

co-payment groups. Analysis used the auto-regressive integrated moving-average model in STATA 9.0. **RESULTS:** The overall number of outpatient visits significantly decreased after policy implementation due to a reduction in the number of patients using outpatient facilities, but total costs of care remained unchanged. The policy had its greatest impact on the number of visits to regional and local community hospitals (secondary), but had no influence on those the medical centres (tertiary). Medical utilisation in physician clinics (primary) decreased due to an audit of reimbursement declarations. Overall, the policy failed to encourage referrals from primary care to higher tiers. **CONCLUSIONS:** Further research needs to explore how patients' out-of-pocket payment affects medical utilisation and which forces (not susceptible to co-payment) act in tertiary facilities. It also needs to investigate, whether the reduction in outpatient numbers was due to an affordability barrier to accessing essential care, with a potentially negative impact on the region's health.

PHPI2

HOW NON-REFERRAL OUTPATIENT CO-PAYMENT IN TAIWAN IMPACTS ON PATIENTS' OUT-OF-POCKET COSTS AND PRESCRIPTION PATTERNS

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OBJECTIVES: To deter non-essential visits and encourage initial contact in primary care, Taiwan's National Health Insurance's (NHI) implemented a differential co-payment policy on July 15, 2005. A previous study has examined the impact of this policy on medical utilization and total cost to NHI using a regional reimbursement dataset. This study aimed to explore the impact of this policy on outpatient co-payment and prescription patterns across different co-payment groups and tiers of medical facilities. **METHODS:** A segmented time-series analysis on regional weekly outpatient medical claims (January 2004 to July 2006). Outcome variables for co-payment and prescription patterns were stratified by tiers of medical facilities and co-payment groups. Analysis used the auto-regressive integrated moving-average model in STATA 9.0. **RESULTS:** Despite the decrease in outpatient visits, the overall co-payment to patients increased by 1.2% after policy implementation and also increased in most medical facilities (4.8% to 17.9%). Number of general prescriptions decreased across different medical facilities; the average cost and duration per general prescription decreased in medical centers and regional hospitals. The number of continuous prescriptions did not change, except for non-significant decreases in medical centers and regional hospitals. There was an increase in the number of continuous prescriptions dispensed in pharmacies (7.0%). **CONCLUSIONS:** The police significantly increased patients' out-of-pocket payment for outpatient visits. In response to the policy, physicians might prescribe more expensive drugs and extend prescription duration to help patients get the most benefit from the co-payment, and physician in medical centers are more likely to prescribe continuous prescriptions for patients with stable chronic diseases. Further research needs to identify vulnerable subgroups in obtaining necessary treatment, and to explore the impacts of cost-saving strategies on patients' quality of medical care.

PHPI3

COST-RELATED UNDERUSE OF MEDICINE DUE TO MEDICAID PHARMACY COST-CONTAINMENT POLICY ACTIONS

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OBJECTIVES: We sought to evaluate the impact of pharmacy cost-containment policy actions by state Medicaid programs on cost-related underuse of medicine, controlling for concurrent non-pharmacy cost-containment policy actions and socio-environmental differences among states. **METHODS:** We used the data from the 2003 Community Tracking Study (CTS) household survey, and linked them with the census demographic data and the cost containment policy actions based upon 50 States Surveys on state Medicaid spending growth and cost containment policy actions by the Kaiser Family Foundation in 2003. A cross-sectional study was performed to evaluate the impact of policy actions, by comparing Medicaid beneficiaries to non-Medicaid-pharmacy-cost-containment-action-eligible residents. The outcome measures included: patients do not receive needed medical care, patients cannot afford needed prescriptions, patients postpone needed medical care, and patients worry about the medical care cost. The outcomes were analyzed using logit model, with prior authorization, generic drugs required, copayment method, step therapy of fail-first requirement, limit on number of prescriptions and number of refills per month, preferred drug list, over the counter coverage, and prescription drug payment practices (payment and purchasing policies) as predictors. Additionally, non-pharmacy cost-containment policy actions, patients' demographics and states' socio-environmental variables were controlled. **RESULTS:** On average, each state has implemented 6.5% pharmacy cost containment policy actions in 2003. Only the worrying about costs was statistically significantly associated with individual pharmacy cost-containment policy action; however, such significance disappeared after other concurrent pharmacy cost-containment policy actions were controlled for. When the total number of pharmacy cost-containment policy actions was entered in the regression instead of individual policy action, each incremental policy action was associated with 14% increase in odds ratio for unmet medical needs ($p = 0.003$), and 5% increase in odds ratio for postponing medical needs ($p = 0.02$). **CONCLUSIONS:** There was variable impact of pharmacy cost-containment policy actions when assessed concurrently, and collectively.

HAVE YOUR CAKE OR EAT IT: DO DECISIONS BASED ON COST-EFFECTIVENESS UNDERMINE INCENTIVES FOR RESEARCH AND DEVELOPMENT?

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OBJECTIVES: Although cost-effectiveness analysis allows efficient decisions about the use of existing technologies (static efficiency) it has been argued that it will disincentivise the development of innovative technologies (dynamic efficiency). These concerns have also been raised about the report by the UK Office of Fair Trading which recommended that the price of pharmaceuticals should be based on their cost-effectiveness. We aim to establish whether decisions based on cost-effectiveness necessarily undermine incentives for the development of pharmaceuticals. **METHODS:** The arguments put forward as to why cost-effectiveness decisions might undermine incentives for innovation are examined and are used to consider the implications of the type of value-based pricing which has been proposed in the UK. **RESULTS:** The argument depends on whether the purpose of health care is to improve population health or to maximise welfare (consumer and producer surplus). If it is the former, then achieving static and dynamic efficiency requires a clear and predictable signal of value (cost-effectiveness). The private sector can then choose to invest in developments which it believes will be cost-effective and provide a satisfactory return on investment. Manufacturers should be allowed to appropriate some share of the surplus (monopoly rent) to incentivise investment in R&D. However, they should not take it all. The public sector subsidises research and development in many ways. Therefore, even if society was unconcerned about who benefits from innovation it would not be efficient to allow full appropriation. In other markets where innovation is protected, society simply offers monopoly rent during patent protection but does not allow full appropriation by, for example, facilitating perfect price discrimination. **CONCLUSIONS:** The argument that decisions about the use and price of a technology based on cost-effectiveness will undermine the incentives for R&D is misplaced if the objective is to improve population health given a fixed budget constraint.

PHPI5

ASSESSMENT OF ORPHAN DRUGS DEVELOPED AND DRUG UTILIZATION UNDER THE ORPHAN DRUG ACT: A DESCRIPTIVE EMPIRICAL STUDY

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OBJECTIVES: The Orphan Drug Act (ODA) was developed in 1983 to stimulate new drug development to treat rare diseases. The purpose of this analysis was to review the drug development with orphan drug status and to describe utilization of orphan drugs in the Medicaid program. **METHODS:** A literature review about orphan drug approvals was conducted through search engine like PubMed, as well as government and industry Internet websites. Nationwide Medicaid pharmacy data extracted from the Center for Medicare & Medicaid Services were analyzed from 1991 to 2007 regarding quarterly prescriptions, reimbursements, and cost per prescription for selected orphan drugs. Based on utilization patterns, two categories of orphan drugs were studied, including traditional ones with little use (like antizole, fabrazyme, respigam, myozyme, and panhematin) and non-traditional ones with wide usages (like paclitaxel, epoetin alfa, and imatinib mesylate). **RESULTS:** Since 1983, over 1700 drugs have been designated as having orphan status and 325 drugs have marketing approval to treat orphan diseases, focusing on oncology, metabolic and endocrine disorders, and hematology. From Medicaid pharmacy data, there was very little use for antizole, respigam, myozyme, and other traditional orphan drugs, such as fabrazyme from 15 in 2003 to the peak of 375 in 2006. By contrast, non-traditional orphan drug like epoetin alfa prescriptions increased from 17,282 in 1991 to the peak of 824,485 in 2005, and imatinib mesylate prescriptions increased from 3,877 in 2001 to the peak of 20,323 in 2005. Fabrazyme cost per prescription started with \$22,367 in 2003 and decreased to \$5,558 in 2006. Other expensive orphan drugs included myozyme, panhematin, imatinib mesylate, and ritumximab ranging from \$3,000 to \$10,000 per prescription. **CONCLUSIONS:** ODA has made a significant impact on drug development for rare diseases. Non-traditional orphan drugs with dramatic increased utilization and spending were observed, which might require safety surveillance and appropriate utilization review.

PHPI6

MARKET DISCONTINUATION OF PHARMACEUTICALS IN THE UNITED STATES: ANALYSIS OF DRUGS APPROVED BY THE FDA FROM 1939 TO 2008

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OBJECTIVES: The pharmaceutical industry serves societal needs by bringing innovative products and therapies to market. However, innovation does not guarantee market longevity. Consequently, some products will be evaluated and considered for market discontinuation. The purpose of this study was to identify drug market discontinuations, provide reasons for discontinuation, and characterize discontinued products by application type. **METHODS:** Data were derived from the FDA databases "Approved Drug Products" and the "Approved Drug Products with Therapeutic Equivalence Evaluations," Federal Register, and Medline. Market discontinuations were classified by approval types (New Drug Application -NDA and Abbreviated New Drug Application-ANDA) and by reasons for discontinuation (safety, efficacy and