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initiated STRs; 1,681 (47%) initiated MTRs. Median persistence (95% confidence interval) was 36.5 (31.3, 38.9) months on STRs and 13.2 (11.9, 15.0) months on MTRs (Difference 23.3; P<0.001). Within the subgroups persistent for the first 6 months, median persistence on MTRs was 26.1 (24.2, 28.3) and on STRs was 47.6 (41.2, 54.3) months. Limiting the MTR analysis to those patients who had persistence  $\geq$  6 months still fell short of the overall STR persistence (P<0.001). **CONCLUSIONS:** Patients receiving an STR regimen had significantly longer median persistence, by almost two years, compared to those receiving MTRs. Even those patients who persisted on an MTR for the first 6 months experienced shorter overall persistence than those receiving an STR.

### PIN80

# EVALUATING PATIENT PREFERENCES FOR HIV THERAPY: RESULTS FROM A DISCRETE CHOICE EXPERIMENT IN THE UK AND GERMANY

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OBJECTIVES: The aims of this study were to (1) Estimate the relative strength of preferences for different attributes of Anti Retroviral Therapy (ART) using a stated preference discrete choice experiment (DCE) and (2) incorporate findings from qualitative research to supplement the data from the DCE. METHODS: A European study in France, Italy, Spain, Germany and the UK was undertaken with an estimated 1500 PLWH designed to elicit patients' strength of preference for different attributes of ARTs. This work presents the results from the UK and Germany. Participants were given a series of choice-style questions which presented hypothetical ARTs. Qualitative data were collected separately through individual interviews (n=48) with PLWH recruited from HIV clinics in the UK and Germany. **RESULTS:** In total, 549 patients participated in the DCE (249 in UK) and (300 in Germany). The results showed that a rapid improvement in CD4 count and viral load were treatment attributes valued most highly by patients (UK: OR= 0.79; CI= 0.69-0.90; P<0.001. Germany: OR=0.79; CI=0.71-0.87; P<0.001). In addition, the absence of side effects such as diarrhoea was also valued highly (UK:OR=0.57 CI= 0.51-0.65, p<0.001. Germany: OR=0.79, CI=0.72-0.86; P<0.001), as well as lower risk of long- term toxicities such as decline in renal function and an increase of cardiovascular risk (UK: OR= 0.30 CI= 0.25-0.35, p<0.001. Germany: OR=0.55, CI=0.48-0.63, p<0.001). Other treatment attributes driving patient preference included reduction in treatment failure, absence of food restrictions with ART, and fewer drug-drug interactions (DDIs). The main difference between the German and UK results is that German patients did not value the absence of DDIs, the qualitative data suggests that they felt that these issues are being managed by their clinician. CONCLUSIONS: The DCE demonstrated that patients placed a great deal of importance on treatment efficacy as evidenced by the importance placed on these attributes.

### PIN81

# HEALTH STATE UTILITY VALUES OF HIV INFECTED PATIENTS IN KENYA

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OBJECTIVES: Health state utility values (HSUVs) in HIV are a key component of economic models that include Quality Adjusted Life years (QALY). There are limited HSUVs previously reported in HIV patients from Kenya. The objective of this study was to examine the HSUVs by severity of symptoms in an HIV infected population. METHODS: A Kiswahili translated SF-12 survey was administered to newly diagnosed HIV infected patients participating in a randomized, controlled trial in Nairobi, Kenya between April and October 2013. Patients were also asked if they were experiencing common symptoms of HIV (ie. fatigue, loss of appetite, depression or diarrhea) on a scale including no symptoms, mild, moderate or severe symptoms. SF-12 results were scored using Brazier's SF6D utility algorithm. Mean HSUVs among patients reporting severe symptoms, mild/moderate symptoms or no symptoms were compared using ANOVA. RESULTS: 135 respondents were included in the analysis with 7 observations removed due to missing data. HSUvs among asymptomatic HIV patients was 0.98 (SD=0.04), among patients experiencing mild/moderate symptoms was 0.89 (SD=0.12) and among patients experiencing severe symptoms was 0.73 (SD=0.16). ANOVA showed significant differences (p<0.01) between group and a post-hoc Tukey test confirmed mean HSUVs were significantly different between those reporting severe symptoms and the other categories. CONCLUSIONS: This study measures HSUVs in a Kenyan cohort of HIV patients and confirms that significant differences exist in quality of life between subgroups of these HIV infected patients. The utilities are inline with values measured in studies from other settings. These HSUVs may be used to determine QALYs for use in health economic HIV research in Kenya.

### PIN82

# UTILITY VALUES OF HEPATITIS C PATIENTS IN FRANCE: RESULTS BY LIVER DISEASE STAGE AND TREATMENT OUTCOME

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**OBJECTIVES:** France has a high prevalence of chronic hepatitis C (HCV) and clinical impacts of the disease are well recognized. Despite this, information on utility and health-related quality of life (HRQoL) is limited. While it is generally accepted that HCV patients have reduced HRQoL, delineation of these values by disease stage and treatment outcome is not clear. These differences are important for determining the benefits of treating patients and preventing disease progression. This study assessed utility values of HCV patients in France by disease stage and treatment outcome. **METHODS:** Physicians treating HCV patients in France were recruited to participate in the Hepatitis C Disease Specific Programme®. From October 2012 thru January 2013, physicians completed Patient Record Forms for 10 consecutive patients presenting to their clinic. Information included patient demographics, disease stage, and treatment outcome. Patients completed the

EQ-5D Index and EQ-VAS; these are standardized, preference-based measures of health. Results were reported in descriptive and stratified analyses. Linear regression analyses were performed to determine the independent associations with the EQ-5D. **RESULTS:** There were 297 matched physician and patient response forms. Mean patient age was 50 years and 64% were male. Mean EQ-5D Index was 0.764 (SD=0.283; range=-0.199-1.000). Mean EQ-VAS was 65.85 (SD=21.00; range=5-100). EQ-5D Index and EQ-VAS cores were significantly lower with worsening disease severity. Among patients who had completed treatment, EQ-5D scores were higher for patients who achieved sustained virologic response (SVR) compared to those who did not (EQ-5D Index=0.873 vs. 0.660, p-value=0.0035). Regression models showed higher age and worsening disease severity were significantly associated with lower EQ-5D Index and EQ-VAS scores. **CONCLUSIONS:** In a cross-sectional sample of HCV patients in France, utilities are linearly and significantly associated with disease progression, SVR, and age. This information will be used to understand the benefits of treating patients and preventing disease progression.

#### PIN83

### CHARACTERISTICS, TREATMENT RATES, QUALITY OF LIFE (QOL), AND ACTIVITY IMPAIRMENT AMONG UNITED STATES ADULTS WITH HEPATITIS C—AN ANALYSIS BY BIRTH COHORT

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OBJECTIVES: In 2012, the US Centers for Disease Control and Prevention published recommendations of one-time Hepatitis C virus (HCV) screening for adults born during 1945 through 1965. Evaluating U.S. HCV populations by birth segment may provide insights that could be increasingly relevant to payers and health care providers. METHODS: Unique respondent data from the U.S. National Health and Wellness Survey from 2009-2012 were analyzed. Individuals aged ≥18 years who self-reported a Hepatitis C diagnosis were stratified into 3 cohorts based on birth year: pre-1946, 1946-1964, and post-1964. Characteristics, treatment rates, QOL (SF-12/36), and activity impairment (WPAI) were described. RESULTS: Individuals born between 1946-1964 represented 64.6% of respondents with Hepatitis C (13.0% were older; 22.3% younger). The 1946-1964 cohort had a higher proportion of males than the younger population (65.3% vs. 59.3%, respectively; p<0.05); 64.2% pre-1946 were male. Insured status was higher (p<0.05) in the older cohort (96.5%) versus the 1946-1964 (75.5%) or younger (70.2%) cohort. Reported current HCV treatment use was lower (p<0.05) in the older cohort (3.2%) versus 1946-1964 (10.7%) or post-1964 (21.4%). More than half in each cohort were treatment naïve (64.2% pre-1946; 53.5% 1946-1964; 53.4% post-1964). A lower (p<0.05) proportion (10.3%) of treatment naïve respondents born pre-1946 had a prior doctor recommendation for HCV therapy (versus 21.0% 1946-1964 or 21.1% post-1964). Mean percentage activity impairment was lower (p<0.05) among pre-1946 cohort (34.4%) versus 1946-1964 (45.3%) or post-1964 (45.1%). Mean Mental Summary Scores worsened from oldest to youngest cohorts (pre-1946=50.6; 1946-1964=43.8; post-1964=39.5). Mean Physical Summary Scores were higher for the younger cohort (43.6) versus 1946-1964 (40.2) or pre-1946 (41.2). CONCLUSIONS: In this Hepatitis C population analyzed by birth segment, individuals born 1946-1964 represented the largest segment of the population. Results suggest that differences by birth cohort may exist within this population regarding their characteristics, treatment rates, and patient-reported outcomes.

### PIN84

# SIGNS, SYMPTOMS, AND EXISTING PATIENT REPORTED OUTCOME (PRO) MEASURES IN COMMUNITY-ACQUIRED BACTERIAL PNEUMONIA (CABP): A COMPREHENSIVE LITERATURE REVIEW

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Health (NIH), Bethesda, MD, USA, <sup>6</sup>Bethesda, MD, USA **OBJECTIVES:** No standardized methods to measure outcomes related to commu-

nity-acquired bacterial pneumonia (CABP) have been developed since release of the FDA Patient Reported Outcome (PRO) Guidance. The purpose of this literature review was to identify signs, symptoms, and measurement tools associated with patient experience of CABP. The results will be used to inform the development of a standardized measurement tool for CABP that is consistent with the FDA PRO Guidance. METHODS: A search was conducted using OVID. MEDLINE (1946-present) and EMBASE (1988-2012) were searched using terms related to signs and symptoms of CABP and existing measurement and diagnostic tools. **RESULTS:** The search identified 2158 abstracts. 940 were excluded based on pre-specified criteria. The remaining 1218 articles were scrutinized for eligibility resulting in 39 meeting the inclusion criteria. Thirty-four articles focusing on CABP signs and symptoms were identified in the literature. The most commonly reported symptoms were cough, chest pain, dyspnea, sputum production, and fatigue. The literature revealed that generic PRO instruments and an interviewer-administered measure including 10 CABP symptoms have been used in CABP studies. Four CABP-specific instruments that assess patient-reported symptoms revealed notable methodological limitations and these were developed prior to the FDA PRO Guidance. CONCLUSIONS: There is a paucity of evidence on the most well-defined, reliable, reproducible, and feasible method for measuring efficacy outcomes in CABP trials. Establishing an appropriate PRO endpoint for CABP is essential. Existing CABP-specific instruments were identified, however, they have methodological limitations, and were all developed prior to the FDA PRO Guidance. There is a need to develop a new PRO instrument in accordance with FDA guidance for PRO measures. The instrument should address limitations of current tools and accurately capture data on concepts and outcomes most important to patients.

### PIN85

# DEVELOPMENT OF A NEW PATIENT REPORTED OUTCOME (PRO) MEASURE FOR COMMUNITY-ACQUIRED BACTERIAL PNEUMONIA (CABP)

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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 community-acquired bacterial pneumonia (CABP) patient reported outcome (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 CABP. METHODS: We adhered to the FDA PRO Guidance for instrument development 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, a gap analysis, and interviews with six clinical experts. The most commonly reported symptoms identified by the literature review were cough, chest pain, dyspnea, sputum production, and fatigue. These findings were used to inform the development of a study protocol and interview guide to elicit concepts from CABP patients. Following qualitative analysis of the interview transcripts, the team will draft a PRO instrument based on key concepts identified from CABP 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 will be useful and efficient in developing a new draft PRO measure for CABP, which incorporates published literature and data from qualitative interviews. The team is currently using a similar approach for development of a draft PRO for acute bacterial skin and skin structure infections (ABSSSI).

### PIN86

# DETERMINANTS OF QUALITY OF LIFE IN NEWLY DIAGNOSED HIV INFECTED PATIENTS IN KENYA

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**OBJECTIVES:** Quality of life in HIV infected patients can be determined by a number of factors including severity of disease, social support and coping mechanisms. Common symptoms of HIV can be a key determinant of quality of life. The objective of this study was to examine the influence of symptoms associated with HIV disease on physical and mental of HIV infected patients in Kenya. METHODS: A Kiswahili translated SF-12 survey was administered to newly diagnosed HIV infected patients participating in a randomized, controlled trial in Nairobi, Kenya between April and October 2013. Patients were also asked if they were experiencing common symptoms of HIV (i.e. fatigue, loss of appetite, depression or diarrhea) on a scale including no symptoms, mild, moderate or severe symptoms. SF-12 survey responses were scored to derive a physical component score (PCS) and mental component score (MCS). Linear regression was used to determine which symptoms were significantly associated with each score. RESULTS: 135 respondents were included in the analysis with 7 observations removed due to missing data. Severe fatigue was associated with 15 point (p<0.01) reduction in PCS while severe lack of appetite was associated with an 8.6 point (p<0.01) reduction in PCS compared patients not experiencing these symptoms. Those experiencing severe depression had 12.2 point (p<0.01) lower MCS and those experiencing severe anxiety had 8.4 point (p<0.01) lower MCS compared to those not experiencing these symptoms. CONCLUSIONS: This study is the first to examine which symptoms are associated with lower quality of life outcomes in a cohort of HIV infected patients in Kenya. The drivers of lower physical and mental may be valuable to inform clinical management and program planning efforts in HIV treatment and care.

#### PIN87

# SOCIO-DEMOGRAPHIC CHARACTERISTICS RELATED TO QUALITY OF LIFE IN PATIENTS WITH PULMONARY TUBERCULOSIS IN BAGHDAD, IRAQ

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**OBJECTIVES:** To assess the ability of the socio-demographic characteristics to predict health related quality of life (HRQL) of pulmonary tuberculosis (PTB) patients. **METHODS:** The study was conducted between September 1<sup>st</sup> 2012 and July 31<sup>st</sup> 2013, among consecutive PTB patients treated at Thoracic and Respiratory Disease Specialist Centre in Baghdad, Iraq. Functional Assessment of Chronic Illness Therapy-Tuberculosis (FACIT-TB); a TB-specific HRQL instrument, along with a structured questionnaire to collect data on socio-demographic characteristics were administered. Standard multiple regression analysis was used to assess the ability of the sociodemographic characteristics (age, marital status, education status, household size, breadwinner, financial status and smoking status) to predict HRQL of PTB patients as measured by FACIT-TB total score **RESULTS:** Three hundred and five subjects were recruited over a period of 11 months. Participants ranged in age from 18 to 91 years, 64.6% of them were male and 28.2% were illiterate. Furthermore, 50.8% of the patients in the sample were the major breadwinners for their families. The variables in the model explained 22.9% of the variance in the FACIT-TB total score, F (7,286) = 12.14, P < 0.001. Among the seven variables, education status, being the breadwinner, financial status, and smoking showed a significant bivariate relationship with the FACIT-TB total score. Correlations between these seven variables precluded the condition of

high co-variability, when  $r \ge 0.7$ , for regression analysis. The results of simple linear regression indicated that education status accounted for the greatest variance of the FACIT-TB total score, when the variance explained by all other variables in the model is controlled for (Beta = 0.325, P < 0.001), followed by financial status and smoking status. **CONCLUSIONS:** Our results confirmed that poor educational and financial statuses as well as being smokers are independent determinant of poor HRQL of PTB patients in Iraq.

#### PIN88

### HEALTH RELATED QUALITY OF LIFE OF PEOPLE LIVING WITH HIV/AIDS ATTENDING THE ANTI-RETROVIRAL CLINIC IN THE UNIVERSITY OF BENIN TEACHING HOSPITAL, BENIN CITY Odu GQ<sup>1</sup>, Adeleye OA<sup>2</sup>, Olumese CO<sup>3</sup>

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OBJECTIVES: 1) To assess the overall Quality Of Life (QOL) of people living with HIV/ AIDS (PLWHA); 2) To compare the QOL in the six domains of health; and 3) To determine any association between age, gender, educational level and QOL. METHODS: The study design is a descriptive cross sectional survey and the study population included all PLWHA who have enrolled into the Anti-Retroviral Therapy pharmacy of the University of Benin Teaching Hospital and were currently receiving their Highly Active Antiretroviral Therapy (HAART) for a period of at least six months. A trained interviewer administered a questionnaire that collects data on socio-demographics, clinicals and the items of World Health Organization Quality Of Life (WHOQOL) HIVbref from each participant. Means, standard deviations, and statistical tests for differences were performed. RESULTS: A total of 360 respondents were surveyed. The mean age of the group was 38.58 years. 262 (72.8%) of respondents were females. The overall QOL of respondents was good with a mean score of (3.8 ±0.81). The QOL mean score were highest for the spirituality/religion/personal belief domain (16.03± 0.97) and lowest for the social relationships domain (11.38±1.01). The age of the respondents showed statistically significant differences (P<0.05) in all domains of QOL except in the level of independence domain. Respondents in all the age groups had poor QOL in the social relationships domain. Females had statistically significant higher QOL mean scores in the physical, psychological and spirituality/ religion/ personal beliefs domains (P<0.05) compared to males. The educational level of respondents showed statistically significant differences (P<0.05) in physical, psychological, social relationships and spirituality/ religion/ personal beliefs domains. Respondents with Tertiary education had higher QOL mean scores in the six domains of health. CONCLUSIONS: The study revealed good overall QOL among respondents. The mean QOL scores were highest in the spirituality/religion/personal beliefs domain and lowest in the social relationships.

#### PIN89

THE ASSESSMENT OF PATIENTS' HEALTH RELATED QUALITY OF LIFE DURING THE COURSE OF TUBERCULOSIS TREATMENT IN BAGHDAD, IRAQ

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OBJECTIVES: Quality of life (QoL) has become an accepted outcome measure in clinical research and advances have been made in assessing the impact of many diseases on QoL. The current study aimed to assess health related quality of life (HRQL) of subjects treated for active pulmonary tuberculosis (PTB) during the course of tuberculosis (TB) treatment. METHODS: Consecutive PTB patients treated at Thoracic and Respiratory Disease Specialist Centre in Baghdad, Iraq were administered a validated TB-specific instrument. The Functional Assessment of Chronic Illness Therapy-Tuberculosis (FACIT-TB) total score and its subscales score at onset of treatment, after the intensive phase, and after completion of TB treatment were compared. RESULTS: A total of 136 PTB patients were included in the analysis. After 2 months, physical well-being (PWB), functional well-being (FWB), and FACIT-TB total scores were significantly increased (P < 0.01). However, there were no statistical significant differences in social and economic well-being (SEWB), emotional well-being/living with TB (EWB/TB), and spiritual well-being (SpWB) subscales score. Furthermore, a significant improvement was observed in overall HRQL as indicated by FACIT-TB total score and all subscales except SEWB and SpWB at completion of TB treatment. CONCLUSIONS: The gradual increase in PWB, FWB and EWB/TB subscale scores over the course of TB treatment indicate the positive effect of medical therapy on patients' QoL. However, interventions to offset social distress and dysfunction are important. Therefore individual's perception toward this dimension of QoL should be addressed in future research.

### INFECTION - Health Care Use & Policy Studies

### PIN90

# A MODEL OF CLOSTRIDIUM DIFFICILE INFECTION: DYNAMIC TRANSMISSION BETWEEN HOSPITALS, LONG-TERM CARE FACILITIES AND COMMUNITIES Zowall H, Brewer C, Deutsch A

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**OBJECTIVES:** The transmission of C difficile infection (CDI) has recently changed, resulting in a five-fold increase in the incidence in the general population and an eight-fold increase among the elderly. We developed a simulation model to examine the dynamic relationship between three major subpopulations of CDI transmission: hospitals, long-term care facilities (LTCF), and communities, to evaluate treatment effectiveness and costs. **METHODS:** A stochastic agent-tracking meta-population network model of CDI transmission has been developed. A framework for contagion dynamics between the three subpopulations (hospitals, LTCF and communities) was employed. We identified eight health states: susceptible, gastrointestinal exposure, colonized, diseased, clinically resolved colonized, relapsed, cleared, and deceased. Key parameters include: age-specific incidence rates, disease severity, hospital LOS,