AN OBSERVATIONAL HEALTH ECONOMICS ANALYSIS OF THE COMBINED THERAPY WITH PEGINTERFERON ALPHA-2A (PEGASYS®) AND RIBAVIRIN IN PATIENTS WITH CHRONIC C HEPATITIS (CHC) IN A REAL LIFE SETTING

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OBJECTIVES: To assess in a real life setting, the effectiveness, direct, indirect costs and quality of life of the combined treatment with Pegasys® and ribavirin in patients with CHC in France.

METHODS: An observational naturalistic study was designed to prospectively collect health-economic, quality-of-life and clinical data on a representative sample of newly treated patients. Data were collected to assess Sustained Virologic Response (SVR).

RESULTS: A total of 2101 patients were included of which 70% were naive patients and 17% had cirrhosis. The mean age was 47 years and 62% were male. The genotype distribution was the following: G1 (53%), G2/3 (37%), G4/5 (10%). A SVR was achieved in 58% of all patients and 63% in the naive subgroup (similar to those of the clinical trials –56%—Fried NEJM, 2002). The mean total direct costs per patient over a mean period of 36.9 weeks of treatment was €9977, of which 85.7% (€8538) related to Pegasys®/ribavirin alone, 5% (€495) for hospital care and 5.1% (€513) for biological and viral testing. A proportion of 26.2% of patients had at least one sick leave (mean duration: 49.6 days) with a mean allowance per patient of €636 (6% of direct costs). The mean HQLQ scores were lower on all dimensions during the course of treatment as compared to inclusion and then increased 6 months after its end at higher levels than at inclusion. This improvement was increased in patients achieving SVR.

CONCLUSIONS: This study confirmed the results from the clinical trials for effectiveness and suggested a marked impact on quality of life. In terms of budget impact, the results suggested that the main cost driver was constituted by pharmaceuticals.

PATIENT FLOW PATHWAY FOR PATIENTS ADMITTED TO CRITICAL CARE UNITS WITH A SEVERE BACTERIAL INFECTION IN ENGLAND

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OBJECTIVES: Assessment of patient flow pathway of Severe Bacterial Infection Cases in Critical Care (Intensive Care Units [ICUs] or High-Dependency Units [HDUs]).

METHODS: The analysis is based on inpatient hospital admission data from the National Health Service (NHS)’s Hospital Episode Statistics (HES) Database for England in 2004-05 and 2005-06. The sample group was patients in Critical Care with a Finished Consultant Episode (FCE) (period of care under a single consultant at a single hospital, completed by year-end) that had a primary or secondary diagnosis for a specified Severe Bacterial Infection (SBI). The data extracted contained a count of FCEs, the patient’s location prior to admission to Critical Care, length of stay, outcome and destination post-discharge from Critical Care.

RESULTS: In 2005–06, there were 21,601 FCEs with an SBI in Critical Care for England, increasing from 18,717 FCEs in 2004–05 (15.4% increase). In 2005–06, 56.4% of FCEs occurred in an ICU, 24.6% in an HDU and 19.1% in an ICU/HDU combined ward. The majority of SBI patients in ICU, 63.7% (7,739/12,180) came from a non-critical ward (most commonly Theatre/Recovery 28.5%), 10.9% (1,323/12,180) from Accident & Emergency and 9.1% (1,108/12,180) came from a non-critical ward (most commonly Theatre/Recovery 28.5%), 10.9% (1,323/12,180) from Accident & Emergency and 9.1% (1,108/12,180) came from an HDU in the same hospital. For SBI patients in HDU, 55.6% (2,952/5,306) came from a non-critical ward (most commonly Theatre/Recovery 28.5%), 10.9% (1,323/12,180) from Accident & Emergency and 9.1% (1,108/12,180) came from an HDU in the same hospital. For SBI patients in HDU, 55.6% (2,952/5,306) came from a non-critical ward (most commonly Theatre/Recovery 28.5%), 10.9% (1,323/12,180) from Accident & Emergency and 9.1% (1,108/12,180) came from a non-critical ward (most commonly Theatre/Recovery 28.5%).

PHARMACOGENOMICS: RELEVANCE AND APPLICABILITY IN POST-GENOMIC ERA (HIV- THERAPY)

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OBJECTIVES: The study aims to explore the evidence of pharmacogenomic testing in clinical trials of anti-HIV drugs. This study reviews the challenges and barriers to pharmacogenomic research, highlights opportunities, reveals gaps, and aids in identifying specific, achievable goals that will advance the field.

METHODS: HIV drugs with a confirmed linkage between the drug and genomic variations exhibited by individuals were identified from database (hiv-pharmacogenomics.org). We searched a clinical trials registry (clinicaltrials.gov) for the prevalence of pharmacogenomic parameter as outcome measure in studies of HIV drugs with confirmed linkage.

RESULTS: Clinically significant and confirmed pharmacogenomic relationships were identified for seven HIV drugs. Out of the 980 potential studies, 326 (33.3%) met the inclusion criteria. Of the included studies only 28 (8.6%) assessed pharmacogenomic variation as one of the evaluable parameter (3 as primary, 9 as secondary and 16 as one of the determinants in study). Use of pharmacogenomic testing in the included studies was frequently observed in Indinavir (22.2%) followed by Efavirenz (15.4%), Saquinavir (15.0%), Abacavir (13.3%), Atazanavir (10.4%), Nevirapine (9.3%) and Ritonavir (4.0%). The included studies reported were intervention (24) and observational (4), which included 9 randomised controlled trials. Approximately 57% of the studies were phase IV post-marketing clinical trial. Out of 28 studies assessing pharmacogenomic parameter, 11 (39.3%) were sponsored by the industry, 11 (39.3%) by government agencies, 4 (14.3%) by universities and 2 (7.1%) by other sources.

CONCLUSIONS: There are several, well-established pharmacogenomic relationships relevant to HIV and its treatments. However, collection of outcomes data that would support targeting treatments to patient groups defined through pharmacogenomics is not widely carried out, without which there is a possibility of ignorance of outcomes in groups of patients where the treatment effects may be most clinically significant.