from PQRI and HEDIS 2010 requirements; pharmacy measures included 14 PQA measures being tested for these diseases. Measures were reviewed to identify: 1) type (process/outcome) 2) constructs and 3) data requirements (pharmacy, medical, laboratory).

RESULTS: Forty-eight measures were included (13 HEDIS, 21 PQRI, 14 PQA).

CONCLUSIONS: Despite well-designed measures for diabetes and independent pharmacy reimbursement (achievement of Hgb A1c and LDL goals) and % receiving recommended screenings, while PQA measures emphasize process adherence as gaps in therapy and proportion of days covered), excessive doses of diabetes medications, and suboptimal treatment (% on diabetics prescription without an ACEI or ARB), HEDIS, PQRI, and PQM measures for asthma assess use of controller medications, though 1 PQA measure also assesses overuse of beta agonists. Differences in the types and constructs of measures suggest opportunities for alignment. A bi-level framework that employs reporting pharmacy measures among patients who have not met the physician measures to facilitate a team approach for diabetes and hypertension quality, though this would only be feasible for organizations holding both medical and pharmacy data.

The results of this study were: 1) to determine the trend in market share of AGs during the first six months for drugs launched with a first-filer(180-day exclusivity period), and in market share of AGs launched during IG exclusivity; 2) to determine the effect of AGs launched during IG exclusivity on the market share of the brand and generic products. Each product selected had three subcategories: a brand name drug, an AG and at least one IG on the market. The unit of analysis was the number of prescriptions dispensed, regardless to the dispensed quantity.

RESULTS: At the end of the first year, market shares of AGs launched with the exclusivity of an IG in the cases of Zocor®, Proscar® and Norvasc® were 37%, 52% and 49%, respectively. Meanwhile, market shares of AGs launched without the exclusivity of an IG in the cases of Arava® and Amben® were 21% and 14%, respectively. CONCLUSIONS: AGs launched during IG exclusivity dominated the market and had the largest market share when compared to any other single market participant for the case. AGs launched during IG exclusivity obtain a dominant market share position and in the long run might discourage IG companies from timely generic introductions. Policy limiting the entry of AGs during the exclusivity of IG exclusivity might prevent delayed generic entry.

PHPB9

DESCRIPTION AND EVALUATION OF THE KNOWLEDGE OF THE BRAZILIA POPULATION FOR THE POLITICS OF ECONOMIC MEDICINE REGULATION IN BRAZIL
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OBJECTIVES: The primary objective was to evaluate the knowledge of the drugstore consumers from Brasilia and workers of ANVISA, for the regulation of prices of medicines. The specific objectives were to assess the knowledge of the populations on PMC, different price of generic medicines, estimate monthly expenses of the two samples and a preliminary comparative analysis between the two samples. METHODS: The study developed is a cross descriptive and analytical study. Based in the applications: a bi-level framework for diabetes and hypertension quality measurement would be worthwhile.

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

THE ROLE OF AUTHORIZED GENERICS IN THE PRESCRIPTION DRUG MARKETPLACE
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OBJECTIVES: Authorized generics (AGs) are products manufactured by a patent holder but marketed by a subsidiary or a third party company. AGs might increase competition and reduce generic prices when launched during the 180-day exclusivity period of the brand or in market share of AGs for the first six months for drugs launched without first-filer(180-day exclusivity period). METHODS: Five drugs were selected as cases to assess the effect of AGs launched during the exclusivity of IGs on market share of the brand and generic products. Each product selected had three subcategories: a brand name drug, an AG and at least one IG on the market. The unit of analysis was the number of prescriptions dispensed, regardless to the dispensed quantity.

RESULTS: At the end of the first year, market shares of AGs launched with the exclusivity of an IG in the cases of Zocor®, Proscar® and Norvasc® were 37%, 52% and 49%, respectively. Meanwhile, market shares of AGs launched without the exclusivity of an IG in the cases of Arava® and Amben® were 21% and 14%, respectively. CONCLUSIONS: AGs launched during IG exclusivity dominated the market and had the largest market share when compared to any other single market participant for the case. AGs launched during IG exclusivity obtain a dominant market share position and in the long run might discourage IG companies from timely generic introductions. Policy limiting the entry of AGs during the exclusivity of IG exclusivity might prevent delayed generic entry.

HEALTH CARE USE & POLICY STUDIES – Beyond Drug Interventions

DIFFERENCES IN CLINICIAN REPORTED EASE OF USE BETWEEN 2 HEMOSTASIS TREATMENT METHODS: RESULTS FROM A RANDOMIZED CONTROLLED STUDY
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OBJECTIVES: To evaluate treatment group differences in clinician reported ease of use between Fibrin Pad (FP) and Surgicel for hemostasis in subjects with mild or moderate bleeding using a novel survey tool. METHODS: The Ease of Use Questionnaire (EUQ) was used as part of a randomized, controlled, clinical study of FP versus Surgicel for intra-operative hemostasis. Subjects were randomized at 11 institutions with a 2:1 FP to Surgicel ratio. Additional subjects were enrolled to reduce the 1% type II error. Subjects were stratified by bleeding severity. Up to the first three subjects completed the EUQ at each institution. The final sample was N = 20 FP and N = 8 Surgicel (randomized) and N = 2 FP (non-randomized). The EUQ is a 19-item instrument evaluating clinicians’ perceptions and preferences for hemostasis products on five subscales (Ease of Use, Satisfaction with Product Properties and Efficiency, Confidence in Efficacy, Global Confidence, and Global Satisfaction). Differences in ease of use between treatment groups were evaluated using five ANCOVA models where subscale scores were the dependent variables, treatment group was the independent variable, and severity of bleeding was controlled for as the covariate. RESULTS: Mean subscale scores for Confidence in Efficacy (FP = 4.70 vs. S = 3.30), Global Confidence (FP = 4.70 vs. S = 4.13) and Global Satisfaction (FP = 4.85 vs. S = 4.04) were significantly higher for the FP group as compared to the Surgicel group (all p < 0.05). Mean subscales scores for Ease of Use (FP = 4.82 vs. S = 4.66) and Satisfaction (FP = 4.71 vs. S = 4.34) were higher for the FP group, but non-significant. CONCLUSIONS: Physicians reported higher ease of use, satisfaction with product properties and global confidence with FP compared to Surgicel when treating moderate and severe bleeding. Non-significant results in the Ease of Use and Satisfaction subscales likely resulted from small sample sizes. Future studies should evaluate ease of use in the full range of bleeding severities and larger sample sizes.
data on patient demographics, functional status, and mobility, for consenting patients, and then the patients entered information regarding functional abilities, satisfaction, and then the patients entered information regarding functional abilities, satisfaction, pain, quality of life and cost of care. RESULTS: A total of 43 patients participated in the pilot survey. Respondents were predominately insured through Medicare (43%) and Medicaid, including data on functional abilities, 19% of the consumers required help with at least one activity of daily living. The percent of consumers experiencing an improvement in their ability to perform activities such as exercise, walking, bathing and dressing independently, all after receiving their device ranged from 10% to 51%. Consumers also reported improved mood (68.9%), high satisfaction with their device (81.1%) and their provider (100%), and improved confidence (73%) after using their device. Several patients reported problems with ability to pay the out-of-pocket costs for their device (12.5%) or to afford device repair costs (9%). CONCLUSIONS: Preliminary results suggest that collecting outcomes data on the use of O&P devices, and value of O&P devices, and ultimately inform health insurance coverage and the out-of-pocket costs for their device (12.5%) or to afford device repair costs (9%). Consumers also reported improved mood (64.9%), high satisfaction with their device (81.1%) and their provider (100%), and improved confidence (73%) after using their device. Several patients reported problems with ability to pay

WHEN ARE DIAGNOSTIC LABORATORY TESTS COST-EFFECTIVE? A SYSTEMATIC REVIEW OF COST-UTILITY ANALYSES

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OBJECTIVES: Diagnostic laboratory tests may add critical information to guide treatment and improve patient outcomes, but payers have often questioned its value. We reviewed the methodology and results of published cost-utility analyses (CUAs) of laboratory tests through 2008. METHODS: We screened all papers related to laboratory diagnostic tests in the Tufts Medical Center Cost-effectiveness Analysis Registry (www.cearegistry.org) which contains detailed information on over 2,000 published CUAs from 1976 to 2008. In addition to the standard auditing process, we recorded information on the reported test accuracy and IVD cost. We also captured whether any account was taken for potential value (or harm) unrelated to treatment consequences such as the “reassurance value of testing” or additional anxiety produced by test information. RESULTS: We identified 141 published CUAs pertaining to diagnostic laboratory tests, which contained 433 separate incremental cost-effectiveness ratios. The full interquartile range of potential incremental costs has rapidly in recent years. The most common areas of clinical application were hematology/oncology (n = 42, 29.8%), and OB/GYN (n = 36, 25.5%). Approximately 63% (89/141) of studies addressed the accuracy of the test. Only 10% (14/141) mentioned test safety or associated risks. A small number (n = 13, 9.2%) of CUAs mentioned or considered the potential value or harm of testing unrelated to treatment consequences. Over 55% of the reported ICERs were either dominant (more QALYs for less cost), or below $50,000 per QALY gained (in $US 2008). CONCLUSIONS: The number of CUAs evaluating laboratory tests technologies has increased substantially with applications to diverse clinical areas. The vast majority of CUAs have not attempted to measure the potential value or harms of diagnostic testing unrelated to treatment.

THE BUDGET IMPACT OF ORAL NUTRITIONAL SUPPLEMENTS IN THE COMMUNITY SETTING IN THE NETHERLANDS

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OBJECTIVES: To assess the budget impact of introducing oral nutritional supplements (ONS), being a medical nutrition product, in elderly patients from the perspective of the society in The Netherlands in 2009. METHODS: A model was developed to calculate the budgetary impact of using ONS in patients who are eligible for ONS due to disease-related malnutrition (DRM). The analysis is based on the cohort of elderly patients (>65 years) in the community setting in The Netherlands in 2009. RESULTS: The budget impact of ONS was assessed using a linear decision analytic model reflecting cost functions related with DRM. The model allowed the assessment of the costs reductions resulting from improvement in DRM due to treatment with ONS. Clinical probabilities and resource utilization were based on clinical trials and published literature. The annual cost of care savings of €13.3 million (18.9%), when all eligible patients are treated. The additional costs of ONS (€37.0 million) are more than balanced by a reduction on other health care costs (€70.3 million). Sensitivity analyses were performed on all parameters, including duration of treatment with ONS and the proportion of the society in 2009. METHODS: This health economic analysis is based on a comparison of the use of ONS versus “no ONS” in patients who are eligible for ONS due to disease-related malnutrition (DRM). The base case analysis is based on a comparison in elderly patients (>65 years) in the community setting. The costs of the two treatment strategies ONS versus “no ONS” were assessed using a linear decision analytic model reflecting costs related with DRM. The model structure allowed for differences in costs for ONS and other resource utilization. Clinical probabilities and resource utilization were based on clinical trials and published literature; cost data were from official price tariffs. RESULTS: The use of ONS reduces the total costs from €133.5 to €181.80, which corresponds with a €173 (12.8%) cost savings per patient. The additional costs of ONS are more than balanced by a reduction on hospitalization costs. Sensitivity analyses were performed on all parameters, including length of stay and improve- The additional costs of ONS are more than balanced by a reduction on hospitalization costs. Sensitivity analyses were performed on all parameters, including length of stay and improve-