OBJECTIVES: Skeletal-related events (SREs) defined as pathologic fracture, radiation to bone, bone pain, or spinal cord compression, are considered as consequences of bone metastasis. Prior studies have shown that SREs increase the utilization of health care resources, including hospitalizations. We estimated the decrease in hospitalizations when a novel superior therapy is used (denosumab), in substitution of zoledronic acid (zol), to treat patients with bone metastases secondary to breast cancer in Germany. METHODS: An analysis was run for predicting the number of SREs and the reduction in number of hospitalizations attributable to treatment with denosumab. The number of breast cancer patients was collected from a German registry using the International Classification of Disease codes. Epidemiological data were then utilized to derive the number of hospitalizations due to bone metastases. The number of patients treated for SREs prevention was obtained from market research and applied to either treatment. The total number of hospitalizations at- based in the SREs rates seen in a phase 3 clinical trial. German data from a multina- tional retrospective chart review was used to quantify the inpatient hospitalization rates associated with patients with breast cancer treated with current therapy. RESULTS: The results of the benefit assessment, compared with expected base- case scenario, yielded a 1% decrease in hospitalizations and a 3.5% decrease in inpatient days associated with bone metastases estimated to be treated with denosumab or zol in Germany. The resulting 2,100 SREs prevented per year led to a reduction of approximately 700 hospitalizations per year. The total number of hospitalizations avoided by using denosumab instead of zol was approximately 5,000 per year. CONCLUSIONS: The superior efficacy of denosumab compared to zol reduces the disease burden by decreasing the number of SREs and consequently the number of hospitalizations and inpatient days.

PCN175

CALCULATING IMPLEMENTATION OF GENOMIC SEQUENCING IN PEDIATRIC ONCOLOGY: IDENTIFICATION AND VALUATION OF RESOURCES AND COSTS ASSOCIATED WITH NEXT-GENERATION SEQUENCING

OBJECTIVES: Beyond understanding the pure cost of genomic sequencing, the real costs associated with implementing next-generation sequencing (NGS) into clinical practice are often unknown. We aimed to allocate the real costs associated with NGS and serve as a starting point toward identifying and valuating resources associated with NGS and the whole sequencing workflow including costs associated with directed therapy for pediatric patients.

METHODS: A cost model was calculated using 25 pediatric cancer patients who underwent clinical genomic sequencing at Columbia University Medical Center. Our institutional workflow developed by the Precision in Pediatric Sequencing (PiPS) Program in the Division of Pediatric Oncology and the Personalized Genomics Medicine Laboratory in the Department of Pathology guided the identification of resources and costs associated with NGS.

RESULTS: 17 pediatric patients received NGS testing and 11 patients received transcriptional profile testing using illumina HiSeq 2500 technology. 7 patients received targeted cancer panel testing using illumina MiSeq technology. The total cost per case per test ($CWS (tumor)/normal), $4,459; transcriptome (tumor), $1,764; targeted panel (tumor), $383) was calculated from summing the total variable cost (reagent cost, pathologist time) with the fixed cost per case (annual machine cost, annual main- tenance, tech labor cost, informatics cost, space for NGS hardware, server time, NGS analysis lease, and data storage). Clinical utility was demonstrated by iden- tifying a potentially actionable mutation in 24% of participating patients. Since the reimbursement landscape for clinical genomic sequencing is currently unknown, a comprehensive cost calculation reflecting resource utilization across the workflow including costs associated with directed therapy based on molecular profiling results is necessary. These data serve as a starting point toward identifying and valuating resources associated with NGS and serve as a first step toward demystifying reimbursement for clinical genomic sequenc- ing in Pediatric Oncology.

PCN176

AMNOG BENEFIT ASSESSMENT FOR ONCOLOGIC AND ORPHAN DRUGS IN GERMANY – IMPLICATIONS FOR PRICE DISCOUNTS

OBJECTIVES: With the start of AMNOG in 2011, industry is demanded to submit evidence as well as negotiate discounts for new drugs with an addi- tion to the benefit demonstrated in the clinical trial. AMNOG is a legal framework that mandates industry to submit evidence and defend evidence as well as negotiate discounts for new drugs with an addi- tion to the benefit demonstrated in the clinical trial.

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PCN177

TARGETED LITERATURE REVIEW OF MEDICATION EVENT MONITORING SYSTEMS TO EVALUATE ADHERENCE IN OBSERVATIONAL REAL-WORLD STUDIES

OBJECTIVES: To identify and review methods employed to evaluate medication adherence in studies of oral antineoplastic agents, with particular interest in the opportunities and challenges associated with medication event monitoring systems (MEMS) implemented in observational studies. METHODS: A targeted literature review was conducted. The identify studies that have measured adherence with anti- neoplastic agents. Our review included studies that were published between January 1990 and May 2014. Key data abstracted from each study included patient charac- teristics, study design and type, treatment, MEMS methodology and results. Based on preliminary results, a second targeted review was conducted to evaluate the literature on the risk of the Hawthorne effect in observ- ational studies utilizing MEMS in any therapeutic area. RESULTS: We identified 69 studies that utilized MEMS and evaluated the Hawthorne effect (n=3), mixed results were observed. In two studies, patients reported their behavior was affected by their awareness of being evaluated. This was demonstrated by a significant decrease in adherence in one study but not measured in the second. The third study showed no change in adherence scores over time and concluded there was no Hawthorne effect. Potential ways to minimize the Hawthorne effect include: study blinding of patients and, perhaps, results to be published with non-MEMS downloads, and use of a patient-completed ‘debriefing form’ to assess behavior modifications. CONCLUSIONS: MEMS have been utilized in observational studies evaluating oral antineoplastic agents. The Hawthorne effect may be present with MEMS caps, but can be minimized and is not prohibitive to study conduct.

PCN178

A SYSTEMATIC REVIEW OF HEALTH STATE UTILITY VALUES FOR ADVANCED OVARIAN CANCER

OBJECTIVES: Identifying appropriate utility values to inform cost-effectiveness analysis is a common problem. The aim of this study was to review health-state utility values (HSUVs) for patients with advanced ovarian cancer and make recom- mendations about their use in the economic evaluation of a targeted maintenance therapy for platinum-sensitive recurrent (PSR) ovarian cancer.

METHODS: A system- atic search of Embase®, MEDLINE®, and MEDLINE® in Process was conducted in June 2013 for studies reporting direct (standard gamble (SG) or time trade off (TTO)) or indirect (EQ-5D, SF-6D, or HUI-3) utility values for patients with advanced ovarian cancer. HTA agency websites were also searched. Study design, country, HSUV elicitation method, health state (HS) description, and who valued the HS were extracted. Mean (SD) utility scores, or medians (ranges), if means were unavailable, were recorded for each HS. RESULTS: A total of 10 publications were found, rep- resenting five primary sources of utility values. Two were derived from trial-based patient-reported EQ-5D utility scores, five used utility scores from patients with ovarian cancer and utility values from a sample of the general population using a SG; two derived HSUVs from a sample of women without cancer using a TTO. These studies represented utility values for 18 different health states. Wide discrepancies were possible, utility values differed widely: clinical remission 0.83-0.977; progression-free after surgery 0.51-0.625; recurrent disease 0.58-0.715; progressive disease 0.50-0.725. None of the studies reported values for patients receiving maintenance therapy. CONCLUSIONS: There is limited health-state utility data for advanced ovarian cancer and HSUVs in sample- able size, methods of elicitation, populations used to provide utility values, and in health state descriptions. Further research is required to provide robust estimates to populate an economic model for a targeted maintenance therapy for PSR ovarian cancer. Given the limitations of the current evidence base additional methods, such as mapping algorithms should be considered.

PCN179

HEALTH-STATE UTILITY VALUES IN BREAST AND PROSTATE CANCER MEASURED USING THE EQ-5D: A SYSTEMATIC REVIEW OF THE LITERATURE

OBJECTIVES: In cost-effectiveness analyses (CEA), a paucity of health-related qual- ity of life (HRQoL) data often necessitates use of utility values from populations which may be ill-matched with the disease modelled. Use of the most pertinent data increases model precision and the accuracy of CEA. This systematic literature review aimed to identify utility values derived from the EQ-5D in patients with breast cancer and prostate cancer, and to populate an economic model for targeted maintenance therapy using Medline, Embase and Cochrane databases. Eligible studies for inclusion comprised those reporting EQ-5D utility values in patients with BC or PC at any stage, choosing utility values that were not receiving any anti-cancer treatment specific to breast cancer ( BC, 17, PC, 14). Utility values for metastatic BC (6 studies) ranged from 0.55–0.77 and were lower for patients receiving palliative chemotherapy (CT) or terminal care (0.51–0.60), while for stage G-III disease (9 studies), values ranged from 0.74–0.88. In early stage prostate cancer during follow-up, the rapid and sustained recovery was observed following high-dose (HD) CT and was main- tained long-term post-HDCT and following adjuvant CT. Values for metastatic PC (9 studies) ranged from 0.63–0.85 and were lower for patients with bone metastases, worse performance status or undergoing palliative care. For locally PC (2 studies),