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Aspinall, E.J.; Mitchell, W.; Schofield, J.; Cairns, A.; Lamond, S.; Bramley, P.; Peters, S.E.; Valerio, H.; Tomnay, J.; Goldberg, D.J.; Mills, P.R.; Barclay, S.T.; Fraser, A.; Dillon, J.F.; Martin, N.K.; Hickman, M.; Hutchinson, S.J.

*Published in:*  
Journal of Viral Hepatitis

*DOI:*  
[10.1111/jvh.12580](https://doi.org/10.1111/jvh.12580)

*Publication date:*  
2016

*Document Version*  
Author accepted manuscript

[Link to publication in ResearchOnline](#)

*Citation for published version (Harvard):*

Aspinall, EJ, Mitchell, W, Schofield, J, Cairns, A, Lamond, S, Bramley, P, Peters, SE, Valerio, H, Tomnay, J, Goldberg, DJ, Mills, PR, Barclay, ST, Fraser, A, Dillon, JF, Martin, NK, Hickman, M & Hutchinson, SJ 2016, 'A matched comparison study of hepatitis C treatment outcomes in the prison and community setting, and an analysis of the impact of prison release or transfer during therapy', *Journal of Viral Hepatitis*, vol. 23, no. 12, pp. 1009–1016. <https://doi.org/10.1111/jvh.12580>

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# **A matched comparison study of Hepatitis C treatment outcomes in the prison and community setting, and an analysis of the impact of prison release or transfer during therapy**

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*Number of tables:* 4

*Number of figures:* 0

*Keywords:* Hepatitis C, prison, treatment

*Word count, excluding title page, abstract, references, figures, and tables:* 3118

**ABSTRACT (Word count 250)**

**Background**

Prisoners are a priority group for hepatitis C (HCV) treatment. Although treatment durations will become shorter using directly acting antivirals (DAAs), nearly half of prison sentences in Scotland are too short to allow completion of DAA therapy prior to release. The purpose of this study was to compare treatment outcomes between prison- and community-based patients, and to examine the impact of prison release or transfer during therapy.

**Methods**

A national database was used to compare treatment outcomes between prison treatment initiates and a matched community sample. Additional data were collected to investigate the impact of release or transfer on treatment outcomes. Treatment naïve patients infected with genotype 1/2/3/4 and treated between 2009 -12 were eligible for inclusion.

**Results and Conclusions**

291 prison initiates were matched with 1,137 community initiates: SVRs were 61% (95% CI 55% to 66%) and 63% (95% CI 60% to 66%) respectively. Odds of achieving a SVR were not significantly associated with prisoner status ( $p = 0.33$ ).

SVRs were 74% (95% CI 65% to 81%), 59% (95% CI 42% to 75%) and 45% (95% CI 29% to 62%) among those not released or transferred, transferred during treatment, or released during treatment respectively. Odds of achieving a SVR were significantly associated with release ( $p < 0.01$ ), but not transfer ( $p = 0.18$ ).

Prison-based HCV treatment achieves similar outcomes to community-based treatment, with those not released or transferred during treatment doing particularly well. Transfer or release during

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therapy should be avoided whenever possible, using anticipatory planning and medical holds where appropriate.

## INTRODUCTION

Chronic hepatitis C is an important cause of liver-related morbidity and mortality worldwide. [1] People who inject drugs (PWID) are at increased risk of hepatitis C (HCV), and are also over-represented within the judicial system, with global prevalence of HCV antibody among the prison population estimated to be 26%, and 64% among prisoners who report a history of injecting drug use. [2] With more than 10 million people incarcerated at any one time, [3] this equates to over 2 million HCV antibody positive detainees worldwide. [2] Prisoners with HCV pose a considerable risk of onward transmission, through the use of non-sterile injecting equipment in a setting where needle exchange is limited or absent. [4] For this reason, the European Association for the Study of Liver Disease (EASL) has recommended that incarcerated individuals should be prioritised for HCV therapy. [5]

In Scotland, approximately 1,500 prisoners have evidence of current or previous infection with HCV, [6] and it is estimated that over 70% of HCV antibody positive PWID have been incarcerated at some point. [7] Since the publication of treatment targets in the Hepatitis C Action Plan in 2008, [8] the proportion of treatment initiations in the prison setting has increased from 4% to 14% (translating to a seven-fold increase in treatment uptake). [9]

This drive to increase treatment uptake has led to the development of dedicated prison-based HCV services, as well as a willingness to commence treatment in short-term prisoners who are likely to be released or transferred prior to their treatment completion date. While a US study has reported on treatment outcomes among prisoners incarcerated for the full treatment duration, [10] no such investigation has hitherto examined treatment among prisoners whose release might pre-date treatment completion, or assessed the impact of inter-prison transfer. The introduction of all-oral directly-acting antiviral (DAA) therapies will shorten the duration of HCV treatment from 24-48 to 8-16 weeks of treatment, and reduce the incidence of side-effects. [11] However, nearly half of all

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prison sentences in Scotland are less than six months, [12] providing limited time for HCV testing, assessment, and treatment completion, even in the DAA era. An added complexity is that treatment disruption due to prison transfer is set to increase, given the growing prison population and changes to the prison estate. [13].

In the context of the potential benefits of DAAs [11] and the EASL recommendations on priority access for prisoners, the aim of this study was to compare treatment outcomes among prisoners and a matched population in the community, and to investigate factors (including prison release or transfer during therapy) that might be associated with adverse treatment outcomes. Such information will inform future clinical guidance on treatment strategies for prison inmates.

## **MATERIALS AND METHODS**

### **Hepatitis C treatment and care**

In Scotland, healthcare is delivered by fourteen geographically-defined Health Boards as part of a national universal service. Health Boards are free to design their Hepatitis C services according to local population needs, although outcomes are monitored nationally through the Scottish Government Blood Borne Virus Framework and the HCV Outcome and Quality Indicators. [14, 15] The majority of treatment for HCV in Scotland is delivered by Specialist Nurse Practitioners overseen by Consultant Physicians, and is based in hospital clinics or delivered by a dedicated prison-liaison team. This team develop close working relationships with prison staff, allowing early information sharing about potential prisoner release or transfer. In the three Health Boards where additional data were collected, prisoners who need to continue treatment after release or transfer are referred (in writing and by telephone) to the receiving community- or prison-based service. Addictions support, including opiate replacement therapy (ORT), is available to both prison and community patients, although prisoners may be prioritised within some Health Board areas for ORT treatment slots.

### **Data collection**

In Part 1 of the study, the Scottish HCV Clinical Database was used to compare treatment outcomes between prison and community treatment initiates. This database holds information on all patients treated for HCV at NHS clinics in Scotland (accounting for >95% of total treatment initiations). Health Boards with comprehensive data on both prison and community treatment initiations were included in the study i.e. NHS Forth Valley, Lothian, Greater Glasgow & Clyde, Tayside, Grampian, Fife, Lanarkshire, Borders, and Highlands.

In Part 2, additional data were collected from medical records of prison treatment initiates in three Health Boards with the largest prisoner case-load (Forth Valley, Greater Glasgow and Clyde, and Lothian) to investigate factors associated with treatment completion and treatment outcome among this population.

### **Inclusion criteria**

Patients were eligible for inclusion in Part 1 of the study if they were treatment-naive adults aged  $\geq$  20 years infected with genotype 1, 2, 3, or 4, treated with PEG/RBV +/- a protease inhibitor, and were initiated on treatment after 1<sup>st</sup> June 2009 (when prisoner status started to be reliably reported on the clinical database) and before 1<sup>st</sup> December 2011 (genotypes 1 and 4) and 1<sup>st</sup> June 2012 (genotypes 2 and 3), to allow adequate time for ascertainment of treatment outcomes.

Patients were eligible for inclusion in Part 2 of the study if they met all of the inclusion criteria applying to Part 1 of the study, *and* had initiated treatment in prison in one of the three selected Health Board areas.

### **Definitions of Treatment Outcomes**

Treatment completion: reached the end of planned course of therapy, regardless of whether attended for SVR check

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SVR: undetectable HCV RNA at 24 weeks post treatment completion

Relapse: HCV RNA negative at treatment completion, but subsequently HCV RNA positive at 12-24 weeks post treatment completion.

No response: HCV RNA detectable at end of treatment

### **Data analysis**

#### Part 1:

Patient characteristics were compared between patients who initiated HCV treatment in prison, and patients who initiated treatment in the community (for both the total community sample, and the matched community sample).

Variable ratio matching was used to match each prison treatment initiate with up to five community initiates. Matching was based on age at treatment commencement, sex, treatment type, cirrhosis status at or within 30 days of treatment commencement, and HCV genotype. Matching on categorical variables was exact, and matching on continuous variables was optimal, using mahalanobis distance scores. Variable ratio matching may lead to differences in characteristics between the prison and the matched community sample, which can be adjusted for in further analysis.

The odds of achieving a SVR among prison treatment initiates compared to community initiates were calculated for all patients and by genotype (GT 1/4 and GT 2/3), using conditional logistic regression to account for the matched study design. Two different populations were used for analysis: the intention to treat population (ITT), (i.e. all patients who received at least one dose of treatment, regardless of whether they were followed-up) and the per protocol population (i.e. all patients where the outcome of treatment was known). An unmatched logistic regression was conducted as a sensitivity analysis.

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### Part 2:

The characteristics of patients initiated on therapy in prison were compared between those who did and did not complete treatment, and who did or did not achieve a SVR (using both the ITT and the per protocol population). Because some prisoners were both transferred and released from prison during treatment (and release was considered to be more important in determining treatment outcome), a hierarchical variable was created as follows: i) neither released nor transferred, ii) transferred but not released, and iii) released, whether transferred or not.

Logistic regression was used to investigate factors associated with completing treatment, and achieving a SVR, for all patients, and by genotype. An additional variable 'Intention to complete treatment in prison' presented in the univariate analysis was not included in the multivariate analysis, due to a high degree of correlation with the 'Released during treatment' variable.

### Ethical approval

A submission was made to the South East Scotland Research Ethics Committee (application 14/WM/1045), who advised that ethical submission was not required for this study.

## RESULTS

### Part 1: Matched analysis of Scottish clinical database

There were 2,657 individuals who met the study inclusion criteria: 291 initiated treatment in prison, and 2,366 initiated treatment in the community. Characteristics of the 291 prison initiates and the matched 1,137 community 'controls' are shown in Table 1. More than 90% of initiates in both treatment settings were treated with PEG/RBV alone.

### Treatment outcomes

SVRs were 61% (95% confidence interval [CI] 55% to 66%) among patients initiated on treatment in prison, compared to 63% (95% CI 60% to 66%) among patients initiated on treatment in the

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community. The odds of achieving a SVR were not significantly associated with prisoner status at treatment initiation, whether calculated using conditional logistic regression (odds ratio [OR] 0.87, 95% CI 0.67, 1.15;  $p = 0.33$ ), or unmatched logistic regression (OR 0.90, 95% CI 0.70, 1.17;  $p = 0.45$ ) (Appendix 1). The same findings were observed when stratified by genotype (Table 2 and Appendix 1).

### **Part 2: Additional data collection from selected Health Board prison clinics**

The characteristics of the 200 patients included in the additional data collection were comparable to the total population of prison treatment initiates in Part 1 of the study, except for a slightly higher proportion of younger prisoners in the subsample (56% were aged 20-39 years in the total prisoner population, compared to 66% in the subsample) (Table 3).

#### **Treatment intentions**

Of 200 prisoners initiating treatment, 128 (64%) intended to complete treatment while incarcerated, 38 (19%) intended to complete treatment in the community, and 34 (17%) had unknown treatment intentions. Of the 128 patients intending to complete treatment in prison, 43 (34%) had GT1/4 infection and 85 (66%) had GT2/3 infection. Ninety-eight (77%) remained in prison for the full treatment duration, 22 (17%) were transferred, and 8 (6%) were released during treatment. Of the 38 patients intending to complete treatment in the community, 22 (58%) had GT1/4 infection and 16 (42%) had GT2/3.

#### **Prison transfer and release**

Among the 200 prisoners, 125 (63%) remained in the same prison for the full treatment duration, 37 (19%) were transferred but not released, and 38 (19%) were released during treatment. Among the 38 individuals released during treatment, this was a planned event for 28 (74%), and not planned or not known for 10 (26%) prisoners.

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SVRs were 74% (95% CI 65% to 81%) for those not released or transferred, 59% (95% CI 42% to 75%) for those transferred, and 45% (95% CI 29% to 62%) for those released during treatment. Using per protocol analysis (excluding individuals where the SVR outcome was not known), SVRs were 84% (95% CI 75% to 90%) among those not released or transferred, 81% (95% CI 62% to 94%) among those transferred, and 74% (95% CI 52% to 90%) among those released during treatment (Appendix 2).

### **Factors associated with treatment completion**

Of the 200 prisoners, 147 (74%, 95% CI 67% to 80%) completed a full course of treatment and 35 (18%) did not. Treatment completion status was not known for 18 (9%) individuals: for the purposes of logistic regression it was assumed that these individuals had not completed treatment. In the multivariate analysis including all genotypes, treatment completion was significantly associated with cirrhosis status (OR 0.16, 95% CI 0.03, 0.81,  $p=0.03$ ), being transferred during treatment (OR 0.41, 95% CI 0.17, 1.00,  $p=0.05$ ), or being released during treatment (OR 0.10, 95% CI 0.04, 0.24,  $p<0.01$ ) (Table 4).

### **Factors associated with achieving a SVR**

Of the 200 prisoners, 131 (66%, 95% CI 59% to 72%) achieved a SVR, and 27 (14%) did not. SVR status was unknown for 42 individuals (21%): for the purposes of logistic regression it was assumed that these individuals did not achieve a SVR. In the multivariate analysis, achieving a SVR was significantly associated with GT 2/3 (OR 2.1, 95% CI 1.12, 3.90,  $p=0.02$ ) and being released from prison during treatment (OR 0.33, 95% CI 0.15, 0.71,  $p < 0.01$ ), but not with transfer during treatment (OR 0.58, 95% CI 0.26, 1.27,  $p=0.18$ ) (Table 4).

## DISCUSSION

The use of prison-based treatment programmes for chronic HCV has become an increasingly important strategy in recent years, with the publication of a number of prioritisation statements and treatment targets relating to prison healthcare. [5, 8, 16, 17] The results of this study suggest that HCV treatment in the prison setting is both feasible and effective. Among nearly 1,500 individuals treated for HCV, outcomes were similar for prison-initiates (61% [95% CI 55% to 66%]) and a matched sample in the community (63% [95% CI 60% to 66%]). For those prison-initiates who were not released or transferred during therapy, outcomes appeared to be even better than for community initiates (although the two groups could not be matched and are therefore not directly comparable): SVRs were 61% (95% CI 47% to 74%) for GT1/4, and 75% (66% to 83%) for GT2/3 in the prison setting, compared to 56% (95% CI 51% to 60%) for GT1/4, and 68% (64% to 71%) for GT2/3 in the community. A previous study that restricted treatment to prisoners incarcerated for the full treatment duration found similar outcomes between prison- and community-based patients, but their prison population were more likely to have advanced liver disease. [10]

The observed benefits of prison-based therapy are likely to be related to improved treatment compliance within the prison regime, which is of particular relevance to the DAA era and the increased risk of viral resistance compared to standard PEG/RBV regimens. [18] The findings are consistent with recent cost-effectiveness studies of HCV case-finding in prisons. Short prison sentences and a lack of continuity of care between prison and the community attenuate the cost-effectiveness of case-finding initiatives in prisons, based on traditional PEG/RBV regimens. However, case-finding may become cost-effective in the DAA era, because treatment is more likely to be completed during the prison sentence [19, 20].

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Our results suggest that prison-based treatment programmes should be encouraged, both as a means of improving population health (given that the majority of HCV-infected PWID will pass through the prison system at some point [7]), and of offering individuals the best possible chance of achieving a SVR.

However, it is evident that prison-based treatment is not without its challenges. In this study, nearly 40% of prisoners were either released or transferred during HCV therapy, and outcomes were poorer for these individuals. This pattern was observed among both GT1/4 and GT2/3 patients, and was still evident (although attenuated) using per protocol analysis, suggesting that only part of this difference is due to increased loss to follow-up or failure to attend for a final SVR check among those who are transferred or released (Appendix 2, 3, and 4).

Poorer treatment outcomes among transferred prisoners raise a number of issues for both healthcare providers and custodial staff. In contrast to prisoners who are released, transferred prisoners remain under the care of the prison system, and any unplanned interruption in therapy is by definition the responsibility of the system, rather than the patient. Transferring prison not only means a change in regime (potentially changing the timing of medication and access to or timing of clinical review), but also a change of healthcare staff, and the need to build new relationships mid-way through a course of therapy. For this reason, our results suggest that transfer during treatment should be prevented wherever possible, using a policy of medical hold (whereby prisoners receiving a course of medical treatment are prohibited from moving prison, except for security reasons) if necessary. The use of medical holds may be inconsistently applied and may in some cases disadvantage a prisoner who wishes to transfer for family reasons or training opportunities. [22] However, their use may be sensible in situations where the prisoner has made an informed decision to forgo any potential benefits of transfer while treatment is being completed. For those situations where transfer is obligatory, healthcare services may wish to agree a set of minimum requirements

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for prison transfers (e.g. such as provision of a minimum quantity of medication, and maximum waiting times for an appointment with the receiving team).

Poorer treatment outcomes in this study among those released during therapy are also concerning, and it may be prudent in some cases to delay treatment until after a prisoner's release. Decisions need to be made on a case by case basis, taking into account the duration of incarceration, willingness to commence treatment, and the existence of any support structures after release. There is currently a lack of published evidence in this area, but a number of factors are likely to contribute to treatment completion post-release; including strong family support, stable housing and employment, and links to other healthcare providers in the community. Patient motivation through provision of test results that demonstrate improvements in liver function (e.g. fibroscan results or liver function tests) [23] might also be helpful.

In a small number of cases, release during treatment may be an unexpected event; for example, if a prisoner is released directly from a court hearing. In this study, only 6% of patients who intended to complete treatment while incarcerated were actually released prior to completion, suggesting that healthcare practitioners have sufficient knowledge of prisoner trajectory when treatment is started. However, it may still be of value to agree contingency plans for prisoners where incarceration for the full treatment period cannot be guaranteed; for example seeking the prisoner's permission for HCV services to contact their GP, a close family member, or Addictions Services in the event that they are released and lost to follow-up. Developing close links with Addictions Services may be particularly useful, given that those on OST programmes are much more likely to stay in touch with services.

Finally, the risk of reinfection among prisoners following treatment has been shown to be considerable. [24] For those still incarcerated, the greatest risk lies in the continuation of injecting practice in a setting where needle exchange provision may be limited or absent. [4] For those released, there may be a return to old behaviours and injecting partners, many of whom will not

have had the benefit of priority access to HCV treatment while in prison. Treatment guidelines suggest that the risk of reinfection should be fully explained, and that patients should be counselled on ways to minimize this risk, [5, 17] although there is currently a lack of evidence around how this counselling can be effectively delivered.

This study has demonstrated that prison-based treatment is feasible, and achieves comparable or in some cases even better outcomes than community-based treatment. However, treatment in the prison setting is not without its challenges, particularly with respect to transfer and release from prison while therapy is ongoing. Treatment disruption due to release or transfer needs to be prevented wherever possible, while ensuring that contingency measures to maximise treatment success are in place where transfer or release is unavoidable.

## **ACKNOWLEDGEMENTS AND DISCLOSURES**

MH acknowledges support from the National Institute for Health Research Health Protection Research Unit (NIHR HPRU) in Evaluation of Interventions at University of Bristol.

NM acknowledges support from the National Institute for Drug Abuse [grant number R01 DA037773-01A1] and University of California San Diego Center for AIDS Research (CFAR), a National Institute of Health (NIH) funded program [grant number P30 AI036214]. The views expressed are those of the authors, and not necessarily those of the UK NHS, the UK NIHR or the UK Department of Health

The authors would like to acknowledge the Clinical Database Monitoring Committee, the Clinical Database data entry staff at the participating NHS Health Boards, and the Scottish Government for funding the Scottish Clinical Database.

JD has received honoraria for lectures, advisory panels, and support to attend conferences from Janssen, Roche, MSD, Gilead, BMS, Boeringer Ingelheim, and his institution has received grants for research from Janssen, Roche, MSD, Gilead, and BMS. SL has been on the nurse advisory board for Abbvie and BMS. DJG has received honoraria for educational contributions (e.g. lectures, reports) and for providing advice on aspects of Hepatitis C and public health from Abbvie, Merck, Gilead, BMS, and Janssen. MH has received unrestricted research grants as co-investigator from Gilead and honoraria from Gilead and Janssen. NM has received unrestricted research grants from Gilead unrelated to this work and honoraria from Merck, AbbVie, and Janssen. All other authors declare that they have no conflicts of interest in relation to this manuscript.

## **AUTHOR CONTRIBUTIONS**

EJA, SJH & DJG designed the study; WM, JS, AC, SL, SEP & PB conducted the data collection; HV & HI provided the clinical database extract, EJA conducted the data analysis drafted the manuscript; PRM, SB, AF & JD are members of the Scottish Clinical Database Monitoring Committee; SJH supervised the study; JT, SJH, PRM, SB, AF, JD, MH, NM & DJG provided expert review of the manuscript.

## REFERENCES

1. Lavanchy D. The global burden of hepatitis C. *Liver International*, 2009; 29 (s1): 74-81
2. Larney S, Kopinski H, Beckwith C.G *et al.* The incidence and prevalence of hepatitis C in prisons and other closed settings: Results of a systematic review and meta-analysis. *Hepatology*, 2013; 58: 1215-1224
3. Walmsley R. World Prison Population List (tenth edition). International Centre for Prison Studies. International Centre for Prison Studies, 2013. Accessed online 2<sup>nd</sup> June 2015, URL: [http://prisonstudies.org/sites/prisonstudies.org/files/resources/downloads/wpppl\\_10.pdf](http://prisonstudies.org/sites/prisonstudies.org/files/resources/downloads/wpppl_10.pdf)
4. Hunt DR, Saab S. Viral hepatitis in incarcerated adults: a medical and public health concern. *Am J Gastroenterol*, 2009; 1024-31
5. European Association for the Study of Liver Diseases. EASL Clinical Practice Guidelines, 2015.
6. Taylor A, Munro A, Allen E *et al.* Low incidence of hepatitis C virus among prisoners in Scotland. *Addiction*, 2013; 108: 1296-304
7. University of the West of Scotland, Health Protection Scotland, University of Strathclyde, and the West of Scotland Specialist Virology Centre. The Needle Exchange Surveillance Initiative (NESI): Prevalence of HCV and injecting risk behaviours among people who inject drugs attending injecting equipment provision services in Scotland, 2008/2009 & 2010. University of the West of Scotland, September 2012
8. Scottish Government. Hepatitis C Action Plan for Scotland: Phase II: May 2008 – March 2011. Scottish Government, 2008. Accessed online 27<sup>th</sup> October 2014, URL: <http://www.scotland.gov.uk/Resource/Doc/222750/0059978.pdf>
9. Public Health England. Hepatitis C in the UK: 2014 Report. Accessed online 18<sup>th</sup> June 2014, URL: [https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/337115/HCV\\_in\\_the\\_UK\\_2014\\_24\\_July.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/337115/HCV_in_the_UK_2014_24_July.pdf)
10. Rice JP, Burnett D, Tsotsis H *et al.* Comparison of Hepatitis C Virus Treatment Between Incarcerated and Community Patients. *Hepatology*, 2012; 56: 1252-1260
11. Kohli A, Shaffer A, Sherman A, Kottlil S. Treatment of Hepatitis C: A Systematic Review. *JAMA*, 2014; 312: 631-640
12. Scottish Government. Statistical Bulletin Crime and Justice Series: Prison Statistics Scotland: 2012-13. Accessed online 30<sup>th</sup> September 2015, URL: <http://www.gov.scot/Topics/Statistics/Browse/CrimeJustice/Datasets/PrisonsDatasets/prisdata1213>
13. Audit Scotland. Managing increasing prisoner numbers in Scotland. Audit Scotland, May 2008. Accessed online 8<sup>th</sup> June 2015, URL: [http://www.audit-scotland.gov.uk/docs/central/2008/nr\\_080508\\_prisoner\\_numbers.pdf](http://www.audit-scotland.gov.uk/docs/central/2008/nr_080508_prisoner_numbers.pdf)
14. Scottish Government. The Sexual Health and Blood Borne Virus Framework 2011-15. Accessed online 1<sup>st</sup> June 2015, URL: <http://www.gov.scot/Resource/Doc/356286/0120395.pdf>
15. Healthcare Improvement Scotland. Quality Indicators for Hepatitis C, APRIL 2012. Accessed online 5<sup>th</sup> May 2015, URL: [http://www.healthcareimprovementscotland.org/our\\_work/long\\_term\\_conditions/hepatitis\\_c/hepatitis\\_c\\_quality\\_indicators.aspx](http://www.healthcareimprovementscotland.org/our_work/long_term_conditions/hepatitis_c/hepatitis_c_quality_indicators.aspx)
16. Ministerial Advisory Committee on AIDS, Sexual Health and Hepatitis, Hepatitis C Subcommittee. Hepatitis C Prevention, Treatment and Care: Guidelines for Australian Custodial Settings, 2008. Accessed online 12<sup>th</sup> August 2015, URL:

[http://www.health.gov.au/internet/main/publishing.nsf/Content/DA9F4D3AA93288EFCA257BF00021DF13/\\$File/prison-guidelines.pdf](http://www.health.gov.au/internet/main/publishing.nsf/Content/DA9F4D3AA93288EFCA257BF00021DF13/$File/prison-guidelines.pdf)

17. American Association for the Study of Liver Diseases. Recommendations for Testing, Managing, and Treating Hepatitis C.
18. Poveda E, Wyles DL, Mena A, Pedreira JD, Castro-Iglesias A, Cachay E. Update on hepatitis C virus resistance to direct-acting antiviral agents. *Antiviral Res*, 2014; 108: 181-191
19. Martin NK, Hickman M, Miners A, Hutchinson SJ, Taylor A, Vickerman P. Cost-effectiveness of HCV case-finding for people who inject drugs via dried blood spot testing in specialist addiction services and prisons. *BMJ Open*, Aug 2013; 3(8)
20. Martin NK, Vickerman P, Brew IF, Williamson J, Miners A, Irving WL, et al. Is increased hepatitis C virus case-finding combined with current or 8-week to 12-week direct-acting antiviral therapy cost-effective in UK prisons? A prevention benefit analysis. *Hepatology*, 2016; 63: 1796-1808
21. United Nations Human Rights. Basic Principles for the Treatment of Prisoners, 1990. Accessed online 12<sup>th</sup> August 2015, URL:<http://www.ohchr.org/EN/ProfessionalInterest/Pages/BasicPrinciplesTreatmentOfPrisoners.aspx>
22. Humphreys C, Lombard M, Newton A, O'Moore E, Railton C. An audit of hepatitis C services in a representative sample of English prisons. Public Health England and Department of Health, 2013. Accessed online 21<sup>st</sup> July 2015, URL:[https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/337401/An\\_audit\\_of\\_hepatitis\\_C\\_services\\_in\\_a\\_representative\\_sample\\_of\\_English\\_prisons\\_2013.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/337401/An_audit_of_hepatitis_C_services_in_a_representative_sample_of_English_prisons_2013.pdf)
23. Vergniol J, Foucher J, Castera L *et al.* Changes of non-invasive markers and FibroScan values during HCV treatment. *Journal of Viral Hepatitis*, 2009; 16: 132-140
24. Marco A, Esteban JI, Sole C *et al.* Hepatitis C virus reinfection among prisoners with sustained virological response after treatment for chronic hepatitis C. *Journal of Hepatology*, 2013; 59: 45-51

## Hepatitis C treatment in prisons

Table 1: Characteristics of 2,657 patients (291 prison-based and 2,366 community-based) commencing Hepatitis C treatment 2009-2012, by incarceration status

	Commenced treatment in prison (n= 291)	Commenced treatment in community	
		All (n= 2,366)	Matched sample (n=1,137)*
Age**			
20-29 years	27 (9.3%)	133 (5.6%)	70 (6.2%)
30-39 years	136 (46.7%)	773 (32.7%)	513 (45.1%)
40-49 years	108 (37.1%)	897 (37.9%)	461 (40.6%)
> 50 years	20 (6.9%)	563 (23.8%)	93 (8.2%)
Sex			
Male	261 (89.7%)	1,714 (72.4%)	995 (87.5%)
Female	30 (10.3%)	652 (27.6%)	142 (12.5%)
Major HCV genotype			
1 or 4	115 (39.5%)	872 (36.9%)	461 (40.4%)
2	16 (5.5%)	134 (5.7%)	55 (4.8%)
3	160 (55.0%)	1,360 (57.5%)	621 (54.6%)
Cirrhosis**			
Diagnosed with cirrhosis	8 (2.8%)	277 (11.7%)	40 (3.5%)
Not diagnosed with cirrhosis	283 (97.3%)	2,089 (88.3%)	1097 (96.5%)
Year treated			
2009	43 (14.8%)	325 (13.7%)	160 (14.1%)
2010	108 (37.1%)	767 (32.4%)	385 (33.9%)
2011	93 (32.0%)	781 (33.0%)	369 (32.5%)
2012	47 (16.2%)	493 (20.8%)	223 (19.6%)
Treatment outcome (all genotypes)			
SVR	176 (60.5%)	1,425 (60.2%)	715 (62.9%)
No response/Relapse	35 (12.0%)	478 (20.2%)	196 (17.2%)
Unknown	80 (27.5%)	463 (19.6%)	226 (19.9%)
Treatment outcome by genotype			
<b>Genotypes 1 and 4</b>	<b>115 (100%)</b>	<b>872 (100%)</b>	<b>461 (100%)</b>
SVR	56 (48.7%)	439 (50.3%)	256 (55.5%)
No response/Relapse	22 (19.1%)	275 (31.5%)	122 (26.5%)
Unknown	37 (32.2%)	158 (18.1%)	83 (18.0%)
<b>Genotypes 2 and 3</b>	<b>176 (100%)</b>	<b>1,494 (100%)</b>	<b>676 (100%)</b>
SVR	120 (68.2%)	986 (66.0%)	459 (67.9%)
No response/Relapse	13 (7.4%)	203 (13.6%)	74 (10.9%)
Unknown	43 (24.4%)	305 (20.4%)	143 (21.2%)

\* Community-based sample were matched on age at treatment commencement, sex, treatment type, cirrhosis status at or within 30 days of treatment commencement, and HCV genotype \*\*At treatment commencement

Table 2: Conditional logistic regression of the odds of SVR by prisoner status, among i) the intention to treat population, and ii) the population where the outcome of treatment is known

	Intention to treat population		Population where outcome of treatment is known	
	Odds ratio* (95% CI)	p value	Odds ratio * (95% CI)	p value
<b>ALL GENOTYPES</b>				
Community	1	-	1	-
Prison	0.87 (0.67, 1.15)	0.33	1.18 (0.76, 1.83)	0.46
<b>GENOTYPE 1/4</b>				
Community	1	-	1	-
Prison	0.72 (0.47, 1.09)	0.12	1.11 (0.62, 1.99)	0.73
<b>GENOTYPE 2/3</b>				
Community	1	-	1	-
Prison	1.02 (0.71, 1.46)	0.93	1.28 (0.66, 2.49)	0.47

\*Matched on age at treatment commencement, sex, treatment type, cirrhosis status at or within 30 days of treatment commencement, and HCV genotype

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Table 3: Characteristics of 200 patients commencing Hepatitis C treatment in prison in three large Health Board areas, 2009-2012

Patient characteristics	All patients N (%)	Completed treatment, n (row %)			Achieved SVR, n (row %)		
		Yes	No/ not known <sup>a</sup>	p value <sup>c</sup>	Yes (n= 131)	No/not known <sup>b</sup> (n= 69)	p value <sup>c</sup>
<b>All patients</b>	200 (100%)	147 (74%)	53 (27%)	-	131 (66%)	69 (35%)	-
<b>Age<sup>d</sup></b>							
20-29 years	28 (14%)	21 (75%)	7 (25%)	-	21 (75%)	7 (25%)	-
30-39 years	103 (52%)	79 (77%)	24 (23%)	0.85	64 (62%)	39 (38%)	0.21
> 40 years	66 (33%)	47 (71%)	19 (29%)	0.71	45 (68%)	21 (32%)	0.51
Not known	3 (2%)	0 (0%)	3 (100%)	-	1 (33%)	2 (67%)	-
<b>Sex</b>							
Male	173 (87%)	126 (73%)	47 (27%)	-	113 (65%)	60 (35%)	-
Female	27 (14%)	21 (78%)	6 (22%)	0.54	18 (67%)	9 (33%)	0.89
<b>Major HCV genotype</b>							
1 or 4	77 (39%)	49 (64%)	28 (36%)	-	41 (53%)	36 (47%)	-
2 or 3	123 (62%)	98 (80%)	25 (20%)	<b>0.01</b>	90 (73%)	33 (27%)	<b>&lt;0.01</b>
<b>Cirrhosis<sup>d</sup></b>							
Yes	7 (4%)	3 (43%)	4 (57%)	-	3 (43%)	4 (57%)	-
No	193 (97%)	144 (75%)	49 (25%)	<b>0.08</b>	128 (66%)	65 (34%)	0.22
<b>Baseline viral load</b>							
Low	133 (67%)	101 (76%)	32 (24%)	-	91 (68%)	42 (32%)	-
High	61 (31%)	43 (70%)	18 (30%)	0.42	36 (59%)	25 (41%)	0.20
Not known	6 (3%)	3 (50%)	3 (50%)	-	4 (67%)	2 (33%)	-
<b>Drug injecting history</b>							
Within last one year	48 (24%)	34 (71%)	14 (29%)	-	32 (67%)	16 (33%)	-
More than one year ago	132 (66%)	103 (78%)	29 (22%)	0.32	88 (67%)	44 (33%)	1.00
Never/unknown	20 (10%)	10 (50%)	10 (50%)	-	11 (55%)	9 (45%)	-
<b>Opiate replacement<sup>d</sup></b>							
Yes	98 (49%)	72 (74%)	26 (27%)	-	69 (70%)	29 (30%)	-
No	30 (15%)	24 (80%)	6 (20%)	0.47	22 (73%)	8 (27%)	0.76
Not known	72 (36%)	51 (71%)	21 (29%)	-	40 (56%)	32 (44%)	-
<b>Treatment intentions<sup>e</sup></b>							
Intend to complete in prison	128 (64%)	109 (85%)	19 (15%)	-	94 (73%)	34 (27%)	-
Intend to complete in community	38 (19%)	12 (32%)	26 (68%)	<b>&lt;0.01</b>	16 (42%)	22 (58%)	<b>&lt;0.01</b>
Not known	34 (17%)	26 (76%)	8 (24%)	-	21 (62%)	13 (38%)	-
<b>Prison sentence</b>							
< 4 years	131 (66%)	96 (73%)	35 (27%)	-	84 (64%)	47 (36%)	-
≥ 4 years	42 (21%)	33 (79%)	9 (21%)	0.49	30 (71%)	12 (29%)	0.39
Not known	27 (14%)	18 (67%)	9 (33%)	-	17 (63%)	10 (37%)	-
<b>Movement during treatment</b>							
None	125 (63%)	107 (86%)	18 (14%)	-	92 (74%)	33 (26%)	-
Transferred but not released	37 (19%)	26 (70%)	11 (30%)	<b>0.04</b>	22 (59%)	15 (41%)	<b>0.10</b>
Released (+/- transfer)	38 (19%)	14 (37%)	24 (63%)	<b>&lt;0.01</b>	17 (45%)	21 (55%)	<b>&lt;0.01</b>
<b>Patients with GT 1/4</b>	77 (100%)	49 (64%)	28 (36%)	-	41 (53%)	36 (47%)	-
<b>Released during HCV treatment*</b>							
No	56 (72%)	42 (75%)	14 (25%)	-	34 (61%)	22 (39%)	-
Yes	21 (27%)	7 (33%)	14 (67%)	<b>&lt;0.01</b>	7 (33%)	14 (67%)	<b>0.03</b>
<b>Patients with GT 2/3</b>	123 (100%)	98 (80%)	25 (20%)	-	90 (73%)	33 (27%)	-
<b>Released during HCV treatment*</b>							
No	106 (86%)	91 (86%)	15 (14%)	-	80 (75%)	26 (25%)	-
Yes	17 (14%)	7 (41%)	10 (59%)	<b>&lt;0.01</b>	10 (59%)	7 (41%)	0.15

<sup>a</sup> Treatment completion status not known for 18 (9%) cases; <sup>b</sup> Treatment outcome not known for 42 (21%) cases; <sup>c</sup> p value refers to comparison between proportion 'Yes' and proportion 'No/not known'; <sup>d</sup> At treatment commencement; <sup>e</sup> 'Intention to complete treatment in prison' was not included in the multivariate model, due to correlation with 'Released during treatment'

\* Variable collapsed due to cell sizes < 5

## Hepatitis C treatment in prisons

Table 4: Logistic regression of odds of treatment completion and SVR among 200 patients who commenced Hepatitis C treatment in prison, and stratified by genotype

Patient characteristics	Odds of completing treatment		Odds of achieving a SVR	
	Adjusted odds ratio	p value	Adjusted odds ratio	p value
<b>ALL GENOTYPES</b>				
<i>Major HCV genotype</i>				
1 or 4	1	-	1	-
2 or 3	1.75 (0.85, 3.58)	0.13	<b>2.09 (1.12, 3.90)</b>	<b>0.02</b>
<i>Cirrhosis *</i>				
No	1	-	1	-
Yes	<b>0.16 (0.03, 0.81)</b>	<b>0.03</b>	0.31 (0.06, 1.46)	0.14
<i>Movement during treatment</i>				
None	1	-	1	-
Transferred but not released	<b>0.41 (0.17, 1.00)</b>	<b>0.05</b>	0.58 (0.26, 1.27)	0.18
Released (+/- transfer)	<b>0.10 (0.04, 0.24)</b>	<b>&lt;0.01</b>	<b>0.33 (0.15, 0.71)</b>	<b>&lt;0.01</b>
<b>GENOTYPE 1/4</b>				
<i>Cirrhosis *</i>				
No	1	-	1	-
Yes	0.33 (0.19, 5.89)	0.45	0.50 (0.29, 8.71)	0.63
<i>Movement during treatment</i>				
None	1	-	1	-
Transferred but not released	1.17 (0.30, 4.47)	0.82	0.50 (0.16, 1.59)	0.24
Released (+/- transfer)	<b>0.17 (0.05, 0.54)</b>	<b>&lt;0.01</b>	<b>0.25 (0.08, 0.78)</b>	<b>0.02</b>
<b>GENOTYPE 2/3</b>				
<i>Cirrhosis *</i>				
No	1	-	1	-
Yes	0.12 (0.01, 0.97)	<b>0.05</b>	0.24 (0.04, 1.52)	0.13
<i>Movement during treatment</i>				
None	1	-	1	-
Transferred but not released	<b>0.17 (0.05, 0.56)</b>	<b>&lt;0.01</b>	0.66 (0.22, 1.99)	0.46
Released (+/- transfer)	<b>0.06 (0.02, 0.23)</b>	<b>&lt;0.01</b>	0.43 (0.14, 1.31)	0.14

\*At the time of treatment commencement