Abstracts

PHP78

STABILITY OF PHYSICIAN QUALITY PERFORMANCE ON PAY-FOR-PERFORMANCE PROCESS MEASURES OVER TIME: EFFECT OF PATIENT DENOMINATOR THRESHOLDS

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OBJECTIVE: The purpose of this study was to determine stability of physician performance rates on process metrics by patient volume threshold level and by alternative algorithms of deriving a global physician performance score. METHODS: Preferred provider organization (PPO) health plan claims data between April 2003 and March 2005 were analyzed. Six alternative algorithms of calculating a global metric rate from several process metrics were compared. Stability was also assessed across the different patient thresholds within each algorithm, where patient volume thresholds of 0, 5, 10, 15 and 20 were applied for each process measure. Trend test was used to compare longitudinal stability across patient volume thresholds and across global score algorithms. RESULTS: A total of 2036 generalist and specialist physicians were included. The sample size of eligible physicians decreased with increasing minimum patient volume thresholds. The greatest drop occurred when the threshold was increased from 0 to 5 patients (17–21% decrease, varying by year). The average indicator denominator size ranged from 95 patients (S.D. ± 160) in 2003 to 172 patients (S.D. ± 337) in 2005. Physician performance rates were least stable when no minimum patient volume threshold was required for analysis. No significant differences in score stability over time were observed between the different patient volume thresholds of 5 patients or above. CONCLUSION: A minimum patient volume threshold of 5 patients is likely necessary to preserve stability of physician performance rates over time. Increasing the level of threshold beyond 5 patients, however, did not seem to significantly increase longitudinal stability of performance rates.

PHP79

PHYSICIAN QUALITY MEASUREMENT IN THE HEALTH PLAN PPO SETTING: THE IMPORTANCE OF SCORING ALGORITHMS

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OBJECTIVE: Various methodologies for measuring quality have been developed within pay-for-performance programs. This study sought to examine whether the relative ranking of physicians with regard to their quality performance is affected significantly by alternative scoring algorithms. METHODS: Administrative claims data from a preferred provider organization plan for 2004–2005 were used to measure physician performance on a set of 54 previously validated quality indicators. Three physician composite scoring approaches (binary, quartile, sum) were compared. In the binary method, each indicator was scored based on a comparison to the median. In the quartile method, the score for each indicator was based on the quartile of the physician’s performance. In the sum method, the score is a ratio of all numerator cases over all denominator cases summed across all indicators. Wilcoxon rank-sum test, Spearman rank-correlation coefficient, and kappa statistic were used to evaluate differences between the alternative methodologies. RESULTS: A total of 2,744 physicians were included, representing a total of 41 specialties. Physician scores were not highly correlated and achieved only a moderate level of agreement when using the different composite scoring algorithms. The “sum” strategy tended to result in the highest physician scores compared to the other scoring methods. CONCLUSION: The type of scoring algorithm considerably affects physician quality performance scores measured by clinically appropriate quality of care metrics. Using binary or quartile composite scoring methods can lead to a significant loss of information compared to the sum method.

HEALTH CARE USE & POLICY STUDIES—Regulation of Health Care Sector

PHP80

ANALYSIS OF FDA WARNING LETTERS TO MANUFACTURERS OF PHARMACEUTICALS CONCERNING HEALTH OUTCOMES-RELATED PROMOTIONAL CLAIMS VIOLATIONS

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OBJECTIVE: To conduct a formal content analysis of FDA warning letters to manufacturers of pharmaceuticals concerning misleading health outcomes claims. METHODS: Two judges formally trained in content analysis procedures critically evaluated warning letters issued by the FDA from 2000 to 2006. An abstraction form was developed to capture information such as company name, product information, type of violation, target audience, and media type. Misleading health outcomes claims were classified into several categories including economic violations, quality of life (QoL) violations, misleading outcomes claims, misleading patient adherence claims, and misleading claims of preference by physicians or patients. The researchers derived a count of all letters and notices and calculated frequency statistics, as appropriate. Disagreements among judges were adjudicated by a third researcher. Inter-rater reliabilities among the judges were determined through kappa statistics. RESULTS: A total of 249 FDA letters to manufacturers were reviewed: 53 (21.3%) warning letters and 196 (78.7%) notices of violations. Misleading outcomes claims accounted for 33 (4%) of the total 809 violations. Misleading health outcomes claims included misleading pharmacoeconomic or cost advantage claim (n = 8, 0.9%), misleading claim of improved QoL (n = 11, 1.4%), misleading outcomes claims (n = 4, 0.5%), misleading patient adherence claims (n = 3, 0.4%) and misleading claims of preference by physicians or patients (n = 7, 0.9%). Target audience for these violations included health care providers (n = 11, 33%) and patients (n = 10, 30%). Inter-rater reliabilities among the 2 judges were exceptional, ranging from 0.86 to 1.00. CONCLUSION: Given that a large portion of drug selection decisions are made on the basis of outcomes data, it is not surprising that the FDA has begun monitoring outcomes research claims to ensure dissemination of accurate and reliable information. The small number of health outcomes violations could be attributed to Section 114 of the 1997 FDA Modernization Act that allows pharmaceutical companies to directly communicate such data to formulary decision-makers.

PHP81

PROGRESSIVE LICENSING AND VALUE FOR MONEY: USE OF RESPONDER ANALYSIS IN ECONOMIC EVALUATION

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OBJECTIVE: In responder-based reimbursement scenarios, patients who have demonstrated benefit after a test period are
reimbursed for continued use of a therapy. Benefit is evaluated based on a priori criteria regarding what constitutes a clinically important improvement. Payers incur costs for the patients who meet established responder criteria for a given therapy.

METHODS: An economic evaluation of Sativex(r) vs. standard analgesic care in adults with Multiple Sclerosis and neuropathic pain is used to illustrate the application of a responder-based reimbursement scenario (N = 66). Sativex(r) response was defined as a reduction in pain score (2-points on BS-11) on the 10th day of treatment based on clinician opinion. Base case and responder-based incremental cost-utility ratios (ICUR) were determined. Efficacy and safety data were based on a phase III pivotal trial. Costs (CND$ 2006) were based on provincial sources. Direct medical resources were taken from a burden of disease: 14.8%, and respiratory system diseases: 13.2%, musculoskeletal diseases: 18.0%, genitourinary system diseases: 24.0%, and reproductive system diseases: 21.8%.

In the base case, the incremental cost was $5339 and incremental QALY was 0.13. The ICUR was $70,103/QALY. In the responder-based economic analysis, 55.9% of Sativex(r) patients were defined as responders, incremental costs was $9352 and incremental QALY was 0.21, resulting in an ICUR of $44,917/QALY. CONCLUSION: Progressive licensing, in the form of conditional approvals, allows for earlier market access to pharmaceutical products. Based on the conditional nature of these approvals, the evidence for a new therapy may not be definitive. However, their potential benefit, by filling a void for previously unmet medical need, is significant. As payers are interested in maximizing value for money, they may not feel compelled to fund a conditionally-licensed product, when the data supporting its value is considered uncertain. To increase the confidence in the value for money proposition, responder-based reimbursement scenarios may be an option.

**REFERENCES**

**Abstracts**

**CANCER—Clinical Outcomes Studies**

**PCN1**

**DIAGNOSIS OF HER2 PROTEIN OVEREXPRESSION IN PATIENTS WITH BREAST CANCER IN BRAZIL**

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OBJECTIVE: Protein HER2 identifies a more aggressive subtype of breast cancer. For this type of tumor, currently there are specific treatments (trastuzumab and lapatinib), which, if used in early phase of the disease can render a higher chance of cure and survival to the patients (the HERA study showed that the use of Herceptin after a standard chemotherapy in adjuvant tumors has reduced by 46% the risk of a tumor to return). The study objective is to assess the performance of the diagnostic tests of this protein for Brazilian patients with breast cancer.

METHODS: A diary study with 220 Brazilian clinical oncologists was used; in the end of the study, a total of 3994 patients with breast cancer were followed up. RESULTS: Fifty-eight percent of the patients found were in the public market, and 42% were from the private market. We also have that 64% of the patients have early tumors (adjuvant or neoadjuvant), and 36% have metastatic tumors. The HER2 test is performed in 80% of the patients in the private market, with only 36% of the patients of the public market being tested. The test performance rate has little correlation with the disease phase (P value = 0.81); however, there is some correlation of the performance of this test with the patient’s age (P value = 0.3). Physicians from several Brazilian states have different behavior while performing this exam (P value = 6^162). CONCLUSION: We verified that few patients of the public market (36%) perform this test comparing with the private market (80%). We also verified great differences in the performance of it in the different regions of the country. An increased performance rate of this exam would increase the chances of survival and cure for the patients, since it allows the use of specific treatments for positive HER2 tumors.

**PCN2**

**SYSTEMATIC REVIEW OF PALONOSETRON IN CHEMOTHERAPY-INDUCED NAUSEA AND VOMITING**

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OBJECTIVE: The purpose of this study is to systematically review the evidence of palonosetron in chemotherapy-induced nausea and vomiting (CINV) and to understand its place in therapy.

METHODS: The English-language literature in OVID and Cochrane databases were searched using the following terms: palonosetron, antiemetics, CINV, and delayed. Of the 168 abstracts identified, 3 pivotal trials were deemed relevant by 2 independent reviewers. Guidelines from the American Society of Clinical Oncology, National Comprehensive Cancer Network (NCCN), and Multinational Association of Supportive Care in Cancer and the Food and Drug Administration (FDA) reviewers' comments on palonosetron were also obtained.

RESULTS: The trials, all non-inferiority studies, compared palonosetron 0.25mg to single-dose intravenous ondansetron or dolasetron.

**Abstracts**

**PHP82**

**RECENT TRENDS IN THE INCLUSION OF PATIENT-REPORTED OUTCOME (PRO) DATA IN APPROVED DRUGS LABELING BY FDA AND EMEA**

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OBJECTIVE: The PROLabels database (www.mapi-prolabels.org) was developed to provide easy access to patient-reported outcomes (PROs) included in approved labeling of products in Europe and the USA. Two years after its launch, the coverage of FDA labels has been extended to give a more comprehensive image of the current use of PROs in clinical studies.

METHODS: In 2006, the database opened with drugs approved in Europe through the centralized procedure established by the EMEA in January 1995 and with New Molecular Entities (NME) approved in the USA since January 1998. The extension project focused on other chemical types approved by FDA (e.g. New dosage form, New combination, etc.) and on NME approved before 1998. Once a PRO claim was identified in a label, the drug was added in PROLabels and the following information was retrieved: the PRO claim, description of clinical studies supporting the claim, description of PRO endpoints and measures used, pharmacological action of products and information source.

RESULTS: New figures resulting from this major extension of PROLabels will be presented. These new figures will include the number of drug products present in the database with the FDA/EMEA distribution, the most represented therapeutic areas (currently nervous system diseases: 32.0%, immune system diseases: 24.0%, musculoskeletal diseases: 18.0%, genitourinary system diseases: 14.8%, and respiratory system diseases: 13.2%), and the most frequently measured PROs (currently Signs and Symptoms followed by Health-Related Quality of Life (HRQL)). Finally, any change in the rate of PRO data found overall in FDA approvals will be checked.

CONCLUSION: This extension of the FDA coverage of the PROLabels database allows a clearer picture of the use of PROs to assess patients’ treatment benefit to be drawn. In addition, it facilitates the examination of the discrepancies between the US and European regulatory agencies.