

used to apply hospital- and revenue center-specific cost-to-charge ratios to estimate pharmaceutical costs from charges at the discharge level. The Diagnosis-Related Group (DRG) methodology was used to case-mix adjust the results. Relative value units were derived from the hospital specific cost estimates. After trimming at  $\pm$  three standard deviations, cluster analyses methods were applied to the hospitals to allocate each hospital into one of four levels of pharmaceutical service intensity.

**RESULTS:** The data set included 959 acute care hospitals, representing inpatient pharmacy cost information on more than 6.9 million discharges. The time period was federal fiscal year 2000. DRG 495, lung transplant, was the most costly group, while the least costly group was DRG 391, normal newborn. Of the 959 hospitals, 11 (1.15%) were excluded after trimming on intensity score. The mean relative value score for the remaining 948 hospitals was 2.77, with a range of 1.17 to 5.02. The standard deviation was 0.59.

**CONCLUSIONS:** These results provide empirical evidence from a very large sample of hospitals that the intensity of pharmaceutical interventions in acute care hospitals in the U.S. exhibits considerable variability. A four-fold difference was detected in intensity score between the lowest intensity hospitals and the highest. This DRG-adjusted difference was not due to differences in case-mix across hospitals. Further research should be done to determine whether patient outcomes are associated with low versus high pharmaceutical service intensity.

#### M18

### DEVELOPING A QUALITY APPRAISAL INSTRUMENT TO EVALUATE THE PEDIATRIC HEALTH ECONOMICS LITERATURE

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**OBJECTIVES:** The Pediatric Economic Database Evaluation (PEDE) Project features a database of 787 pediatric economic evaluations published between 1980 and 1999. A goal of the PEDE Project is to appraise the quality of pediatric economic evaluations published over this period. The objective of this research was to develop a valid and reliable quality appraisal instrument applicable to economic evaluations in the pediatric population. **METHODS:** A draft instrument was constructed from published checklists and questionnaires. New questions pertaining to the pediatric population were incorporated. An expert panel reviewed the draft instrument and the proposed scoring scheme for face and content validity. A revised version was pilot-tested by three independent appraisers. After addressing discrepancies in scores, a final version was created and subjected to inter-rater and test-retest reliability assessment.

**RESULTS:** The 57 items in the final questionnaire were mapped onto fourteen domains: economic evaluation, comparators, target population, time horizon, perspective, costs and resource use, outcomes, quality of life, analysis, discounting, incremental analysis, sensitivity analysis, conflict of interest, and conclusions. Among the 57 items, 46 have response options that are scored from 0 to 1. Inter-rater reliability was 0.75 (95% CI 0.66–0.81) and test-retest reliability was 0.92 (95% CI 0.71–0.98).

**CONCLUSIONS:** The Pediatric Quality Appraisal Questionnaire is a comprehensive instrument demonstrating face and content validity and very good reliability for application in the appraisal of pediatric economic evaluations. The instrument is currently being used in a quality appraisal of a random sample of 150 publications from the PEDE database.

### HEALTH POLICY—CONSUMER ADVERTISING ISSUES

#### HP5

### THE RELATIONSHIP OF DIRECT-TO-CONSUMER ADVERTISING AND CLINICIAN BEHAVIORAL INTENTIONS

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**OBJECTIVE:** To examine the relationship between the exposure of a patient to direct-to-consumer advertising (DTCA), and the likelihood of clinician behavioral intentions to provide information and medications.

**METHODS:** A randomized mail survey of Arizona primary care physicians (n = 1080) and physician assistants (n = 704) was conducted. Questionnaires were created with a hypothetical patient scenario varying according to the informational exposure of the patient (2 levels: DTCA or drug reference book). All other wording in the hypothetical scenarios was controlled. Clinicians were randomly assigned one form of the questionnaire. Each form solicited responses to questions related to the likelihood of respondent behavioral intentions (6-point scale, 6 = very likely to 1 = very unlikely) when faced with the hypothetical patient scenario.

**RESULTS:** The response rate for useable questionnaires was 44% (40.5% physicians and 49.3% physician assistants). No overall statistically significant differences were found between the early responders and late responders. Also, no statistically significant differences were found between responders and non-responders based on the metropolitan designations of their practice settings. Relative to clinicians who received the “drug reference book” patient scenario, clinicians who received the DTCA patient scenario were: more likely to become annoyed with a patient for asking for more information about medications (p = 0.003); less likely to answer the patient’s questions (p = 0.028) or provide additional written information (p = 0.007); more likely to attempt to change the subject rather than discuss an advertised

medication ( $p = 0.017$ ); more likely to become frustrated ( $p = 0.003$ ) and annoyed ( $p < 0.001$ ) with the patient for asking to try a medication; and less likely to provide samples ( $p = 0.001$ ) or a prescription ( $p < 0.001$ ) for a medication.

**CONCLUSION:** Clinicians are amenable to patients asking for drug information and medications, but their level of receptiveness is associated with the source from which the patient's questions originate.

**HP6**

**RELATIONSHIP OF DIRECT-TO-CONSUMER ADVERTISING SPENDING AND DRUG PRICING FOR THE TOP TWENTY DRUGS FROM 1997 TO 2000: AN EXPLORATORY STUDY**

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There exists an ongoing debate regarding the effect of direct-to-consumer (DTC) advertising spending on drug prices. The two opposite views are: (a) increase in DTC advertising spending would be added to drug prices (b) DTC advertising would increase competition and thus reduce drug prices.

**OBJECTIVE:** Explore the relationship of DTC advertising spending and drug pricing for the top twenty drugs from 1997 to 2000.

**METHODS:** Top twenty drugs were selected on the basis of their DTC advertising spending (source: Competitive Media Reporting, NY) for 1997. For analysis, average wholesale price (AWP) per unit was used from the Blue Book AWP Unit pricing. For each of the top twenty drugs, the following trend graphs were plotted for 1997 to 2000: (a) the total DTC advertising spending and per unit price of the drug; (b) the percent changes in the DTC advertising spending and drug price. The percent change in DTC advertising spending and drug price for a year was calculated as percent change from the previous year.

**RESULTS:** Only sildenafil (Viagra) and sibutramine (Meridia) showed an increase in the actual drug price with an increase in the DTC advertising spending. However, for these two drugs in year 2000, the percent change in DTC advertising spending decreased and the percent change in drug price increased. No trend was evident from the graphs of the other eighteen drugs. On an average DTC advertising spending for most of the drugs decreased with time while drug prices continued to increase.

**CONCLUSION:** Results indicate a very weak relationship between DTC advertising spending and drug prices. The increase in drug price in spite of the decrease in the DTC advertising spending contradicts both rationale i.e. DTC advertising spending reduces drug price through competition or increase in drug price is due to increase in DTC advertising spending.

**IMPACT OF DIRECT TO CONSUMER ADVERTISING—THE CONSUMER SEARCH FOR INFORMATION**

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**HP7**

**OBJECTIVE:** The purpose of this study is to identify factors associated with consumers' seeking various information sources about medications sought in response to direct to consumer advertising.

**METHODS:** In the spring and summer of 1999, the FDA, Division of Drug Marketing, Advertising, and Communication conducted a national telephone survey of adults regarding Direct-to-Consumer (DTC) promotion of prescription drugs and its effects on visits to the doctor. In addition to consumer attitudes, opinions and responses to direct to consumer advertising, the survey also elicited responses regarding consumer utilization of information sources such as reference books, 800-telephone number, and health care providers. There were 1081 total respondents, of whom 769 completed the required questions regarding information sources. Chi Square analysis was used to assess associations between consumer demographic information and the different types of informational resources that consumers used after exposure of direct to consumer advertising.

**RESULTS:** The analysis showed significant associations ( $p \leq 0.05$ ) between gender, race, education, health status, self-perceived knowledge of health, prescription medication use, and internet use and many of the following information resources: reference books, asking friends/neighbors, 800-telephone number, primary doctor, pharmacist, specialist, and nurse. Across all information sources, female gender, decreased health status, low education, and higher than average medication use were the variables that had the strongest associations. A model was developed depicting the associations between these findings. Results pertaining to specific sources will be presented.

**CONCLUSIONS:** This study evaluated how different consumers seek information from different sources as a result of direct to consumer advertising. This study will assist those interested in identifying and further educating consumers about their health and novel treatments or therapies.

**HP8**

**FDA REGULATORY ACTIONS AGAINST MISLEADING OR UNSUBSTANTIATED ECONOMIC AND QUALITY-OF-LIFE CLAIMS: AN ANALYSIS OF WARNING LETTERS AND NOTICES OF VIOLATION**

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