PHN8
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. The PRO will be addressed to the FDA Quality of Life application for IND or NDA approval, 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 condition 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 start data collection for 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 two or three iterative debriefing interviews. Its development will be guided by the PRO-Concepts (7) and refined through cognitive debriefing interviews with patients. The PRO instrument will be pilot tested in a randomized clinical trial (RCT) to determine the feasibility and acceptability of the PRO. The PRO instrument will be applied in clinical trials of antibacterial drugs for CABP and employed. We identified eight health states: susceptible, gastrointestinal exposure, colonized, diseased, clinically resolved colonized, relapsed, cleared, and deceased. The states will be translated into the spirituality/religion/personal belief domain (16.03± 0.97) and lowest in the social relationships 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, and social relationships and spirituality/religion/personal beliefs domains. Respondents with tertile 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 belief domain and lowest in the social relationships.

PHN8
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 health of HIV infected patients in Kenya. METHODS: A Kwantu 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 diaphoresis) on a scale including none, 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 applied to the scores which were significantly associated with each symptom 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) lower MCS compared to males. The educational level of respondents showed statistically significant differences (P<0.05) in physical, psychological, and social relationships and spirituality/religion/personal beliefs domains. Respondents with tertile 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 belief domain and lowest in the social relationships.

PHN8
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 (HRQOL) of subjects treated for active pulmonary tuberculosis (TB) during the course of tuberculosis (TB) treatment. METHODS: Consecutive PTB patients treated at The Pediatric Tuberculosis and HIV/AIDS Centre in Baghdad, Iraq were administered a validated TB-specific instrument. The Functional Assessment of Chronic Illness Therapy—Tuberculosis (FACT-TB) total score and its subscales score at onset of treatment, after the intensive phase of treatment and at completion of treatment were compared. RESULTS: A total of 136 PTB patients were included in the analysis. After 2 months, physical well-being (FWB), functional well-being (FWB), and FACT-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 HRQOL as indicated by FACT-TB total score and all subscales except SEWB and SpWB at completion of TB treatment. CONCLUSIONS: The gradual increase in FWB, 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 imperative. 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
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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 ongoing epidemic among the elderly. We developed the early warning system which was refined through a mathematical model that examined 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 contact dynamics between the three subpopulations (hospitals, LTCF and communities) was employed. We identified eight health states: susceptible, gastrointestinal exposure, hospitalized, diseased, clinically resolved colonized, relapsed, cleared, and deceased. The model used an SIR (Susceptible-Infected-Recovered) framework, and the parameter estimates were based on the most recent data from the United States. Key parameters include age-specific incidence rates, disease severity, hospital LOS,
treatment effectiveness, recurrence rates, mortality rates, and costs. RESULTS: In the general population, 95% of adults were estimated to be asymptomatic carriers of CDI but up to 80% of the elderly in LTCFs are colonized. Over 50% of cases are associated with hospitals and LTCFs. Growing number of cases have onset in the community. 9% of patients over 65 experience severe episodes compared to 4% for those under 65. For elderly patients, their CDI experience almost twice the recurrence rate (38%), compared with younger populations (18% - 22%). The rates for a second recurrence are 38% for those 65+ versus 24% below 65. Combination treatments for recurrent CDI are more recurrent CDI experience. Recurrences were associated with major increases in hospital LOS and in costs. CONCLUSIONS: Our age-specific model allows to project and to quantify the impact of a CDI outbreak in terms of clinical burden and costs. Using a scenario-based approach, each one of the assumptions of the novel approach of duodenal infusion (fecal transplant) are carried out.

PIN91
TWO-DOSE INFLUENZA VACCINATION COVERAGE AMONG UNITED STATES CHILDREN, 2008-2011
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BACKGROUND: Children 6 months through 18 years of age are consistently identified as a high-risk population for influenza infections. Since 2007, the Advisory Committee on Immunization Practices (ACIP) emphasized children aged 6 months to <9 years receive two doses of influenza vaccine in a season. Poor compliance with this two-dose regimen has been described in recent years. However, since ACIP's two-dose recommendation in 2007, periodic vaccination compliance have not been assessed using vaccination based on medical claims. OBJECTIVES: This study examined data from seasons 2008-2011 to examine two-dose compliance for children aged 19-35 months. This analysis tests for significant demographic and socioeconomic differences in one- and two-dose influenza vaccinations. METHODS: Seasonal influenza vaccinations of children were estimated from the National Immunization Survey (NIS). The analysis results were nationally representative by weighting the study population according to census-based weights for each state. Results: Two-dose vaccination rates were significantly higher in the one doses and two doses of influenza vaccine during September 1 through December 31 of the season. For each season, the proportion of children with partial and full influenza vaccinations were calculated. Multivariate regressions modeled the effect of maternal age, race, education, and income on two-dose vaccination. RESULTS: For all four seasons, adjusted one dose influenza vaccination was significantly lower among children 24-35 months compared to children 19-23 months (range from 7.8-44.5%, p<0.05). Furthermore, one- and two-dose influenza vaccination was lowest among children living below the poverty level compared to children living above the poverty level (range from 9.4-53.7%, p<0.05). CONCLUSIONS: Policies to improve one- and two-dose influenza vaccination rates should target children living below the poverty level. Also efforts to improve one-dose vaccination rates among older infants and children should continue. Further studies are needed to determine the reasons for initiating influenza vaccinations among children less than 24 months of age.

PIN92
UNWARRED USAGE OF BROAD-SPECTRUM ANTIBIOTICS
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OBJECTIVES: This study aimed to evaluate if high antibiotic consumption is explained by inappropriate prescribing, given current practice guidelines. This is assessed through examining the proportion of Upper Respiratory Tract Infection (URTI) treated by GPs with Co-amoxiclav, and Urinary Tract Infection (UTI) treated with fluoroquinolones, comparing across population subgroups for differential treatment patterns. METHODS: A retrospective cohort study including all CYPs from all Clalit Health Services physicians from 4300 clinical practices during 2011. Rule-based algorithms were used to classify primary care visits into discrete URTI and UTI events and link these with AB prescriptions and dispensing. Infectious events and antibiotic prescription rates were calculated. Differences in distributions across districts and population subgroups were then tested with Chi-square analysis; for prescribing ratios for UTI the result was nationally representative by weighting the study population according to census-based weights for each state. Results: Two-dose vaccination rates were significantly lower among children 24-35 months compared to children 19-23 months (range from 7.8-44.5%, p<0.05). Furthermore, one- and two-dose influenza vaccination was lowest among children living below the poverty level compared to children living above the poverty level (range from 9.4-53.7%, p<0.05). CONCLUSIONS: Policies to improve one- and two-dose influenza vaccination rates should target children living below the poverty level. Also efforts to improve one-dose vaccination rates among older infants and children should continue. Further studies are needed to determine the reasons for initiating influenza vaccinations among children less than 24 months of age.

PIN93
EVALUATION OF INFECTABLE FOSFOXYCINE USE IN A MEDICAL CENTER
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OBJECTIVES: To evaluate efficacy, safety (concerning hypernatremia), and usage of UFO® in a medical center METHODS: A retrospective medical record review was conducted for patients who is treated with UFO® in Wan-fang hospital during 2012/5/1 to 7/8. Patients with cancers were excluded. Patients with suspected or diagnosed infections and more than one dose of UFO® were included. For hypernatremia analysis, only 1% of adults with serum sodium level and no hypernatremia events prior treatment use UFO®. Microsoft excel and student t-test were used for analyzing data and p-values RESULTS: Thirty-eight patients were included and the common infections diagnosed were UTI (N=13); cellulitis (N=5) and sepsis (N=9). The common pathogens were Staphylococcus (19%) and Pseudomonas species (21%). Twenty-one percent of cases used UFO® as empirical or first-line therapy. Combination therapies with cephalosporins (26%) or penicillins (24%) were more frequently utilized. Of cephalosporin combination therapies 18% were 3rd generation cephalosporins and 76% were 1st generation. Combination therapies with clindamycin were 3rd cephalosporins (75%). In penicillins combination therapy, the most combined antibiotics is oxacillin (40%). Mean treatment duration of UFO is 9.4 days. In early-cohort, there were 71% cases using common dose of UFO®, 8.12 g/day, and 29% using low dose, 4.6 g/day. In patients with UFO®, 74% had negative outcomes (defined as patient died, hypotension events and changed to other antibiotics) and 26% had positive outcomes (defined as patients discharged, disease improved and no recurrent fever). Most patients developed hypernatremia (serum sodium level >145 mEq/L) after using UFO® for 4-6 days, patients with creatinine clearance above 50 ml/min did not develop hypernatremia. CONCLUSIONS: The serum sodium level did not significantly change between patients starting UFO®. For patients with higher baseline serum sodium level and renal dysfunction, serum level should be monitored closely while using UFO®. Using UFO® as adjunct for first line or empiric treatments is lack of evidence. Further antibiotic prescribing regulations should be implemented concerning prescribing UFO®.

PIN94
ANTIMALARIAL DRUGS USE PATTERN IN RETAIL OUTLETS IN ENUGU URBAN SOUTH EAST NIGERIA; IMPLICATION FOR MALARIAM TREATMENT POLICY
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OBJECTIVES: Drug retail outlets constitute a major source of malaria treatment in developing countries requiring regular and accurate information for enhancing strategies for improving the use of Artemisinin-based Combination Therapy (ACTs) and self-medication, sales and prescribing of antimalarial drugs. The aim of the study was to describe current utilization of antimalarial drugs in private retail outlets to assess the current state of compliance to policy. METHODS: A prospective cross-sectional survey of randomly selected drugs retail outlets in Enugu urban South East Nigria was conducted between May 13, 2013, to determine the types, range, prices and sales pattern of antimalarial drugs as well as concomitant medications, from pharmacies and patent medicine outlets. Data was collected and analysed for antimalarial drugs demanded for and sold by self-medication, treatment by retail outlets and prescriptions from hospitals. RESULTS: With a total of 1,321 dispensed antimalarial drugs, ACTs accounted for 72.7% while monotherapy was 27.3%. AMFm drugs contributed 32.7% (n = 314) of ACTs. 46.5% (n = 614) of the drugs were dispensed from self-treatment by patients. Treatment by retail outlets accounted for 35.8% (n = 473) while 17.7% of the drugs were dispensed from hospital prescriptions. The median cost of the ACTs, at $3.23 is about three times the median cost of monotherapy ($0.97). Total cost of treatment, including concomitant medications and retail outlets, averaged $3.48 (±$0.30). The most used ACT, at 69.3% (n = 666). Self-medication accounted for the highest number of monotherapy at 82%. CONCLUSIONS: The use of ACTs as predominant antimalarial drugs of choice has more widespread in the retail outlets, with significant contributions from AMFm drugs. This portends positive implications on the implementation of antimalarial drugs policy. However costs of policy recommended drugs remain higher than intended and the use of monotherapy particularly through self-medication is significant suggests measures to directly target consumers for improved use of antimalarial drugs.

PIN95
REAL WORLD DRUG UTILIZATION OF HIV THERAPIES IN CANADA
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OBJECTIVES: To describe current utilization of HIV drugs in Canada. METHODS: Longitudinal pharmacy retail data were obtained from most Canadian provinces. Eligible patients received their first HIV drug prescription during the selection period, and consistently filled subsequent prescriptions at the same pharmacy. Selection periods included an early cohort (initiating therapy January 2008 to July 2009) and a late cohort (initialing therapy August 2010 to February 2012). The observation period was 43 months for the early cohort and 12 months for the late cohort. RESULTS: 905 patients in the early cohort and 1,411 patients in the late cohort were analysed. Single-tablet regimens were the initial therapy for 32% of patients (early cohort) and 33% (late cohort). The most commonly used regimen was a backbone + protease inhibitor (PI): 45% of total days on therapy (DOT) for early cohort, 39% for late. Darunavir was increasingly chosen as the initial PI (3% for patients old in adults prior to October 2009, 73% in early cohort) Whence plus integrase inhibitor (II) increased from 2% DOT (early cohort) to 11% in the late cohort. The majority of II patients were treatment-naive (71%) in the late cohort, despite funding limitation to treatment-experienced patients in most jurisdictions. After 3 years of follow-up in the early cohort, 45% were still on their first therapy. For early-cohort patients who switched to a second therapy, 33% did so within 3 months. Subsequent lines of therapy phased in more gradually in both cohorts. Darunavir and II use increased in later lines of therapy for both cohorts, but particularly for the late cohort. CONCLUSIONS: This research documented changing patterns for HIV drug use in Canada, with increasing use of darunavir and II over time (irrespective of funding restrictions) and frequent early therapy switches suggestive of tolerability issues.

PIN96
PHARMACIST VACCINATION PROGRAMS FOR COMMON INFECTION DISEASES: A SYSTEMATIC REVIEW OF THE LITERATURE ON THIS EMERGING MODEL OF CARE
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