2005-2011 for new drugs and new indications for existing drugs were identified from the European Medicines Agency (EMA) website. The decision to undertake an appraisal was obtained from the NICE website and NIHR Horizon Scanning Centre records, and the associations between this and characteristics of the drug and intended patient population were then determined. **RESULTS:** For 2005-2011, we identified 134 MAs granted by the EMA (116 new drugs and 18 new indications) of which 72 (54%) were selected for appraisal. The decision to undertake an appraisal was significantly associated with an MA granted 2009-2011 (OR=2.3, p<0.01), the drug being a biological agent (OR=3.9, p<0.01), administered on a long-term basis (OR=1.8, p<0.05), indicated for a patient population <1 in 1,000 (OR=2.1, p<0.05), or for malignant disease (OR=5.1, p<0.01). It was not associated with an indication for more severe disease (OR=2.0, p=0.06), an MA issued for a new indication (OR=1.4, p=0.50), or whether a drug was first-of-kind (OR=1.8, p=0.10). **CONCLUSIONS:** We identified several characteristics associated with the decision to undertake an appraisal relating to both the drug and intended patient population that do not completely match published topic selection criteria (e.g. severity). Further analyses are required to determine which are the most relevant factors in this decision.

PHP201
DETERMINATION OF COST-EFFECTIVENESS THRESHOLD FOR MALAYSIA
Lim YW, Shafie AA, Chua GN, Hassali MAA
Universiti Sains Malaysia, Penang, Malaysia
OBJECTIVES: Decision on the cost-effectiveness (CE) of health care technologies usually creates an argument especially when alternatives are more expensive but more effective. In this situation, external criterion in the form of CE threshold or willingness-to-pay for a quality-adjusted life-year (WTP/QALY) needs to be applied to decide on its CE. Nevertheless, the lack of empirical and well-accepted CE threshold in Malaysia is recognized as one of the most important barriers in using health technology assessment for decision making. This study was mainly done to determine the CE threshold value across Malaysian population, estimated in terms of societal WTP for a QALY. **METHODS:** A cross-sectional, contingent valuation study was conducted using stratified multistage cluster random sampling technique in the states of Penang, Kedah, Selangor and Kuala Lumpur Federal Territory. Respondents were asked for the socioeconomic background, quality of life and their WTP for a hypothetical EQ-5D health state scenario (treatment, extended life in terminal illness and life saving situations with three health severities – mild, moderate and severe, and two QALY gained levels – 0.2 QALY and 0.4 QALY) using pre-designed questionnaires. Interval model analysis was applied to determine the CE threshold. **RESULTS:** One thousand thirteen respondents aged between 20–60 years old who can understand either English or Malay language were interviewed face-to-face. The mean value of CE threshold was determined at the range of MYR 19,929 to MYR 28,469 (~ USD 6,200 to USD 8,900). **CONCLUSIONS:** By comparing our results to Malaysian GDP per capita in the year 2013; ~ MYR 33,754 (~ USD 10,548), we noted that the mean WTP/QALY is ranged between 0.59–0.84 times of GDP per capita.

PHP202
SYSTEMATIC REVIEW OF ECONOMIC EVALUATION OF HEALTH TECHNOLOGIES DEVELOPED IN BRAZIL FROM 1980-2013
Decimoni TC[1], Leandro R[1], Soarez P[1], Craig D[2]
[1]*Sao Paulo University, São Paulo, Brazil,* [2]*University of York, York, Brazil*
OBJECTIVES: The aim of this study is to review published economic evaluation of health technologies conducted in Brazil. **METHODS:** Systematic review of economic evaluations studies published in MEDLINE, EMBASE, LILACS, SciELO, NHS EED, HTA Database, Web of Science, SCOPUS, BVS ECOS and SISREBRATS from 1980 to 2013. Full (Cost consequence analysis - CCA, cost minimization analysis - CMA, cost-effectiveness analysis - CEA, cost-utility analysis - CUA, and cost-benefit analysis - CBA) and partial (cost description - CD and cost analysis - CA) economic evaluation studies were eligible for inclusion if at least one of the authors was Brazilian and was affiliated to a Brazilian institution. Two independent reviewers screened articles for relevance and carried out data extraction. Disagreements were resolved through discussion or through consultation with a third reviewer. We performed a qualitative narrative synthesis. **RESULTS:** We identified 11946 records and 557 met inclusion criteria. One hundred and ninety (34.1%) were full (of these, 56.6% CEA, 20.3% CCA, 12.7% CUA, 5.6% CMA, and 4.7% CBA), and 367 were partial economic evaluation (of these, 64.7% CD and 32.3% CA). The main health problem studied were Infectious and Parasitic diseases (17.1%), Diseases of the Circulatory System (12.3%) and Neoplams (10.3%). The majority (72.9%) was conducted by authors from the southeast region, and south region (12.6%), mainly linked to academia (69.5%), and 54.2% were published in medical and 18.9% in public health journals. Seventy-two (14.7%) studies reported to be funded by industry and 16% was considered to have conflict of interest. **CONCLUSIONS:** There was a considerable growth in the conduct and publication of economic evaluation studies in Brazil. A qualitative evaluation of the methodology used in those studies is important to legitimize their use in the process of local decision-making.

PHP203
A LITERATURE REVIEW OF PATIENT ADVOCACY GROUP (PAG) INVOLVEMENT IN HTA
Hicks N[1], Hawken NA[2], Arvin-berod C[1], Toumi M[3]
[1]*Commutateur, Paris, France,* [2]*Creativ-Ceutical, Luxembourg, Luxembourg,* [3]*University Aix-Marseille, Marseille, France*
OBJECTIVES: Patient input is an important part of the assessment process, yet sometimes seen as having a low evidence base. Previous work by the authors shows more research is needed on identifying how the patient group contribution is impacting decision making. Our objective was to review and critically appraise existing publications on PAG involvement in HTA. **METHODS:** A search in Pubmed, Cochrane and ISPOR databases since 2009 was undertaken to identify studies on patients or PAG involvement in the HTA decision. Studies were evaluated for relevancy. We extracted information on perceptions of patient input, process improvement recommendations, comparison of patient pathways and specific type of patient input desired. Two reviewers extracted methodological details, study designs, and outcomes into summary tables. **RESULTS:** We identified 21 articles out of a total of 18,829 studies. Articles covered multiple subject areas. Process improvements were most common (4 studies) followed by current perceptions (3 studies), comparison of patient pathways (2 studies) and specific type of patient input desired (1 study). Research methodologies and stakeholders varied widely including telephone, web audit, interview /questionnaire and literature review. Stakeholders varied between national & international HTA agencies, experts and patient groups. Three studies involved patient groups and one involved patients. These studies informed the role, process and nature of input but did not address the impact on HTA decision making. **CONCLUSIONS:** Compared to other HTA areas there is a lack of published material on PAG involvement. There have been many attempts to provide a framework for patient involvement but so far none has been used in HTA decision-making. Existing data does not help to quantify role of the patient in HTA decision making. Additional research is needed to understand and quantify patient group input in HTA decisions.

PHP204
TRENDS AND KEY DECISION DRIVERS FOR REJECTING AN ORPHAN DRUG SUBMISSION ACROSS FIVE DIFFERENT HTA AGENCIES
Mardiguian S, Stefanidou M, Sheppard F
PAREXEL, London, UK
OBJECTIVES: Access to orphan drugs is often inconsistent, and is hindered by difficulties in demonstrating value in HTA appraisals due to the small patient populations and insufficient data. To inform future submissions, we examined the trends and key decision drivers that resulted in a submission being rejected across five HTA agencies. **METHODS:** The Orphanet database was searched for orphan drugs with a marketing authorisation between 2002 and 2014. To assume a certain level of competition, awareness and commercial potential, rare diseases for which two or more orphan drugs were available were selected. Decisions from five HTA agencies were considered: AWMSG (Wales), CADTH (Canada), NICE (England), PBAC (Australia), and SMC (Scotland). Assessments that resulted in a rejection were examined for key decision drivers, and for trends and variation by disease type. **RESULTS:** A total of 28 licensed orphan drugs were available for the treatment of eight rare diseases. The number of orphan drugs assessed, and rejection rates, varied by HTA agency; PBAC and SMC had the lowest rejection rates (4/18; 22% and 6/22; 27%, respectively), while NICE had the highest rejection rate with 40% (4/10). Uncertainties regarding clinical efficacy, and concerns over the robustness of economic evidence were the key decision drivers that led to a rejection. Examination of data by disease type indicated a trend towards higher rejection rates for diseases with a higher prevalence rate. **CONCLUSIONS:** The proportion of rejected submissions varied by HTA agency, particularly within the HTA bodies in the UK, highlighting inconsistencies in decision-making. An association between prevalence rate and the proportion of rejected submissions was found, with lower rates of disease prevalence correlating with higher acceptance rates. This is most likely due to the lower budget impact incurred in smaller patient populations.

PHP205
PREDICTORS OF GERMAN AMNOG DECISIONS AND GKV REBATE NEGOTIATIONS: A DATABASE ANALYSIS
Verleger K[1], Schoeman O[1], Schmidt R[1], Wilke T[2], Heeg B[1]
[1]*Pharmerit International, Berlin, Germany,* [2]*IPAM - Institute for Pharmacoeconomics and Medication Logistics, Wismar, Germany*
OBJECTIVES: G-BA, IQWiG and GKV are the main governmental stakeholders in the German AMNOG process. Based on manufacturer-submitted dossiers, the G-BA assesses the drugs' additional benefit per pre-defined subgroup. Subsequently, the GKV negotiates rebates by drug. This research aims to describe factors influencing GB-A decisions and assess the association between additional benefit and rebate. **METHODS:** All G-BA decisions up to March 2014 were analyzed. Univariate logistic regression was used to investigate the relationship of G-BA decisions (dependent variable: additional benefit (y/n) per subgroup) with study characteristics. Study characteristics included were disease area (ATC-code), superiority/non-inferiority study design, comparators used in the submitted trials (in/direct; in/adequate comparator according to GBA ["ZVT"]), main area of claimed benefit e.g. overall survival (OS). Linear regression was used to assess the impact of added benefit (in at least one subgroup) on rebate. **RESULTS:** Sixty-eight G-BA decisions, with in total 137 G-BA subgroups, were included and analyzed. In total, 60.3% of assessments resulted in an additional benefit. Most commonly, dossiers were submitted to the G-BA for ATC-codes L and A (39.7%; 19.1%). Out of 40 ATC-code L subgroups (27 drugs), 70.0% resulted in a positive assessment, with 50% demonstrating a benefit in OS. Univariate logistic regression showed a significant relationship between added benefit and: ATC-codes A/J/L; improvements in morbidity; adverse events; direct comparators; and the ZVT (ORs: 0.1; 11.2; 6.0; 55.2; 24.3; 20.9; 15.2; all p<0.05). All drugs showing an OS advantage received a positive benefit assessment. Added benefit reduced the rebate significantly by 13.1% (p<0.05). **CONCLUSIONS:** Key factors for a positive G-BA benefit assessment are improved OS, morbidity, and adverse events, demonstrated through the use of direct "ZVT" comparators. ATC-codes J and L carry the highest chance of gaining a positive assessment. The rebate negotiated with the GKV decreases significantly if an added benefit is determined.

PHP206
NICE RESTRICTIVENESS COMPARED TO THE MARKET AUTHORIZATION
Jaksa A, Westbrook L, Rubinstein E, Daniel K, Ho YS
Context Matters, Inc., New York, NY, USA
OBJECTIVES: To determine how often NICE recommendations are more restrictive than the market authorizations. **METHODS:** 161 NICE Technology Appraisal decisions from 2007-2013 were evaluated. These reviews included 80 unique drugs from 37 disease conditions. For each generic drug included in a review, the corresponding