

had blood taken 90 (61.1%) were HCV PCR positive. HCV PCR negative individuals were provided with harm reduction advice, were encouraged to access drug treatment, and discharged from further HCV follow-up. All PCR positive individuals were offered referral onto drug treatment and/or specialist HCV services for assessment and treatment. Abstract P68 table 1 lists summary of outcomes.

Abstract P68 Table 1 Engagement of HCV PCR positive individuals

	Number	%
In HCV and drug treatment programme	44	48.9
In current contact with addiction services	12	13.3
In drug treatment programme	21	23.3
Disengaged with services/lost to follow-up	12	13.3
Died	1	1.1

**Conclusion** The study has shown DBST is easy to use and can be carried out without difficulty by staff within drug services. The offer of HCV testing was well received by this particular client group with over 90% of individuals returning for their results. The study has shown that DBST in practice significantly increased the number of new diagnosis within our region by 77% from 245 in 2007–2008 to 435 in 2009–2010. DBST led a significant number of people into drug and HCV treatment services and therefore proves that diagnosing hepatitis C can have life improving benefits for people.

P69

**HOW TO RE-ENGAGE PATIENTS WITH HEPATITIS C INFECTION: LINKING TO METHADONE PRESCRIBING WORKS**

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**Introduction** New patients' attendance rates at the specialist clinic for hepatitis C virus (HCV) management in Grampian are around 45% and a significant proportion of those attending fail to remain under follow-up for a variety of reasons. In an attempt to increase the number of HCV positive individuals attending specialist care, an appointment with a Hepatology Nurse Specialist at their General Practice surgery or community hospital was offered to all those previously referred, still alive and living in our Health Board area.

**Aim** (1). Describe the demography of those previously referred, still alive and living in the area but no longer attending specialist care; (2). Evaluate different strategies for re-engagement with Hepatitis C services; (3). Compare the demographic features of those accepting and declining offer of re-engagement.

**Method** Subjects were identified from the Grampian HCV database and the re-engagement exercise was conducted using three methods depending on the preference and resources of General Practice Surgeries: (1). Appointments coincided with provision of existing Methadone prescriptions; (2). Patients were telephoned and chose the time of their appointment. If patients were uncontactable by telephone, appointments were sent by post; (3). Appointments were allocated and time communicated by letter. Only one surgery linked appointments with current Methadone prescriptions. Data were analysed using PASW Statistics V.18. Characteristics of individuals under follow-up were compared to individuals requiring appointments using the Continuity corrected  $\chi^2$  test for categorical data and the non-parametric Mann–Whitney test for skewed continuous data. A logistic regression model was fitted to investigate whether gender, age and Carstairs' deprivation category could influence loss to follow-up. The same statistical tests were used to compare

characteristics of individuals who re-engaged with those who failed to attend clinic appointments. Associations between clinic attendance and method of re-engagement were examined using the Continuity corrected  $\chi^2$  test for categorical data.

**Results** We identified 276 patients requiring follow-up. Those lost to follow-up were significantly younger than patients under continued follow-up (median (IQR) age 34 (30–40) vs 39 (32–49)) ( $p < 0.001$ ). Patients under continued follow-up were more likely to live in deprivation category 1 (OR 2.50 (CI 1.07 to 5.85)) ( $p = 0.035$ ) and 2 (OR 2.43 (CI 1.27 to 4.62)) ( $p = 0.007$ ) than those lost to follow-up, although the gender distribution was similar in both groups. All 276 patients not under follow-up were offered appointments: 96 (35%) attended and 11 declined. Gender, age and deprivation category had no significant effect on re-engagement. Linking appointments with Methadone prescriptions resulted in 89% (31/35) attendance, significantly higher than arranging appointments by prior telephone discussion 43% (24/56) ( $p = 0.009$ ) or allocating appointments with communication by letter 24% (41/174) ( $p < 0.001$ ).

**Conclusion** Linking appointments with Methadone prescriptions was associated with significantly higher attendance than other methods although this was only possible in 13% of cases. Allocation and communication by letter resulted in very disappointing attendance rates. This study has demonstrated that a change in the traditional method of service delivery may be required for the successful re-engagement of those with hepatitis C infection and effort should be directed in linking appointments for management of Hepatitis C with their Methadone appointment in appropriate individuals.

P70

**TELAPREVIR IN COMBINATION WITH PEGINTERFERON AND RIBAVIRIN IN GENOTYPE 1 HCV TREATMENT-NAIVE PATIENTS: FINAL RESULTS OF PHASE 3 ADVANCE STUDY**

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**Aim** The ADVANCE study is a 3-arm double-blind, randomised, placebo-controlled Phase 3 study assessing efficacy and safety of two telaprevir (TVR, T)-based response-guided regimens compared with peginterferon alfa-2a 180  $\mu$ g/week and ribavirin 1000–1200 mg/day (PR) in treatment-naive patients with chronic genotype 1 HCV infection.

**Method** Treatment arms were (a) T 750 mg q8 h in combination with PR for 8 weeks, followed by additional weeks of PR; (b) T 750 mg q8 h in combination with PR for 12 weeks, followed by additional weeks of PR; (c) PR for 48 weeks (control arm). Patients in T arms achieving an extended rapid viral response (eRVR, undetectable HCV RNA at weeks 4 and 12) received a total of 24 weeks of therapy while those who did not received a total of 48 weeks of therapy. Randomisation was 1:1:1 and patients were stratified by HCV RNA ( $< 800\,000$  IU/ml,  $\geq 800\,000$  IU/ml), and genotype 1a vs. 1b. The primary endpoint was SVR (undetectable HCV RNA 24 weeks after last planned dose of treatment). The primary analysis was based on the Full Analysis (intention-to-treat) dataset. Safety is presented for TVR/Placebo duration phase.

**Results** Of 1088 patients, 839 (77%) had HCV RNA  $\geq 800\,000$  IU/ml, 631 (58%) were genotype 1a, 636 (58%) male, 94 (9%) black, 117 (11%) Latino/Hispanic, 231 (21%) had bridging fibrosis or compensated cirrhosis. The most common ( $> 25\%$ ) AEs in the T arms were fatigue, pruritus, nausea, headache, anaemia, rash, influenza-like illness, insomnia, fever, and diarrhoea. Discontinuation of treatment due to AEs occurred in 8% in T8PR, 7% in T12PR and 4% in PR48; due to rash occurred in 0.5%, 1.4% and 0.0% and

due to anaemia occurred in 3.3%, 0.8% and 0.6% in T8PR, T12PR and control arms, respectively.

**Conclusion** A significantly greater proportion of patients achieved SVR with 12-week and 8-week telaprevir-based combination regimens (75% and 69%, respectively), compared with PR48 control arm (44%,  $p < 0.0001$ ). The safety and tolerability profile of telaprevir in the ADVANCE trial was consistent with the profile previously reported, with an improvement in treatment discontinuation rates due to adverse events, including rash and anaemia. These first Phase 3 results confirm the clinical benefit previously reported in Phase 2.

Abstract P70 Table 1 Viral response

	T8PR N=364	T12PR N=363	PR48 N=361
Patients achieving RVR, n (%)	242 (66)	246 (68)	34 (9)
Patients with HCV RNA undetectable at end of treatment (EOT), n (%)	295 (81)	314 (87)	229 (63)
Patients achieving SVR, n (%)	250 (69)*	271 (75)*	158 (44)
Difference in SVR rates, TVR arms vs control, % (95% CI)	25 (18 to 32)	31 (24 to 38)	NA
Patients with relapse, n (%)	28 (9)	27 (9)	64 (28)

\* $p < 0.0001$ , Denominator is number of patients with HCV RNA undetectable at EOT.

## Transplant

### P71 A MODEL TO IMPROVE PERFORMANCE OF CURRENT CATEGORY 9 UK LISTING CRITERIA: EARLY LIVER GRAFT DYSFUNCTION. A SINGLE CENTRE COHORT

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**Introduction** Current super urgent criteria for listing for early liver graft dysfunction (ELGD) in the UK (category 9, C9C) is defined as fulfilling 2 out of 4 of the following criteria within 7 days post liver transplant (LT): AST  $> 10\,000$  IU/l, INR  $> 3$ , Lactate  $> 3$  mmol/l and absence of bile production. We demonstrated that these criteria have critically low sensitivity in predicting early post LT death or need for re-LT (Al-Freah, *et al. Hepatology* 2009;50 Suppl 4:A148).

**Aim** To develop an improved predictive model for early re-LT or death using early post-LT clinical parameters.

**Method** Retrospective study of all patients transplanted at our centre 1 January 2000 to 31 December 2008. Daily clinical and laboratory parameters for the first 7 days post LT were reviewed. These included AST, bilirubin, INR, lactate, vasopressor requirement and/or haemofiltration.

**Results** Over the study period, 1286 patients underwent first LT at our centre. Patients excluded (28) because of re-LT for hepatic artery thrombosis (22), died on table (5) and one re-LT because of donor cancer. We analysed data on 1258 patients (median age 51 (16–74) years (16–74), 60% male). The most common aetiology was viral hepatitis in 303 patients (24%) and alcohol related liver disease in 227 patients (18%); 181 patients (14.4%) with hepatocellular carcinoma. Median MELD score was 16 (6–40). Death or re-LT rate at 3 months was 9.9% (124). Only 27 (2.1%) fulfilled C9C at 3 months: 17 (63%) of those died or had re-LT within 3 months ( $p < 0.001$ ). C9C had sensitivity of 14% (9.8–17%), specificity 99% (98–99%), positive likelihood ratio (LR+) 15.533 (7.41–32.73) and negative likelihood ratio (LR-) 0.87 (0.83–0.91). Abstract P71 table 1 shows the univariate and multivariate analyses of predictors of 3 months liver-related death or re-LT using Cox regression hazard method. Accordingly, we generated a model comprises any 1 of the following 5 to predict ELGD and death or re-LT: vasopressor requirement at day D7, D1 lactate  $> 3$  mmol/l, D7 AST  $> 500$  IU/l

and D7 bilirubin  $> 100$   $\mu$ mol/l. Those scored 1, 2, 3, 4 or 5 points had OR of risk of death/re-LT within 3 months of 1.26 (0.897–1.766,  $p = 0.184$ ), 1.345 (0.8817–2.051,  $p = 0.171$ ), 2.811 (1.669–4.732,  $p = 0.0001$ ), 15.561 (7.425–32.611,  $p < 0.0001$ ) and 36.509 (13.188–101.074,  $p < 0.0001$ ), respectively. 85 of 124 patients who had a 3 month liver related outcome met this criterion compared to 16 who met C9C. This gave sensitivity 68% (58–77%), specificity 67% (64–70%), LR+ 2.08 (1.77–2.45) and LR- 0.48 (0.36–0.63).

Abstract P71 Table 1 Cox regression hazard analysis of predictors of 3 months liver related deaths or re-LT

Variables	Univariate		Multivariate	
	OR (95% CI)	p Value	OR (95% CI)	p Value
D7 AST $> 500$ IU/l	2.188 (1.162 to 4.121)	0.0159	1.807 (0.953 to 3.425)	0.0711
D1 lactate $> 3$ mmol/l	2.500 (1.739 to 3.594)	$< 0.0001$	1.939 (1.400 to 2.872)	0.001
D7 bilirubin $> 100$ mol/l	1.530 (1.149 to 2.036)	0.0037	1.469 (1.101 to 1.960)	0.0094
D7 on vasopressors	5.241 (3.143 to 8.739)	$< 0.0001$	4.067 (2.395 to 6.906)	$< 0.0001$

**Conclusion** The new model is simple to use and significantly improved the sensitivity of detection of severe ELGD. Validation in another cohort of LT patients is warranted.

### P72 LIVER TRANSPLANTATION FOR FAMILIAL AMYLOIDOSIS; LONG-TERM DATA FROM THE FAMILIAL AMYLOID POLYNEUROPATHY WORLD TRANSPLANT REGISTRY (FAPWTR)

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**Introduction** Liver transplantation (LT) is the only available treatment for familial amyloid polyneuropathy (FAP). The Familial Amyloid Polyneuropathy World Transplant Registry (FAPWTR), established shortly after LT was introduced as potential treatment for FAP in 1990, is a centralised service based in Karolinska Institute in Sweden for the collection, monitoring and analysis of international data on LT for FAP.

**Aim** We present here the long-term FAPWTR results on the 20 years anniversary of LT for FAP.

**Results** Between April 1990 and January 2010, data on 1782 liver transplant procedures and regular follow-up were reported to the FAP registry from 70 transplant centres in 18 countries. Annual international transplant activity for FAP has remained stable at 80–120 procedures since 1996. Among those 866 liver transplants were performed in Portugal, 216 in France, 130 in Sweden, followed by USA 79, UK 78, Brazil 77, Spain 74, Japan 65. The Mediterranean Val30Met transthyretin (TTR) mutation was identified in 83% of cases. A further 50 different variants were reported, collectively referred to as non-ValMet30, and additionally a dozen of non-TTR mutations such as Glu526Val and ApoA1 Gly26Arg. The Ser77Tyr and Thr60Ala mutations appear to be the commonest among non-Val30Met variants. Median age at LT was 38 years (range 21–72 years), 57% of patients were male. Median disease duration prior to transplantation was 3 years (range 0–30 years). Of patients in the Val30Met group 98% received isolated LT, while 11% of non-Val30Met cases required either simultaneous (9%) or sequential heart and liver transplant (2%). Overall 1-, 3-, 5-, and 10-year survival after LT in the entire FAP population including all variants was 86.9%, 81.8%, 77.6% and 71%. Five-year and 10-year survival in the Val30Met group was 80.9% and 73.4% respectively, significantly superior to 57.8% and 43.9% in the non-Val30Met group ( $p < 0.001$ ).