impact of the HTA system will be revealed by the number of drugs recommended that are subsequently placed on the reimbursement list, and with what restrictions.

PHP246

DIRECT EVIDENCE VERSUS LACK OF DIRECT EVIDENCE AND THE IMPACT ON HTA ACCEPTANCE

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OBJECTIVES: Health technology assessment (HTA) agencies generally prefer the submission of direct evidence when appraising new interventions; however, an absence of head-to-head trial data is relatively common and indirect comparison is often required to determine relative effectiveness. To inform future submissions, acceptance rates across six HTA agencies were compared between submissions presenting direct evidence (active-comparator studies) and submissions lacking direct evidence. **METHODS:** All single HTA appraisals from 2014 for NICE (England), SMC (Scotland), CADTH (Canada), PBAC (Australia), IQWIG (Germany), and HAS (France) were included in the analysis, including resubmissions. Multiple technology appraisals, vaccination programmes, requests for advice, and submissions where the clinical evidence base was not described were excluded. The recommendation, reasoning behind the recommendation, and type of evidence presented were extracted. Fisher's exact test was used to test for statistical significance. **RESULTS:** In 2014, NICE accepted 92% (11/12) of all submissions presenting direct evidence versus 88% (7/8) of submissions lacking direct evidence, SMC accepted 79% (26/33) versus 87% (13/15), CADTH accepted 90% (9/10) versus 53% (10/19), PBAC accepted 50% (26/52) versus 82% (14/17), IQWIG accepted 48% (13/27) versus 13% (2/15), and HAS accepted 97% (42/43) versus 92% (35/38). A lack of direct evidence tended to be acceptable in cases where hard endpoints could be compared, and in disease areas with small patient numbers or a lack of therapeutic alternatives. Adjusted indirect comparisons were generally favoured over unadjusted comparisons, where presented. **CONCLUSIONS:** With the exception of IQWiG (p=0.025), acceptance rates for submissions reporting direct evidence were not significantly different to rates for submissions lacking direct evidence for each agency, although acceptance rates varied across HTA agencies. Single-arm or placebo-controlled trials continue to be viewed as acceptable clinical evidence by most HTA agencies when such study designs are justifiable, and when relative efficacy can be demonstrated through robust indirect comparison.

PHP247

HEALTH TECHNOLOGY ASSESSMENT ARCHETYPE: IMPLICATION ON LAUNCH PLANNING AND EVIDENCE SYNTHESIS

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OBJECTIVES: We aimed to quantitatively segment the health technology assessment (HTA) agencies into functional archetypes to sort countries with similar functional objectives and process into one group. **METHODS:** Through literature search, we developed a Likert scale comprising 77 question from 18 best practice principles, and 6 functional domains. Each question is marked on a scale of 0-5, with higher score (4 or 5) indicating best practice/ease of accession and low score (0 or 1) indicating lack of guidance/difficulty in accession. Our scale includes the key attributes of HTA process, i.e. general submission process, pharmacoeconomics, pricing, and evidence requirements under six functional domains: transparency, process, technical, equity, speed and implementation. **RESULTS:** We evaluated HTA guidelines and process of 66 HTA agencies worldwide, followed by scoring and weighted analysis. Using univariate analysis on total weighted score, we segregated the dataset into five percentiles, with definition reflecting functional objectives: 0-25% (Price Managers), 26-50% (Formulary Managers), 51-75% (Cost Advisors), 76-90% (Value Appraisers), and 91-100% (Value Implementers). Characteristically, Price Managers (eg. Singapore, India, Hong Kong) are free pricing markets, where setting drug price is the only hurdle in market access. Formulary Managers (eg. US, China) control drug price based on budget and regulatory approval. Cost Advisors (eg. Brazil, Mexico) are emerging HTA agencies that use HTA to advice cost. Value Appraisers (eg. South Korea, New Zealand) perform HTA on regular basis, but regional requirements overcome implementation of findings to drug price and reimbursement. Value implementers (eg. England, Canada, Germany) are the most mature markets, with pay for performance measures being the primary functional objective. **CONCLUSIONS:** Our analysis provides a new approach to quantitatively benchmark and group HTA agencies into archetypes based on functional objectives and local priorities. Analysis at domain and principle level helps mapping the similarity of requirements by each archetype, enabling evidence-based launch planning.

PHP248

EVALUATING THE SAFETY IMPACT OF LIGHT EMITTING DIODE (LED) GUIDED DRUG PICKING IN AN OUTPATIENT PHARMACY

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OBJECTIVES: Medication errors may occur during the drug picking process whereby the wrong drug, strength or quantity is picked. In May 2012, LED were installed and tagged to drug bins at the outpatient pharmacy in Singapore General Hospital with the intent to prevent these costly errors. Upon scanning a Quick Response (QR) code on the drug label, the LED corresponding to the drug bin will light up, signaling the picker to the correct drug bin. This study seeks to evaluate the safety impact of LED-guided drug picking and pharmacy staff's acceptance of this system. **METHODS:** The primary outcome of this study is the safety of the drug picking process measured in terms of the frequency of picking near misses. Near miss data before (January to April 2012) and after (May to August 2012) implementation of LED-guided drug picking were extracted electronically for statistical comparison. A survey was administered on pharmacy staff (n = 50) to find out their acceptance on drug picking with and without LED-guidance. Data from the survey were collated and analyzed descriptively. **RESULTS:** The implementation of LED-guided drug picking significantly reduced near misses for wrong drug [7.18 ± 3.17 vs 2.71 ± 1.36, p<0.001] and wrong strength [3.47 ± 2.48 vs 1.82 ± 1.13, p=0.02]. There was no significant difference in the frequency of picking near misses for wrong quantity [17.8 ± 9.88 vs 14.0 ± 4.64, p=0.162]. Overall, there was a significant reduction in the frequency of total picking near misses [28.4 ± 13.2 vs 18.1 ± 5.44, p=0.007]. Pharmacy staff's acceptance towards LED-guided picking was generally positive with majority preferring the LED over no LED-guided drug picking. **CONCLUSIONS:** Incorporation of LED into drug picking significantly decreased near misses of wrong drug and strength that potentially prevented costly medication errors. Pharmacy staff were generally receptive to LED-guided picking.

PHP249

EVIDENCE REVIEW GROUP (ERG) CRITIQUE OF SYSTEMATIC REVIEWS (SR) SUBMITTED TO NICE AS PART OF SINGLE TECHNOLOGY APPRAISALS (STA) OR MULTIPLE TECHNOLOGY APPRAISALS (MTA) IN THE LAST THREE YEARS

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OBJECTIVES: The aim of this review was to assess the critiques highlighted by the ERG for SR submitted to NICE by manufacturers as part of STA or MTA. **METHODS:** ERG reports available on the NICE website were systematically searched for the last three years (2013-2015). The ERG comments in the documents were carefully assessed along with the submission documents. Emphasis was placed on ERG comments regarding search strategy design, electronic databases used for article retrieval, inclusion/exclusion criteria in SR, and reporting of SR methodology. **RESULTS:** Fourteen ERG comment documents were identified by the search conducted in May 2015. Ten documents were identified in 2013, three in 2014, and one in 2015. Comments on search strategies, such as incorrect search terms, missing terms, and wrong explosion, were made on seven submissions. Major findings such as chances of omission of key studies, missing intervention synonyms, and improper presentation of search strategies were cited in two submissions. Two submissions did not search the minimum number of electronic databases indicated by NICE. ERG comments around SR inclusion/exclusion criteria were ambiguity in the study selection criteria, omission of the intervention of interest, selection of inappropriate follow-up duration, introduction of additional exclusion criteria at a later stage, exclusion of studies based on sample size, a clinically irrelevant primary outcome, exclusion of non-English studies even in cases of data gaps, and exclusion of some geographical subgroups without rationale. The write-up of SR was inadequate in two submissions because of ambiguity around the number of reviewers at each stage, unclarity around second check of extracted data, poor reporting of methodology, and an incorrect study selection flowchart. **CONCLUSIONS:** The ERG findings demonstrate a gap in manufacturer's search strategy design, rationale for inclusion/exclusion criteria, and writing-up of the SR methodology which has led to additional work while providing clarifications to NICE.

PHP250

EVOLUTION & INFLUENCE OF HTA IN EMERGING MARKETS

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OBJECTIVES: The objective of this study was to analyze the influence and development of 13 HTA bodies in select Emerging Markets. **METHODS:** This study examined 13 HTA bodies in Latin America (Argentina, Brazil, Colombia, and Mexico), Asia (Korea, Taiwan, China, Singapore, Malaysia, and Thailand), Africa (South Africa), Middle East (Saudi Arabia), as well as Central and Eastern Europe (Turkey). The countries were selected based on the diversity associated with the HTA evaluation process, and were assessed for their review timeline, influence on the pricing and reimbursement process, and anticipated future developments as indicated from their websites and other publications. **RESULTS:** Among the 13 selected HTA bodies, five countries (KOR, TWN, BRA, TUR, and ARG) have a defined review timeline; assessment outcomes will generally become available within a 1-year of submission. However, a standard timeline has yet to be defined for the rest of the countries. Four countries (KOR, TWN, BRA, and MEX) have formal HTA bodies, and assessments are mandatory in the pricing and reimbursement process. In other six countries (SGP, ARG, COL, THA, SAU, and TUR), HTA assessments may be considered in the pricing and reimbursement evaluation. For CHN / MYS / ZAF, although an HTA body is under development, it does not currently have any impact on the reimbursement decision-making. For future HTA developments, the focus remains on scope expansion, capability building, and international collaboration. **CONCLUSIONS:** Emerging markets have developed or are in the process of developing HTAs for the evaluation of formulary inclusion and as a method of cost containment. The HTA bodies in the selected emerging markets have varying impact over the pricing and reimbursement process. The ones with greater influence tend to have a defined review timeline and an HTA body that is a formal authority with a mandatory and / or influential assessment.

PHP251

ASSESSMENT OF CONSUMER LIKELIHOOD TO ADOPT AN ELECTRONIC HEALTH RECORD (EHR) MOBILE APPLICATION AND THE IMPACT OF PERCEIVED RISK OF PRIVACY LEAKS

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OBJECTIVES: This study was designed to understand consumer likelihood to adopt a mobile application designed to allow individuals to view their personal health record on a mobile device as a function of risk tolerance of private medical data leaks, including variability by various demographics. **METHODS:** A representative (U.S.) sample of 1,000 adults completed an online survey about their interest in an EHR mobile application. Interest in the application was elucidating using a 7-point Likert scale and a standard gamble (SG) exercise. The multivariate relationship between overall likelihood of mobile application use and SG utilities, education level, age, income level, and satisfaction with personal physician was assessed. **RESULTS:**

Prior to any indication of a potential privacy risk, 31% of consumers indicate they would be very likely to download an EHR mobile application (rated 6 or 7 on 7-point Likert scale; 4.0 mean). This likelihood decreased with age. After introducing variable levels of privacy risk, and within the multivariate framework, age and educational level revealed inverse statistical associations with risk tolerance (greater age and educational achievement were less likely to download the hypothetical app). In contrast, higher income levels and higher levels of patient satisfaction with their physicians were associated with greater likelihood to download. These results were statistically significant at $\alpha = 0.05$. **CONCLUSIONS:** One in three consumers reports they would be very likely to download an EHR mobile application. Younger demographics are more likely to download the app and are more accepting of risk of those data being leaked to a 3rd party. While the likelihood to download the app increases with income level, higher levels of education may actually reduce the likelihood of downloading. Physician satisfaction is also a driver of increased likelihood to download the application.

PHP252

PREVALENCE AND INCIDENCE ESTIMATIONS IN GERMAN AMNOG APPLICATIONS – THE ROLE OF REAL-WORLD EVIDENCE (RWE)

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OBJECTIVES: 90% of the German population is insured in the statutory health insurance which covers nearly all healthcare services with only little co-payments. German health insurance claims data therefore constitute an important basis for real world evidence (RWE) on morbidity and healthcare costs. Aim of this study was to investigate to which extent RWE was used for estimation of prevalence and incidence in German AMNOG assessments since introduction 4 years ago and its impact on price discounts. **METHODS:** German AMNOG dossiers with published benefit assessments until March 2015 were evaluated. They were screened for use of RWE in assessing prevalence and incidence and also target populations. After description and discussion of methods and data sources used, statistics were applied to explore a potential influence of use and quality of RWE data on magnitude of price discounts. **RESULTS:** 134 AMNOG dossiers were included of which 50% utilized RWE to assess prevalence, incidence, and target populations. German claims data were employed in 16 dossiers (24%), registry data in 7 dossiers (10%), and other data sources like Delphi panels in 49 dossiers (73%). Claims data were mostly applied for prevalence estimations of both the underlying disease and target populations. Compared to numbers stated by the Federal Joint Committee, target populations were accepted as reported in 56% and underrated numbers in 44% of those dossiers specifically using claims data. Price negotiations were completed for 80 AMNOG assessments. A t-test evaluating the association between use of RWE and negotiated price discounts indicated that price discounts were lower in assessments that did incorporate RWE data (p=0.049). **CONCLUSIONS:** German claims data constitute a valuable and valid data source for assessing epidemiologic evidence in German AMNOG assessments and can be a valuable tool for subsequent price negotiations.

PHP253

THE CHALLENGES OF CARRYING OUT AN INDIRECT COMPARISON WITH SINGLE-ARM STUDIES

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OBJECTIVES: To assess guidance for using single-arm studies in indirect comparisons (ICs) to support health technology assessment submissions. ICs enable comparison of different treatments using data from separate studies. The published methodology for conducting ICs outline the requirement for multiple arm studies to form connections between direct and indirect evidence. This is not possible when trials have single arms, a particular issue for treatments for new indications or for rare diseases. **METHODS:** Guidelines were searched for advice on the use of single-arm trial data in ICs: National Institute of Health and Care Excellence [NICE], Cochrane; Centre for Reviews and Dissemination; and Preferred Reporting Items for Systematic Reviews and Meta-Analyses. In addition the NICE website was searched for new drug submissions including single-arm studies in ICs. **RESULTS:** There is minimal current guidance for dealing with single-arm studies in ICs. NICE recommends that such analyses should be treated as observational and appropriate steps taken to adjust for possible bias. There are very few submissions where single-arm trial evidence has been used in an IC. Those that attempted to compare outcomes from single-arm studies were mostly in oncology and in many cases the reviewing committee had requested this additional information. Cost-effectiveness calculations using these data were acknowledged as being highly unreliable, even after attempts had been made to adjust for possible between-study bias. **CONCLUSIONS:** A number of methods could be used to compare results across multiple single-arm studies. A Bayesian hierarchical model that includes random effects allowing for heterogeneity between studies is a good choice. However, there is a need for clear guidance from organisations such as NICE and Cochrane, who provide recommendations on carrying out systematic reviews and indirect comparisons, on this and other approaches to synthesising information from single-arm studies.

PHP254

NICE DECISION MAKING: TO APPEAL OR NOT TO APPEAL?

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OBJECTIVES: In order for NICE to issue final guidance regarding a new or existing medicine to the NHS, the appeal period for the technology appraisal has to have passed and if an appeal is submitted, it has to be resolved. The Appeal Panel considers appeals which meet one or more of the grounds of appeal defined by NICE. The objective of this study was to identify the past appeal decisions and report the respective results. **METHODS:** A review of past NICE appeals decisions was conducted via a comprehensive search of the NICE website. Published technology appraisals in which appeals were lodged were identified. Only completed appraisals with final appeal results were included in the study. The appeals were grouped under broader disease area categories and the appeal decision materials were reviewed. The grounds of appeals and outcomes of each appeal were extracted. Summary statistics were used to present the number of rejected or upheld appeals. **RESULTS:** The most common area of NICE appeals is oncology followed by rheumatology and respiratory diseases. More than 50% of the total appeals were lodged in oncology in which 30% were breast cancer. The majority of the appeals identified were dismissed by the appeal panel on all grounds submitted, whilst approximately a third of the appeals were upheld on individual points. **CONCLUSIONS:** The majority of appeals submitted to NICE have been rejected by the appeal panel on all grounds. This study has only summarized outcomes from NICE appeals, further analysis is required to assess factors that influence whether appeals are upheld.

PHP255

BIOSIMILARS: ACCESSING THE UK MARKET

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OBJECTIVES: The EMA has in place evolving guidelines on biosimilars since 2005. Biologics Price Competition and Innovation Act (BPCIA) passed by the US Congress in 2009 brought focus on biosimilars in the US. The impending expiration of patents for many top-selling biologics has also made biosimilars commercially exciting. This research evaluates the national and local market access challenges facing biosimilars in the short to medium term. **METHODS:** Formal current positions from HTA bodies like NICE, SMC, AWMSG, as well as positions at a national level from payers in the NHS in England, Scotland, and Wales, where available, are reviewed to inform the national market access situation. Local market access considerations like focus on budgets, pricing, discounts and stakeholder perceptions are evaluated by checking formulary uptake of two recently (2015) launch biosimilars for infliximab – Remsima and Inflectra. **RESULTS:** NICE, SMC, and the NHS in Scotland recently have or are known to be working on formal positions on biosimilars. NICE (for STAs) and SMC have recently decided not to appraise biosimilars and there were no questions from the AWMSG for the biosimilars it accepted for use recently. However, expected (30%) and actual (10%) list-price reductions have not matched. Local discounts, budget considerations as well as payer, physician, and patient perception can play a crucial role in getting biosimilars on formularies. **CONCLUSIONS:** The number of biosimilars accessing the UK market is rising. By all counts formal HTA assessments are not to be regularly expected in the UK, leaving such agencies to focus on innovative medicines at a national level. Decision on access to biosimilars in the UK hinges crucially on local market issues like price and perception.

PHP256

COMPARISON BETWEEN HTA REPORTS IN VENETO AND EMILIA ROMAGNA: DRUGS ASSESSMENT DECISION CRITERIA AND PRIORITIES

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OBJECTIVES: To review and compare HTA reports produced by two Italian Regions: Veneto and Emilia Romagna. To highlight analogies and differences between the elements evaluated in the reports and the outcomes of the assessments made. **METHODS:** A descriptive analysis of HTA reports produced by the Coordinamento Regionale Unico sul Farmaco (CRUF) of Veneto and Commissione Regionale del Farmaco (CRF) of Emilia Romagna. In order to obtain a direct comparison on the assessment methods of the two regions, only reports regarding the same active principles were considered. The analysed reports were published between 2011 and 2014. Coherently with the principle of transparency professed by these HTA institutions, all the data included in the analysis were directly obtained from the agencies' websites. **RESULTS:** For all of the 5 drugs analysed in the reports, Veneto and Emilia Romagna considered same elements, such as safety, comparators, indication, and concluded the identical results about them. Both Regions provided always the same efficacy studies; in 2 cases Emilia Romagna evaluated more secondary endpoints, while in 1 it considered more studies than Veneto, nevertheless the two regions drew equal conclusions about efficacy. Different approaches were taken when conducting economic evaluations: both Regions considered drugs' costs but Emilia Romagna, on the contrary of Veneto, never developed neither a budget impact analysis nor a target population study. Finally, in 3 out of 5 cases Commissions drew different conclusions about the selection of patients to which give the drug to or whether including or not the drug in the Prontuario Terapeutico Regionale (PTR). **CONCLUSIONS:** Divergences in final decisions highlight different priorities of each HTA region regarding the criteria used to make evaluations. Because of the goal of transparency both Regions have, the lack of evidence of mechanisms they adopt in taking assessments should be filled.

PHP257

COMPARISON OF ECONOMIC EVALUATION BETWEEN THREE MAJOR HTA AGENCIES. IS THERE A FRENCH TOUCH?

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OBJECTIVES: The newly established French Economic Evaluation and Public Health Commission (CEESP) provides recommendations and opinions to decision makers about economic evaluations (EEs) for innovative and expensive treatments. In this context, our aim was to compare the differences between EEs conducted in three major health authorities in Europe: SMC, NICE and CEESP. **METHODS:** Using the Prismaccess database, we identified all technology appraisals (TAs), excluding vaccines, published by CEESP prior to June 2015. For these products, we sought corresponding guidance published by English and Scottish agencies (NICE, SMC) and compared methodology and results of the EEs. Data collected for each TA included: study population, comparator, type of analysis, model, time horizon, perspective, clinical and utility data, costs and results. **RESULTS:** We