

challenged by payers and regulatory authorities to develop evidence describing the burden of illness and justifying the payer investment.

HC2

HEALTH CARE EXPENDITURES AND DEPRESSION AMONG ADULTS WITH CANCER

Pan X¹, Sambamoorthi U²

¹West Virginia University, Morgantown, WV, USA, ²West Virginia University School of Pharmacy, Morgantown, WV, USA

OBJECTIVES: Determine the relationship between health care expenditures and depression in individuals with cancer compared to those with cancer and depression, after controlling for demographic, socio-economic, access to care and other health status variables. **METHODS:** Cross-sectional data on 4766 adults from multiple years (2006, 2007, 2008, and 2009) of the nationally representative household survey, Medical Expenditure Panel Survey (MEPS) were used. Cancer and depression was identified from Medical conditions file. Dependent variables consisted of total, inpatient, outpatient, emergency room, prescription drugs and other expenditures. OLS on logged dollars and generalized linear models with log-link were performed. All analyses accounted for the complex survey design of the MEPS. **RESULTS:** Overall, 14% of individuals with cancer reported having depression. Among individuals with cancer and depression the average health care expenditures were \$18,401 compared to \$12,091 among those without depression. After adjusting for demographic, socio-economic, access to care and other health status variables, those with depression had about 32% greater total expenditures compared to those without depression. Expenditures for every type were higher among individuals with depression compared to those without depression. Individuals with cancer and depression were more significantly more likely to use emergency rooms (AOR = 1.46) and prescription drugs (AOR = 3.56) compared to their counterparts without depression. **CONCLUSIONS:** Among adults with cancer, those with depression had higher health care utilization and expenditures compared to those without depression. Policy efforts to reduce excess health care expenditures associated with depression may include screening for depressive symptoms and preventing major depression, timely depression treatment once depression is detected.

HC3

DISCREPANCIES BETWEEN FDA APPROVAL AND CMS COVERAGE FOR DRUGS AND DEVICES

Chambers JD, Neumann P¹

Tufts Medical Center, Boston, MA, USA

OBJECTIVES: Following FDA approval, medical technology must still gain Centers for Medicare and Medicaid Services (CMS) coverage before Medicare reimbursement. However, the two agencies use approval processes based on different evidentiary standards. We identified the type and nature of discrepancies between FDA approval and CMS national coverage determinations (NCDs) for drugs and devices. **METHODS:** We used the Tufts Medical Center NCD database, which contains detailed information on 165 NCDs since 1999. For each device or Part B drug considered in an NCD (1999-2011) (n=69), we searched the FDA website to identify the approved indication. We classified CMS coverage as: more restrictive than FDA approval, i.e., conditions were placed on coverage beyond the FDA-approved label; equivalent to FDA approval; or less restrictive than FDA approval, i.e., CMS covers off-label indications. Further, we categorized conditions placed on CMS coverage as: "patient-related", e.g., restricted to patients with certain comorbidities or characteristics; "place in therapy", e.g., tied to use as second-line therapy; or "technology-related", e.g., restricted to a particular application of the drug or device. **RESULTS:** CMS has covered FDA-approved drugs or devices taken through the Medicare NCD process in 80% of cases (55/69). For CMS covered drugs and devices (n=55), coverage was more restrictive in 32 cases (58%), equivalent to FDA approval/clearance in 16 (29%), and less restrictive in seven (13%). Most common coverage restrictions were patient-related (78%), e.g., laparoscopic gastric banding to treat obesity is covered for patients suffering from an obesity-related comorbidity, and place in therapy (38%), e.g., coverage for extracorporeal immunoadsorption is covered for rheumatoid arthritis patients who have failed three disease-modifying antirheumatic drugs (DMARDs). In roughly one third of cases, CMS placed multiple restrictions on coverage. **CONCLUSIONS:** CMS coverage determinations are generally more restrictive than corresponding FDA approval. CMS often restricts coverage to patients with the most severe disease.

HC4

HOSPITALIZATION COSTS AND OUTCOMES AMONG ELDERLY CANCER PATIENTS IN THE UNITED STATES

Khanhna R¹, Jariwala K², Bentley JP¹, Patel A³

¹University of Mississippi, University, MS, USA, ²University of Mississippi, Oxford, MS, USA,

³Medical Marketing Economics, LLC, Oxford, MS, USA

OBJECTIVES: To assess the patient, hospital, and discharge-level characteristics, and hospitalization rates among elderly patients with cancer in the United States (US). Hospitalization outcomes (length of stay [LOS], total charges, and mortality) among elderly patients with cancer were also studied. **METHODS:** A cross-sectional descriptive analysis of the 2009 Healthcare Cost and Utilization Project (HCUP) database was conducted. Patients were identified based on diagnosis (any-listed) of cancer using Clinical Classification Software (CCS). A control group of patients without cancer were identified by matching on age and gender (1:2 case-control). Analyses were conducted using PROC SURVEY procedures in SAS v9.2. **RESULTS:** In 2009, a total of 3,325,174 (weighted) hospitalizations occurred among elderly patients with cancer in the US. Elderly cancer patients had higher total hospital charges (\$39,406 vs. \$37,756), longer LOS (5.7 days vs. 5.4 days), and higher mortality (4.8% vs. 3.6%) as compared to those

without cancer. A greater proportion of hospitalizations among cancer patients occurred in teaching hospitals (44.1% vs. 38.9%; p<0.001). In terms of location, a greater proportion of hospitalizations for cancer patients occurred in hospitals located in urban areas in comparison to those without cancer (88.1% vs. 84.7%; p<0.001). Total charges for hospitalizations among elderly patients with prostate (average LOS=4.9 days), lung (average LOS=6.1 days), and breast cancer (average LOS=4.9 days) were roughly \$19.2, \$16.1, and \$16.0 billion, respectively. Mortality rates during hospitalization were the highest for those with pancreatic (10%), liver (9.7%), and lung cancer (8.7%). **CONCLUSIONS:** Elderly patients with cancer had significantly greater hospitalization burden as compared to those without cancer. Hospital mortality rates were the highest for elderly patients with pancreatic, liver, and lung cancer, respectively.

PODIUM SESSION I:

HEALTH TECHNOLOGY ASSESSMENT STUDIES

HT1

INTER-COUNTRY VARIABILITY IN COVERAGE DECISIONS FOR ORPHAN DRUGS: CRITERIA DRIVING HTA RECOMMENDATIONS IN SIX COUNTRIES

Nicod E, Kanavos P

London School of Economics and Political Science, London, UK

Inter-country variability in access to orphan drugs across countries has been highlighted in a number of studies. Understanding the reasons driving coverage decisions is a way forward in identifying areas where HTA methods may be improved. **OBJECTIVES:** Objectives are three-fold: a) to establish a methodological framework enabling to systematically compare HTA processes across countries; b) to identify the criteria driving HTA recommendations for a sample of orphan drugs, and; c) to understand the reasons for diverging recommendations and propose ways to minimize these. **METHODS:** All common orphan drug-indication pairs appraised in six countries (England, Scotland, France, Sweden, Canada and Australia) between 2001 and 2012 were selected. Agreement levels in HTA outcomes between countries were measured using Cohen's kappa scores. Thematic analysis, by creating an NVivo-9 coding manual, was conducted to systematically compare each compound. Reasons for diverging HTA outcomes were differentiated based on whether they are a consequence of country-specific considerations or of the HTA process, and ranked by frequency of occurrences. **RESULTS:** Fourteen orphan drug-indication pairs were retrieved. Agreement in HTA outcomes was poor (k = [-0.5; 0.3]). Eight drug-indication pairs appraised by at least four HTA bodies were analyzed, five of which received diverging outcomes. Preliminary results suggest that in four of five cases, reasons for diverging recommendations were a consequence of the HTA process. Examples of non-homogeneous assessments include: lack of appropriate primary endpoint, lack of long-term data, evidence not reflecting clinical practice, orphan status or unmet clinical need. **CONCLUSIONS:** Preliminary results identify the criteria driving the assessments and reasons why they result in diverging HTA outcomes, enabling a better understanding of these processes by elucidating the expectations and value judgments from HTA bodies, particularly on the orphan status, and identifying areas where more consensus on what constitutes appropriate HTA methodologies is needed. Final results will quantify these criteria in a systematic manner.

HT2

AGENCY AGREEMENT IN HEALTH TECHNOLOGY ASSESSMENT REIMBURSEMENT DECISIONS

Jaksa A, Demb J, Ho YS, Daniel K

Context Matters, Inc., New York, NY, USA

OBJECTIVES: HTA agencies often review the same drugs for the same/similar indications. How often do agencies agree on their reimbursement decisions? Previous research has compared reimbursement recommendations (for the same drugs) for a limited number of agencies, but studies have rarely focused on more than 2 agencies. We collect and analyze a large number of health technology assessments from several countries to explore how often the agencies agree on their reimbursement decisions. **METHODS:** The data covered five agencies that make reimbursement decisions: NICE, SMC, PBAC, HAS and CADTH's Common Drug Review. Our analysis only included decisions for drugs that were reviewed by at least two agencies. If a drug was reviewed multiple times by an agency for the same indication (i.e. resubmissions or updates) we used the most recent review for the analysis. A total of 78 drugs were reviewed by at least 2 agencies, producing a total of 195 reviews. **RESULTS:** There was generally a high level of agreement between all pairs of agencies, ranging from 56% (PBAC, CADTH) to 91% (NICE, HAS). It is important to note that within the sample of drugs reviewed, all agencies issued positive recommendations at very high rates - all but CADTH issued positive recommendations for more than 80% of the drugs reviewed. This fact alone would produce high levels of agreement, even if agencies' recommendations were statistically independent. Actual agreement rates observed were close to those implied by independence. **CONCLUSIONS:** Agencies agree on their reimbursement decisions quite often, but at rates close to those implied by their high overall positive recommendation rates alone. Future research will focus on identifying the determinants of agencies' high rates of agreement.

HT3

ISSUES IN THE SELECTION OF COMPARATORS FOR REGULATORY AND HTA SUBMISSIONS

DeLozier AM¹, Murray JF¹, Klopchin MN¹, Johnston JA¹, Grainger D²

¹Eli Lilly and Company, Indianapolis, IN, USA, ²Eli Lilly and Company USA /Australia, West Ryde, Australia