apresentação gráfica do conteúdo textual (verificadas no estudo analítico) podem influenciar negativamente nas estratégias de leitura da bula, particularmente pelos participantes com pouca experiência de leitura com este tipo de documento. CONCLUSÕES: Com base nos resultados de ambos os estudos foram elaboradas diretrizes e espera-se que estas possam contribuir com a melhoria na qualidade da estrutura e apresentação gráfica do conteúdo textual da bula de medicamento no Brasil.

PIH13

THE IMPACT OF FAMILY PHYSICIAN PROGRAM ON HEALTH INDICATORS IN IRAN (2003–2007)

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OBJECTIVES: " Family Physician" program has been launched since 2005 as a fundamental health plan in Iran. In spite of valuable information gathered through vital horoscope, only a few studies have been done in order to evaluate the performance of this program. So this research has been carried out to assess the impact of this program on heath indicators. METHODS: The research involved collecting data about 11 main health indicators extracted from the official annual report of the deputy for health from 2001 to 2006 and analyzing them through t- paired test in SPSS RESULTS: Statistical analysis shows that the changes in 6 main indicators during these years including infant mortality rate, (IMR), crude birth rate, under-5 mortality rate (U5MR), neonatal mortality rate (NMR), maternal mortality rate (MMR), and percentage of deliveries attended by unskilled persons were significant (p-value < 0/05) and all of the above indicators have decreased during these years. Although other 5 indicators such as crude death rate(CDR), general fertility rate, percentage of deliveries in hospitals, percentage of family planning coverage and still birth rate had an appropriate improvement during these years, their changes were not statistically significant (p-value > 0/05). CONCLUSIONS: Findings indicates that there is an acceptable improvement in many of the health indicators since starting this program. But this does not mean that the other factors that might have affect on these indicators should not be considered.

INFECTION – Clinical Outcomes Studies

PIN1

GENDER DIFFERENCES IN METABOLIC PROFILE AND CARDIOVASCULAR RISK AMONG BRAZILIAN HIV-INFECTED PATIENTS ON HAART: RAPID II STUDY

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OBJECTIVES: Gender differences in cardiovascular risk (CVR) among HIV-infected patients have been reported, with conflicting results. We have previously reported data from the Registry and Prospective Analysis of Patients Infected with HIV and Dyslipidemia (RAPID II study) a higher CVR in males and higher rates of obesity, metabolic syndrome (MS), and lack of physical exercise in females. We now compare gender differences among Brazilian individuals METHODS: Adult HIV-infected patients with at least 6 months of HAART were enrolled in this longitudinal study that is being conducted in 7 countries. Metabolic profile, anthropometric parameters, CD4-cell count, viral load (VL), types of HAART, CVR factors, and Framingham score were compared by gender RESULTS: A total of 1001 Brazilian patients were enrolled, 655 (65.4%) were males. Mean (SD) age was 44 (10) years, mean time on HAART was 48.4(36.4) months, 48% were on a protease inhibitors-based HAART, mean CD4-cell count was 519 (274) cells/mm3, and mean VL was 2.29 (0.9) log10 copies/ml. Males were found to have higher 10-year CVR (15.9 ± 30.1 vs 11.0 ± 29.6; P = 0.0136) and were more likely to belong to the high-risk category (15.9% vs 10.4%; P = 0.021) than females. No gender differences were found in the rates of hypertension, type II diabetes, or MS. Female patients showed higher prevalence of obesity (12.7% vs 7.2%; P = 0.005) and physical inactivity (66.5% vs 53.6%; P < 0.001) than males. In contrast, male patients were older (44.5 ± 9.4 vs 43.0 ± 10.4 years; P = 0.0194), and had higher rates of smoking (24.4% vs 17.6%; P = 0.016) and dyslipidemia (81.8% vs 74.6%; P = 0.009) than females CONCLUSIONS: Brazilian individuals sheds light on gender differences whose recognition may be important for appropriate intervention on modifiable CVR factors.

PIN2

INTEGRATION OF PHARMACO-ECONOMIC OUTCOME BASED RESEARCH WITH LOCAL CONTEXT: A MODEL FOR RATIONAL HEALTH CARE DECISION-MAKING IN DEVELOPING COUNTRIES

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BACKGROUND: Extrapolation of research data from developed countries, without considering the local context can sometimes result in outcomes different from the research setting, emphasizing the need to integrate external research with local context. An example of hepatitis B vaccination in India is presented as a model. OBJECTIVES: To decide whether hepatitis B vaccination should be introduced in India, by integrating pharmaco-economic research data with the local context. METHODS: Detailed literature search was undertaken to identify evidence for: 1) hepatitis B disease burden in India; 2) efficacy and safety of Hepatitis B vaccination; 3) economic implications; 4) feasibility of universal administration; 5) local situation; and 6) expected short and long term outcome. Evidence was sought in the following hierarchy: systematic reviews, randomized trials and case control/cohort studies. RESULTS: A current systematic review1 identified Hepatitis B prevalence as 1.7%; another (Cochrane) review2 reported relative risk of hepatitis B following vaccination as 0.12(0.03–0.44) in per-protocol analysis, suggesting that prevalence could be decreased by 88% through universal vaccination. The cost of vaccine would be approximately 0.15US$ per dose and vaccination cost per child approximately 0.60US$ (1.8US$ for three doses) if added to DPT vaccination administered to infants at 6,10,14 weeks of age; thereby making the intervention highly cost-effective in terms of reduction in disease prevalence (short-term outcome) and hepatitis B morbidity/mortality (long-term outcome). However current national data3 shows that DPT vaccine coverage is only 55.3%; further over one-third of hepatitis B infection is acquired perinatally4 and cannot be prevented through this vaccination schedule. Therefore, integrating local context with research data suggests that the expected 88% reduction in prevalence (from research data) would practically translate to only 37% reduction, whereby hepatitis B vaccination may no longer be cost-effective to reduce disease burden. CONCLUSIONS: It is critical to incorporate local contextual issues when pharmacoeconomic outcome data is extrapolated from external research, especially in developing countries.

PIN3

HEPATOCELLULAR CARCINOMA (HCC) RISK ESTIMATION BASED ON CHRONIC HEPATITIS B (CHB) VIRAL LOAD LEVELS IN BRAZILIAN PATIENTS

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OBJECTIVES: The objective of this analysis was to apply a risk estimation model (REVEAL study by Chen, 2007) to predict HCC development in Brazilian CHB-infected subjects and to estimate the level of risk according to Viral Load distribution. METHODS: We evaluated: gender, age, family history of HCC, prevalence of alcohol consumption, ALT, HBeAg and HBV DNA levels. Patients were from different regions of Brazil, diagnosed with CHB at the DASA in 2007. Regression coefficients derived from the Cox models of Chen's study were converted into risk scores (RS) and the predicted risks of HCC over 5 and 10 years calculated by predicted 5/10 years HCC risk = 1-(1-P0) exp (RS-RS0); being: P0: Predicted probability of HCC within 5/10 years for persons with the reference-level risk score RS0 and RS: Risk score of which HCC risk to be predicted. Costs for treatment was reported by Castelo (2007). RESULTS: Of the total population (564) 64.5% were males and 62.1% were HBeAg negative. The median HBV DNA level was 1,789 and 72,924 copies/mL for HBeAg negative and positive patients, respectively. Patients male, older with high HBV DNA levels had the greatest risk of developing HCC. The mean (SD) estimated risk for 5 and 10 years in 1000 patients are 7.87 (6.82) and 18.30 (15.77), respectively. In patients older than 40 years old this risk is 27.34 (13.82) and for patients with HBV DNA levels higher than 10,000, the risk is 26.54 (15.75). The costs for treating these patients can vary from US$34,861.50 to US$50,558.70, if these patients are transplanted these costs can be from US$639,548.40 to US$927,519.92. CONCLUSIONS: This study suggests that the risk of HCC in the Brazilian HBV population is considerable and may signicantly impact the health care system.

INFECTION – Cost Studies

PIN4

IMPACT OF CHRONIC HEPATITIS B IN THE BRAZILIAN HEALTH SYSTEM ACCORDING WITH DATA FROM DATASUS (ADMINISTRATIVE DATABASE) FROM MINISTRY OF HEALTH

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OBJECTIVES: The distribution of Chronic hepatitis B virus (HBV) in various Brazilian regions is not well understood. The public health and economic impact of Hepatitis B and its complications such as cirrhosis, and liver cancer in the Brazilian Unified Health System (SUS) will give further insights of the importance of the disease in Brazil. DATASUS is a public administrative database maintained by MoH and can contribute to the study of HBV. METHODS: HBV and its complications in the Brazilian SUS was evaluated in the public database DATASUS between 2000 to 2007. Data were tabulated according with different Brazilian states. RESULTS: Mortality data indicate a peak of viral hepatitis and liver cirrhosis between 40 to 60 years old, followed by another mortality peak due to liver cancer between 60 to 80 years old, this pattern is found in the states studied. The average hospitalization time for liver-related