Purpose We aimed to describe the incidence of neuropsychiatric disorders in a cohort of HCV-infected patients treated with interferon and ribavirin, and their impact on treatment adherence and viral response rate (SVR).

Materials and Methods Data from a cohort of HCV patients who visited an outpatient pharmacy service (OPS) included all adult patients mono-infected with HCV who had completed treatment in 2010. Monitoring of neuropsychiatric disorders was assessed at weeks 0, 4, 12, 24, 48, and 72 through the self-administered questionnaires Hospital Anxiety and Depression Scale (HADS) and General Health Questionnaire (Goldberg). Adherence to treatment was assessed by counting drugs dispensed and patient reporting. Virological response was determined by the physician according to standard criteria.

Results Of the 76 patients included, 19 (25%) had a pre-existing psychiatric disorder, mostly depression and anxiety. The incidence of medically-confirmed neuropsychiatric disorders was 33% (n = 25), with a peak of abnormal results in the tests in week 12. Patients with and without pathological scores did not differ in baseline characteristics, except for pre-existing psychiatric disorder (60.0% vs. 7.8%, respectively (p < 0.001). Antidepressants and/or anxiolytics were prescribed to 48% of patients with medically confirmed disorders (n = 12). Overall, 45% of patients achieved an SVR. Strict adherence (96% vs. 90%; p = NS) and SVR (59% vs. 52%; p = NS) were similar in patients with or without medically confirmed disorders.

Conclusions Patients often develop neuropsychiatric disorders during interferon therapy. Neuropsychiatric side effects had a non-significant effect on adherence to treatment and attainment of SVR. Multidisciplinary monitoring provided during the treatment of hepatitis C can contribute to early detection and management of neuropsychiatric disorders and to improve integrated patient care.

No conflict of interest.

Background Non-formulary drugs are prone to cause medication errors due to their less common use in the daily routine on the ward. Therefore non-formulary drug (NFD) management in the hospital pharmacy includes checking the dose and indication which is usually very time consuming. In 2010 the drug information centre had to deal with 12,903 prescriptions for NFDs.

Purpose Loss of relevant drug information at the interface between pharmacy and ward has been observed in some cases. Therefore a survey was performed to detect information gaps. Did the pharmacist’s recommendation reach the medical staff?

Materials and Methods During a period of four weeks all NFD prescriptions were documented concerning the type of medicine. If a treatment-relevant intervention (e.g. dose correction) was made the trainee pharmacist visited the ward to clarify if the pharmacist’s advice was received. In addition the medical staff were interviewed about the general procedure of information transfer within the ward staff.

Results 1158 NFDs were ordered. Out of these 261 required extensive action with pharmacist intervention. 256 interventions were accepted on the ward and only 5 were rejected. In only one case out of these the pharmacist’s information had to be resupplied to the ward as it had not reached the staff. The survey showed a very high acceptance (98.1%) of the drug information provided. 83 drugs within the ATC Code “antibiotics for systemic use” were particularly counselling-intense. Dosing problems were the most frequent drug-related problem (52%). Information transfer within the ward turned out to be highly inhomogeneous.

Conclusions The pharmaceutical advice offered to the ward was accepted to a very high percentage. To prevent information loss on the ward a standardised system for information transfer amongst the staff needs to be established.

No conflict of interest.

Background Intended copies of originator medicinal products (MPs) are categorised as generics or biosimilars (complex large molecular biological MPs) with distinct regulatory pathways for marketing authorization. In recent years, a new category of non-proteins and non-biotech-derived MPs has emerged, the non-biological complex drugs (NBCDs) comprising IV iron...
carbohydrates (polynuclear iron (III)-oxyhydroxy cores stabilised by carbohydrates), glatiramoids (polypeptides) and liposomal drugs [1]. Like biological MPs, NBCDs are complex MPs consisting of non-HOMO molecular, partially nanoparticle, structures. Composition, in vitro and in vivo characteristics are defined by manufacturing. Subtle changes of the manufacturing modify quality, efficacy and safety of the MP. NBCDs are not fully characterised physicochemically. In contrast to biosimilars, a regulatory framework is not established.

**Purpose** Intended copies of NBCDs such as the iron sucrose similars have been approved in several countries by the classical generic pathway. Growing scientific evidence in the non-clinical and clinical setting has raised doubts about interchangeability and/or substitutability.

**Material and Methods**

Science-based statements for comparability of intended copies and reference MPs were discussed among experts from regulatory science, clinicians, hospital pharmacists and industry in a Workshop at FIP 2012. The conclusions were used to propose regulatory requirements for NBCDs.

**Results** The FIP 2012 consensus meeting confirmed the lack of an appropriate regulatory market authorization of intended copies of NBCDs. For liposomes, physicochemical equivalence testing seems to be more likely to be achievable, but clinical efficacy trials are needed on a case-by-case base (EMA). Glatiramoids, with a not-understood mode of action, also need a broad, as yet to be defined, regulatory approach. Nanoparticle assessment includes sizing and morphology (FDA) and also evaluation of in vivo biodisposition (EMA). The upcoming Terminology and a White Paper will integrate these conclusions.

**Conclusions** For NBCDs and their specific characteristics a regulatory pathway is needed to assess comparability and eventually therapeutic equivalence of originator and intended copy MPs. In multiprofessional medicines management specific attention to the limits of interchangeability and substitutability is mandatory.

**References**


No conflict of interest.