evaluating, deciding and procuring new technologies. A mini-HTA sheet was tested during the interview and questions asked about the relevance and clarity of the questions. **RESULTS:** The current processes of the uptake of technologies is relatively similar in all studied hospitals. There are no standard, transparent evidence requirements, nor systems to assess and document the rationales for uptake. The clinicians report their needs in free format; the HTA-tools are not know nor used. After reducing the number of questions in the mini-HTA-sheet and making some changes to its content, order and terminology, the willingness to use increased. Information needed for budget impact analysis was considered of particular interest. Procurement officials were strong proponents of systematic and transparent assessment. **CONCLUSIONS:** HTA tools need to be tailored to the hospitals. Instead of top-down requests for HTA, a low threshold tool is needed to document and justify the need of a new technology. This would pave the way for managers with financial responsibility to request more thorough assessments. This is the point where the new AdHopHTA tools could come in place.

PHP44

REIMBURSEMENT OF TELEMEDICINE IN GERMANY: QUO VADIS - ANYTHING BEYOND SELECTIVE CONTRACTS?

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OBJECTIVES: Telemedicine has been an innovation driver within e-health initiatives in health care in recent years. However, the uptake of such initiatives in Germany is low. Key question on that is if non-adequate reimbursement/funding might be the key reason for the slow introduction of e-health. **METHODS:** We have reviewed German e-health initiatives and assessed the requirements for available reimbursement pathways specifically for telemedicine initiatives in Germany and grouped them according to the application setting. **RESULTS:** Overall there are currently 289 e-health initiatives implemented in Germany in only few centers (mainly Berlin, Bad Oeynhausen, Munich, Hamburg). Telemedicine is being handled as medical devices in Germany within the market access pathway. The exact process depends if the device is an inpatient or outpatient product. In the inpatient setting relevant DRG and OPS codes are applicable; theoretically NUB and additional fee (Zusatzentgelt) could also be applied for. In the outpatient setting, the reimbursement of e-health devices is driven through the respective catalogue of aids and appliances whereas the actual physician service would need to be reimbursed through the EBM (Einheitlicher Bewertungsmassstab). Currently there is no specific EBM code available, and health politicians have missed a deadline in 2014 to create one. Besides the self-payment option as individual physicians services (IGeL) there is the opportunity through selective contracts, particularly Disease Management Programs (DMPs) or integrated care contracts. Most telemedicine projects are currently being covered and tested in the latter ones (e.g. telemonitoring CHF, video Parkinson therapy). An alternative new route could also be the experimental coverage by the joint federal committee. **CONCLUSIONS:** Currently the most relevant market access pathway for telemedicine initiatives in Germany is through selective contracts. Once health politicians put e-health as a priority the introduction of specific DRG and EBM codes could initiate fast adaption and more telemedine introductions in Germany.

PHP45

THE BRITISH ISLES HTA LEAGUE TABLE 2014

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OBJECTIVES: The British Isles comprise 4 countries, each with their own distinct Health Technology Assessment (HTA) body: National Institute of Health and Care Excellence (NICE) in England, National Centre for Pharmacoeconomics (NCPE) in Ireland, Scottish Medicines Consortium (SMC) in Scotland and All Wales Medicines Strategy Group (AWMSG) in Wales. Although all four bodies are obligate cost-utility HTA agencies, they do utilise distinct assessment processes. This research aims to compare the number and type of appraisals and recommendation rates between these bodies during 2014. **METHODS:** All publically available NICE Single Technology Appraisal, SMC, NCPE and AWMSG HTA reports were identified in 2014 and the drug, indication and outcome extracted. **RESULTS:** NCPE conducted the greatest number of appraisals (60) followed by the SMC (52), NICE (29) and the AWMSG (25). However, it should be noted that 68% of NCPE appraisals were through its rapid review pathway (not needing a full pharmaco-economic assessment). The highest rate of positive full recommendations was made by NICE (86%), followed by AWMSG (84%), SMC (79%), and the NCPE (39%). However, there was variation in what proportions of these recommendations were for a restricted sub-population: SMC (47%), AWMSG (29%), NICE (15%) and NCPE (5%). The proportion of oncology drugs appraised was highest by NICE (37%) followed by NCPE (37%), SMC (21%) and AWMSG (4%). **CONCLUSIONS:** The NCPE reviewed the greatest number of medicines but also had by far the highest rejection rates. Although NICE, AWMSG, and SMC had similar acceptance rates, the SMC displayed a greater propensity to restrict indications, and AWMSG (and to a lesser extent the SMC) reviewed a low number of oncology drugs, typically high cost agents that have greater difficulties in attaining positive reimbursement decisions. Thus it appears that in 2014 NICE appeared to be the most generous HTA body in awarding positive recommendations!

PHP46

AN EVALUATION OF A NEW REGIONAL DECISION MAKING PROCESS IN SWEDEN FOR HIGH-COST HOSPITAL THERAPIES

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OBJECTIVES: The decision to fund an in-patient drug is currently made on a regional level by formulary committees in each of the 21 Swedish county councils. A pilot project for a centralised route of assessment for expensive, new in-patient treatments was replaced by a permanent body, Nya Terapier Rådet (NT-rådet), for centralised evaluation in January 2015. The objective of this research is to understand this new process and identify any implications for manufacturers. **METHODS:** Relevant county council and agency websites were used to gather insight into the new NT-rådet evaluation process. A non-systematic literature review was conducted to identify information illustrating potential implications of this new process. **RESULTS:** NT-rådet selects in-patient drugs for centralised evaluation and specifies the degree to which treatment introduction will be centralised. For high priority treatments, Tandvårds- och Läkemedelförmånsverket (TLV), will perform a health economic evaluation, upon which NT-rådet will base their recommendation, which will be accompanied by a monitoring protocol to ensure the organised introduction of treatments to all county councils. For low priority treatments, only a health economic evaluation and recommendation will be issued. Any other treatments will go through decentralised reimbursement processes. NT-rådet plan to publish recommendations on approximately 25 products or important indications per year. To date, NT-rådet has issued eight recommendations, including one joint recommendation for the use of six Hepatitis C therapies. This particular recommendation followed a first of its kind risk-sharing agreement between all 21 county councils and industry, which was a key product of this new process. **CONCLUSIONS:** The new assessment process has centralised the evaluation of some in-patient drugs, but not all. Most new treatments will still undergo the decentralised process. Due to its infancy, the impact of the NT-rådet process on the uptake of new expensive drugs remains to be confirmed.

PHP47

A COMPARISON OF TIME TO LAUNCH AND REIMBURSEMENT FOR NEW MEDICINES ACROSS DEVELOPED COUNTRIES

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OBJECTIVES: To understand the differences in time to launch between countries and the differences in time to reimbursement from launch **METHODS:** We compared time to launch as well as the time to reimbursement from launch of new molecular entities granted marketing authorization between 2009 and 2013 across 18 developed countries. In addition, we conducted a sub-analysis comparing these measures for oncology and first-in-class medicines. A comprehensive analysis of the regulatory and market access landscapes was also assessed in order to understand the reasons behind any differences. **RESULTS:** A large variation in time to launch of all new molecular entities (90 to 430 days) and time to reimbursement from launch was observed across studied countries (90 to 540 days). However, countries could be classified into three distinct groups: Countries with faster time to launch as well as faster time to reimbursement from launch - tended to have regulations mandating quick access, especially immediate coverage through public reimbursement after regulatory approval (e.g. Germany, Japan). Countries with faster time to launch, but slower time to reimbursement - had large private insurance markets but delayed public reimbursement negotiations (e.g. Canada). Countries with slower time to launch but fast reimbursement after launch - had almost exclusively public reimbursement but lengthy public reimbursement negotiations (e.g. France and Italy). Among the slower to launch countries, both first-in-class and oncology products achieved faster times to launch than the average across all new medicines. There was no difference observed in the fast launch countries. **CONCLUSIONS:** Time to launch and time to reimbursement from launch in a country is highly dependent on local market structure and market access regulations.

PHP48

FDA BREAKTHROUGH STATUS VERSUS ACCELERATED APPROVAL – WHAT'S THE DIFFERENCE?

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OBJECTIVES: Since 2013, Food and Drugs Administration (FDA) Breakthrough Therapy status has enabled expedited development and review of therapies where preliminary evidence suggests substantial clinical improvements for serious/life-threatening conditions. However, there was a pre-existing FDA expedited pathway: Accelerated Approval enabling market entry of drugs for serious conditions based on a surrogate endpoint likely to predict clinical benefit with confirmatory trials completed post-approval. This abstract aims to compare access of therapies under both pathways to determine in which distinct circumstances they are being used **METHODS:** All FDA approvals from January 2013-March 2015 were screened for any approvals under Breakthrough Status and/or Accelerated Approval and the disease areas and supportive data packages were extracted. **RESULTS:** Since November 2013, when the first therapy was approved under Breakthrough status, 13 drugs have been FDA-approved under Accelerated Approval and 21 under Breakthrough Status including 8 supported by both expedited programs. For the 14 approvals under Breakthrough Status alone, 11 (79%) were supported by Phase 3 data with the remaining 3 (21%) supported by Phase 2. Of the 6 drugs under Accelerated Approval alone, 2 (33%) were approved on Phase 3 data with the remaining 4 (66%) supported by Phase 2. Of the 7 approved under both programs, only 1 (14%) was supported by Phase 3 data, 4 (57%) by Phase 2 data and 2 (29%) by only Phase 1 data. 86% (12/14) Breakthrough Status alone approvals were for non-oncology drugs versus just 16% (1/6) for Accelerated Approval alone and 0% (0/7) for under both programs. **CONCLUSIONS:** Whereas Accelerated Approval is typically used for oncology drugs, Breakthrough Status has been frequently applied to non-oncology medicines. Accelerated Approval also frequently enables expedited access without available supporting Phase 3 data, unlike Breakthrough Status. Products with supported by both programs have gained access supported by only Phase 1 data.

PHP49

ANALYSIS OF THE REPORTS OF THE NATIONAL COMMITTEE FOR TECHNOLOGY INCORPORATION (CONITEC) IN THE BRAZILIAN PUBLIC HEALTH SYSTEM (SUS), 2012-2015

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