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MULTICENTRE PROSPECTIVE COHORT STUDY TO EVALUATE THE SAFETY PROFILE OF HAART IN HIV OUTPATIENTS: 1 YEAR FOLLOW-UP RESULTS

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BACKGROUND: Safety of HAART is a matter of concern since it is one major limitation to treatment success.

OBJECTIVES: To assess the long-term safety of different HAART combinations and their impact on patient care.

PATIENTS AND METHODS: On January 1998 a multicentre prospective cohort study in three Spanish teaching hospitals was started. Adult patients on antiretroviral (ARV) therapy have been recruited prospectively. Data on demographics and HIV infection history, laboratory tests results, drug treatment and clinical and biological evolution are recorded and updated at each follow-up visit. Suspected adverse drug reactions (ADR) are reported by clinicians when clinically relevant (those that motivate drug discontinuation or drug withdrawal). All notified ADR are documented and assessed by clinical pharmacologists.

RESULTS: Until January 1999, 1181 patients have been recruited. Most of them are men (844; 71%). Half of them are injection drug users (IDU) (554; 47%). Mean (\pm SD) age is 37.5 (\pm 0.3) years. At entry, 88% of patients were receiving three or more drugs. Mean follow-up is 9 months and cumulative exposure (patient-months) for the most frequently used drugs is: lamivudine 7185; stavudine 5873; indinavir 4609; zidovudine 3165; saquinavir 2052; didanosine 1358; ritonavir 843; nevirapine 756; and nelfinavir 718. 283 ADR involving 224 patients have been reported. Incidence of ADR is 0.9 per 1000

patient-years. Overall, there have been 704 treatment modifications affecting 402 patients, of which 196 have been caused by ADR.

CONCLUSIONS: ADR is a major cause of treatment discontinuation in patients on HAART, accounting for almost half of treatment modifications. Long-term data are needed in order to assess the impact of ADR on patient care.

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