OBJECTIVES: A multi-centre, prospective, observational study aimed to recruit 500 newly diagnosed AF patients and 500 matched controls to assess AF symptom burden and HRQOL using THIN UK primary care data. Patient enrolment as soon after diagnosis as possible was vital. Existing methodology of identifying patients from fully processed data would not have enrolled patients as quickly as necessary to assess newly diagnosed AF. The objective was to assess the effectiveness of a novel methodology used to recruit patients as soon after diagnosis as possible from THIN. **METHODS:** Cases and controls matched by age, gender and geography were identified as soon as data were received from THIN practices rather than after data were fully processed (normal route for identifying patients). Patients were therefore identified within one week of diagnosis being recorded. Practices were contacted by THIN staff and asked to confirm eligibility. Practices invited eligible patients to participate, ensuring no direct contact between THIN staff and patients. Patients were asked to complete HRQOL questionnaires at enrolment, 6 and 12 months' follow-up. **RESULTS:** Within 18 months, this method was successful in recruiting beyond the necessary sample size (516 case-control pairs). This methodology minimised the impact of recruitment and follow-up on clinical management of patients, who were seen at a frequency determined in accordance with their normal medical care only. Diagnostic assessments of patients were not required and so, other than the questionnaires, there was no additional burden to normal clinical practice. **CONCLUSIONS:** This is an innovative method for patient recruitment using THIN primary care patient data. Newly diagnosed AF patients who might be eligible and for whom clinical information is already available can be quickly identified. Large numbers of newly diagnosed patients can be recruited more rapidly compared to existing methods and followed up in an efficient and cost-effective way.

PRM180

HOW PERSONALIZED SHOULD WE BE? A SYSTEMATIC REVIEW OF TAILORED & TARGETED HEALTH COMMUNICATION INTERVENTIONS TO IMPROVE ADHERENCE

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OBJECTIVES: To target patients with "personalized" interventions with the highest probability of success, understanding what works with other behaviors provides empirical guidance, as few outcomes are explicitly medication adherence-related. This study's purpose is to glean 1) the characteristics of individuals or interventions examined in "tailored" or "targeted" health communication interventions, and 2) the components or combination of successful strategies tailored to the individual's needs and targeted to the social groups in which the patient is embedded. **METHODS:** A systematic review was conducted, with articles identified via searches in MEDLINE and Embase, using keywords representing individual, interventional, and behavioral factors. Inclusion criteria: published peer-reviewed articles in English, 2000-2012; 77 studies reflected behavioral outcomes (medication adherence, preventive screening, health promotion, and self-management of disease). The review specified individual factors (sociodemographic, behavioral, contextual, disease) as well as elements upon which interventions were customized (delivery, content, form, dose/frequency, setting, level of analysis). **RESULTS:** Across all outcomes assessed (n=133), 52.6% of tailored or targeted interventions demonstrated statistically significant benefit, with additional 12.8% effective (not statistically), 9.8% mixed, 24.8% non-significant. Regarding behaviors associated with multiple morbidities: most studies evidenced health promoting effects (medication adherence, 66.7%; diet/obesity, 65.9%; physical activity, 47.4%; screening, 71.4%). Disease-specific outcomes reflected stronger findings. Individual characteristics were clustered into groups for analysis, with significantly positive effects for 3 of 4 clusters: sociodemographic, 59.0%; behavioral, 63.4%, contextual, 52.6%. Within group differences indicated support for specific factors within each cluster (age vs. education, barriers vs. self-efficacy). Effects were moderated by intervention-type (tailored vs tailored+targeted). **CONCLUSIONS:** A matrix developed for this review permits a refined approach to creating interventions focusing on the interaction ("person x intervention") features of effective strategies. Several candidate characteristics of patients to prioritize in medication adherence program development were identified, using evidenced-based selection of patient-centered strategies that appropriately match what has worked and for whom.

PRM181

DEVELOPMENT OF A NEW PATIENT REPORTED OUTCOME (PRO) MEASURE FOR ACUTE BACTERIAL SKIN AND SKIN STRUCTURE INFECTIONS (ABSSSI)

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OBJECTIVES: We describe the process and progress of the Foundation for the NIH Biomarkers Consortium Project Team, a public-private partnership of government, academia, non-profit, and industry. The goal is development and qualification of a new ABSSSI PRO instrument incorporating reliable, well-defined and relevant endpoints for patients in terms of how they feel and function in clinical trials of antibacterial drugs for ABSSSI. **METHODS:** We adhered to the U.S. Food and Drug Administration (FDA) PRO Guidance for instrument development (2009) and the 2010 FDA qualification process for drug development tools (DDTs). This guidance describes the process for DDTs intended for use in multiple drug development programs, the goal of the current effort. Once qualified, drug developers can use DDTs for the qualified context in Investigational New Drug (IND) and New Drug Application (NDA)/Biological License Application (BLA) submissions without FDA reconsideration of the DDTs suitability. **RESULTS:** The initial phase of instrument development included a literature review and gap analysis (see Cimms et al., 2013 ISPOR abstracts) and interviews with 9 clinical experts. The most commonly reported symptoms were pain and tenderness across all ABSSSI subtypes- cellulitis (n=8), wound infection (n=7), and abscess (n=7). These efforts led to the development of a study protocol and interview guide to elicit concepts from ABSSSI patients. Following qualitative analysis of the interview transcripts, the team will draft a PRO instrument based on key concepts identified from ABSSSI patients and experts. The draft PRO will be evaluated by an expert panel and refined through cognitive debriefing interviews with patients. **CONCLUSIONS:** A consortium-based approach was useful and efficient in developing a new draft PRO measure for ABSSSI, which incorporates published literature and data from qualitative interviews. The team is planning a similar approach for development of a draft clinician reported outcome for ABSSSI and a CABP PRO.

PRM182

METHODOLOGICAL CHALLENGES IN MAPPING A DISEASE SPECIFIC PSYCHOMETRIC INSTRUMENT TO A DISEASE SPECIFIC UTILITY INSTRUMENT: THE EFFECT OF ALTERNATE UTILITY TRANSFORMATIONS AND WITHIN-INSTRUMENT SUB-SCALE CORRELATIONS ON MODEL FIT

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OBJECTIVES: a) Determine the effect of utility transformations on the fit of linear regression used to map psychometric disease-specific instrument scores to disease-specific utility scores and b) determine whether the model fit is dependent upon the correlation between the disease specific and non-specific items of the preference-based instrument. **METHODS:** We compare regression models mapping scores from the UCLA Prostate Cancer Index (PCI), a psychometric instrument measuring Health Related Quality of Life for prostate cancer patients, to utility responses from PORPUS-U, a prostate cancer-specific utility instrument with disease-specific and generic subscales. Models were fitted using a dataset from prostate cancer patients, while fit was assessed on three separate datasets, using the Root Mean Squared Error (RMSE) in the retransformed scale. The often poor fit of regression-based mapping models may be due to limited overlap between the constructs addressed by preference-based and psychometric instruments. We investigated this hypothesis employing a simulation procedure where we: a) fitted a multivariate regression model estimating how the generic subscales depend on the disease-specific ones, b) used these estimates, with varying noise, to simulate generic subscale scores, c) calculated utility scores from the true disease-specific and simulated generic subscales, d) applied linear regression to map PCI scales to "semi"-simulated PORPUS-U utilities, and f) evaluated the mapping using RMSE, determining whether a "tighter" correlation structure improves the fit. **RESULTS:** The arcsin transformation appears to give the best fit, with RMSE values of 0.0405, 0.0605 and 0.0457 for the three test datasets. The simulation experiments showed that larger correlation between disease specific and non-disease specific instrument domains only yields a marginal benefit in the mapping. **CONCLUSIONS:** Transforming utility scores does affect model fit, and appears to be an important step in utility mapping. Limited construct overlap between disease-specific and generic items in prostate cancer quality of life instruments did not evidently explain suboptimal fit in our mapping models.

PRM183

THE EFFECT OF INCLUDING AN OPT-OUT OPTION IN DISCRETE CHOICE EXPERIMENTS

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OBJECTIVES: To study to what extent an opt-out option in a Discrete Choice Experiment (DCE) influences the attribute estimates and the conclusions drawn from the DCE. **METHODS:** A questionnaire was sent to 2,500 Dutch Diabetes Mellitus Type 2 (DM2) patients, each questionnaire contained 9 choice tasks with and 9 without an opt-out alternative. Panel-mixed-logit models were used to estimate the relative importance of the five attributes included (menu schedule, physical activity (PA) schedule, consult structure, expected outcome and out-of-pocket costs). It was empirically tested whether the relative importance of the attributes differed between a DCE with or without opt-out alternative. Additionally, it was tested whether results differed between respondents that were offered the opt-out option in the first 9 choice tasks and those who could choose to opt-out only in the second 9 choice tasks. **RESULTS:** In both datasets (with and without opt-out), consult structure (β=-0.54, β=-0.53), expected outcome (β=0.64, β=0.77) and out-of-pocket costs (β=-0.79, β=-0.67) showed significant attribute estimates (P<.001). However, the relative importance of these attributes differed between both datasets. The frequency of choosing to opt-out was higher among participants that first had this option, compared to respondents that were first forced to make a choice. The regression analyses on these subgroups showed different results with respect to the elaborate PA schedule (β=0.10; P>.05 versus β=0.13; P<.05). **CONCLUSIONS:** Conclusions drawn

from the DCE with and without out-out differed. Results suggest that including an opt-out reduces efficiency with respect to power.

PRM184

THE INFLUENCE OF CHOICE TASK LAYOUT ON THE OUTCOMES OF A DISCRETE CHOICE EXPERIMENT

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OBJECTIVES: To empirically test to what extent the layout of choice tasks (i.e., displayed in words or graphics) in a Discrete Choice Experiment (DCE) influences the attribute estimates and the conclusions drawn from the DCE. **METHODS:** A DCE questionnaire was sent to the parents of 2500 newborn babies aged 6 weeks at maximum. Each questionnaire contained two times the same 9 choice tasks, ones words were used to describe the attributes and levels and ones graphics were used. The DCE consisted of five attributes related to the decision of parents to vaccinate their newborn baby against the rotavirus (vaccine effectiveness, frequency of severe side effects, protection duration, location, costs). Mixed logit models were conducted to estimate the relative importance of the attributes. **RESULTS:** Preliminary results are based on 279 observations from 31 parents. In February 2013 data collection will be completed and analyzed. When comparing the choices of every respondent per choice tasks, 58% chose inconsistent at 1 or more choice tasks and 35% chose inconsistent in two or more choice tasks. In both datasets (layout in words and graphics), vaccine effectiveness ($\beta_{\text{effects code 1}}$=0.64 and $\beta_{\text{effects code 1}}$=1.00, $\beta_{\text{effects code 2}}$=0.67 and $\beta_{\text{effects code 2}}$=0.01), frequency of severe side effects ($\beta_{\text{effects code 1}}$=0.26 and $\beta_{\text{effects code 1}}$=0.41, $\beta_{\text{effects code 2}}$=1.22 and $\beta_{\text{effects code 2}}$=0.89) protection duration (β=0.37, β=0.17) and costs (β=-0.10, β=-0.11) showed significant attribute estimates (P<.05). However, the relative importance of these attributes differed between both datasets. **CONCLUSIONS:** For now it can be concluded that the presentation of the choice sets (by either using words or graphics) in a DCE influences study outcomes. Besides extensive pilot testing to ensure the choice tasks are understood and interpreted as intended, it might be worthwhile to include discussions about the layout of the choice tasks in the focus group stage of the DCE designing process.

PRM186

EVALUATING AND IMPROVING METHODS FOR COGNITIVE DEBRIEFING PRO QUESTIONNAIRES

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OBJECTIVES: Cognitive debriefing is critical to the content validity of patient-reported outcome (PRO) questionnaires. The goal of this poster is to evaluate the time needed to adequately debrief PRO questionnaires and to generate a set of questions that could facilitate the timely and successful completion of cognitive debriefing interviews. **METHODS:** To evaluate cognitive debriefing methods, two research activities were conducted. First, a time-to-complete analysis was conducted using n=44 audio-recorded patient interviews to understand how much time was required to debrief single PRO items. Next, select studies (n=15) were reviewed to document the researcher stated objectives of their cognitive debriefing activities. This list of objectives was used to inform a set of questions that could be asked of patients during debriefing to accomplish those objectives. **RESULTS:** The time-to-complete analysis showed that single questionnaire items required approximately 5 minutes and 45 seconds to be fully debriefed. Primary objectives of cognitive debriefing interviews included the evaluation of a) patients' interpretation of the instructions, items, and response options relative to questionnaire developer's intentions; b) the extent to which item concepts assessed in the questionnaire are comprehensive to the general concept of measurement; c) item language that reflects patient experience, and d) response options as representative of patient health status. **CONCLUSIONS:** Results suggest that it takes approximately 60 minutes to fully debrief a PRO questionnaire constructed of 10 items. Though longer interviews are possible, interviews lasting longer than 60 minutes may produce data of poor quality due to patient fatigue. Therefore, debriefing studies require clearly stated objectives along with targeted questions to help the interviewer successfully and efficiently meet those objectives. The interview questions discussed in this poster can be used by researchers to facilitate the timely and targeted completion of cognitive debriefing interviews for the purpose of supporting content validity of a PRO questionnaire.

RESEARCH ON METHODS – Statistical Methods

PRM187

COMPARISON BETWEEN TIME-DEPENDENT COX AND MARGINAL STRUCTURAL MODELING APPROACHES TO ESTIMATING THE EFFECT OF PRESCRIPTION COST-SHARING ON PERSISTENCE WITH FIRST-LINE ANTIRETROVIRAL THERAPY AMONG TREATMENT ANTIRETROVIRAL-NAÏVE HIV PATIENTS

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OBJECTIVES: Prescription cost-sharing and pill burden may predict duration of persistence with antiretroviral therapy (ART) in HIV patients. These predictors are correlated and may vary with time, necessitating sophisticated modeling approaches to generate unbiased and consistent estimates of their effects on ART persistence. This analysis compared the estimated effect of ART cost-sharing on ART persistence when adjusting for ART pill burden through traditional time-dependent Cox versus newer marginal structural modeling (MSM) approaches. **METHODS:** Retrospective observational cohort study using a large U.S. claims database. Subjects were commercially-insured antiretroviral-naïve HIV patients initiating ART during the period January 1, 2003 to December 31, 2007. ART persistence was measured as the number of days from ART initiation until addition of a new antiretroviral, 30-day gap in possession of an initiated antiretroviral, or censoring at loss to follow-up. During the period of persistence, ART cost-sharing per 30-day supply of the ART regimen and daily average ART pill burden were measured within a patient-quarter repeated-measures panel dataset. Time-dependent Cox and MSM approaches were compared with respect to their estimated effect of ART cost-sharing (>$50 versus ≤$50) on ART persistence. MSM was implemented using inverse probability of treatment weights within a weighted Cox model with generalized estimating equations. **RESULTS:** Sample comprised 3,731 patients producing 19,199 patient-quarters: mean age=41.1 years; male=83.2%; median ART cost-sharing=$40; median ART pill burden=3.2. Using time-dependent Cox modeling, ART cost-sharing >$50 (versus ≤$50) was estimated to be not significantly associated with ART persistence (Hazard Ratio [HR]=0.96, 95% confidence interval [CI]=0.78-1.18, p=0.733). In contrast, using MSM, ART cost-sharing >$50 was estimated to be significantly associated with shorter durations of ART persistence (HR=1.28, 95% CI=1.16-1.43, p<0.001). **CONCLUSIONS:** Appropriate model choice is critical in the presence of complex relationships between correlated time-varying predictors and outcomes. Using MSM, ART cost-sharing >$50 was found to be significantly associated with shorter durations of ART persistence.

PRM188

EFFICIENCY OF DIALYSIS CENTERS IN THE UNITED STATES: AN UPDATED EXAMINATION OF FACILITY CHARACTERISTICS THAT INFLUENCE PRODUCTION OF DIALYSIS TREATMENTS

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OBJECTIVES: Medicare has announced plans to include efficiency measures in the End-Stage Renal Disease Quality Incentive Program. Few studies have analyzed US dialysis center efficiency, despite ongoing payment incentives to deliver dialysis care more cost-effectively. The objective of this study was to assess overall dialysis center efficiency as well as the impact of anemia drug choice on efficiency. **METHODS:** Using 2010 data from Medicare Renal Cost Reports, a data envelopment analysis (DEA) was performed to model the technical efficiency of 4,343 free-standing dialysis centers. DEA uses a linear programming technique that converts multiple inputs (costs, staffing levels) and an output measure (number of dialysis sessions) to a relative efficiency score between 0 and 1, where scores are proportional to the efficiency frontier (score of 1.0.) A second DEA was conducted to assess changes in score distribution if labor and supply cost inputs were reduced due to switching to less frequent dosing of anemia drugs. Regression analysis was performed to account for variations in organizational and environmental conditions. **RESULTS:** About 78% of facilities were owned by the two largest chains. Nearly 93% of facilities were for-profit; 75% were in urban areas. 33% of facilities were functioning efficiently (efficiency scores ≥.90); 30% had scores between .70 and .90, and 37% scored <.70. Neither the intensity of market competition nor the profit status of the facility had a significant effect on efficiency. Facilities that were members of large chains were less likely to be efficient. Cost and labor savings due to changes in drug protocols had little effect on overall dialysis center efficiency. **CONCLUSIONS:** Opportunities exist for continued improvements in the efficiency of US dialysis facilities. DEA may be a useful tool for evaluating dialysis center efficiency. Future studies should incorporate quality of care dimensions and case-mix adjustment in the measurement of efficiency.

PRM189

A SYSTEMATIC REVIEW OF THE NETWORK META-ANALYSIS LITERATURE

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OBJECTIVES: Network meta-analysis is a relatively new statistical approach for synthesizing evidence. Network meta-analysis includes both ''direct'' and ''indirect'' comparisons to strengthen inference concerning the relative efficacies of treatment pairs. Further, the approach facilitates simultaneous inference regarding all treatments, allowing the ranking of therapeutic options by effectiveness. This study reviewed published network meta-analyses pertaining to pharmaceuticals, and identified trends in the literature. **METHODS:** Using the PubMed electronic database, we performed a systematic search using the following terms; "network meta-analysis", "mixed treatment comparison", and "indirect treatment comparison". Two reviewers assessed each study. We excluded studies that did not include pharmaceuticals or biologics, pertained to methods, did not report efficacy endpoints, or were not published in English. For each study we reported publication year, funding source (industry or non-industry), disease type, and whether the study included a biologic treatment. **RESULTS:** A total of 142 of the 288 abstracts identified through the systematic search were included. Over time, there has been a rapid growth in the literature, with nine studies published between 1997 and 2008, 14 in 2009, 18 in 2010, 38 in 2011, and 63 in 2012. The majority of studies were non-industry funded (55.6%). Drugs for musculoskeletal and rheumatic disease were the most frequently evaluated (22.5%), followed by drugs for cardiovascular disease (14.8%), cancer (11.3%), e.g., breast cancer and lung cancer, and infectious disease (11.3%), and psychiatric and neurological conditions (10.5%). A total of 35.9% of studies included at least one biologic. **CONCLUSIONS:** The number of published network meta-analyses is growing rapidly. Studies are performed across a range of