HEALTH CARE USE & POLICY STUDIES – Disease Management

PHP2 VALIDITY OF THE ADHERENCE ESTIMATOR IN THE PREDICTION OF PERSISTENCE WITH CHRONIC MEDICATIONS ASSESSED OVER 14 MONTHS

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OBJECTIVES: Our objective was to assess the predictive validity of the Adherence Estimator® (AE), a three-item instrument designed to estimate patients’ propensity to adhere to prescription medications for chronic disease. METHODS: The AE was part of a larger survey mailed to adults who had an index prescription fill for one of five chronic conditions: adherence over time was assessed using the continuous measure of medication gaps (CMG) from pharmacy claims data. The Wilcoxon rank sum test was used to assess differences in median PDC between pairs of the adherence risk groups [low/medium/high risk]. Sensitivity, specificity, and positive predictive value (PPV) of the AE were assessed. RESULTS: Adherence to all required doses of vaccine. Despite strong clinical evidence, policy and reimbursement aspects.

PHP3 EFFECTIVENESS OF A PATIENT PERSISTENCY PROGRAM TO INCREASE COMPLIANCE FOR VACCINATION

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OBJECTIVES: One of the major challenges with vaccination is achieving high compliance for all required doses of vaccine. Despite strong clinical evidence, policy and marketing efforts, the compliance for several vaccination programs remains low. Often patients fail to receive the required subsequent doses of the vaccine. We conducted a study to evaluate the AE in the prediction of non-persistence were calculated at 45 days, and three, nine, 12, and 14 months. Multiple linear regression was used to assess whether the AE was a significant predictor of persistence at different time intervals, controlling for demographics and comorbidity. RESULTS: There were 1,674 usable responses for an overall survey response rate of 24.3%. Overall, 42.4% of the respondents were classified as being at low risk for non-adherence; 35.1% at medium risk; and 22.2% at high risk. At 14 months, median therapy gaps (CMG) for the low risk group (38.2%) were significantly lower than those for the medium-risk (48.7%) and high-risk groups (59.6%). At 14 months, sensitivity, specificity, and PPV for the AE remained constant over time; the PPV increased as more respondents fell off therapy. Starting at three months, the AE risk groups (low vs. medium/high risk) significantly predicted subsequent gaps in therapy as measured by the CMG. CONCLUSIONS: Patients’ propensity to adhere to prescription medications for chronic disease as measured by the AE significantly predicted patients’ adherence behavior from three to 14 months post-index fill.

PHP4 IMPROVING ACCESS-TO-CARE LEADS TO OPTIMAL OUTCOMES IN PHARMACIST-LED MEDICATION THERAPY MANAGEMENT (MTM) PROGRAM

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OBJECTIVES: Providing specialized patient care to patients with no insurance can enable them to better manage their medications, experience optimal outcomes, and ensure more effective use of health care services. This study measured improvement in low-income diabetic patient outcomes through participating in a MTM program. METHODS: Patients comprised of residents participating in the CareNet program, in Lucas County, OH which provides coordinated health care for low-income residents. Patients received MTM services from their pharmacists on a quarterly basis. Patients were provided diabetic supplies, such as lancets and test strips, at no cost to encourage participation. The study used a prospective pre-post design following patients for a year. Clinical (HbA1c, level, systolic blood pressure (SBP), and diastolic blood pressure (DBP), humanistic (patient satisfaction, adherence, knowledge, and quality of life) and social (caffeine and alcohol consumption, smoking, exercise) outcomes were measured at staggered intervals. RESULTS: A total of 100 patients were enrolled. Clinical measures. Mean HbA1c concentration decreased from baseline to the three-month follow-up. Patients who had an HbA1c level greater than 7% at baseline saw a decrease of 0.5% from baseline to three months. Mean SBP and DBP values decreased significantly from baseline. Patients with a baseline SBP > 140 mmHg experienced a significant change in BP at 3 months (~16 mmHg). Patients with a baseline DBP of greater than 90 mmHg experienced a significant decrease of 16.60 mmHg from baseline. Humanistic measures. Patient knowledge increased for all disease states and overall patient satisfaction increased significantly. Social measures. There was a decrease in caffeine and alcohol consumption, a significant decrease in smoking, and increase in exercise. Nine months for all outcomes will be presented. CONCLUSIONS: Pharmacists can improve quality of care, access to care and positive outcomes for low-income patients in a relatively short amount of time.

PHP5 UNCOVERING REASONS OF NON-COMPLIANCE IN EPRO STUDIES TO IMPROVE PRO DATA COLLECTION

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OBJECTIVES: To better understand ways to influence greater patient compliance in providing more accurate data collected via patients during clinical trials. Uncovering reasons that patients are not compliant and reviewing measures that electronic patient reported outcomes (ePRO) service vendors offer to increase compliance will result in an opportunity to overall improve the collection of patient reported outcomes data and increase compliance. METHODS: A total of 24 clinical articles from 2001-2009 were identified that collected and provided comments on patients’ reasons for non-compliance of completing patient perspective data during clinical trials. These articles were reviewed and the non-compliance information was summarized to help identify which reasons were most commonly stated. Measures that many ePRO vendors use to help Sponsors increase patient compliance for their studies were identified. The measures offered by ePRO vendors were examined and matched up to reasons for non-compliance to identify if there are areas where methods are needed for improved patient compliance. RESULTS: Out of the 24 articles reviewed, there were 70 responses for non-compliance. Across these responses, there were seven major themes (Time, Reminders needed, No access, System issues, Equipment loss, Health and Length of study). The most frequent two reasons correlated with Time (lack of) and Reminders. In comparing these reasons to available ePRO vendors compliance tools, the match-up results were acceptable since reminders (alarms, outbound calling) are currently being used by many vendors. REGARDING TIME, these results really emphasize how important it is not to over burden patients with the addition of a diary/assessment to their normal routine. It is clear if they reach a point of distress, they apt not to do the diary/assessment. CONCLUSIONS: Discussion will include further detail of the non-compliance reasons, major themes, tools offered by ePRO vendors and new methods that could be developed based on the analysis.

HEALTH CARE USE & POLICY STUDIES – Drug/Device/Diagnostic Use & Policy

PHP6 QUANTITATIVE ANALYSIS OF THE INFLUENCE OF DISEASE AND PRODUCT CHARACTERISTICS ON THE PRICE OF ORPHAN DRUGS IN EUROPE

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OBJECTIVES: Specific regulation and incentives to develop new orphan drugs in US and Europe, as well as increased revenues associated with sales of orphan drugs have boosted the interest of pharmaceutical companies in this field. Pricing is a key success factor for manufacturers as sales volumes are very limited. We investigated the determinants of orphan product prices in five European countries: France, Italy, Germany, Spain and UK, using regression analysis. METHODS: Products with orphan designation approved by EMAE were identified up to June 2009. Yearly prices per product were derived from public prices, WHO defined daily dose, and treatment duration based on guidelines or summary product characteristics. The analysis included disease-related variables: prevalence, disease area, prognosis, age and vulnerability of target population, seriousness, number of available treatments and course of illness, and drug-related parameters: year of approval, trial size, number of trials, comparator in trials, ATC code, evidence of benefit. A generalized linear model was used to identify the price of health care services. RESULTS: Fifty-one products were part of the 5 countries, which respectively 37, 35, 28, 36 and 39 were available in France, Germany, Italy, Spain and UK respectively. Available products did not overlap across countries. Prices were highest in Italy and lowest in UK. No significant correlation was found between any of the above metrics and orphan drug prices. Comparisons between countries showed that alternative sites seemed associated with high prices, but these trends were not statistically significant. CONCLUSIONS: Pricing of orphan drugs is a complex process, with no identifiable objective price determinant. Patient group pressure, low overall impact on health care expenditure budget, increasing competiveness of other treatments, and the ability of levering the importance of unmet need in the target population might play an important role. This analysis generated hypotheses for further research into drivers of prices for orphan drugs.