

for PILLAR, QUEST-1 and QUEST-2, respectively. Having VR only had a minor positive impact, and was not statistically significant for most endpoints/trials. Female patients had significantly lower values for EQ-5D-VI, and numerically lower values for all other QoL-measures. **CONCLUSIONS:** These findings suggest that short-term QoL impairment due to HCV-therapy is driven more by the longer duration of PR-therapy than by not obtaining VR.

PIN88

EVALUATION OF PATIENT REPORTED OUTCOMES (PRO) IN OBESE PATIENTS IN AN ACUTE BACTERIAL SKIN AND SKIN STRUCTURE INFECTIONS (ABSSSI) PHASE 3 TRIAL

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OBJECTIVES: Limited Patient Reported Outcomes (PRO) data exists for obese patients with ABSSSI. This study sought to evaluate health-related quality of life (HRQL) in obese patients (BMI >30) with a positive clinical response (cured, complete resolution of all baseline signs and symptoms and improved, some symptoms remain, but no further antibiotics are necessary) patients during an ABSSSI trial. **METHODS:** Adult patients diagnosed with ABSSSI were enrolled in a prospective phase 3, randomized, double-blind study to evaluate antibiotic treatment. An analysis of PRO was conducted to understand the difference between cured obese patients (COP) and improved obese patients (IOP) with respect to patient reported HRQL at End of Treatment (EOT) and late follow up (LFU, study day 21-28). HRQL was measured by Extremity Soft Tissue Infection (ESTI) Score[i], a 20 question survey using a 5-point Likert scale (5 equals highest degree of importance/impairment to the patients) measured symptoms, daily functioning, emotional functioning, and social interactions. **RESULTS:** Obese patients compromised 29% of the study (660 patients, 589 included in analysis, 193 obese). IOP at EOT were less likely to proceed to cure than non-obese patients (26%, 16%) at LFU. The ESTI Score was higher at LFU in IOP than COP (46.4, 26.3, p=0.029). At LFU, IOP were more likely than COP to report having continued difficulty performing a job (29.0%, 9.6%, p=0.008) and earning an income (32.3%, 14.0%, p=0.032). **CONCLUSIONS:** IOP had more difficulty than COP with HRQL measures at LFU. IOP at EOT may have persistent HRQL issues that require further utilization of health care resources. Additional research is needed to determine the potential economic impact of this data. [i] Storck et al, Development of a Health-Related Quality of Life Questionnaire (HRQL) for patients with Extremity Soft Tissue Infections (ESTI), BMC Infectious Diseases 2006, 6:148

INFECTION – HEALTH CARE USE & POLICY STUDIES

PIN90

WHAT COST-EFFECTIVENESS DEMANDS AND MARKET ACCESS CHALLENGES WILL NOVEL ANTIBIOTICS FOR MDR GNPS APPROVED VIA THE STREAMLINED LPAD PATHWAY FACE?

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OBJECTIVES: The FDA plans to institute a novel regulatory pathway to expedite approval of high-need antibiotics, including those for multidrug-resistant gram-negative pathogens (MDR GNPs). Under this Limited Population Antibacterial Drugs (LPAD) approval mechanism, submission of clinical efficacy data from relatively small patient populations with high unmet need would be permitted. However, drugs approved via this pathway will have limited safety data and likely carry significant price premiums over standard-of-care. This study assessed potential market access hurdles for LPAD pathway-approved agents providing improvements in clinical cure rates, mortality rates and/or length of hospital/ICU stay for infections caused by MDR GNPs. **METHODS:** A total of 30 U.S. hospital pharmacy directors (PDs) and 141 U.S. hospital-based infectious disease (ID) and non-ID specialists were surveyed regarding their views on reimbursement and likely uptake of LPAD pathway-approved drugs, assuming these agents cost ≥\$15,000/treatment course. **RESULTS:** Among surveyed physicians and PDs, <25% and <50%, respectively, were aware of the proposed LPAD pathway. Based on a short explanation, 87% of surveyed PDs would include LPAD pathway-approved agents. Among these PDs, 96% would implement prescribing restrictions on top of those included in the product label, although only 27% indicated they would restrict these agents to last-line therapy. Among physician respondents, 84% reported that they would use formulary-included LPAD pathway-approved agents providing improvements over standard-of-care, with agents demonstrating lower mortality rates relative to comparators more likely to see uptake. Furthermore, surveyed physicians who would use an LPAD pathway-approved agent are most likely to do so for the same infections and drug-resistant pathogens evaluated during the LPAD process. **CONCLUSIONS:** Physicians and payers are receptive to LPAD pathway-approved agents despite potential for safety risks and high price premiums. However, prescribing restrictions and price limitations are certain among payers, while primary prescribing drivers are improvements in clinical cure and mortality rates.

PIN91

TACKLING THE TARIFF FOR SOFOSBUVIR IN HCV – INDISPENSABLE INNOVATION VERSUS BUDGET-BUSTING POTENTIAL

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OBJECTIVES: Sofosbuvir is an indispensable innovation in hepatitis C virus (HCV) treatment. However, it has the potential to bust tight EU5 healthcare budgets. This study examined early uptake of sofosbuvir, and explored evolving mechanisms in the EU5 used to manage its high cost burden. **METHODS:** In September

2014, 251 EU5 gastroenterologists were surveyed regarding their perceptions and uptake of sofosbuvir. Additionally, 15 reimbursement-influencing payers were interviewed. **RESULTS:** At the time of surveying, approximately one-quarter of treatment-naïve cirrhotic and non-cirrhotic HCV-1 patients in France and Germany (where sofosbuvir was then widely available) were on sofosbuvir-based regimens, alongside a slightly lower percentage of treatment-experienced such patients, and those with HCV-2/3. This speedy uptake reflects sofosbuvir's high efficacy, which previously encouraged physician familiarity via early-access schemes. However, interviewed payers insist sustained uptake for large HCV patient populations is not viable due to cost, stressing that sofosbuvir be reserved for patients with more advanced liver fibrosis or cirrhosis. These payers add that measures such as those in France involving treatment caps and a proposal to tax manufacturers when caps are exceeded exemplify the innovative cost-containment strategies necessary to manage the burden of sofosbuvir. **CONCLUSIONS:** The EU5 healthcare authorities have adapted to include sofosbuvir within their budgets. As indicated by our primary research, and confirmed since, creative cost-containment is the order of the day across the EU5 for sofosbuvir, with payers forced to reexamine their traditional P&R schemes and reevaluate how they define cost-effectiveness. However, such aggressive cost-containment measures have consequences, as demonstrated when thousands took to the streets in Spain in January, 2015, protesting for fairer allocation of HCV treatment. Manufacturers of such premium-priced agents may learn from Janssen's negotiations on simeprevir, which offered trade-offs using telaprevir, as careful balancing of long-range price expectations and reimbursement and uptake potential will be required going forward.

PIN92

PREDICTORS OF VACCINATION AMONG MOTHERS OF INFANTS IN AN APPALACHIAN COMMUNITY

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OBJECTIVES: Misbeliefs regarding vaccine safety and strict immunization exemption policy have led to anti-vaccination sentiments in West Virginia which might affect the vaccination of children. This study assessed the levels of worry and hassles towards vaccination and their association with up-to-date vaccination status and future intentions to follow recommended vaccinations. **METHODS:** A cross-sectional online survey was conducted among 176 mothers of children under 3 years old in West Virginia who could read and understand English. Worry and hassles scales were developed, and mean scale scores were used to measure worry and hassles to vaccination. Chi-square, t-tests and logistic regression analyses were conducted. **RESULTS:** Participants were predominantly white (94.3%), non-Hispanic Appalachians (98.3%), with annual household income >\$50,000 (72.6%) and health insurance (92.0%). Approximately 3.8% of participants' children had not received any vaccination. Further, many participants' children (14.2%) were not up to date with recommended vaccinations, and 13.6% of mothers reported no future intention to follow recommended vaccination. Chi-square analyses indicated that being a full time worker and self or family as child caretaker were associated with being up-to-date with recommended vaccination and future intention to follow recommended vaccinations (p's<0.05). After adjusting for demographic variables, hassle scale was a significant predictor of up-to-date vaccination status (AOR = 0.12) and future intention to follow recommended vaccinations (AOR = 0.17). Similarly, worry scale was a significant predictor of up-to-date vaccination status (AOR = 0.24) and future intention to follow recommended vaccinations (AOR = 0.27). **CONCLUSIONS:** Despite having higher socio-economic status, many study participants' children exhibited low immunization coverage, and had no future intention to follow recommended vaccination. The study highlights the need to increase awareness about safety of vaccine contents and its efficacy in preventing still endemic diseases like measles.

PIN93

ENCOURAGING ORPHAN DESIGNATION FOR NEW EBOLA TREATMENTS – COULD THIS DO MORE HARM THAN GOOD?

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OBJECTIVES: The current Ebola Virus outbreak has been responsible for over 5,000 deaths. This disease, with no effective treatment has a fatality rate around 50%. In October, the EMA publically encouraged developers of Ebola treatments and vaccines to apply for orphan designation and FDA have already granted orphan designation for ZMapp. This research aimed to evaluate the appropriateness of utilising the orphan designation as an incentive in these circumstances or whether it could actually prove counter-productive. **METHODS:** A detailed review of EMA and FDA orphan designation procedures and the historical context in which they were developed were undertaken, alongside a review of the current Ebola treatment and vaccinations pipeline. **RESULTS:** EMA and FDA orphan drug legislation comprise a set of incentives for pharmaceutical companies to develop and market medicinal products to treat rare diseases, which were being neglected by drug developers due to the poor economic potential of such diseases. These include scientific advice, fee reductions, access to grants and, most importantly, market exclusivity (7 and 10 years for the FDA and EMA respectively). However, in contrast to most orphan diseases with a lack of pipeline candidates, there are already 7 pipeline drugs for Ebola (brincidofovir, favipiravir, ZMapp, TKM-Ebola, AVI-4753, hyperimmune horse sera, and BCX4430) and 2 vaccines (ChAd 3, VSV-EBOV). **CONCLUSIONS:** Granting orphan status to pipeline Ebola candidates means that the first-to-market will attain market exclusivity in that jurisdiction, such that any later candidates, even if clearly more effective, will be prevented from launching until the data exclusivity period has expired. This could not only potentially deny Ebola patients in US and Europe access to the most efficacious treatments but could also disincentivize companies developing potentially more effective therapies. We recommend that the market exclusivity aspect of the orphan drug designation should be waived for candidate Ebola treatments.

PIN94

PROJECTING CHANGES IN TOTAL DAYS OF THERAPY (DOT) IN PATIENTS HOSPITALIZED FOR ACUTE BACTERIAL SKIN AND SKIN STRUCTURE INFECTION (ABSSSI)

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OBJECTIVES: Most patients admitted to hospital for ABSSSI complete antibacterial treatment following discharge. This study examined the potential impact of tedizolid versus linezolid on antibacterial DOT, based on real-world inpatient use of linezolid in patients hospitalized for ABSSSI, and two pivotal phase 3 studies of patients with ABSSSI that demonstrated comparable efficacy and safety between a 6-day course of tedizolid (once daily) and a 10-day course of linezolid (twice daily). **METHODS:** Duration of in-hospital therapy for ABSSSI was based on analyses of an electronic database containing comprehensive clinical records on ~38 million inpatient admissions from >100 contributing general, acute-care US hospitals. All patients aged ≥18 years admitted during 2011 with a principal diagnosis consistent with ABSSSI who received ≤10 inpatient DOT with linezolid were identified. Total DOT for linezolid and tedizolid (i.e., inpatient + outpatient) were assumed to be 10 and 6 days, respectively. Patients receiving <10 days of in-hospital therapy with linezolid were assumed to receive the remainder as outpatients; corresponding values for tedizolid were estimated assuming a 6-day DOT. Patients receiving ≤6 inpatient DOT with linezolid were modeled to receive the same number of inpatient days of tedizolid; patients with >6 days of in-hospital therapy with linezolid were modeled as completing a course of tedizolid in hospital. **RESULTS:** Among the 3,734 ABSSSI patients who met study entry criteria, 153 (4%) received linezolid. Mean inpatient DOT was 3.7 days; consequently, expected duration of outpatient therapy was 6.3 days. Use of tedizolid instead of linezolid was estimated to reduce average inpatient DOT by 0.2 days and outpatient DOT by 3.8 days. **CONCLUSIONS:** Based on real-world use of linezolid for ABSSSI and findings from tedizolid pivotal trials, use of tedizolid in hospitalized patients with ABSSSI may substantially reduce mean total DOT compared with linezolid, primarily on an outpatient basis.

PIN95

THE STUDY OF HEALTHCARE UTILIZATION AMONG HIV-INFECTED POPULATION: AN ANALYSIS OF THE MEDICAL EXPENDITURE PANEL SURVEY

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OBJECTIVES: The objective of this study is to examine the decisive factors associated with the use of antiretroviral therapy (ART) among a Human Immunodeficiency Virus (HIV) infected population utilizing Andersen's Behavioral Model. **METHODS:** This study is a retrospective data analysis of individuals infected with HIV in panels 14 to 16 of the Medical Expenditure Panel Survey in years 2009 to 2012. A logistic regression analysis was conducted to evaluate the association between ART usage and the factors nested in Andersen's Behavioral Model, which includes predisposing, enabling and need components. **RESULTS:** For predisposing characteristics, patients taking ART were slightly older (age: 46.14±0.98) than patients not taking ART (age: 43.34±0.91). Being a male and African American was highly associated with the use of ART, as compared to being a female or white (P value: <0.0001; 0.00119). People living in the Northeast were more likely to take ART than individuals living in other regions in the United States (P value: 0.0032). Among enabling components, difficulty in receiving medical care and having non-public insurance coverage were associated with not taking ART (P value: 0.0851; 0.0013). Having private insurance coverage was positively correlated with nonuse of ART (odds ratio: 0.190; 95% CI: 0.047-0.779; P value: 0.00003). However, family income was not associated with the use of ART among the HIV-infected population. With respect to the health status in the need component, using ART was associated with reported improved health status in general, compared with those not using ART; however, the association was not statistically significant. **CONCLUSIONS:** Predisposing and enabling factors were found to be significantly associated with ART usage; however, need factors were not found to be significant. More effort is needed to improve the healthcare utilization inequality among minority populations.

PIN96

ANALYSIS OF PURCHASE OF ANTIBACTERIAL DRUGS WITHIN THE GUARANTEED VOLUME OF FREE MEDICAL AID IN THE REPUBLIC OF KAZAKHSTAN

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OBJECTIVES: Study of drug coverage in the Republic of Kazakhstan as one of the most important components of medical care and an important measure of social support of citizens. **METHODS:** The List of drugs for purchase in 2014 by Single Distributor "SK-Pharmacy" was analyzed. The percentage of antimicrobial drugs for certain groups of antibiotics and synthetic antibacterial agents of different chemical structure was studied. The analysis of drugs from domestic and foreign drug manufacturers was performed. **RESULTS:** Among all antibacterial drugs a big part consisted from antibiotics - 71%, synthetic chemotherapeutic drugs amounted to 29%. Of the total number of antibiotics the proportion of beta-lactam antibiotics amounted to 61,36%, macrolides and azalides - to 15,91%, aminoglycoside - to 6,82%, tetracyclines and glycopeptides to 2,27%, antibiotics from other groups - to 11,36%. Among beta-lactam antibiotics a big part consisted from semisynthetic penicillins with wide spectrum - 29.6%, mainly amoxicillin and its "secured forms". Cephalosporins consisted 51.85% of the total number of antibiotics, and were bought mainly drugs of 3rd generation. Carbapenems amounted to 11.11%, monobactams were not bought. From the group of aminoglycosides following drugs were bought: amikacin, kanamycin, streptomycin, gentamicin. Synthetic antibacterial drugs of different chemical structures were represented mainly by fluoroquinolones (66,67%): moxifloxacin, ofloxacin, norfloxacin, pefloxacin, ciprofloxacin. The half (50%) of procured medicines are products of domestic pharmaceutical companies. The main

importers of antimicrobial medicines are: India (25,8%), Russia (16%), China (9.7%), Ukraine (9.7%), France (6.5%), and manufacturers from other countries consisted - 3.2%. **CONCLUSIONS:** A large part of the drugs purchased within the guaranteed volume of free medical aid in the Republic of Kazakhstan consist from basic beta-lactam antibiotics. In the list were presented the outdated drugs (gentamicin), which is not recommended for use. Predominant drug are drugs from domestic pharmaceutical companies.

PIN97

EVALUATION OF ECONOMIC IMPACT OF TUBERCULOSIS CONTROL IN MALAYSIA USING DYNAMIC TRANSMISSION MODEL

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OBJECTIVES: Despite all the control efforts, Malaysia has yet to effectively reduce the incidence rate of tuberculosis (TB). TB is not only highly contagious but also causing a significant economic burden in the order of USD16 million/year as reported by World Health Organization (WHO) in 2014. This study aimed to evaluate the economic impact of TB control in Malaysia using a dynamic transmission model. **METHODS:** Prior to model building, a disease burden study was performed in the state of Selangor representing 18% of the Malaysian population. Identified patient medical records from public hospitals and clinics were randomly selected for study. All direct costs of TB management were captured for analysis. A dynamic transmission model was built to project future disease and economic burdens over a 10-year period. The study was performed from a government perspective. All costs are expressed as USD median (interquartile range). A 3% discount rate was used for projections. **RESULTS:** A total of 436 successfully treated cases were included in this study. Of these, 195 (44.7%) cases required hospitalisation during treatment period. USD616 (487-763)/patient was used for non-hospitalisation cases compared to USD1,848 (1,164-3,284)/patient for those requiring hospitalisation representing a 3-fold increase. 119 incomplete treatment cases were selected for comparison. USD337 (193-902)/patient was used for these incomplete cases. Our model suggests that the total TB cases will increase by 65% in 10 years' time. Using the baseline TB population in 2011, an estimated total of USD22.9 million (15.5-37.6 million)/year was used for direct medical costs. Based on a local estimated 6.9% incompleteness treatment rate, an extra USD5.3 million (3.5-8.6 million)/year (22.9% increase) would be required by 2021. **CONCLUSIONS:** Our findings are consistent with WHO report. In Malaysia, hospitalisation appears to be the major cost driver for TB patients receiving treatment. Healthcare strategies such as early detection, increased awareness of TB and improved compliance may potentially reduce TB health budget.

PIN98

COST OF ADMINISTRATION OF A SINGLE DOSE OF ROTAVIRUS VACCINE IN CANADA

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OBJECTIVES: Differences in vaccine schedules may result in additional costs beyond the differences due to pricing variation between two products. There are two oral rotavirus vaccines approved for use in Canada; one vaccine is approved as a two-dose schedule while the other is approved as a three-dose schedule. The objective of this study is to explore the cost of administration of a single dose of either rotavirus vaccine in each Canadian province as well as for the country overall. **METHODS:** Two extremes were considered: Every dose administered by a physician either (i) requires a visit solely for that purpose (cost = administration + visit), or (ii) occurs as part of a regular visit (cost = administration only). All costs were derived from the relevant fee for service agreement of each province and territory in Canada. Assumptions included 90% vaccine coverage across each province's 2013 birth cohort and no significant changes since 2007 to the ratio of physicians to public health nurses (PHN) administering vaccines in each province. Delivery by PHN was assumed to incur no cost. **RESULTS:** Scenarios (i) and (ii) above yielded administration costs of \$6.4M and \$600k, respectively, per vaccinated Canadian cohort. Provinces with high percentage of physician delivery accounted for the majority of this cost in both Scenario (i) (NL: \$128.6k, NB: \$279.3k, NS: \$312.1k, QC: \$832.5k, ON: \$3.8M, MB: \$386.3k, BC: \$544.1k) and Scenario (ii) (NB: \$60.4k, NS: \$114.2k, QC: \$258.8k, MB: \$85.1k, BC: \$72.8k). **CONCLUSIONS:** Administration fees can be a costly factor in universal immunization schedules. As such, it is essential to account for the differences in approved administration schedule when evaluating vaccines during the assessment of publically funded program implementation.

PIN99

RESOURCE UTILIZATION AND COSTS ASSOCIATED WITH MULTI-DRUG RESISTANT ACINETOBACTER BAUMANNII: A SYSTEMATIC REVIEW OF THE LITERATURE

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OBJECTIVES: Infections caused by multi-drug resistant (MDR) Acinetobacter baumannii (AB) are an increasing global problem. Several studies examining outcomes and resource utilization associated with MDRAB have been conducted; however, findings are inconsistent. The purpose of this research was to identify and characterize available research concerning resource utilization associated with MDRAB, assess strengths and weaknesses of the available research and identify future research priorities. **METHODS:** A systematic review of the literature was conducted using MEDLINE and electronically available conference abstracts. Articles were considered relevant if they reported resource utilization or cost information comparing MDRAB patients to controls. Controls could include susceptible AB, other organisms, or uninfected patients. **RESULTS:** Initial searches of the literature returned 204 potential citations for inclusion. Title and abstract review excluded 171 articles, and full-text review excluded 20 additional articles, leaving a total of 13 articles eligible for data abstraction and review. Length of stay (LOS) was reported in nine