for peptic ulcer associated with anti-platelet therapy used alone or in combination with PPI by patients previously diagnosed with peptic ulcers. In total, 14,627 patients (aspirin [12,001] and clopidogrel [2,626]) who had history of peptic ulcer before he or she began using antplatelet agent were selected. Recurrence of peptic ulcer was analyzed using Cox proportional hazards model, with adjustment for age, gender, medical history, using of non-steroidal anti-inflammatory drugs, and other medications. Propensity score method was used in adjustment for self selection bias. RESULTS: The incidences of recurring peptic ulcer per person years were 0.125 for aspirin without PPI, 0.102 for aspirin with PPI, 0.128 for Clopidogrel without PPI, and 0.152 for Clopidogrel with PPI. Patients taking clopidogrel were at significantly lower risk of hospitalization for peptic ulcer (HR 0.85 [95% CI: 0.76-0.95]) than those taking aspirin. Concomitant use of PPI significantly lowered the risk for aspirin users [0.76 [0.64-0.91]], but did not appear to offer the same protection to clopidogrel users (1.08 [0.89-1.31]). An adjusted survival curve of risk of recurring peptic ulcer showed that the risk increased significantly faster in clopido- grel users than patients using aspirin and PPI, though their average drug cost per person year was NT $12,500.08 ± 15,134.46, which was much higher than NT $1,712.39 ± 14,608.05 spent by Aspirin-PPI users. CONCLUSIONS: Aspirin plus a PPI could be considered more cost-effective to clopidogrel in reducing risk of peptic ulcer, when used for the secondary prevention of cardiovascular events in high-gastrointestinal risk group.

PODIUM SESSION II: FORMULARY DEVELOPMENT STUDIES

FD1

PREFERRED DRUG BENEFIT PLAN FOR CIVIL SERVANT MEDICAL BENEFIT SCHEME IN THAILAND: A CONJOINT ANALYSIS

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OBJECTIVES: To examine Thai Civil Servant Medical Benefit Scheme (CSMS) beneficiaries’ preferences for attributes of drug benefit plans. METHODS: Based on conjoint analysis, a self-administered questionnaire was designed to include ten hypothetic drug benefit plans which were described by four attributes e.g. patient cost sharing, formulary restrictiveness, quantity restrictiveness, and accessibility restrictiveness. Each attribute contained various levels. A total of 600 questionnaires were placed at various governmental offices in a province of southern Thailand. The respondents were asked to evaluate and determine overall preference for each plan. Pair-worth utility values for each level of each attribute for each beneficiary were estimated. Importance score for each attribute was calculated and averaged across all the beneficiaries. A segmentation analysis was also analyzed from the results of conjoint analysis. RESULTS: Response rate was about 66%. Average age of the respondents was about 43 years old. Most of them were female (60.6%) and married (69.9%). More than 80% of them had either a bachelor degree or higher. Their average monthly income was about 22,832 Baht. The estimated relative importance from a conjoint analysis indicated that the cost sharing was the most important attributes (44.95% relative importance). Among the levels of cost sharing attribute, co-insurance at 25% was the most preferred choice. Formulary restrictiveness was the second most important attribute (25.54% relative importance), while the restrictions of accessibility and quantity had similar relative importance for the beneficiaries. The results from market segmentation analysis showed that almost half of the respondents considered cost sharing attribute as the most important attribute for their preferred plan. CONCLUSIONS: This study demonstrated the CSMS beneficiaries’ preferences for the attributes of drug benefit schemes. Among four studied attributes, the most important attribute that the respondents chose was cost sharing.

FD2

ORPHAN DRUGS’ MARKET ACCESS IN THE UNITED STATES

Dode JF, Sepulveda B

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OBJECTIVES: The increase 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 the top selling FDA-designated orphan drugs (alglucerase, imiglucerase, imatinib, adalimumab, lamotrigine, lidocaine patch, modafinil, cinacalcet, bunepronephine/nalone/xolane, topiramate) were analyzed for seven of the most populous Medicare managed care plans (Aetna, SilverScript, Coventry, Medco, Cigna, United HealthCare, Humana). METHODS: The formulary tier structure, out-of-pocket costs (OPC) and utilization restrictions (URs) —pre-authorization (PA), quantity limits (QL) and step therapy (ST) —were obtained from CMS (www.medicare.gov). Orphan drugs analyzed were the top ten in 2007 retail sales (SDI VONA). OPC was reported as a percentage of the drug’s costs paid by patients, determined by averaging initial, gap, and catastrophic coverage (GAP). Among the seven plans covering the ten drugs, PA was the most common UR (40.4%), followed by QL (35.7%) and ST (2.9%). Alglucerase, the 3rd most expensive drug, had the highest OPC (59.9%) on average among all seven plans. Modafinil, the 4th least expensive drug, had the lowest OPC (40.3%) on average. However, modafinil was subjected to utilization restrictions by all plans studied and most frequently overall (13 of 21 possible restrictions: 61.9% OPC) while alglucerase, lamotrigine (3rd least expensive), bunepronephine/nalone/xolane (5th least expensive) were the least frequently restricted (14.3% each). Medco had the highest OPC for the ten drugs (72.9%) while SilverScript had the lowest (40.1%). Coventry employed URS most frequently (53.3%) while SilverScript used them least frequently (6.7%). CONCLUSIONS: Orphan drugs do not appear to be immune to market access limitations. URs on orphan drugs were prevalent in the most populous plans, with patients bearing 40-60% of the drugs’ costs out-of-pocket. The extent of restrictions was not proportional to the drugs’ price, suggesting that more research is warranted to investigate myriad factors related to orphan drug access.

FD3

CONCEPTUAL ISSUES IN THE DEVELOPMENT OF A MEASURE OF FORMULARY CULTURE

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OBJECTIVES: Hospital formularies are variously viewed as tools for enhancing patient safety by promoting more rational prescribing to obviate cost barriers that negatively affect patient care. The objective of this study was to describe the development of a measure for assessing clinical practitioners’ knowledge, attitudes and behaviors with respect to the formulary process and committee. METHODS: The Formulary Culture Survey (FCS) was modeled on the established literature of patient safety culture measurement. Focus group interviews of formulary committee members identified specific themes for item development within five conceptualized domains: (1) Global Trust, Confidence and Credibility, (2) Structure and Process of Formulary Committee, (3) Dimensions of Formulary Performance, (4) General Attitudes, (5) Familiarity of Drug Information Resources. Items were pilot tested in a 30 question online survey. These items were then categorized according to expert judgment into 14 domains. Refinement to the FCS was guided by factor analysis and Rasch models. RESULTS: Attending and resident physicians from a university (n = 54) and county hospital (n = 131) completed the initial survey. The 30 items indicated 14 separate underlying constructs. Exploratory factor analysis supported 4 domains that accounted for 39% of the variance in the responses: Physician Attitudes Towards Formulary (General), Trust in Formulary Committee Decisions, Beliefs About Formulary Approval Process and Physician Attitudes Towards Pharmaceutical Industry Influence. Based on Rasch and factor analysis, 12 items were identified for modification in future versions. CONCLUSION: Preliminary evidence supports the conceptual basis for a tool to measure formulary culture. The identification, operationalization and validation of the constructs that comprise the knowledge, attitudes and behaviors of clinical practitioners with respect to drug formularies may provide insight into the perceived role of formularies in promoting good clinical outcomes. Future research involves a larger scale validation study.

FD4

THE EFFECTS OF NICE HTAs ON DRUG PRESCRIBING AND EXPENDITURES IN THE UNITED STATES

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OBJECTIVES: As the US reimbursement landscape becomes increasingly restrictive, we hypothesized that health technology appraisals (HTAs) published by the National Institute for Clinical Excellence (NICE; UK) would influence drug prescribing and expenditures in the US. The primary objective was to determine whether HTAs have impacted trends in prescription volume (TRx), average retail price (ARP) and out-of-pocket costs (OPC) of 11 drugs covered in recent HTAs. METHODS: SIX NICE HTAs published since 2007, evaluating a total of 11 non-injectable drugs, were analyzed, of which three freely advocated use of the drugs studied, two encouraged use for restricted populations and one discouraged utilization. TRx, ARP and OPC were collected monthly for the same duration pre- and post-HTA until November 2008. Parameters were collected using SDI’s VONA and VOPA databases. Statistical analyses were performed using one-way ANOVA; statistically significant results had p <0.05. RESULTS: A NICE appraisal supporting the use of four Alzheimer’s drugs (donepezil, galantamine, rivastigmine, memantine) was associated with significant increases in TRx, ARP and a nearly significant increase in OPC (p < 0.07). There was a significant decrease in OPC of hepatitis B and natalizumab, correlated with an HTA supporting its use in addition to a discouraging guidance of its competitor, bevacizumab. Guidance restricting the population and duration to receive hyperparathyroidism drug, cinacalcet, was associated with significant increases in TRx, ARP and OPC. An HTA cautiously highlighting the success of opioid-abstinence drug, naltrexon, in convalesced patients correlated with significant increases in all three market metrics. CONCLUSIONS: NICE HTAs decisions appear to be associated with mixed effects on prescription utilization and expenditures in the US. The influence of NICE decisions on the US market should be monitored as HTAs are expected to play a more significant role in a more judicious reimbursement environment, in which payers increasingly seek evidence to support formulary decisions.