

and older). The impact of arthritis on physical unhealthy days was stronger among those aged 45–64. (Odds Ratio (OR) = 2.1 for aged 18–44; OR = 3.1 for aged 45–64; OR = 2.1 for aged 65 and older). Unlike a physical unhealthy day, younger people were more likely to experience a mental unhealthy day in the general adult population (42.0% for 18–44 years old; 33.4% for 45–64 years old; 17.8% for 65 and older). The impact of arthritis on having mental “unhealthy day” was also stronger among those aged 45–64 (OR = 1.8 for aged 18–44; OR = 2.3 for aged 45–64; OR = 1.3 for aged 65 and older). **CONCLUSION:** The data shows that arthritis has a significant impact on the experience of physical or mental unhealthy days. Although arthritis is more prevalent among adults aged 65 and older, its impact on mental “unhealthy days” was stronger among younger adults. These findings should be considered in implementing public health programs.

#### CANCER—Clinical Outcomes Studies

##### PCN1

#### COLONIC STENTING VERSUS SURGERY FOR MALIGNANT LARGE BOWEL OBSTRUCTION: COMPARATIVE ASSESSMENT OF OUTCOMES AND COST

Bapat B<sup>1</sup>, Subramanian S<sup>2</sup>

<sup>1</sup>RTI Interntional, Research Triangle Park, NC, USA, <sup>2</sup>RTI International, Waltham, MA, USA

**OBJECTIVES:** Colorectal cancer is the third most common malignant neoplasm worldwide and the second leading cause of cancer deaths in the United States. Advanced colorectal cancer often presents as large bowel obstruction. With colonic stenting the creation of a stoma can be avoided and procedural mortality can be reduced. The objective of this study is to compare the outcomes and cost of colonic stenting compared to surgery for large bowel obstruction. **METHODS:** We used the 2001 Medicare Standard Analytic Files to identify patients who underwent colon stenting and surgery for large bowel obstruction caused by colorectal cancer using a combination of procedure codes and diagnosis codes. For each patient we analyzed the first stenting procedure (index event) we identified. We summarized patients’ demographic characteristics including age, sex and race. Outcomes and resource utilization measures (inpatient and outpatient costs, ER visits, in-hospital mortality, and length of stay) were computed for the index hospitalization and 90-day follow-up period. **RESULTS:** We identified 212 patients with stent placements and 969 who underwent surgical intervention. The two groups were similar in demographics and risk factors. In-hospital mortality was lower for the stent group compared to the surgery group but this difference was not statistically significant (8.0% versus 11.4%;  $p = 0.156$ ). Emergency room visits during the 90 day follow-up period was significantly higher for the surgery group (11.3% versus 17.0%;  $p = 0.040$ ). Adjusted cost for the 90-day follow-up period was \$6726 ( $p = 0.000$ ) lower for the stent group compared to the surgery group. The 90-day mortality was similar for the two groups **CONCLUSION:** Patients who underwent stent placements appear to have fewer complications during follow-up as they require fewer emergency room visits. Stent placement appears to be less expensive than surgery. Additional analysis with larger sample size and longer follow-up is required to confirm the results from this study.

##### PCN2

#### ASSESSING THE NET HEALTH OUTCOMES OF A 4D ELECTROMAGNETIC TUMOR TRACKING SYSTEM DURING RADIOTHERAPY FOR CLINICALLY LOCALIZED PROSTATE CANCER: A HEALTH TECHNOLOGY ASSESSMENT OF THE CALYPZO® 4D LOCALIZATION SYSTEM WITH BEACON® TRANSPONDERS

Williams E, Najib MM

AEQUITAS, San Diego, CA, USA

**OBJECTIVES:** Without accurate tumor localization, radiotherapeutic efficacy is suboptimal and sources of geometric variations, such as organ motion and patient movement, can result in irradiation of normal tissues. An evidence-based health technology assessment evaluated whether using a real-time 4D electromagnetic tumor tracking system, (Calypso® 4D Localization System with Beacon® Transponders; “Calypso® 4D Localization System;” Calypso Medical, Seattle, Washington), improves the net health outcomes of patients irradiated for clinically localized prostate cancer. **METHODS:** We addressed the following questions: 1) Does the Calypso® 4D Localization System accurately localize prostate tumors? 2) Does real-time 4D electromagnetic tracking reduce radiation-induced toxicity? 3) How do the outcomes of real-time 4D electromagnetic tracking compare to those of alternative technologies? Comparators included electronic portal imaging devices, computed tomography, ultrasound, and stereoscopic X-ray. We searched electronic bibliographic databases and systematically reviewed studies reporting target shifts between treatment and linear accelerator isocenters, percentages of shifts exceeding tolerable limits, radiation-induced toxicities, and quality of life measurements. Unpublished data on the Calypso® 4D Localization System were also reviewed. **RESULTS:** Based on 1027 intra-subjects comparisons, the Calypso® 4D Localization System was statistically significantly ( $P < 0.0001$ ) concordant with standard radiographic localization. One prospective multicenter clinical trial showed that the Calypso® 4D Localization System detected clinically meaningful misalignments in 1174 of 1524 (77%) treatments for 41 patients positioned by conventional lasers and skin tattoos. Complications from Beacon® Transponders placement were comparable to those of transrectal biopsy and prostatic fiducial implantation. Fifteen of 41 (35%) patients experienced minor acute bladder toxicities; none experienced acute rectal complications. **CONCLUSION:** Published evidence suggests that real-time 4D tracking confers greater accuracy than alternative methods, but head-to-head clinical trials are lacking and there are currently no alternative methods for real-time tumor tracking. This technology may also reduce overall treatment-related morbidity; however, we await mature data on late toxicities and tumor control.

##### PCN3

#### CORRELATION BETWEEN TIME TO PROGRESSION AND OVERALL SURVIVAL IN PATIENTS WITH METASTATIC BREAST CANCER

Sherrill B<sup>1</sup>, Hirst C<sup>2</sup>, Wu Y<sup>1</sup>, Amonkar MM<sup>3</sup>, Stein S<sup>3</sup>

<sup>1</sup>RTI Health Solutions, Research Triangle Park, NC, USA, <sup>2</sup>RTI Health Solutions, Manchester, UK, <sup>3</sup>GlaxoSmithKline, Collegeville, PA, USA

**OBJECTIVES:** The relationship between disease progression endpoints and overall survival (OS) has been demonstrated in colorectal, colon and non-small lung cancers (Johnson et al. Lancet 2006; Sargent et al. JCO 2005). Patient access to novel and efficacious therapies for metastatic breast cancer (MBC) could be expedited if disease progression was documented as a valid surrogate outcome for OS in pivotal clinical trials. We assessed the correlation between time to tumor progression