PMD161
SYSTAMATIC REVIEW ON EFFICACY OF THE F-18 FLUOROMISONIDAZOLE PET OR PET/CT
Yoo K
National Evidence-based Healthcare Collaborating Agency, Seoul, South Korea
OBJECTIVES: The purpose of this study was to evaluate whether the F-18 fluoromisoni-
dazole PET or PET/CT (FMISO) was safe and effective for malignant tumor patients and
to determine a possibility of the introduction in Korea reimbursement regula-
tion. We conducted a systematic literature review to evaluate the safety and effectiveness for FMISO. The 27 articles were selected and two reviewers evaluated independently the quality of these selected articles using the Scottish Intercollegiate Guidelines Network (SIGN) tool. RESULTS: The correlation between tumor hypoxic imaging via FMISO and tumor imaging using existing imaging methods was weak and tumors in 14 articles was almost weak. By evaluating the hypoxic tumor lesions via FMISO, it was able to plan an intense radiotherapy that irradiate high dose in hypoxic tumors and examine the therapeutic response (prognosis) in 5 articles.
CONCLUSIONS: The FMISO supplement the information of the heterogeneous tumor microenvironment as an add-on test and is a safe and effective test to determine the treatment direction through dose planning, prognosis, checking of therapeutic response for malignant cancer patients. Based on this evidence, FMISO will be introduced to the market within reimbursement regulation.

PMD162
THERMOMODULATION TECHNIQUE FOR VASCULAR ACCESS FLOW MEASUREMENT: A SYSTEMATIC REVIEW
Kun J
National evidence-based healthcare collaborating agency, Seoul, South Korea
OBJECTIVES: The purpose of this study was to explore the effectiveness of thermoloi-
dation technique method for vascular access flow measurement for the patients in hemodialysis.
RESULTS: A systematic review was conducted to identify relevant articles published until May 4, 2015. Ovid-MEDLINE, Ovid-EMBASE, The Cochrane Library and the international databases of health technology agen-
cies were searched using the term ‘thermodilution’. The SIGN (Scottish Intercollegiate Guidelines Network) methodology checklists were used for critical appraisal. Two review authors independently applied the extracted data and assessed the study quality. After data extraction, descriptive analysis was carried out. RESULTS: A total of 12 literatures were included in the final assessment by applying our inclusion criteria. As the result of systematic review, the correlation of thermomodulation technique method and saline dilution method obtained excellent correlation. Statistically significant differences were obtained in patients age (<65 years old) and peripheral vascular disease were associated with a significantly lower flow access. Reproducibility of thermomodulation technique method and saline dilution method, expressed as relative differences, was significantly different from saline method. CONCLUSIONS: Based on the current findings, we concluded that thermomodulation technique method is effectiveness technology when used on patients with hemodialysis.

PMD163
AN ANALYSIS OF DRIVERS OF POSITIVE AND NEGATIVE APPRAISALS BY NICE’S MEDICAL TECHNOLOGY EVALUATION PROGRAMME (MTEP)
Blissett S, So C, So C, £
CBPartners, London, UK, #CBPartners, San Francisco, CA, USA, %CBPartners, New York, NY, USA
OBJECTIVES: This study analysed the National Institute of Health and Care Excellence (NICE) Medical Technology Evaluation Programme (MTEP) to identify the drivers of decisions for medical devices. METHODS: All published MTEP appraisals were reviewed to capture data on the quality of submissions and outcomes, using a pre-defined framework. RESULTS: A descriptive analysis of the 24 MTEP decisions were publically available. It was unclear if all submissions included a systematic literature review (SLR) as this was not routinely referenced. The clinical evidence submitted varied from unpublished observational data, to twenty-eight pre-defined data-extraction form. Results were analysed descriptively. RESULTS: Of PMSs included in the SLR submitted for diagnostic devices. Studies were defined by generic names, and IHD events were defined as structured MedDRA (OM) references, thus keeping the registries up to date. The coding (unique device identifier) permitted the comparison of devices and the manage-
MENTHODS: A systematic review of published MDs by hospitals of the NHS. CONCLUSIONS: The system provides solid information about available MDs in the market, their respective manufacturer, distributor and pricing to which they are sold to the NHS. The system is a support for decision makers, payers, and HTA processes. It facilitates the management and traceability of medical devices in hospitals and has impact on reimbursement, access and pricing varies by market.

DISEASE – SPECIFIC STUDIES
CARDIOVASCULAR DISORDERS – Clinical Outcomes Studies

PCV1
THE LINK BETWEEN PROTON PUMP INHIBITORS AND ISCHEMIC HEART DISEASE COULD BE EXPLAINED BY PROTOPATHIC BIAS: A PHARMACOVIGILANCE ANALYSIS
El Lilly and Company, Indianapolis, IN, USA
OBJECTIVES: There have been recent concerns about the association of ulcer-healing medications, including proton pump inhibitors (PPIs) with ischemic heart disease (IHD), including heart attacks. This issue has brought about media attention and could have implications on patient care in real-world settings. This pharmacovigilance analysis aims to detect signals of IHD in patients treated with PPIs. METHODS: Adverse event reports submitted to the FDA Adverse Event Reporting System were used (cumulative to June 2014), and Multi-item Gamma Poisson Shrinker dispro-
PORTIONALITY analysis algorithm was applied to calculate Empirical Bayes Geometric Mean (EBGM) and corresponding 95%CI (EB05-EB95) as association metrics. PPIs were defined by generic names, and IHD events were defined as structured MedDRA queries of Preferred Terms denoting to IHD. Safety signals were defined as drug-
event associations with EB05-2.0. Signal detection of myocardial infarction (MI) was conducted as sensitivity analysis. RESULTS: There were 1,731 cases of IHD reported for PPIs; of those, 74% (n=1,279) were for MI. 52% of IHD reports were females (mean age=63 years); 75% were from the US; 93% were reported by PPIs manufacturers. Within 15 days of IHD occurrence 96% of reported IHD events were serious, corresponding to 13% fatalities; 7% life-threatening events; 50% required hospitalization; 6%; and 2% required medical intervention. Healthcare costs associated to IHD were estimated to 13% and 4% of reported IHD events, respectively. No disproportionality reported of IHD (EBGM=0.74; EB05-EB95=0.72-0.77) nor MI (EBGM=0.69; EASE-EB95=0.66-0.72) was found for PPIs. 57% of IHD cases had previous and concurrent treatment with cardiovascular medications (mean=3 medications). Ulcer-healing medications with PPIs is not associated with IHD, and protopathic bias could have contributed to the observed casual association in published studies, where PPIs could have been prescribed to treat gastric peRodinal symptoms of. Pharmacoeconimologic studies are required to further evaluate the impact of this bias.

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