population-based studies to address the cost-effectiveness of various treatments to delay or prevent graft loss. The method allows policymakers to assess population costs after taking into account the probability of event occurrence.

COMPARISON OF PATIENT SELF-REPORTED HEALTHCARE RESOURCE UTILIZATION TO ELECTRONIC RECORD DATA: LESSONS LEARNED FROM A STUDY OF HERPES ZOSTER PATIENTS

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Healthcare resource utilization (HCRU) may be evaluated through patient interviews in multicenter clinical trials but the accuracy of self-reported data should be assessed. OBJECTIVE: This study evaluated the consistency between electronic record data and patient self-reported HCRU for herpes zoster (HZ) through telephone interviews. METHODS: HZ patients (N = 116) were recruited from a managed care organization in Boston. HZ-related hospitalizations, Emergency Department (ED) visits, outpatient visits and telephone calls were compared separately, with further differentiation among outpatient contacts with primary care providers and specialists. Medication use comparisons were made for antivirals, antiviral medications, and other prescription medications. Judgments of consistency were based on intraclass correlation coefficients (ICC) unless data were sparse.

RESULTS: Two patients with HZ hospitalizations were found in the electronic records versus three in the questionnaire. Four patients with ED visits were found in the electronic records versus 34 in the questionnaire. The ICC for outpatient visits was 0.46 (CI 0.06–0.85; n electronic records = 268, n questionnaire = 265). The ICC for telephone calls was 0.51 (CI 0.06–0.96; n electronic records = 87, n questionnaire = 110). By outpatient provider type, the ICC ranged from 0.27 for primary care visits to 0.84 for specialist visits. ICCs of 0.55, 0.64 and 0.56 were found for pain medications, antiviral medications, and other medications, respectively. CONCLUSION: Patient self-reported HCRU reasonably (ICC ≥ 0.4), but imperfectly matched the electronic records across most categories, with no systematic bias observed. Patient misclassification of urgent care visits as ED visits may account for some of the observed discrepancies between ED and primary care visits. This study, which represents one of the first efforts to evaluate the design of a patient self-report HCRU questionnaire for use in clinical trials, identified limitations to comparisons between the two types of data sources and offers insight into potential improvements for the design and validation of such questionnaires.

THE IMPACT OF REQUIRING A FIXED PERIOD OF ELIGIBILITY IN ECONOMIC AND EPIDEMIOLOGICAL STUDIES THAT UTILIZE LONGITUDINAL DATA

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OBJECTIVES: In economic and epidemiologic studies utilizing longitudinal data, researchers often require a fixed follow-up period. By allowing differential follow-up, researchers can eliminate one source of selection bias. Our objective was to compare analyses of two study populations from the General Practice Research Database (GPRD) differing only in length of follow-up time.

METHODS: Study population 1 (SP1; n = 28,643) included patients with a given condition first diagnosed between June 1988 and February 1999. Study population 2 (SP2; n = 21,289) included only those patients in SP1 with at least a year of follow-up. Comorbid conditions, resource use, and reasons for loss to follow-up were
examined. RESULTS: Approximately 26% (n = 7,354) of patients in SP1 were excluded from SP2. Reasons for exclusion were death (22%), loss to follow-up (34%), and right-censoring (44%). Age, gender, and calendar year of the index event were not dramatically different between the two populations. Both crude and age-adjusted prevalence rates of most comorbid conditions at index date were lower in SP2. Mortality was significantly higher in SP1 (5.7 vs. 3.8/100PY; p < 0.05). There was a decrease in the proportion of patients never treated with drugs for the selected condition from 42% in SP1 to 36% in SP2. Mean and median values for annualized rates were lower in SP2, possibly indicating that some patients with higher resource use were selectively excluded. CONCLUSIONS: The impact of selection bias associated with defining patient cohorts based on minimum follow-up time affects both economic and epidemiologic analyses. Overall, the results of this study suggest that researchers should define a cohort without regard to follow-up whenever possible. The appropriate and necessary follow-up period will clearly vary by condition and perhaps by local practice patterns. The data themselves can help inform the appropriate time frame for follow-up.

AUTOMATING ECONOMIC ANALYSIS OF CO-MEDICATION USE IN CLINICAL TRIALS

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OBJECTIVES: Resource utilization of co-medication use in clinical trials is often cumbersome because it involves thousands of co-medications, which are not assigned standard codes, such as National Drug Codes (NDC), making analysis difficult at the individual drug level. We developed an automated routine that allowed each co-medication to be matched to published NDC prices, in turn allowing, costing at the individual drug level. METHODS: Computer-based automated mapping routines (SAS, v8.2) were developed to handle co-medication trial data collected using the World Health Organization’s (WHO) Anatomical Therapeutic Chemical (ATC) classification system, along with the daily dose. Our approach was to map the ATC code descriptions to their generic names, and merge these with those in the Food and Drug Administration’s (FDA) NDC table, thereby obtaining the NDC for each co-medication used. An average cost was calculated by averaging the average wholesale price (AWP) per milligram for each NDC that matched the generic names. The average daily cost for the co-medications was then calculated by multiplying the daily dose by the average costs. RESULTS: A random sample of 1000 observations of co-medications data was drawn from a randomized cardiovascular trial. This sample contained 238 unique WHO ATC codes. Our computer-based automated procedures matched 209; i.e., about 88% of the codes. This translated into 956 out of the 1000 observations being matched (96%). Comparing the entire trial dataset with NDC table showed a 92% match. CONCLUSIONS: The proposed methodology provides an automated routine allowing WHO ATC coded co-medications to be transcribed to unique NDC codes. This methodology can also be extended to handle medications described as generic or brand names in any format. This allows co-medication costs to be assigned at the individual drug level, improving the feasibility and rigor of within-trial economic analysis.

QUALITY OF LIFE/PATIENT PREFERENCES

QLI

QUALITY OF LIFE, UTILITY, AND WILLINGNESS TO PAY IN PATIENTS WITH DIABETES

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OBJECTIVE: The objectives of this study were to measure diabetic patients’ quality-of-life (QOL), utility, and willingness-to-pay (WTP), and to examine the interrelationship between these measures. METHODS: Diabetic patients ≥18 years old were randomly selected from 2 hospital endocrinology clinics. Patients were interviewed to measure utility values using a visual analogue scale (VAS) and standard gamble (SG), and measure WTP for pharmacist-provided education using contingent valuation. QOL was measured via self-administered questionnaire containing the 36-item Short-Form health survey (SF-36), Diabetes Quality of Life instrument (DQOL), and Health Utility Index (HUI). Relationships between scales of QOL instruments, utilities, and WTP were tested using Spearman’s correlation coefficients and regression analysis, and differences by study variables were tested using t-tests and analysis of variance. RESULTS: Two-hundred eighty-three patients completed the interview and questionnaire. Mean health-utility was 0.72 from VAS, 0.83 from SG, 0.83 from HUI2 and 0.73 from HUI3. Mean scores for SF-36 physical component (PCS) and mental component (MCS) were 45.4 and 50.2, respectively, and mean score for total DQOL was 0.70. Patients’ mean WTP was $32.65. Age and number of diabetic complications were significant factors for VAS. The PCS and MCS were both significantly positively correlated with total DQOL, HUI2, HUI3, and VAS (all p < 0.0001), but not SG or WTP. VAS and total DQOL were significantly correlated with each other, SF-36 subscales, HUI2, HUI3, and SG (all p < 0.05), except for WTP. WTP was neither significantly correlated with any utility values (VAS, SG, HUI2, and HUI3) nor any QOL measures (SF-36 and total DQOL), but correlations were in the expected directions. CONCLUSIONS: The DQOL demonstrated strong correlation with SF-36 and utility values measured using VAS, SG, and HUIs, but weak correlation with WTP. Further research is warranted to