

absolute error was on average 0.15 but was considerably high (>0.34) if the observed EQ-5D value was below 0.5. Sensitivity analysis revealed that different EQ-5D value sets resulted in different algorithms but similar predicting ability. **CONCLUSIONS:** Our study showed that there are conceptual differences between the CCQ and EQ-5D and mapping should be considered as second-best option compared to directly collected EQ-5D data. Furthermore, the mapping performance seems to depend on the severity of the study population.

QL2

MEASURING PATIENT-RELEVANT TREATMENT BENEFIT IN DERMATOLOGY – DEVELOPMENT AND VALIDATION OF THE SHORT QUESTIONNAIRE “PATIENT BENEFIT INDEX 2.0”

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OBJECTIVES: Evidence on patient-relevant treatment benefit is the main criterion for reimbursement decisions in many European countries. Usually, an increase of quality of life (QoL) during treatment is used as benefit indicator. The Patient Benefit Index (PBI) method, in contrast, evaluates benefit retrospectively: Before treatment, patients rate importance of treatment goals; after treatment, they rate goal achievement. This prevents any bias due to response shift which has repeatedly been found in pre-post QoL assessment. Here, we developed a short PBI version (“PBI 2.0”) applicable to different skin diseases. **METHODS:** Treatment goal items for the PBI 2.0 were developed based on nine validated disease-specific PBI versions. Items were tested for content, completeness, and comprehensiveness in qualitative interviews with n=16 patients with atopic dermatitis, leg ulcers, psoriasis, and vitiligo. Items were revised on basis of patient feedback. The PBI 2.0 was tested for convergent validity, completeness, and congruence with disease-specific PBI versions in a cross-sectional study on n=379 patients with the above-mentioned diagnoses. **RESULTS:** The 74 disease-specific items could be condensed to 15 pilot items. Based on the qualitative interviews, we could reduce to 12 items. The majority of patients rated the PBI 2.0 to be comprehensible (93–98%, depending on diagnosis group), readable (94–100%), easy to answer throughout (78–90%), and complete (65–88%). Treatment goals mentioned as missing mostly concerned goals unrelated to benefit of medical treatment (e.g. information on the disease). The percentage of missing values ranged from 0.0% to 2.9%. PBI 2.0 preference-weighted global scores correlated significantly with QoL as measured with Dermatology Life Quality Index and EQ-5D (r=0.19 to 0.58). Convergent validity of the PBI 2.0 and the respective – about twice as long – disease-specific versions were equal, except for the vitiligo version. **CONCLUSIONS:** The PBI 2.0 is a qualitatively and quantitatively validated short questionnaire on patient-relevant treatment benefit in dermatology.

QL3

THE MEASUREMENT OF HEALTH-RELATED QUALITY OF LIFE: GERMAN FINDINGS FROM THE MULTI-INSTRUMENT COMPARISON (MIC) STUDY

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OBJECTIVES: Different multi-attribute utility (MAU) instruments are known to produce different values for “utility” and measure different constructs, despite the common label “utility”. To date, the Multi-Instrument Comparison (MIC) project has been the largest comparative study of health and well-being instruments undertaken worldwide. Here we report the first results from the German branch of the study. **METHODS:** A total of 1269 German respondents (either healthy or suffering from defined chronic disorders, i.e., asthma, arthritis, cancer, depression, diabetes, hearing loss, heart disease) were recruited and participated in the study, completing various MAU instruments, including the EQ-5D, SF-6D, HUI3, 15D, QWB, AqoL(-4D and -8D). Cross-validation tests drew heavily on correlation. Preliminary findings, based upon Pearson correlation coefficients (indicating the extent to which changes in one variable correspond with changes in another), showed low correlations between measures of utility and measures of subjective well-being. While preferences might differ from subjective well-being, their correlation might be higher. Hence, a better measure should be intraclass correlation (ICC). **RESULTS:** Intraclass correlations between MAU instruments ranged from to 0.8 (HUI3 vs. AqoL-8D) to 0.4 (AqoL-4D vs. 15D). Linear regression results, reflecting the comparative performance of the various MAU instruments with regard to changes in measured utilities (as applied in standard cost utility analysis), and detailed results including pairwise comparisons of instruments, especially as to sensitivity to changes in a given dimension, will be presented. **CONCLUSIONS:** A major conclusion of the present study is that, despite some similarity in the mean scores, the instruments tested are dissimilar with regard to virtually all other criteria used to compare them. In effect, each instrument appears to measure a different construct of “health”. Implications for the presumably “generic” measurement of “utility” may be far reaching and will be discussed.

QL4

PSYCHOMETRIC VALIDATION OF PERCEIVED DEFICITS QUESTIONNAIRE – DEPRESSION (PDQ-D) IN PATIENTS WITH MAJOR DEPRESSIVE DISORDER (MDD)

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OBJECTIVES: The Perceived Deficits Questionnaire (PDQ) provides a self-report measure of cognitive dysfunction. The current work aims at assessing the psychometric properties of the PDQ adapted for MDD (PDQ-D). **METHODS:** A non-interventional, online panel survey with baseline assessment and 6-week follow-up of US and UK residents (aged ≥18 years) with and without MDD [diagnosed with depression by a physician and current Patient Health Questionnaire-9 (PHQ-9) score ≥10]. In addition to PDQ-D, the following instruments were included: Medical

Outcomes Study Cognitive Functioning-Revised [MOS COG-R]; PHQ-9, Patient Global Impression of Severity [PGIS] and Change [PGIC]; SF-36 Health Survey [SF-36], Lam Employment Absence and Productivity Scale [LEAPS], Sheehan Disability Scale [SDS] and Work Productivity and Activity Impairment: Specific Health Problem [WPAI:SHP]. **RESULTS:** The study population consisted of 855 subjects at baseline (418 US and 437 UK), with MDD patients representing 49% of the sample in each country; 169 and 153 MDD patients were invited for the follow-up in the US and UK, respectively. Internal consistency was high for the total scale and for the four proposed subscales (Attention, Retrospective memory, Prospective memory, and Planning), with Cronbach's alpha ranging from 0.81 to 0.96. Convergent validity was supported by strong correlations with other measures of cognitive functioning (0.8 Pearson's coefficient) and moderate correlations with several construct measures known to be associated with cognitive functioning, including health-related quality of life, productivity at work, and other functional impairment (Pearson's coefficients ranging from 0.3 to 0.6), and by substantial differences in scores in subgroups known to differ in cognitive functioning impairment. The PDQ-D was also responsive to changes in depression symptom severity. Confirmatory factor analyses supported the scoring of a global scale for perceived cognitive functioning. **CONCLUSIONS:** The PDQ-D is a reliable, valid and responsive instrument for assessing MDD patients' perception of deficits related to cognitive functioning.

RESEARCH POSTER PRESENTATIONS – SESSION I DISEASE-SPECIFIC STUDIES

INDIVIDUAL'S HEALTH – Clinical Outcomes Studies

PIH1

MOTHERS' OWN MILK FOR THE FEEDING OF PRETERM INFANTS: A SYSTEMATIC LITERATURE REVIEW

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OBJECTIVES: To conduct a systematic review to examine the incremental benefits of mothers' own milk (MM), with or without fortification, compared with donor milk (DM) and/or preterm formula (PF) for the nutritional support of preterm infants both in the neonatal intensive care unit (NICU) and following hospital discharge. **METHODS:** English-language studies published post-1990 were identified from electronic databases (Medline, EMBASE and Cochrane Library) and conference proceedings. Eligible studies enrolled infants with mean gestational age less than 35 weeks with no restriction on geographical location. **RESULTS:** Thirty-three unique studies met eligibility criteria: United States (n=12), Canada (n=2), Australia (n=2), Mexico (n=1), Israel (n=2), Europe (n=13) or multinational (n=1). There was a paucity of both RCT data (n=7) and studies which reported exclusive use of MM feeding (n=3). In addition, there was considerable heterogeneity between studies with regard to study design, duration of follow up and amounts of MM ingested, and a robust meta-analysis was therefore not feasible. However, a significant beneficial effect for MM over DM and/or PF for the incidence of sepsis, necrotizing enterocolitis (NEC) and longer-term neurodevelopment was reported in a number of individual studies. With regard to anthropomorphic outcomes of body weight, length and head circumference, there was no clear consensus on the effect of feeding regimen. Sixteen studies reported the relationship between the dose of MM received and outcomes; increased MM dosages in the feeding regimen were associated with significantly lower rates of sepsis, NEC, and hospital readmissions, reduced NICU costs, and improved neurodevelopment. **CONCLUSIONS:** Exclusive or high-dose MM with or without fortification is associated with short- and long-term beneficial effects in preterm infants. These results confirm MM to be the optimal nutrition for preterm infants and stress the importance of developing comprehensive strategies to overcome the challenges of providing MM and improving breastfeeding rates in preterm infants in the NICU.

PIH2

UTERINE-SPARING SURGICAL TREATMENT MODALITIES IN WOMEN WITH UTERINE FIBROIDS: A SYSTEMATIC REVIEW AND INDIRECT TREATMENT COMPARISON

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OBJECTIVES: To evaluate the safety and effectiveness of conservative surgical treatments for uterine fibroids in women who wish to preserve their uterus. **METHODS:** A systematic literature search of electronic databases (MEDLINE, EMBASE, CENTRAL) and grey literature up to October 2012 identified 5 RCTs (436 patients): 2 comparing uterine artery embolization (UAE) with myomectomy (MYO) and 3 comparing UAE with laparoscopic uterine artery occlusion (LUAO). Primary outcome measures included patients' satisfaction, re-intervention and ovarian failure rate. Secondary outcomes were clinical failure, hysterectomy and complication rates, hospitalization and recovery times, pregnancy rate, pregnancy complications and live-birth rate. Standard and network meta-analysis were performed on relevant outcomes. **RESULTS:** Of the three most popular uterine-sparing surgical treatments for fibroids, network meta-analysis showed that MYO and UAE resulted in higher rates of patient satisfaction and lower rates of clinical failure than LUAO in the first year after treatment [OR 2.56, 95%CrI 0.56–11.75, P(better)=11% and 2.7, 95%CrI 1.1–7.14, P(better)=1%; 0.29, 95%CrI 0.06–1.46, P(better)=7% and 0.37, 95%CrI 0.13–0.93, P(better)=2% respectively]. Moreover, MYO resulted in lower re-intervention and hysterectomy rates than UAE and LUAO [0.08, 95%CrI 0.02–0.27, P(better)<1%, 0.08, 95%CrI 0.01–0.37 P(better)<1%]; 0.16, 95%CrI 0.01–0.85 P(better)=2%, 0.15 95%CrI 0–8.74 P(better)=16% respectively] even though the later techniques had an advantage over MYO due to shorter hospitalization and quicker recovery. There was no evidence of convincing difference between the three techniques in the number of women experiencing ovarian failure, minor or major complications. However, MYO may lead to better conception outcomes in

comparison to UAE (pregnancies: 3.44, 95%CI 1.18- 10.03; live-births: 3.02, 95%CI 1.00- 9.09). **CONCLUSIONS:** LUAO is less effective than UAE and MYO in the treatment of symptomatic fibroids for women who want to preserve their uterus. The choice between UAE and MYO should be based on individuals' short and long-term expectations.

PIH3

META-ANALYSIS OF BCG VACCINE EFFICACY FOR INFANTS IN IRELAND

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OBJECTIVES: BCG vaccination policy is greatly debated. An important issue for countries using the vaccine is to try and estimate any influence it has on the tuberculosis (TB) incidence in their population. The aim of this study is to estimate the effectiveness of the BCG vaccine in infants in Ireland. **METHODS:** We searched PubMed and Embase for studies assessing a relative reduction in TB events after vaccination in infants. Studies meeting relevant inclusion and exclusion criteria were sought. Observational data from Ireland was combined with raw data from studies identified in the literature in a random-effects meta-analysis model to estimate the relative risk (RR) of vaccine efficacy against pulmonary TB, extra-pulmonary TB (EPTB), TB meningitis and TB deaths. **RESULTS:** Two meta-analyses were found. The first meta-analysis reviewed identified 5 randomised control trials and 11 case control studies against pulmonary TB (Trials 0.26 95% CI 0.17, 0.38; Cases 0.48 95% CI 0.37, 0.62) and TB deaths (Trials 0.35 95% CI 0.14, 0.88). The second meta-analysis identified a further 7 case-control studies and evaluated BCG efficacy against EPTB (0.23 95%CI 0.13, 0.42) and TB meningitis (0.27 95%CI 0.21, 0.33). Estimates from observational data from Ireland for pulmonary TB were (0.14, 95%CI 0.09, 0.20), EPTB (0.11, 95%CI 0.05, 0.21), TB meningitis (0.17, 95%CI 0.04, 0.75) and TB deaths (0.13, 95%CI 0.00, 6.37). Pooled RR estimates from Irish data and international estimates show a significant reduction in TB cases: Pulmonary TB: 0.26 (95% CI: 0.13, 0.54), EPTB: 0.16 (95%CI: 0.08, 0.34), TB meningitis: 0.27 (95%CI: 0.21, 0.34) and TB deaths: 0.33 (95%CI: 0.14, 0.81). **CONCLUSIONS:** This meta-analysis of local observational data with international trial data indicates that vaccination of infants with the BCG vaccine reduces the risk of pulmonary TB, EPTB, TB meningitis and TB deaths.

PIH4

CO-ADMINISTRATION OF ANTIPSYCHOTICS AND ANTI-DEMENTIA DRUGS IN AUSTRIA

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OBJECTIVES: The use of antipsychotics for people with dementia is regarded as problematic, causing cerebrovascular side effects and increasing mortality. In some countries, health-policy makers have already addressed a need for action to reduce the prescription of antipsychotics in dementia. The main goal of the analysis is to determine the extent of co-medication of antipsychotics for patients with medically-treated dementia in Austria, stratified by age and sex. **METHODS:** Provided in a pseudonymised manner, the data comprise all filled prescriptions of cholinesterase inhibitors and memantine in the years 2011 and 2012 at the expense of the 13 major Austrian health insurance funds, covering more than 97% of the Austrian population. Additionally, antipsychotic medication of the involved patient pseudonyms is included, as well as age, sex and - where occurred - date of death. For the analysis, the overlapping time frame is relevant, i.e. when both substance groups were consumed. Descriptive statistics are used to capture the extent and variability of a co-medication of these two substance groups. **RESULTS:** Starting with 72,549 patients included in the data (66% female), 31,605 (43.6%) were concurrently being prescribed antipsychotics to their anti-dementia drugs. The median for the overlapping time frame is 294 days, for anti-dementia prescriptions it is eleven and for antipsychotics it is seven. Age is a factor for increasing antipsychotic medication. Considering demography, there are no remarkable differences between men and women. **CONCLUSIONS:** Our data demonstrate that the use of antipsychotics in dementia is notably common in Austria, with a high prevalence as well as a tendency to long-term use. The results reflect the prescription reality and can be used as a solid basis for discussions, possible actions and evaluations about antipsychotics in dementia in the Austrian health system.

PIH6

ASSESSING PRODUCT SAFETY VIA PATIENT BASED ACTIVE SURVEILLANCE (AS): A STUDY IN 30.000 WOMEN USING HORMONE REPLACEMENT THERAPY (HRT)

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OBJECTIVES: The novel progestin drospirenone (DRSP) has antimineralocorticoid properties with potentially beneficial as well as unfavorable effects on cardiovascular outcomes compared to other progestins. A patient based AS study was set up to compare incidence rates of serious adverse events - in particular cardiovascular outcomes - in users of oral continuous combined preparations. **METHODS:** Prospective, controlled cohort study (2002-2011) with three arms: women using 1) DRSP/estradiol; 2) other oral continuous-combined HRT (occHRT); and 3) all other oral HRTs. The study population included women aged 40 or older in seven European countries starting or switching to an oral HRT at time of inclusion in the study. Outcomes were collected from the patients and validated by the treating physicians. A multifaceted 4-level follow-up procedure was to ensure low loss to follow-up rates. The analysis is based on Cox regression models comparing the cohorts. **RESULTS:** A total of 30,597 users of oral HRT preparations - reflecting more than 101,000 WY of observation - were recruited by 1,052 centers. Incidence rates of DRSP/estradiol and low-dose occHRT for venous thromboembolic events were 17.5 (95% CI: 11.2-26.0) and 18.2 (95% CI: 11.9-26.6) per 10,000 WY, respectively. The respective incidence rates for arterial thromboembolism were 10.9 (95% CI: 6.1-18.0) and 29.8 (95% CI: 24.1-36.4) per 10,000 WY with a hazard ratio adjusted for age, BMI, hypertension, region, family history of fatal ATE, diabetes, user status

of 0.5 (95%CI: 0.3-0.8) for DRSP/estradiol vs. other occHRT. **CONCLUSIONS:** Results indicate a good safety profile with respect to cardiovascular risk for DRSP/estradiol. Serious cardiovascular events occur less frequently in DRSP/estradiol users compared to users of other continuous-combined HRT. This specific AS approach proved to be a successful approach with high long term follow-up success and high validity of safety results.

INDIVIDUAL'S HEALTH - Cost Studies

PIH7

BUDGET IMPACT OF HPV16/18 GENOTYPING TESTS FOR THE MANAGEMENT OF NON-CONCORDANT COTESTING CERVICAL CANCER SCREENING RESULTS: A UNITED STATES PAYER PERSPECTIVE

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OBJECTIVES: To assess the impact of managing women with high-risk HPV positive and Pap negative results (hrHPV+/Pap-) attending cervical cancer (CxCa) screening with a Pap and HPV test (co-testing). The strategies tested reflect different options available if a hrHPV test versus a hrHPV including 16/18 genotyping (3-in-1 test) is used upon initial screen. **METHODS:** A budget-impact model was developed, from a US payer perspective. Data from the ATHENA (Addressing The Need for Advanced HPV Diagnostics) trial and published literature were used to populate the model. The scenarios tested include repeat co-testing in 12 months, reflex genotyping HPV16/18, or routine co-testing with genotyping results already available from a 3-in-1 test for triage to colposcopy. The model examined the annual cost of testing and treatment for cervical intraepithelial neoplasia grade 2 or worse (\geq CIN2) and the cost of patients loss-to-follow-up. For a hypothetical population of women between ages 30 to 69, it assumes 48.5% were co-tested within the CxCa screening program every 3 years. Of those, 6.7% of women receive hrHPV+/Pap- results. Test performance was modeled as equivalent for both genotyping scenarios. **RESULTS:** In the hrHPV+/Pap- population, the cost of \geq CIN2 cases detected and treated for each testing strategy and the rate of progression to invasive CxCa per 10,000 hrHPV+/Pap- results was \$10,530/9.2 (repeat co-testing at 12 months), \$8,500/2.6 (reflex HPV16/18) and \$7,278/2.6 (routine co-testing with 3-in-1 test). Using HPV16/18 genotyping to manage discordant co-testing results increased \geq CIN2 cases detected and prevented disease progression. Compared to other HPV tests that require reflex genotyping, screening with a 3-in-1 test reduced the cost of follow-up by 17% annually. **CONCLUSIONS:** Genotyping for HPV 16/18 improved the detection of \geq CIN2 cases over repeat co-testing in 12 months; moreover, compared to other HPV testing strategies, the 3-in-1 test reduced costs and may be a prudent screening alternative.

PIH8

ECONOMIC IMPACT OF THE USE OF AN ABSORBABLE ADHESION BARRIER IN PREVENTING ADHESIONS FOLLOWING OPEN GYNECOLOGIC SURGERIES

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OBJECTIVES: Abdominal adhesions are common after gynecologic surgeries, often resulting in complications such as bowel obstruction and chronic pain, which may lead to increased length of stay and more frequent readmissions. GYNECARE INTERCEED[®] Absorbable Adhesion Barrier is associated with fewer adhesion-related outcomes compared to surgeries without an adhesion-barrier. This analysis assesses the budget impact of GYNECARE INTERCEED[®] for reducing the incidence of postoperative adhesions in open surgical gynecologic procedures. **METHODS:** A model was constructed to evaluate the budget impact to hospitals of adopting GYNECARE INTERCEED[®] for women undergoing open surgical gynecologic procedures. C-section surgery, hysterectomy, myomectomy, ovarian surgery, tubal surgery, and endometriosis surgery were modeled with and without the use of GYNECARE INTERCEED[®]. Incremental GYNECARE INTERCEED[®] material costs, medical costs arising from complications, and adhesion-related readmissions were considered. GYNECARE INTERCEED[®] use was assumed in 50% of all procedures. Budget impact was reported over a 3-year period from a US hospital perspective (US\$2013). **RESULTS:** Assuming 100 gynecologic surgeries of each type and an average of one GYNECARE INTERCEED[®] sheet per surgery, a net savings of \$439,975 with GYNECARE INTERCEED[®] over 3 years is estimated. GYNECARE INTERCEED[®] use resulted in 80 fewer patient cases developing adhesions. Although the use of GYNECARE INTERCEED[®] added \$91,500 in material costs, this was completely offset by the reduction in complication costs (\$230,766 savings) and fewer adhesion-related readmissions (\$300,709 savings). By preventing adhesion-related complications, GYNECARE INTERCEED[®] prevented over 206 additional hospital days for patients. **CONCLUSIONS:** This analysis represents the first economic assessment of GYNECARE INTERCEED[®] use in open gynecologic surgeries that incorporates the cost of the adhesion barrier, complications, and readmissions. Adoption of GYNECARE INTERCEED[®] absorbable adhesion barrier for appropriate gynecologic surgeries would likely result in significant savings for hospitals which would largely be driven by clinical patient benefits in terms of fewer complications and adhesion-related readmissions.

PIH9

BUDGET IMPACT OF DIENOGEST IN TREATING ENDOMETRIOSIS ASSOCIATED PELVIC PAIN IN BRAZIL: A PUBLIC PERSPECTIVE ANALYSIS

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OBJECTIVES: Evaluate the budget impact to the public health care system in Brazil after introducing dienogest (2 mg) as a treatment option in detriment of GnRH analogues (GnRHa) for patients with endometriosis-associated pelvic pain (EAPP). **METHODS:** The analysis was conducted from the public perspective over a five-year time horizon. The budget impact model (BIM) specifically considered