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 teleprevir, 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.