PHP150 PRACTICAL PROBLEMS OF COMPARATOR SELECTION TO ASSESS COST-EFFECTIVENESS OF NEW DRUGS FOR REIMBURSEMENT DECISION: A QUALITATIVE STUDY IN SOUTH KOREA
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OBJECTIVES: Under the positive drug listing system, pharmaceutical companies in Korea are required to provide cost-effectiveness (CE) evidence of newly approved drugs for listing on the National Health Insurance (NHI) drug formulary. It has been argued that selection criteria of comparator treatments suggested by the CE guideline are too limited and unrealistic to conduct a valid CE assessment. Therefore, our study was conducted to investigate types of practical problems in comparator selection in order to improve the validity of CE analysis.

METHODS: We conducted focus group interviews (FGI) with experts working in research-based drug companies and HTA agencies in both Germany (IQWiG) and France (TC) to assess the quality of CE guidelines in South Korea as well as other countries, and to improve assessment of the true value of pharmaceutical intervention.

PHP151 BUILDING QUALITY IN HTA PROCESS AND DECISION MAKING: CAN KEY PERFORMANCE MEASURES OF GOOD PRACTICES IN HTA BE IDENTIFIED?
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OBJECTIVES: To establish a working definition of “quality” in the HTA context; to identify key performance measures of high quality HTA procedures and decision making.

The outcome of the research will be used to facilitate the development and adoption of best practices in HTA submissions, assessment processes and decision making. We conducted a systematic review of key performance indicators (KPIs) of HTA review processes and procedures. International experts representing HTA/coverage agencies, academics and pharmaceutical companies were invited to discuss and identify from the key performance indicators (KPIs) of HTA review processes and procedures. The experts were asked to rate the KPIs on a five-point scale and to explain their reasoning. The results of the study will be used to develop an instrument to measure quality of HTA processes based on identified KPIs and to be piloted and validated by key stakeholders.

PHP152 HOW ARE TOPICS SELECTED AND PRIORITIZED BY THE NATIONAL INSTITUTE OF HEALTH AND CARE EXCELLENCE (NICE) AND WHAT MIGHT BE THE OPTIONS IF A TECHNOLOGY IS NOT SELECTED?
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OBJECTIVES: In contrast to the Scottish Medicines Consortium, NICE does not evaluate all new medicines, but uses a set of specific selection criteria. Where a technology is not selected for assessment the affected products may face difficulties in achieving payer and physician uptake. We aim to demonstrate and evaluate the difficulties faced by those seeking market access for products and the consequent inequality of non-selection. Whilst oncology products currently have the Cancer Drugs Fund (CDF) to fall back on, there is an issue of how NICE, CDF and NHS England policies will work together in the future. We further consider the possible options, both for delaying and non-assessment, or failure to obtain reimbursement through other routes.

METHODS: We review the topic selection methodologies and compare the number of marketing authorizations approved in recent years and those subsequently approved by NICE. Examples of orphan drugs that have not been selected are provided. We further review opportunities for redress for the manufacturer where they are not subject to a technology appraisal. We review applications for orphan drugs that have not been selected and are provided. We further review opportunities for redress for the manufacturer where they are not subject to a technology appraisal.

RESULTS: The position of a technology in the approval process may affect the likelihood of being selected for reimbursement by NICE is precarious, forcing them to rely on NHS England policies, local commissioning approvals, individual hospitals within CCGs or, ultimately, legal redress. Currently, there are over 20 NHS England policies to support the commissioning of products in priority areas. NICE also has its own assessment process to determine whether the drug has been assessed for the same indication. The NICE classifies additional benefits as “Major, Considerable, Minor, Non-quantifiable, No Benefit, and Less Benefit”. For the TC, they are categorized as “Major, Important, Significant, Minor, No Improvement, Do Not Recommend”. We also consider the implications associated with the assessment of 67 technologies and the associated KPIs of the applications.

PHP153 ACCESS TO MEDICINE, REIMBURSEMENT AND PRICING IN GERMANY: WHAT ARE THE IMPLICATIONS OF THE NICE HPS DECISION?
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OBJECTIVES: As part of the health care reform in Germany (AMNOG) in 2011, newly approved drugs have to demonstrate their innovation to avoid reference group pricing. The pharmaceutical manufacturer (PM) has to submit a dossier proving additional benefit versus the appropriate comparator recommended by the G-Ba Joint Federal Committee (G-BA). METHODS: Benefit assessments and G-Ba decisions to date were analyzed. Outcome data, indirect comparisons and decisions (until January 2015) were explored with regard to factors potentially impacting the outcome of negotiations. RESULTS: Out of 102 dossier completed the whole assessment process. G-Ba evaluations resulted in 26 minor, 21 considerable, and 55 not quantifiable/no additional therapeutic benefit of assessed vs. comparator drug. In 29 cases the G-Ba did not follow IQWiG’s results: 15 “Minor” ranking awarded by the G-Ba PM was considered “Significant”, 11 “Minor”, 3 “Non-quantifiable” and 1 “No Benefit”.

PHP154 EVALUATING GLOBAL EARLY MARKET ACCESS OPPORTUNITIES FOR INNOVATIVE THERAPIES: FOCUS ON JAPAN, UK AND US
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OBJECTIVES: Early market access schemes are expanding across the globe, presenting health technology suppliers with a variety of opportunities for expediting product approval. This paper aims to provide an overview of three such schemes: The National Healthcare Access Program (NHAP) in Japan, the Conditional Approval Scheme in the UK and the Breakthrough Therapy (BT) designation program in the US.

The position of a technology in the approval process may affect the likelihood of being selected for reimbursement by NICE is precarious, forcing them to rely on NHS England policies, local commissioning approvals, individual hospitals within CCGs or, ultimately, legal redress. Currently, there are over 20 NHS England policies to support the commissioning of products in priority areas. NICE also has its own assessment process to determine whether the drug has been assessed for the same indication.