ease progression. Real-world data on actual health care resource consumption and patient clinical characteristics are used. Time horizon of the models should be long enough to capture meaningful differences in outcomes. The differential clinical attributes of the products are identified and direct links are established with the corresponding economic values. The resulting impact on disease progression and consequences for consumption of health care resources are simulated. The primary goal is the cost avoidance against the chosen comparator, with corresponding breakdown by each clinical attribute. RESULTS: CCEV directly translates the differences in clinical outcomes to the differences in economic values. This methodology has been effectively applied in the decision process at different stages of drug development, such as, to prioritize pipeline projects by comparing the potential economic value of assets under development and quantifying the value of each differentiated output. These insights are used to guide and design the following data generation strategies.

CONCLUSIONS: CCEV methodology directly translates the economic values and is a practical FE tool for decision makers. It can be employed across the entire product life-cycle, starting from the early stages of drug development.

PRM45 ARE MINIMAL CLINICALLY IMPORTANT DIFFERENCE MEASURES (MCID) RELEVANT FOR SURVIVAL OUTCOMES? INTRODUCING THE MCID-CAC

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Minimal Clinically Important Difference margins (MCIDs) are being applied by researchers to assess the comparative efficacy of new medications and comparators. This study aims to determine the MCID for survival outcomes, which is problematic and controversial. A superficial consideration of MCIDs for survival outcomes may lead to the conclusion that the MCID for survival is inappropriate and no difference in survival is acceptable. As such, the MCID for survival should be zero. In this case, such an analysis would become a superiority analysis. If this approach to the assessment of such products were to prevail, new products with a high likelihood of affording patients a survival benefit compared to their comparator products may be rejected even on a cost-minimization basis. Instead, where the point estimate of treatment effect favours the new treatment, serious consideration should be given to reimbursing the new product at the same or higher price. Using indirect comparison methods and real world hazard ratio data this research introduces the concept of MCID-CAC, a new approach to MCID-CAC as an aid to making pragmatic reimbursement decisions for new products that may extend patients lives.

DISEASE-SPECIFIC STUDIES

CANCER-Clinical Outcomes Studies

PCN1 BISPHOSPHONATES AND RISK OF OSTONECROSIS OF JAW IN CANCER PATIENTS: A META-ANALYSIS

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OBJECTIVES: This meta-analysis aims to assess the potential risk of osteonecrosis of jaw and bisphosphonate use in cancer patients. METHODS: The published literature was systematically searched and reviewed using MEDLINE (1950 through July 2011), EMBASE (1980 through July 2011), and the Cochrane Central Register of Controlled Trials (The Cochrane Library 2011 issue 1). Studies that included specific risk estimates were pooled using a random-effects model. The bias and quality of these studies were assessed using the Cochrane risk of bias tool. RESULTS: A total of 32 publications met inclusion criteria, but only 9 studies that included 51,580 subjects for analysis. Extended adjuvant hormonal therapy with aromatase inhibitors (AIs) and non-significantly increased in patients who were treated with AIs (HR=1.12 [95% CI=0.65-1.91]). In addition, the prescribing LDDS rate between AIs treatment and treatment with tamoxifen was non-significantly increased [HR=1.41 [95% CI=0.83-2.38]] in the head to head comparison from this study in Taiwan. CONCLUSIONS: There were 378,118 and 76 breast cancer patients treated with AIs, tamoxifen and didn’t receive hormonal therapy, respectively. Compared to the non-hormonal therapy cohort, the rate of prescribing LDDS was lower in patients who treated with tamoxifen after adjusted age and cancer stages (HR=0.68, 95% CI=0.65-0.71), and non-significantly increased in patients who treated with AIs (HR=1.12 [95% CI=0.65-1.91]). In conclusion, the prescribing LDDS rate between AIs treatment and treatment with tamoxifen was non-significantly increased.

PCN3 IMPROVEMENT OF THE 3RD GENERATION COLORECTAL CANCER GENE CHIP

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OBJECTIVES: Colorectal Cancer (CRC) has now become the second leading cause of death in Taiwan, and is one of the cancers with highest incidence in women. Our goal is to integrate comprehensive information to determine the relationship between omics and clinical pathology by a systematic biomedical approach and further improve our third generation gene chips for higher specificity and sensitivity to warrant early detection of colorectal cancer. METHODS: One hundred and five patients colorectal cancer patients who had undergone curative surgical resection of colorectal cancer were studied. The copy number for each SNP probe set taken from a tumor sample was calculated by comparing the probe intensity from a representative somatic tissue, and the genome wide copy number probe. RESULTS: Among 105 patients with a median follow-up period of 5.6 years (range, 4.1-10.8 years), 23 developed early disease recurrence, whereas 82 did not. Most of them were male and less than 60 years (p=0.04). Stage III, deeper invasive tumor (T3 & T4) and positive lymph node metastasis could be found seriously by 70.5%, 92.4%, and 68.6%, respectively. CEA, EV12B, ATP2A2, S100B, KL7, TM4SF3, and OLFM4 had copy number gains and high expression levels (P<0.05) in no recurrence vs. recurrence. CONCLUSIONS: Patients less than 60 years were significantly risky to get early relapse in colorectal cancer. In comparison to traditional colorectal cancer gene chip, we would weight higher on EV12B (HR=4.62, 95% CI 1.74-12.270, p=0.001), ATP2A2 (HR 4.68, 95% CI 1.443-15.232, p=0.006), and S100B (HR 11.521, 95% CI 2.688-49.377, p=0.001).

PCN4 ROLE OF 5-ALPHA-REDUCTASE INHIBITORS, STATINS, ASPRIN, NSAIDS ON THE DEVELOPMENT OF PROSTATE CANCER IN BENIGN PROSTATIC HYPERPLASIA PATIENTS-A POPULATION BASED STUDY

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OBJECTIVES: The 5-alpha-reductase inhibitors (5-ARIs), statins, aspirin and non-steroidal anti-inflammatory drugs (NSAIDs) were previously reported to have protective effects on prostate cancer. The aim of this study was to simultaneously investigate these drug effects on prostate cancer risk among benign prostate hyperplasia (BPH) patients. METHODS: Newly diagnosed patients enrolled from May 15th, 2007, and the GRADE method of the Cochrane Collaboration. RESULTS: A total of 32 publications met inclusion criteria, but only 9 studies that included 51,580 subjects for analysis. Randomized controlled clinical trials, meta-analysis or quality of life articles were found that contained data for risks or prevalence of osteonecrosis. The results of a meta-analysis that pooled data from 10 cohort studies indicated that the over- all multivariable odds ratio and hazard ratio were 1.11 (95% CI: 0.15, 8.47) and 0.35, respectively. The result of our meta-analysis suggests that the risk of osteonecrosis associated with bisphosphonate was statistically significant. The agglutination of the quality assessment of these studies indicated low scores using the GRADE method. CONCLUSIONS: The uses of bisphosphonates is likely to be associated with the increased risk of osteonecrosis of jaw in cancer patients.

PCN2 THE RELATIONSHIP OF FOLLOWING LIPID-LOWERING DRUGS USED WITH ADJUVANT HORMONAL THERAPY IN BREAST CANCER WOMEN

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OBJECTIVES: Extended adjuvant hormonal therapy with aromatase inhibitors (AIs) or tamoxifen can both effectively reduce the recurrence of breast cancer, but the potential of change lipid profile with AIs compared to tamoxifen was observed in some studies. The aim of this study was to evaluate whether the hormone adjuvant therapy will increase the prescribing rate of lipid-lowering drugs (LLDs) in breast cancer women. METHODS: A retrospective cohort study was conducted using the National Health Insurance Research Database between January 1997 and December 2008. The inclusion criteria were adult women who were newly diagnosed with breast cancer and without past history of hyperlipidemia or other cancer diseases between 1998 and 2008. The study endpoint was defined as emerging of the first prescription of LLLDs within the exposure period. Adjusted hazard ratio (HR) for the first LLLDs prescription was analyzed using multivariant Cox proportions hazard regression. RESULTS: There were 378,118 and 76 breast cancer patients treated with AIs, tamoxifen and didn’t receive hormonal therapy, respectively. Compared to the non-hormonal therapy cohort, the rate of prescribing LLLDs was lower in patients who treated with tamoxifen after adjusted age and cancer stages (HR=0.68, 95% CI=0.65-0.71), and non-significantly increased in patients who treated with AIs (HR=1.12 [95% CI=0.65-1.91]). In addition, the prescribing LLLDs rate between AIs treatment and treatment with tamoxifen was non-significantly increased [HR=1.41 [95% CI=0.83-2.38]] in the head to head comparison from this study in Taiwan. CONCLUSIONS: There were 378,118 and 76 breast cancer patients treated with AIs, tamoxifen and didn’t receive hormonal therapy, respectively. Compared to the non-hormonal therapy cohort, the rate of prescribing LLLDs was lower in patients who treated with tamoxifen after adjusted age and cancer stages (HR=0.68, 95% CI=0.65-0.71), and non-significantly increased in patients who treated with AIs (HR=1.12 [95% CI=0.65-1.91]). In addition, the prescribing LLLDs rate between AIs treatment and treatment with tamoxifen was non-significantly increased [HR=1.41 [95% CI=0.83-2.38]] in the head to head comparison from this study in Taiwan. CONCLUSIONS: There were 378,118 and 76 breast cancer patients treated with AIs, tamoxifen and didn’t receive hormonal therapy, respectively. Compared to the non-hormonal therapy cohort, the rate of prescribing LLLDs was lower in patients who treated with tamoxifen after adjusted age and cancer stages (HR=0.68, 95% CI=0.65-0.71), and non-significantly increased in patients who treated with AIs (HR=1.12 [95% CI=0.65-1.91]). In addition, the prescribing LLLDs rate between AIs treatment and treatment with tamoxifen was non-significantly increased.