frequently on a case-by-case basis, often influenced by previous personal experience. They highlighted the increasing concerns from the participating hospitals' microbiology departments over the use of quinolones due to the risks of selecting drug resistant organisms and *Clostridium difficile* (*C. difficile*) associated diarrhoea. Rifaximin is licensed in use for HE but may have beneficial role in SBP prevention without the high risk of drug resistance, however high costs remains a barrier to its use.

SBP continues to be a significant problem in the management of patients with decompensated liver failure. The Results from these centres demonstrate an evident lack of clarity over the optimum strategy for primary prophylaxis throughout the United Kingdom and hence the need for further high quality research to provide clear guidelines.

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PWE-088 EVALUATION OF DRUG-INDUCED SERIOUS HEPATOTOXICITY (EDISH) ASSESSMENT IN OBETICOLIC ACID-TREATED PATIENTS WITH NASH

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Introduction Evaluation of drug-induced serious hepatotoxicity (eDISH) is a tool used to assess and identify potential cases of drug-induced liver injury (Senior J. *Drug Safety*. 2014;(37): Suppl 1:S9-S17). eDISH was used to evaluate obeticholic acid (OCA) and placebo profiles in 2 double-blind, placebo-controlled studies in patients with NASH. FLINT was a 72 week study, which demonstrated statistically significant improvements in hepatocellular ballooning, steatosis, lobular inflammation, and fibrosis in patients treated with OCA compared to placebo. CONTROL was a 16 week study, which showed that the addition of low-dose atorvastatin reversed OCA-associated changes in LDL-C. The objective of this analysis was to use eDISH to determine if patients with NASH treated with OCA show increased markers of liver injury or whole liver dysfunction.

Methods eDISH Methodology was applied to 278 patients treated with placebo (n=140) or 25 mg OCA (n=138) from FLINT and 84 patients treated with placebo (n=21), 5 mg OCA (n=20), 10 mg OCA (n=21), or 25 mg OCA (n=22) from CONTROL. Individual peak of ALT and total bilirubin values during the double-blind treatment phase were plotted as log₁₀ values of multiples of elevations above the upper limit of the normal (xULN).

Results Overall, no OCA-treated patients were in the Hy's law quadrant (>3 x ULN for ALT and >2 x ULN for total bilirubin) compared with 1 placebo-treated patient in FLINT. The proportion of patients with peak ALT and total bilirubin values in the lower left quadrant (representing normal or near

normal range) was higher in OCA-treated patients compared with placebo (FLINT: 91% OCA vs 84% placebo; CONTROL: 91% OCA vs 86% placebo). 8% of OCA-treated patients from both FLINT and CONTROL presented in the Temple's corollary quadrant (>3 x ULN for ALT and <2 x ULN for total bilirubin) vs 14% (in both studies) for the placebo-treated patients. Across both studies (n=362), 4 patients were in the cholestasis quadrant (>2 x ULN total bilirubin and <3 x ULN for ALT); 1 placebo-treated patient and 3 OCA-treated patients, including 1 patient with Gilbert's syndrome.

Conclusions In these 2 placebo-controlled, double-blind NASH studies, the eDISH analysis showed no trend for liver injury with OCA at doses up to and including 25 mg.

Evaluation of Drug-Induced Serious Hepatotoxicity

PWE-089 ROUTINELY COLLECTED HEALTH DATA TO STUDY THE SURVEILLANCE FOR COMPLICATIONS OF ADVANCED CHRONIC LIVER DISEASE

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Introduction Screening for oesophageal varices and surveillance for hepatocellular carcinoma (HCC) are recommended to improve outcomes for patients with cirrhosis. The adherence with the recommendations is unknown. Disease registries have improved care for patients with heart disease and inflammatory bowel disease. To date there is no registry for patients with cirrhosis. The aim of this study was to determine if information routinely collected in electronic health records (EHR) can be used to evaluate rates of surveillance testing in patients with advanced chronic liver disease (ACLD).

Method Transient elastography (TE) data was collected from St James's University Hospital in Leeds between 2012 and 2017. Inclusion criteria were a valid liver stiffness measurement (LSM) ≥10 kPa to identify patients likely to have ACLD. Disease and procedural coding information sent to NHS Digital and held in EHR was used to determine the number of patients who underwent screening or surveillance. For the purposes of the analysis variceal screening was defined as a gastroscopy within 12 months of TE and HCC surveillance was at least one abdominal ultrasound scan (USS) with a mean interval between scans of 2–9 months during the follow-up period. Patients were stratified based on LSM into two groups: ≥10–15 kPa or >15 kPa. Validation of the coding information was done in a subset of patients where the full clinical record was reviewed to determine the accuracy of the coded EHR data.

Results 1046 patients underwent TE (Median LSM 16.2 kPa; 489 ≥10–15 kPa, 557 >15 kPa). Median follow-up interval was 36 months. Considering only those patients with LSM >15 kPa, 166 (30%) patients had a gastroscopy within 12 months. Of these, 44/166 (27%) patients had a ICD-10 primary diagnosis code for oesophageal varices. Using the primary diagnosis code to determine the presence or absence of varices was validated in 100 patients and showed good performance characteristics: sensitivity 0.91; specificity 0.88. Regarding HCC surveillance, 647/1046 patients (62%) had undergone at least one USS. 45/489 patients (9.2%) with a