excluded if their target population did not specifically focus on women recruitment. We estimated the frequency of RI with which women were recruited by pooling across studies that presented data for RI used to enhance participation; 81% of the studies included at least one strategy to enhance RI, in particular RI using random-effects model. STATA (version 11.0) was used to perform the analysis.

RESULTS: We analyzed 15 interventional studies (n=9266) and 5 observational studies (n=5206). RI were classified into four categories: Referral, Social marketing (SM), health system (HS) and community outreach (CO).

OBJECTIVES: To describe the frequency of RI with which women were recruited to participate in HRS as proportions and 95% confidence intervals (CIs) for each RI using random-effects model. STATA (version 11.0) was used to perform the analysis.

RESULTS: We analyzed 15 interventional studies (n=9266) and 5 observational studies (n=5206). RI were classified into four categories: Referral, Social marketing (SM), health system (HS) and community outreach (CO). SM used in 96%, referrals 77%, CO in 50% and HS 88% studies. In aggregate, SM lead to 63.9% (63.4-64.7), referrals 14.5% (13.5-15.2), CO 20% (19-22), and HS 13.6% (13.4-13.8) in RI participation.

CONCLUSIONS: These results confirmed the findings of previous research that RI are effective in increasing RI participation. The most effective RI in 69% (14 of 20) of studies was SM. Future research should help researchers to develop strategies that will keep to a maximum participation and cooperation in HRS, while informing and protecting prospective participants adequately.

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OBJECTIVES: Resolution no 2/2004 dictates the criteria to establish the entry of new medicines, which are paid for the health system. The purpose of this present study is to assess the extent to which ethical principles are utilized along with other aspects of the HTA process. This research will focus in new products, which are classified in: Category I - new product (patented molecule) with scientific evidences of benefit when compared to others of the same therapeutic indication (greater efficacy, same efficacy with decreased side effects or same efficacy with lower global cost). Category II - new products not classified as I. Price analysis follows a model of price cap, including two constraints: lowest international price (LIP) and price cap which is a list of prices deducted from the production cost of treatment, based on an elected comparator. Price for Category I is based on the lowest international price only and, for Category II, the cost of treatment with that product is compared to the reference product. The goal of this research is to evaluate the application of price regulation since Resolution no 2/2004 publication and its consequences regarding to the costs of medicines for the society.

METHODS: Data of price analysis (new products approved by Office of Economic Regulation in CONITEC and new Technologies of Brazilian Health Surveillance Agency (Anvisa), which supports CMED decisions, were evaluated (2004-2011). RESULTS: In > years, 209 new molecules (563 presentations) were analyzed. The mean difference found between the price pleaded by laboratories and the price determined after analysis was: Category I 21%, Category II 39%. Only 7% of new products proved to be innovative, while 93% of the new products were classified as II (either or not under patent or without proven benefit).

CONCLUSIONS: Resolution no 2/2004 has led to lower entry prices and, consequently, decreased the price to the private and public sector, improving the efficiency of the health care.
have been taken so far to assess the importance associated with the health care decision-makers to incorporate ethical principles into practice. The review serves as an initial basis for a survey to study US decision-makers’ perspectives about the integration of evidence, economics and ethics in health care decision making.

PHPS9

MARKET ACCESS LESSONS FROM EXISTING PRODUCT DEVELOPMENT PARTNERSHIPS (PDPs)

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OBJECTIVES: To give an overview of recent PDPs between the pharmaceutical industry, the public sector, International Health Organizations (IHOs) and academia and draw best practices from two case studies, the Medicines for Malaria Venture (adaptive FDP) and the Malaria Vaccine Initiative (innovative FDP).

METHODS: We surveyed the ‘Health Partnerships Database’ (HPD) to list PDPs from 2004 to 2009 and analyzed the development of drug products for neglected diseases, including orphan drugs, vaccines and other pharmaceutical and diagnostics products. For the case studies, we analysed websites of the specific PDPs. RESULTS: The HPD lists 19 PDPs, which can be classified into two categories: adaptive FDPs, i.e. research and development (R&D) initiatives focused on tailoring existing products to developing countries’ needs, and innovative FDPs, i.e. R&D initiatives focused on developing new products to address developing countries’ diseases. Existing FDPs include the Medicines for Malaria Venture, 8 adaptive FDPs (2 FDPs per PDP) and 1 innovative FDP (malaria [6 FDPs], meningitis [1 FDP] and HIV/AIDS [6 FDPs]). Meanwhile, recently developed FDPs are tailored as an access-to-market strategy for essential and neglected disease treatments in developing countries (4 FDPs). In-depth analysis of two PDPs showed that 1) assessment of specific health care needs in developing countries prior to partnership initiation; 2) local government engagement in partnerships; 3) sustainability of funding flow accompanied by national expertise building; and 4) monitoring, reporting and transparent sharing of results are crucial for the success of PDPs.

CONCLUSIONS: Multinational pharmaceutical companies are increasingly dedi cating part of their development decision-makers to incorporate ethical principles into practice. The review market access.

HEALTH CARE USE & POLICY STUDIES – Formulary Development

PHPS0

FORECASTING THE HEALTH AND HEALTH SPENDING CONSEQUENCES OF VALUE-BASED DRUG INSURANCE DESIGN FOR INSURED WITH FIVE HIGH-COST CONDITIONS

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OBJECTIVES: The goal of value-based insurance design (VBID) is to set encourage use of high-value therapies and discourage use of low-value ones by appealing to evidence of value, rather than a drug’s price, when tiering drugs and setting copayment levels. The aim of this study was to simulate the impact of an illustration of savings and reductions in health care costs. Methods: We conducted a simulation to model an impact of a value-based formulary where drugs with less favorable cost-effectiveness (CE) had higher co-pays, and those with more favorable clinical effectiveness and CE were tiered with lower co-pays. Model inputs included drug utilization and cost data from the Medical Expenditure Panel Survey (MEPS) for 2008 and CE and health gain data from the published literature (Tufts CEA Registry). Estimates of behavioral effects of changing co-pay amounts were based on published studies which linked changes in co-pay conditions included lipid disorders, hypertension, diabetes, esophageal disorders, and depression. In sensitivity analyses we ran the model using a large health plan’s 2010 drug cost and utilization data. Results: In the esophageal and lipid-lowering scenarios, the total annual prescription costs decreased (3-9%), in the hypertension scenario costs remained roughly the same, and in depression and diabetes costs increased slightly (2-4%). Total costs of care decreased in some, but not one, scenario by 1-5%, and remained steady in the hypertension scenario. Health benefits also showed a positive impact across all scenarios, increasing total quality-adjusted life years gained by 118,000, about 1%. The results were similar in scenarios using health plan data.

CONCLUSIONS: The simulation illustrates the importance of involving from the prevalent sub-optimal practice of tiering therapies based largely on drug costs to tiering based on overall value.

PHPS1

COST-SAVING MEASURES IN REIMBURSEMENT OF ORPHAN DRUGS UNDER MEDICARE PRESCRIPTION DRUG PLANS

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OBJECTIVES: The objective is to identify in premium-priced orphan drugs coupled with health care budget constraints will pressure managed care plans to consider restricting market access. Coverage and reimbursement of ten FDA-designated orphan drugs (alpha-glucosidase, bromosulfophthalein, galsulfase, idursulfase, lipofest, lactase, mecamenin, nitisinone, gliclazide) were analyzed for seven popular Medicare PDP (BCBS Rx, AARP Medicare Rx Preferred, Cigna Medicare Rx Plan, One, Humana Enhanced, Aetna/CVS, EmblemHealth, UnitedHealthcare). METHODS: From a payer perspective, marginally, retail costs and utilization restrictions (UR)—pre-authorization (PA), quantity limits (QL) and step therapy (ST)—were obtained from CMS (www.medicare.gov). UR were assigned point values reflecting most to least restrictive—QL, 1; ST, 2; PA, 3; exclusion from formulary, 6. Each drug-plan combination can be assigned a maximum of 6 points. Disease prevalence was obtained from a variety of sources. RESULTS: Monthly retail prices ranged from $782.45 (laronidase) to $11,845.25 (mecasermin). Lipofest was most frequently excluded from formularies (2) and was subject to PA from the remaining five plans. The most frequent drug to drug was mecamerlin (6). There was slight negative correlation between price and prevalence of the disease for which the drugs were indicated (r=0.080). There was slight positive correlation between price and the number of UR points (r=0.046). There was virtually no correlation between UR points and disease prevalence (r=0.004). However, there is a moderate correlation between the number of plans that implement FA for a drug and that drug’s price (r=0.322).

CONCLUSIONS: The number of plans that implement FA for a drug and that drug’s price. However, it is clear that PA is perceived to be the most effective cost-saving measure as it is used for the most expensive drugs.

HEALTH CARE USE & POLICY STUDIES – Health Care Costs & Management

PHPS2

IMPACT OF HEALTH, SOCIAL, LIFESTYLE, AND ECONOMIC FACTORS ON LIFE EXPECTANCY IN OECD COUNTRIES

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OBJECTIVES: This retrospective analysis studied data from the OECD database on the association between life expectancy in 2010 and PI, social/lifestyle (tobacco, alcohol, fruits, vegetables, and physical activity), and economic (health care expenditures and gross domestic product) factors from a sample of 27 developed countries. METHODS: This retrospective study analyzed data from the OECD database on the association between life expectancy in 2010 and PI, social/lifestyle (tobacco, alcohol, fruits, vegetables, and physical activity), and economic (health care expenditures and gross domestic product) factors from a sample of 27 developed countries. Data were pooled according to gender at 40, 60, and 65 years while controlling for the lag variables of alcohol and tobacco (lagged 20 years), food intake variables (7 years), and economic factors (12 years). All variables were transformed via logarithmic form to yield full distributions. A bootstrapped random intercept regression model with sandwich estimators was conducted to determine which social and health factors were associated with a change in life expectancy.

RESULTS: The mean life expectancy for males was 39.02±2.30 years for age 40, 21.44±1.65 years for age 60, and 17.58±1.39 years for age 65. The mean life expectancy for females was 43.22±1.09 years for age 40, 25.1±1.68 years for age 60, and 20.90±1.57 years for age 65. Results of the regression of life expectancy indicated significant associations (p<0.05) of male gender (coefficient= -0.157±0.135), age group of 60 years (-0.570 ± 0.558), age group of 65 years (-0.763, CI: -0.777-0.750), calorie intake (-0.314, CI: -0.296-0.041), fruit and vegetable intake (0.06, CI: 0.036-0.084); overall health care expenditures (-0.047, CI: -0.092-0.021); and GDP (0.252, CI: 0.189-0.314). Pharmaceutical expenditures were not associated with change in life expectancy for any age group.

CONCLUSIONS: Across 27 OECD countries, specific food intake, GDP, and health care expenditures were significantly associated with altering life expectancy. Increased FE was not significantly associated with life expectancy.

PHPS3

HOMELESS PATIENTS USE OF URBAN EMERGENCY DEPARTMENTS IN THE UNITED STATES

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OBJECTIVES: This study compares homeless patients’ utilization of the urban emergency department (ED) in the United States (US) with non-homeless patients and examines the relationship between homelessness and frequency of ED use, arrival to the ED by ambulance, waiting time to be seen, length and type of ED visit. METHODS: The emergency department component of the 2009 National Hospital Ambulatory Care Survey database (NHAMCS-ED) was used for this cross-sectional, descriptive analysis. Patients were included if their patient residence was homeless or private residence and if they visited an urban ED. Descriptive statistics, bivariate analyses, and logistic regression were used to examine the relationship between demographics and ED use variables with homelessness. Nationally representative weights were applied to the estimates. RESULTS: The weighted sample size was 100,847,969 patient visits. A total of n=636,399 (6.3%) of the patients were homeless. The mean age of homeless patients was 44.0 years (95% CI: 41.7-46.3) compared to 34.7 years for non-homeless patients (95% CI: 33.5-35.9, p<0.0001). The majority of homeless patients were male (75.9%) versus only 44.9% of non-homeless patients (p<0.0001). More homeless patients arrived to the ED via ambulance (45.2 vs. 14.9%, p<0.0001). Homeless patients had a significantly different length of ED visits. Homeless patients had a significantly different length of ED visits. Homeless patients were more likely to be older (OR=1.02, 95% CI: 1.003-1.040), male gender (OR=3.34, 95% CI: 1.191-9.349), arrive to the ED via ambulance (OR=7.17, 95% CI: 5.78-9.09), and have a past visit to the ED in the last 12 months (OR=3.03, 95% CI: 1.003-1.008) than non-homeless patients. CONCLUSIONS: In 2009, homeless patients who visited US urban emergency departments did not differ than non-homeless patients in their demographics, frequency, access, and pattern of ED use.

PHPS4

EU PHARMACEUTICAL EXPENDITURE FORECAST