WORK AND HEALTH CONDITIONS DURING PREGNANCY IN WOMEN OF THE MEXICAN SOCIAL SECURITY INSTITUTE
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OBJECTIVES: To compare socio-demographic, reproductive and prenatal attention conditions among women who perform work outside the home (as opposed to housework); in the case of those going out to work, to describe the conditions of such work; and finally to show whether health-related differences exist that correlate with working situation (at home vs. outside the home). METHODS: Transversal study (pilot) carried out in a family medicine unit of the Mexican Social Security Institute (IMSS) between April and July 2003, during which period interviews were effected with 537 pregnant women engaged in either paid work, housework, or both, and registered with the Family Medicine external consultation services. A questionnaire was applied in order to establish demographic and reproductive characteristics, as well as variables related with prenatal control and the existence of symptoms before and after pregnancy; characteristics, as well as variables related with prenatal control and the existence of symptoms before and after pregnancy; finally, to provide information on characteristics of both domestic and extra-domestic work. RESULTS: In total, 36.5% were women with paid work (A), the rest having exclusively domestic work (63.5%) (B). Of those with extra-domestic work (A), 78.6% had clerical or similar jobs, mainly in service activities (45%), and 18.9% were industrial workers. Stress at work is present in 74% of cases interviewed. On analyzing the effect of work on women’s health conditions, it was observed that women who do not go out to work show a higher risk of muscular-skeletal alterations than those who do so (RM: 4.3 IC95% 1.6–11.4). The presence of genitourinary symptoms is greater for those who report muscular-skeletal alterations than those who do so (RM: 4.3 IC95% 1.6–11.4). The presence of genitourinary symptoms is greater for those who do not go out to work. CONCLUSIONS: The monitoring of domestic work is important in view of the need for attention to the conditions in which such work is carried out; it also helps identify potential risks for health.

QUALITY OF LIFE AND HEALTH BEHAVIORS OF VENEZUELAN PHARMACY STUDENTS
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OBJECTIVES: The purpose of this study was to describe health-related quality of life (HRQL) of Venezuelan pharmacy students and to explore the association among quality of life, health behaviors, and demographics. METHODS: A random sample 171 of pharmacy students, ranging in age from 18 to 35 years were surveyed using a written questionnaire. HRQL was determined using the Medical Outcome Study Short Form 36 (MOS SF-36). The associations among HRQL, demographics, and health behaviors were examined using both bivariate and multivariate models. RESULTS: The sample consisted of 127 females and 44 males. The sample had a mean age of 22.3 years. As expected the sample was healthy; only 11 subjects (6.47%) evaluated their health as poor and 30 subjects (17.5%) reported to suffer from an illness. Forty subjects (23.4%) reported current medication use. The prevalence of alcohol consumption during the previous month was 65.8% and for smoking it was 15.5%. One third of the sample reported no exercising during the previous month. Multiple regression analyses were used to model HRQL score as a function of age, sex, income, illness, lack of regular exercise, alcohol consumption, and smoking. The regression model explained approximately 20% of the variance in HRQL. Controlling for other variables in the model, low income, illness, and smoking had a significant negative impact on HRQL. Lack of regular exercise and age were not associated with HRQL. Controlling for other variables male students had significantly higher scores in HRQL than female students. Alcohol consumption was associated with HRQL in bivariate but not in multivariate models. CONCLUSIONS: The overall quality of life of pharmacy students in Venezuela is good. This exploratory study demonstrates sex differences in perceived quality of life of college students. Quality of life is associated to certain predictors of future health status, including health behaviors such as smoking.

ASSESSING THE PSYCHOMETRIC PROPERTIES OF THE PSYCHOSOCIAL SUBSCALE OF THE MENOPAUSE-SPECIFIC QUALIPAUSE INVENTORY (QPI) WITH ITEM RESPONSE THEORY
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OBJECTIVES: To analyse the 8-item, 5-level psychosocial subscale of the QualiPause Inventory (QPI)—a recently developed, condition-specific health-related quality of life (HRQoL) instrument for peri- and post-menopausal women—with item response theory (IRT). METHODS: Data: postal survey of 785 women aged 45–65 years, identified from Sheffield general practice lists. Techniques: “Kernel-smoothing-technique” (KST)—in order to investigate the item-response and test-information curves—followed by the estimation of Muraki’s general partial credit model (GPCM). Software: Testgraph and Parscale, respectively. RESULTS: The non-parametric KST showed that the scale provides most information for above-average psychosocial distress, with a peak for subjects with a trait of approximately 1.5 standard deviations (SDs) above the sample average. Review of category response curves suggests that, in order to optimize model fit: for items 2–5 and 8, response categories 2 (hardly bothered) and 3 (moderately bothered) should be collapsed; for items 1, 6, and 7, categories 2 to 4 (considerably bothered) could be collapsed. The GPCM yielded step parameters lying in the range of ~0.818 and 2.082 with respect to the standard normal distribution and therefore covers the medium-to-severe trait spectrum. Item 2 (feeling tense) has got the highest slope parameter (2.1), and item 1 (difficulty sleeping) has got the lowest (0.573). Overall, items 2–5 contribute most information. CONCLUSIONS: The psychosocial subscale of the QPI is particularly valuable to assess HRQoL of peri- and post-menopausal women with moderate to severe symptoms of emotional distress. The results may be used for further developing of the QPI. In particular, items 1 and 8 may be candidates for deletion as they add little extra information. This type of analysis facilitates the interpretation of patient-reported outcomes and may, therefore, lead to a higher acceptance of such instruments by decision-makers.

ASSESSING THE EXTERNAL VALIDITY OF DROTRECOGIN ALFA (ACTIVATED) CLINICAL TRIALS IN AN OBSERVATIONAL STUDY USING PROPENSITY SCORE MATCHING TO REDUCE RECRUITMENT BIAS
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OBJECTIVE: To match patients from observational studies to patients from randomized controlled trials, we must take into account the characteristics of both of these populations. The aim of this study was to investigate the possible external validity of a drug (Drotrecogin Alfa-activated) in an observational study (OS) using an appropriate matching tool. METHODS: The Groupe d’Etudes et de Recherche de l’Héparine (GERH) network carried out a prospective, multi-centre, observational, longitudinal study of patients aged 45–65 years, identified from Sheffield general practice lists. The primary endpoint was survival. In total, 1,074 patients were included from 33 centres and followed up for 12 weeks. The OS results may be used for further developing of the QPI. In particular, items 1 and 8 may be candidates for deletion as they add little extra information. This type of analysis facilitates the interpretation of patient-reported outcomes and may, therefore, lead to a higher acceptance of such instruments by decision-makers.

ASSOCIATION BETWEEN PREGNANCY OUTCOME AND PREGNANCY-RELATED QUALITY OF LIFE: MATCHING TO REDUCE RECRUITMENT BIAS
A55

METHODS: Transversal study (pilot) carried out in a family medicine unit of the Mexican Social Security Institute (IMSS) between April and July 2003, during which period interviews were effected with 537 pregnant women engaged in either paid work, housework, or both, and registered with the Family Medicine external consultation services. A questionnaire was applied in order to establish demographic and reproductive characteristics, as well as variables related with prenatal control and the existence of symptoms before and after pregnancy; characteristics, as well as variables related with prenatal control and the existence of symptoms before and after pregnancy; finally, to provide information on characteristics of both domestic and extra-domestic work. RESULTS: In total, 36.5% were women with paid work (A), the rest having exclusively domestic work (63.5%) (B). Of those with extra-domestic work (A), 78.6% had clerical or similar jobs, mainly in service activities (45%), and 18.9% were industrial workers. Stress at work is present in 74% of cases interviewed. On analyzing the effect of work on women’s health conditions, it was observed that women who do not go out to work show a higher risk of muscular-skeletal alterations than those who do so (RM: 4.3 IC95% 1.6–11.4). The presence of genitourinary symptoms is greater for those who do not go out to work. CONCLUSIONS: The monitoring of domestic work is important in view of the need for attention to the conditions in which such work is carried out; it also helps identify potential risks for health.
OBJECTIVES: To evaluate, in daily practice, the benefits of detrascogine alfa (DA) in the treatment of severe septic patients with multiple organ failure and optimum intensive care support.

METHODS: In this prospective, observational pre-post study, the clinicians were free to include any patient meeting DA's inclusion criteria before and after DA's marketing. An optimal propensity score matching technique was used to reduce recruitment bias. Survival was modeled using a Cox proportional hazards model with a shared frailty term to account for the clustering of patients within the intensive care units. The number of bleeding events measured DA’s safety. RESULTS: Respectively 509 and 587 patients were included in the before and after groups. There is strong evidence of recruitment bias: patients in the after group are younger, more frequently ventilated, have less comorbidities but more organ failures. After propensity score matching, 340 patients were retained in the analysis, with a better balance between the groups. The use of a frailty model improves significantly the variance explained by the survival model, showing a non-negligible cluster effect. When considering the whole sample of patients, without adjustments, survival is improved in the after (i.e. with DA) group (p = 2.5%), with a hazard ratio (HR) of 0.805. In the matched sample, there are no significant survival differences (HR = 0.900, p = 35.0%). However, after stratifying by the LADS severity score quartiles, significance is reached (HR = 0.795, p = 4.8%). In the matched sample, a negative binomial model best described bleeding events. In this model, patients in the after group have a higher mean of bleeding events (p = 2.0%). CONCLUSION: This observational study confirms DA’s clinical trial results in the real practice setting. However, the use of the propensity score cannot replace randomization to assure perfect balance for all patient characteristics, measured and unmeasured. The results should therefore be considered with caution.

ECONOMIC IMPLICATION OF HEPATITIS B VIRAL (HBV) LOAD REDUCTION FOR ENTECAVIR IN HEPATITIS B E ANTIGEN-POSITIVE CHRONIC HEPATITIS B (CHB) PATIENTS

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OBJECTIVES: To evaluate the cost effectiveness of entecavir in reducing HBV DNA viral load (VL) and subsequent compensated cirrhosis (CC), decompensate cirrhosis (DC), and hepatocellular cancer (HCC). METHODS: The analytic perspective was that of a third-party payer. We used patient-level drug exposure and VL data from a randomized phase III trial of 715 HBeAg+ CHB patients, and estimates of cost offsets and life expectancy gains as a result of the prevention of projected clinical events. The multivariate-adjusted relative risks with VL categories were estimated by Cox proportional hazards models from a Taiwan cohort of 3851 CHB subjects with 42,115 person-years of follow-up, and then applied to the trial patients whose VL were measured at Week 48 to estimate event risks. Entecavir and lamivudine were assigned daily prices of $19.43 and $6.14 respectively, based on recent First Data-Bank reports. Life expectancy for DC and HCC was estimated by the declining exponential approximation of life expectancy (DEALE) method. Other model parameter values were derived from external sources. The uncertainty surrounding event distribution and treatment failure rates beyond trial period were considered using probabilistic sensitivity analyses (PSA) with 1000 replicates. RESULTS: Subjects were male (75%), Asian (57%) or white (40%) with mean age 35 years. Entecavir was superior to lamivudine for the proportion of subjects who achieved HBV DNA < 300 copies/ml by PCR assay at Week 48 (67% versus 37%, respectively) (P < 0.05). One year of entecavir therapy gained 0.7843 quality-adjusted life year (QALY) at an incremental cost of $1607, with a 3% annual discount. Compared with lamivudine, using entecavir cost an incremental $2049 per QALY gained (95%CI: $688, $5134), with 98.8% of PSA-derived estimates below $10,000/QALY. Results are robust and most sensitive to treatment duration, efficacy, and cost. CONCLUSIONS: Entecavir given for one year is clinically effective and highly cost-effective in HBeAg+ patients.