determination. 22 drugs met NICE’s EOL-SPP for the indication for which they were being appraised and 17 of these drugs had an ASMR rating of 3 or 4. Both these criteria applied to only 3 of the 22 drugs for which they were licensed. The EOL-SPP criterion was applied to the cumulative populations of ten drugs which had marketing authorization for more than one indication. The seven drugs that did not meet the EOL-SPP criterion had all individual indications which were within the number of what is considered acceptable (≤7) and had total cumulative populations that were greater than the STAs in particular stand out. The appraisal committee accepted that panitumumab met the EOL-SPP criterion for its current indication but noted that the EMA recommended a marketing extension which would raise the expected patient population to 10,000, and its final appraisal determination for abiraterone NICE overturned its original decision that the drug did not meet the EOL-SPP criterion, even though it noted that abiraterone may be recommended for a marketing extension for a greater patient population.

CONCLUSIONS: There is no evidence to suggest NICE applied the EOL-SPP criterion to the cumulative populations of currently licensed indications plus potential future indications. PCN150

COMPARISONS OF QALYS GAINED, COST PER QALY GAINED AND ASMRs FOR 38 ANTICANCER DRUGS IN FRANCE AND THE UK: VIVE LA DIFFERENCE?

Drummond M1, de Fornarville G2, Haq1, Jones KC3, Saba G2
1Diemocracy, York, UK, 2Else Business School, GerG Pontone, France, 3OptumInsight, Burlington, ON, Canada, 4OptumInsight, Uxbridge, UK

OBJECTIVES: To compare the contrasting approaches in France and the UK for assessing the value added by new drugs

METHODS: We reviewed the technology appraisals performed by the National Institute for Health and Clinical Excellence (NICE) on 38 anticancer drugs in the UK from September 2003 to January 2012. Estimates of the quality-adjusted life years (QALYs) gained and incremental cost per QALY for each drug were then compared to the assessments of the Amsterdam Management of the Service Medical Rendu (ASMR) made by the Haute Autorite de Sante (HAS) in France for the same drugs in the same clinical indications.

RESULTS: In the UK, the estimates of QALYs gained ranged from 0.018 to 1.85 and estimates of incremental cost per QALY from £1800 to £458,000. The estimate of incremental cost per QALY was a good predictor of the level of restriction imposed on the use of the drug concerned. Patient access schemes, which normally imply price reductions, were proposed in 45% of cases. In France, the distribution of ASMRs was 1, 16%; 2, 8%; 3, 21%; 4, 24%; 5, 24%; and uncategorized/ non-reimbursed, 8%. Since ASMRs of 4 and above signify major or improvement over existing therapy, these ratings imply that, in around half the cases, the drugs concerned would face price controls. Overall, the assessments of value added in the two jurisdictions produced very similar results. A superior ASMR rating was a good predictor of both higher QALYs gained and a lower incremental cost per QALY. CONCLUSIONS: We conclude that despite the contrasting approaches employed in France and the UK for assessing the value added by new drugs, the overall assessments of value added produced very similar results. However, the implications of these assessments for patient access and, sizes of, anticancer drugs in the two jurisdictions require further investigation.

PCN151

HTAS FOR THE DEADLIEST DISEASES: WHAT CAN WE LEARN FROM MULTI- NATIONAL COMPARISONS OF ONCOLOGY AND CARDIOLOGY HEALTH TECHNOLOGY ASSESSMENTS?

Hung MD1, De Becker OC2, Doherty D2, Loughlin C3, Atlas M
1Avalere Health LLC, Washington, DC, USA

OBJECTIVES: To examine the similarities and differences in the HTAs conducted in 6 countries in the last 5 decades in the areas of cardiology and oncology, the thera- peutic area with the highest number of innovations. METHODS: We reviewed and abstracted information from 768 cardiology and 960 oncology HTAs conducted from January 1, 2007 to June 23, 2012. Our primary focus was those made by the following public organiza- tions: Canadian Agency for Drugs and Technology in Health, Haute Autorite de Sante, Institute for Quality and Efficiency in Health Care, National Institute for Clinical Excellence, Pharmaceutical Benefits Advisory Committee, Medical Services Advisory Committee, and the Agency for Healthcare Research and Quality. For comparative purposes and overall interest, we also studied the HTAs of the follow- ing private American organizations: BlueCross BlueShield Technology Evaluation Center, California Technology Assessment Forum, Drug Effectiveness Review Pro- gram, Healthcare/Welppoint, Institute for Clinical and Economic Review, and the MedCo Research Institute, and the multinational Cochrane Collaboration. Finally, we included the American Recovery and Reinvestment Act generated CER grants recently made by the federal government to the National Institutes of Health and the Department of Health and Human Services to determine any new directions in the US. Cardiology HTAs were divided into 12 sub-therapeutic categories and oncology HTAs into 51 sub-therapeutic categories. RESULTS: Market entry of drugs and selected devices tended to affect HTA content and timing. Country processes for review also affect these variables and HTAs. HTAs of other single interventions and comparators in different settings or for different indications were more variable as to timing, content, and results. CONCLUSIONS: Both the commonalities and differences found in the HTAs lend themselves to the examination of potential ‘economies’ of evidence assess- ment and bases for optimal patient care. The authors provide suggestions for policy makers.

PCN152

PATIENT-RELEVANT ENDPOINTS (PRE) IN ONCOLOGY - CURRENT ISSUES IN THE CONTEXT OF EARLY BENEFIT ASSESSMENT (EBA) IN GERMANY: AN INDUSTRY PERSPECTIVE


German Association of Research-based Pharmaceutical Companies (vfa), Berlin, Germany, 2GlaxoSmithKline GmbH & Co. KG, Munich, Germany, 3Boehringer Ingelheim Pharma GmbH & Co. KGaA, Ingelheim, Germany, 4Pfizer Pharma, Germany, 5Bristol-Myers Squibb, Dohme GmbH, Haar (Munich), Germany, 6illy Deutschland GmbH, Bad Homburg, Germany, 7Medizinische Hochschule Hannover, Hannover, Germany, 8Janssen-Cilag GmbH, Neuss, Germany

OBJECTIVES: The German AMNOG health care reform includes a mandatory EBA of innovative medicines at launch. As per German social code, EBA is based on registra- tion trials and must include evaluation of the patient-relevant, therapeutic ef- fect of the new medicines compared to an appropriate comparator as defined by the Federal Joint Committee (G-BA). Current EBA decisions released have unveiled issues regarding the acceptance of some PRE as G-BA are IQWIG are grading the endpoints, focusing on overall survival (OS) as the preferred endpoint in oncology.

METHODS: We took a force unifying all HTAs of the German-based Pharmaceutical Companies (vfa) was appointed. Members were experienced German outcomes research, medical, HTA and biostatistics researchers in industry. After agreement on core assumptions developed and outlined by the Task Force, a draft position was prepared. Input on iterative versions was solicited from a panel of reviewers from industry and external stakeholders. RESULTS: Potential fea- tures of registration trials in oncology need to be considered when these studies form basis for EBA, especially in cancer indications with long post-progres- sion survival time, and with several consecutive therapeutic options available follow- ing progression. Besides, ethical committees, caregivers and patients often de- mand cross-over designs diluting over the treatment effect on OS. Also, regulatory authorities require evaluation of morbidity-related study endpoints including sur- vival of patients without their disease getting worse (i.e., progression-free survival). Year-end decision on oncological continued treatments usually requires treatment changes, another strong indicator for its relevance to patients. CONCLUSIONS: PRE in oncology depend on tumor- and tumor-stage- specific factors. For decades, endpoints have been thoroughly evaluated, resulting in specific guidelines and clinical programs that work well with regulatory guidance. This extensive knowledge and experience should be fully acknowledged during EBA when assessing the patient-relevant benefit of innova- tive medicines in oncology.

PCN153

APPLICATION OF REAL WORLD DATA TO INFORM A BREAST CANCER DECISION ANALYTIC MODEL IN AUSTRIA AND THE U.S - PRELIMINARY OUTCOMES OF DATA COLLECTION

Jahn B, Stenehjem D, Saverno KR, Rochau U, Cai B, Siebert U, Bri xen Dr

1UMIT - University for Health Sciences, Medical Informatics and Technology, OncoTyr - Center for Personalized Cancer Medicine, Hall i.T., 2Innsbruck, Tyrol, Austria, 3University of Utah, Salt Lake City, UT, USA, 4UMIT - Univ. for Health Sciences, Medical Informatics and Technology, Hall i.T., Austria

OBJECTIVE: To examine the similarities and differences found in the HTAs conducted in 6 countries in the last 5 decades in the areas of cardiology and oncology, the thera- peutic area with the highest number of innovations. METHODS: We reviewed and abstracted information from 768 cardiology and 960 oncology HTAs conducted from January 1, 2007 to June 23, 2012. Our primary focus was those made by the following public organiza- tions: Canadian Agency for Drugs and Technology in Health, Haute Autorite de Sante, Institute for Quality and Efficiency in Health Care, National Institute for Clinical Excellence, Pharmaceutical Benefits Advisory Committee, Medical Services Advisory Committee, and the Agency for Healthcare Research and Quality. For comparative purposes and overall interest, we also studied the HTAs of the follow- ing private American organizations: BlueCross BlueShield Technology Evaluation Center, California Technology Assessment Forum, Drug Effectiveness Review Pro- gram, Healthcare/Welppoint, Institute for Clinical and Economic Review, and the MedCo Research Institute, and the multinational Cochrane Collaboration. Finally, we included the American Recovery and Reinvestment Act generated CER grants recently made by the federal government to the National Institutes of Health and the Department of Health and Human Services to determine any new directions in the US. Cardiology HTAs were divided into 12 sub-therapeutic categories and oncology HTAs into 51 sub-therapeutic categories. RESULTS: Market entry of drugs and selected devices tended to affect HTA content and timing. Country processes for review also affect these variables and HTAs. HTAs of other single interventions and comparators in different settings or for different indications were more variable as to timing, content, and results. CONCLUSIONS: Both the commonalities and differences found in the HTAs lend themselves to the examination of potential ‘economies’ of evidence assess- ment and bases for optimal patient care. The authors provide suggestions for policy makers.

PCN154

ARE POPULATION-BASED REGISTRIES A SUITABLE TOOL FOR OUTCOMES RESEARCH IN CANCER? EXPERIENCES FROM FOUR REGISTRIES

de Groot S, Blommestein H, Franken M, Uyl-de Groot C, Ruof J7, Ruppert T1, Wirth D8

1German Association of Research-based Pharmaceutical Companies (vfa) was appointed. Members were experienced German outcomes research, medical, HTA and biostatistics researchers in industry. After agreement on core assumptions developed and outlined by the Task Force, a draft position was prepared. Input on iterative versions was solicited from a panel of reviewers from industry and external stakeholders. RESULTS: Potential fea-