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 α = 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 population. 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