

**Recommendations on Hepatitis C Virus
Case Finding and Access to Care
Report of the National Short Life Working Group (SLWG)**

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Version:	1.0
Date:	November 2018

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Citation for this document

Scottish Health Protection Network. ***Recommendations on Hepatitis C Virus Case Finding and Access to Care. Report of the National Short Life Working Group***

Published by Health Protection Scotland

Meridian Court, 5 Cadogan Street, Glasgow, G2 6QE.

Health Protection Scotland is a division of NHS National Services Scotland.

First published January 2019

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DOCUMENT CONTROL SHEET

Key Information:			
Date Published/Issued:	November 2018		
Version/Issue Number:	V1.0		
Document status:	Final		
	Name:	Role:	Organisation:
Author:	Prof John Dillon	Consultant Hepatologist and BBV Clinical Lead on behalf of the SLWG	NHS Tayside
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Owner:	SHPN SHBBV Executive Leads Network		
Approved by and Date:	SHPN Viral Hepatitis Clinical Leads and MCN Coordinators Network 21 January 2019		
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File Location:	F:\PHI\SHPN-PM\02 SHBBV\01 SHBBV 2016-20\05 Reports\Progress		

Acknowledgements

Members of and contributors to the short life working group: Lisa Allerton, Esther Aspinall, Stephen Barclay, Wendy Beadles, Chris Biggam, David Campbell, Marissa Collins, Elizabeth Dickson, John Dillon, Ann Erikson, Jose Fernandez, Andrew Fraser, Charles Gore, Rory Gunson, Allan McLeod, Wendy Mitchell, Andrew Radley, Trina Ritchie, Emma Robinson, Mark Steven, Hilda Stiven, Trish Tougher, Jenny Wares, Amanda Weir, Fraser West, and Leon Wylie.

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Executive Summary

1. Introduction

Scottish Government has set a goal to eliminate hepatitis C infection and hepatitis C related severe disease and death as a major public health concern. This is to be achieved by working with NHS Boards, local authorities, and the third sector to treat a minimum of 2,000 people during 2018-19, 2,500 during 2019-20 and 3,000 people each year thereafter.

Meeting this goal in Scotland will require an ambitious programme of HCV awareness-raising, case-finding, re-engagement, and scale-up of treatment and care. Following a request by Scottish Government, a short life working group (SLWG) was commissioned to develop recommendations on this programme of work. This report describes the methodology, key findings, and recommendations of the SLWG.

2. Context

It is estimated that there are 34,500 people chronically infected with HCV and living in Scotland (HPS, 2016). Approximately 15,500 (45% of the total) have not yet been diagnosed, and a further 13,200 have been diagnosed but have never received treatment. This equates to nearly 30,000 individuals across Scotland who need to be engaged or re-engaged in HCV treatment and care.

3. Methodology

Membership of the SLWG was selected to represent a range of large, small, urban, and rural Health Boards, providing relevant knowledge and expertise. The remit of the group was to review evidence and agree recommendations on four key topic areas: Awareness-raising, Case-finding, Novel approaches to testing, and Access to care. The following sources of evidence were reviewed: a national survey of best practice at Health Boards, interviews with key informants, rapid reviews of the published evidence, and a rapid review of national and international guidance on HCV.

Suggestions of recommendations on the four topic areas were invited from SLWG members, from which a long list was developed for discussion. Members voted on their priorities using the following options: *high, medium, low, or not a priority*; recommendations receiving a majority for *high or medium* priority were included in the short list for discussion at the national stakeholder event in May 2018. Voting was conducted in a similar manner at the national event, with recommendations receiving a majority vote for *high or medium* priority being included in the final report. The draft report was circulated widely for consultation, including all Health Board BBV teams and all delegates attending the national event. An additional consultation was carried out with national Alcohol and Drug Partnership (ADP) leads, facilitated by Scottish Government.

4. Recommendations

General principles

The SLWG agreed the following general principles in developing the recommendations:

- The importance of the full care pathway, from prevention to testing, treatment, and care.
- Reducing barriers to care, particularly for service users who may have experienced stigma in accessing health services in the past.
- Offering patients a choice: some patients value the anonymity of a hospital or specialist setting, whereas others value the convenience of community settings.
- Offering both social and biomedical HCV interventions. Some patients may engage with social support only, but subsequently engage with treatment once support is in place.
- However, social issues should not preclude treatment for those willing to commence, bearing in mind that DAA therapy is straightforward and in most cases requires minimal healthcare intervention.
- BBV should be considered as a core part of the work of services that look after those at highest risk, including Drug Use services and IEP.

Recommendations on case-finding

1. HCV testing should be opt-out at services used by groups at highest risk of HCV, including Drug Use services, specialist IEP services, prisons, asylum services, and homeless/crisis services.
2. Drug Use services must offer all service-users (including OST clients) HCV testing at their initial assessment, and annually thereafter. Testing should be offered more frequently if there has been an episode of risk. The requirement to offer opt-out testing should be written into contracts (or equivalent agreements or understandings) with providers of these services, with reference to the Health Board targets outlined in 5.1.
3. All pharmacies that dispense OST or provide injecting equipment must either offer HCV testing, or have a clear pathway in to testing, treatment, and care. All relevant staff must be confident to provide basic information on BBV issues.
4. BBV MCNs should support GPs to offer testing to those who are at increased risk of HCV, in particular current and former People Who Inject Drugs (PWID). READ codes and OST prescription lists in primary care should be used to identify patients at risk.
5. BBV MCNs should support the development of HCV testing opportunities for: people born or brought up in geographical areas of high HCV prevalence, people admitted to medical or mental health facilities with risk factors for HCV, and all persons found to have a raised ALT.

6. As part of the existing NHS Education for Scotland programme, there should be online training available for professionals on HCV testing, treatment, and care.

Recommendations on novel approaches to testing

7. The gold standard for testing is venepuncture analysed by conventional technology. Dried Blood Spot (DBS) testing can be used where venepuncture would not be feasible or venepuncture skills are not available, for example non-clinical staff, outreach settings, or for those with difficult venous access.
8. Pilots of Point of Care (PoC) testing, self-testing, and other novel testing approaches should be performed to evaluate the impact on access to treatment and care. All testing approaches should be developed in partnership with laboratories to ensure appropriate quality control.

Recommendations on awareness-raising

9. There should be local awareness-raising campaigns about the risks of HCV, test availability, and the effectiveness of new therapies, using conventional and social media approaches. Awareness-raising should be led by Public Health departments and delivered in partnership with services used by people at increased risk of HCV.*
10. BBV MCNs should facilitate education and training for all primary and secondary care health practitioners to raise awareness of HCV and local treatment and care pathways. MCNs should ensure that staff working in services used by people at increased risk of HCV * are appropriately trained to conduct testing, offer advice on treatments, and support patients into care.

Recommendations on access to care

11. BBV MCNs must ensure that all testing venues or testing initiatives either provide treatment at the testing venue, or have a clear pathway in to care. Care pathways must be designed to minimise or remove barriers to providing HCV treatment.
12. BBV MCNs are required to conduct a look-back exercise at least once every three years (and ideally more frequently) to re-engage those who have previously been diagnosed and/or referred to services, but who have never been treated.
13. HCV treatment and care services should accept referrals from patients, peers, and third sector partners, in addition to referrals from healthcare practitioners.
14. HCV treatment should be provided in a variety of locations close to the patient, and must be available in all appropriate Drug Use services (excluding for example drug crisis services or third-sector providers). Treatment may be provided by in-house staff or specialist in-reach services.
15. If appropriate to facilitate access to care, patients should be offered a choice of support, which could include peer, third sector, NHS, or partnership providers.

* Services used by people at increased risk of HCV:

Drug Use services, IEP services, asylum services, sexual health services, homeless/crisis services, GPs in areas of high HCV prevalence, peer support or drug recovery services, criminal justice and detention facilities.

Recommendations for further research

There were a number of interventions that were considered to be of possible benefit, but had insufficient evidence to support a recommendation. These interventions are recommended as pilots or areas of further research, which could be adopted by single health boards or regions and evaluation findings shared nationally.

16. A feasibility study of identifying people at risk from national or local OST or drug addiction records should be conducted.

17. A pilot study should be conducted to assess the feasibility and effectiveness of birth cohort testing in areas of deprivation.

18. A pilot study should be conducted to assess the feasibility and effectiveness of Drug Use and IEP services working with existing clients to identify partners, friends, or associates who are in a risk group and could be offered a test.

5. Monitoring

5.1. Recommendations for monitoring

The recommendations require robust monitoring to ensure that Scotland stays on track to deliver elimination of HCV. Existing measurement and reporting structures should be used to minimise additional workload and prevent duplication. It is recommended that MCNs are responsible for the collation of data for reporting to their local Clinical and Executive leads, and ultimately to the national SHBBV Executive leads group.

1. BBV MCNs should monitor and feed-back on a quarterly basis to relevant services on the number of tests, and the number of positive tests conducted. The number of positive tests should be presented against the estimated number of people still to be diagnosed with HCV in the respective Health Board area.

Suggested testing targets for services used by those at highest risk (Drug Use services, IEP services, and prisons) are:

- i) 90% of clients ever had a test
- ii) 80% tested within the preceding 12 months

It is recognised that individual Health Boards will have different capabilities in terms of data availability and accuracy, and that estimates may be required.

2. BBV MCNs should monitor the number of HCV treatment initiations on a quarterly basis to ensure they are on track to meet their local Health Board targets set by Scottish Government.

3. BBV MCNs should undertake appropriate investigation and action if the above testing, diagnosis, and treatment targets are not met.

4. BBV MCNs should report biannually on their progress to the national SHBBV Executive leads group.

6. Conclusions

Scotland is in an ideal position to take advantage of the HCV therapeutic revolution, and has the leadership, will, and infrastructure to deliver HCV elimination. These recommendations offer a comprehensive and practical approach to HCV diagnosis and treatment at Boards, including a number of recommendations for further research or pilot activity and a proposal for monitoring that utilises existing HCV reporting structures. Effective implementation and monitoring of these recommendations should set Scotland well on course for HCV elimination in the coming decade.

BOX 1: RAPID SUMMARY OF EVIDENCE

Case-finding

A systematic review reported that targeted testing interventions are effective in improving test uptake, diagnosis, and treatment uptake [Aspinall 2015]. However, current evidence suggests that birth cohort screening is unlikely to be cost effective in a Scottish setting, unless additional targeting at areas of higher deprivation is utilised [Collins 2018, unpublished].

A review of national records by NHS Fife was successful in identifying those lost to follow-up and re-engaging in HCV care, although many of the patients re-engaged were not actually 'lost', and were in regular contact with other NHS services. NHS Grampian has conducted a similar project using local database records and has re-engaged 134 people, of whom 68 have already commenced on treatment or have agreed a start date. NHS Tayside has successfully rolled out testing in pharmacies, and NHS Greater Glasgow & Clyde has conducted testing drives in community drug services achieving nearly 100% test uptake for the last three years.

Novel approaches to testing

There is good evidence that dried blood spot (DBS) testing increases test uptake [Coats 2015], and some evidence that it increases the number of HCV diagnoses [McLeod 2014]. The evidence for Point of Care (PoC) testing is weaker, but two studies found an increase in test uptake, and one study found an increase in linkage to care [Bregenzer 2017, Bottero 2015].

Awareness-raising

The evidence for HCV-specific mass media campaigns is weak. One Australian study found small improvements in public knowledge but there was minimal impact on attitudes [Smith 2006], and a US campaign on birth cohort screening led to increased website activity but the impact on knowledge, attitudes, and treatment uptake was not assessed [Jorgensen 2016].

NHS Forth Valley has delivered local awareness-raising via local radio featuring real patients talking about their experiences; people who are interested can phone a hotline for more information. NHS Lanarkshire has conducted social media campaigns and found improved responses when using Lanarkshire-specific strap-lines and local NHS branding.

Access to care

Evidence from the pre directly-acting antiviral (DAA) era suggests community-based treatment achieves similar or slightly improved SVRs compared to hospital-based treatment [Wade 2016]. Findings of a review of studies from the DAA era are awaited. NHS Greater Glasgow & Clyde has improved attendance and treatment uptake through a pilot of consultant outreach at community drug use clinics. NHS Tayside is offering HCV treatment at IEPs and has successfully initiated nearly 100 service-users on therapy. Some patients may prefer the anonymity of a hospital clinic, whereas others value the convenience of community-based clinics: offering patients choice is a priority.

1. Introduction

Scottish Government has set a goal to eliminate hepatitis C infection and hepatitis C related severe disease and death as a major public health concern. This is to be achieved by working with NHS Boards, local authorities, and the third sector to treat a minimum of 2,000 people during 2018-19, 2,500 during 2019-20 and 3,000 people each year thereafter.

Meeting this goal in Scotland will require an ambitious programme of work incorporating HCV awareness-raising, case-finding and re-engagement, and scale-up of treatment and care. Following a request by Scottish Government, the HCV Clinical and Therapeutics group commissioned a short life working group (SLWG) to develop recommendations on HCV case-finding and access care, to support the delivery of HCV elimination in Scotland. This report describes the methodology, key findings, and recommendations of the SLWG.

2. Context

2.1. Epidemiology of HCV in Scotland

It is estimated that there are 34,500 people chronically infected with HCV and living in Scotland [HPS, 2016]. Approximately 15,500 (45% of the total) have not yet been diagnosed, and a further 13,200 have been diagnosed but have never received treatment and are not attending specialist care. This equates to approximately 28,700 individuals across Scotland who need to be either engaged or re-engaged in HCV care. The majority of people living with HCV (90-95%) have injected drugs during their lifetime, with an estimated 30-48% currently injecting or on OST, and 41-65% having ceased injecting and not on OST. Those still injecting and/or using OST are likely to be accessing drug use services, but former drug users may be harder to identify and engage in care. People who inject drugs (PWID) frequently experience stigma when accessing health services, but access to HCV care can be facilitated by combination approaches that encompass both social and biomedical interventions [Harris 2013].

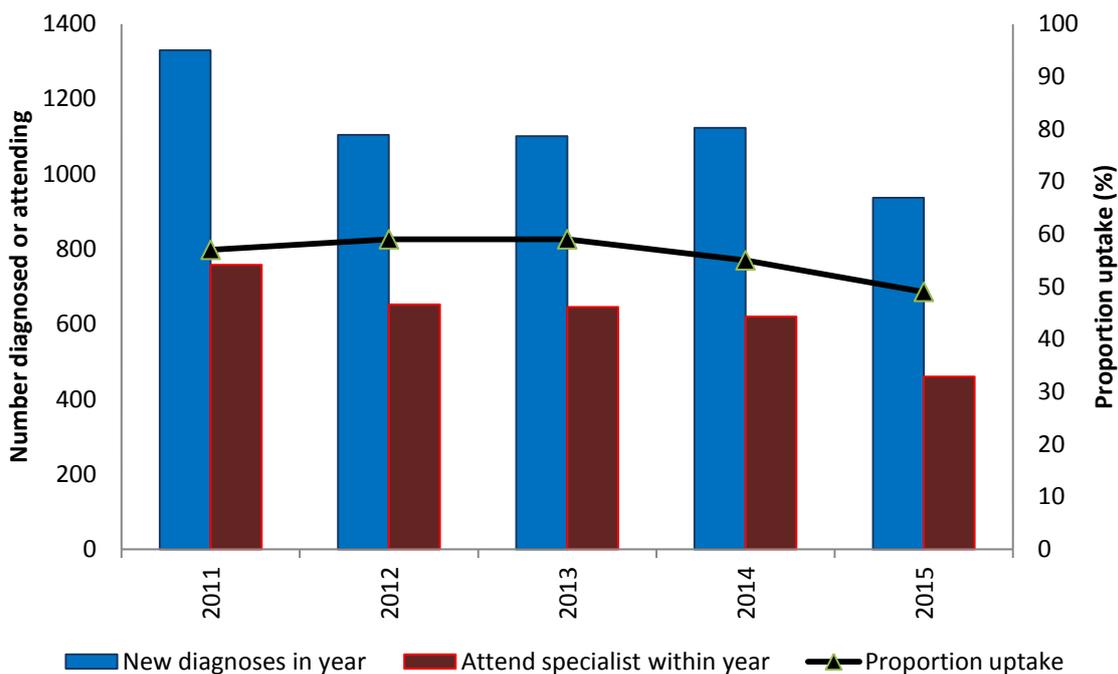
2.2. HCV testing, treatment, and care activity at Health Boards

The annual number of new HCV diagnoses in Scotland fell between 2011 and 2015 (Figure 1), and there was a concurrent decrease in both the number and proportion of people attending a specialist within a year of their HCV diagnosis. In particular, the uptake of specialist services following diagnosis in drug use services has fallen; from over 50% in 2011-13, to 34% in 2015. Of note, the available data largely precedes the roll out (in 2014) of new directly acting antiviral (DAA) therapies, which may be expected to have a positive impact on treatment uptake in subsequent years.

A national survey conducted by Health Protection Scotland in June 2017 found that boards would be able to scale up treatment initiations by 41% (to 2,535 initiations) by 2022: well

below the proposed Scottish Government target of 3,000 per year by 2020. Findings of the survey also suggest that a minimum of 885 people living with HCV are known to HCV services but are considered to be ‘not treatment-ready’. This last figure should be considered an estimate, as the definition of ‘treatment-ready’ is likely to vary due to local Health Board policy and the support available to patients. However, it is evident that a step-change at Health Boards in awareness, testing, treatment, and treatment support will be needed to respond to the new national treatment targets.

Figure 1: Number of new HCV diagnoses and attendances at specialist, Scotland, 2011-15



3. Methodology

3.1. Formulation of the Short-Life Working Group (SLWG)

The SLWG was commissioned by the HCV Clinical and Therapeutics group, with members selected to represent a range of large, small, urban, and rural Health Boards, and relevant knowledge and expertise. Terms of reference, membership, and declarations of conflict of interest are in Appendices 1 and 2. The remit of the group was to review evidence and agree recommendations on four key topic areas: Awareness-raising, Case-finding, Novel approaches to testing, and Access to care. Three half-day meetings were held between November 2017 and April 2018.

3.2. Gathering evidence of best practice

A survey was circulated by email to members of the SLWG and all Blood Borne Virus (BBV) Co-ordinators during December 2017, asking about any initiatives taking place in the four

key topic areas. The survey was supplemented by telephone interviews with a range of key informants at Public Health England, the London School of Hygiene and Tropical Medicine, Hepatitis Scotland, the World Hepatitis Alliance, NHS Forth Valley, and NHS Tayside. The survey and informant interviews were used to identify guest speakers for meetings of the SLWG.

3.3. Rapid reviews of the evidence

Rapid reviews of the evidence were conducted by Health Protection Scotland, NHS Greater Glasgow & Clyde, and the University of Dundee, with support from SLWG members. Four review questions on the key topic areas were agreed by the SLWG:

1. Are awareness-raising interventions among staff and people at risk of HCV effective in increasing knowledge of testing and treatment, increasing test uptake, increasing number of people diagnosed, or increasing uptake of specialist care?
2. Are testing interventions effective in increasing test uptake, diagnosis of HCV, or increasing uptake of specialist care?
3. Are point-of-care or dried blood spot tests for HCV effective in increasing test uptake, HCV diagnosis, or access to care?
4. Is treatment in community settings (to include prison, outreach, addictions, general practice, and community) effective?

Literature reviews were limited to the DAA era (2012 - present) although systematic reviews from earlier years were included to provide additional background information and context.

3.4. Rapid review of national and international guidance

The review of national and international guidance was led by University of Dundee (Appendix 3). The following guidance was included:

- European Association for the Study of Liver Diseases (EASL) Recommendations on Treatment of Hepatitis C, 2018 [EASL 2018]
- National Institute for Clinical Excellence (NICE) Hepatitis B and C testing: people at risk of infection, 2012 [NICE 2012]
- World Health Organisation (WHO) Guidelines for the screening, care and treatment of persons with chronic hepatitis C infection, 2016 [WHO 2016]
- Scottish Intercollegiate Guidelines Network (SIGN). Management of hepatitis C, 2013 [SIGN 2013]

3.5. Process of developing recommendations

Recommendations on the four key topic areas were invited from SLWG members, from which a long list of recommendations was drafted. After reviewing and discussing the available evidence, the SLWG voted on each draft recommendation, using the options: '*High priority*', '*Medium priority*', '*Low priority*', or '*Not a priority*'. Recommendations that received a majority vote for '*high*' or '*medium*' priority were included in the short list for consultation at the stakeholder event.

A national stakeholder event was held on May 24th 2018 to consult on the short list of recommendations. The event report is in Appendix 4. The event was invitation-only with a quota system used to ensure fair access for all stakeholders. Organisations represented were: Scottish Government, all territorial Health Boards, Health Protection Scotland, National Procurement Scotland, Scottish Prison Service, NHS Education for Scotland, Hepatitis Scotland, The Hepatitis C Trust, Scottish Drugs Forum, and Waverley Care. Delegates voted on the options: '*High priority*', '*Medium priority*', '*Low priority*', or '*Not a priority*' using Digi-Voting. Recommendations that received a majority vote for '*high*' or '*medium*' priority were included in the final published list.

3.6. Consultation on draft report

The draft report was circulated widely for consultation, including all Health Board BBV teams, and all delegates that registered for the national event. Additional consultation was carried out with national Alcohol and Drug Partnership (ADP) leads facilitated by Scottish Government. The consultation period was September-November 2018.

4. Summary of evidence

4.1. Case-finding rapid literature review

Ten full text articles and one systematic review met the PICO criteria, of which the eight most relevant studies are highlighted in this summary. Four studies were comparisons of birth cohort screening and risk-based approaches to testing [Litwin 2012, Southern 2015, Reilly 2016, Norton 2016]. All were non-randomised controlled studies based in the USA. Two studies examined the impact of birth cohort screening on test uptake, and one study examined each of diagnosis, referral to care, and treatment commencement, compared to risk-based testing. One study demonstrated a positive impact of birth cohort screening on test uptake (from 8% to 33% of the eligible population [Reilly 2016]), but there was no significant impact on HCV diagnosis, referral, or access to care. One study reported that people diagnosed by the birth cohort approach were less likely to have a raised ALT than people diagnosed by risk-based testing (22% versus 47%, p=0.02).

Recent work on birth cohort screening in a Scottish setting conducted by Glasgow Caledonian University [Collins 2018, unpublished] suggests that one-off screening of adults born 1946 to 1975 would not be cost-effective at current HCV therapy costs. However, this approach is likely to be cost-effective in areas with HCV prevalence above 3%. One possible method is to target GP practices based in areas of high deprivation (Scottish Index of Multiple Deprivation (SIMD) areas 1 and 2).

There was one study comparing approaches to improving test uptake in General Practice [Brady 2017]. This study was a cluster randomised controlled trial (RCT) conducted in the USA during the birth cohort screening era. The study compared the effectiveness of repeated mailing, electronic alerts on medical records, and direct solicitation by a member of the primary care team in increasing test uptake. All approaches increased test uptake

compared to routine practice: from 1-4% using routine practice, to 27% using repeated mailing, 31% using electronic alerts, and 64% using direct solicitation. The impact on diagnosis, referral and access to care was not reported.

There were two studies of testing initiatives in Emergency Departments (ED) [Merchant 2014, Merchant 2015]. Both studies randomised people attending ED and who had a self-reported history of problem drug use to receive the offer of a brief intervention on drug use, and all participants were offered a test for HCV and HIV. Merchant 2014 found that uptake of testing was similar among people who received or did not receive the brief intervention. In a larger RCT (n=957 compared to n=395) conducted to investigate further, the authors found that test uptake was actually lower among those receiving the brief intervention (38% versus 45%). The authors reported that uptake was affected by both the member of staff that offered the test, and the length of time in the intervention (i.e. the longer the brief intervention, the less likely a participant would accept a test).

There was one systematic review on testing interventions [Aspinall 2015], which included studies published up to 2012 (i.e. the pre-DAA era). Sixteen studies were identified, of which 16 examined the impact of testing interventions on test uptake, 14 examined the impact on HCV diagnosis, and 4 studies examined treatment uptake. Testing interventions were significantly associated with increased test uptake, relative risk (RR) 2.9, (95% CI 2.0 to 4.2); HCV diagnosis, RR 1.7 (95% CI 1.3 to 2.2), and treatment uptake, RR 3.7 (95% CI 1.9 to 7.0). There were no studies that examined impact on treatment completion or SVR.

Box 2: Health Board activity on HCV case-finding

Re-engagement in HCV care, NHS Fife

NHS Fife used Health Protection Scotland (HPS) records to identify patients diagnosed with HCV but lost to follow-up. HPS identified 681 people with a diagnosis of HCV. NHS Fife cross-referenced HPS records with their local records to remove duplications, people successfully treated, spontaneously cleared, or deceased. This left 198 HCV PCR positive cases, of which 141 had no record of treatment. Many were known to Addictions. The highest number of individuals at a single General Practice was 12. A conversation tool and workshop were developed for Addictions staff to support referrals into care, with a reasonable uptake from this approach. Direct letters to the GP were used for the small minority of patients not in contact with services. The key finding was that most people 'lost to follow-up' were not really lost, and were making regular contact with other NHS services.

Re-engagement in HCV care, NHS Grampian

NHS Grampian Liver Specialist nurses have used local HCV database records to identify people lost to follow-up by the Liver service. Of 2,728 people on the database, there were 486 HCV PCR positive patients who had no record of HCV treatment and were no longer in touch with the Liver service. Records were verified with Practitioner Services and patients were contacted by telephone to offer an appointment. A template letter was sent to patients if telephone contact was unsuccessful. Of 390 contacts attempted, 180 people agreed to an appointment, 191 did not respond, 6 declined, and 13 people no longer required an appointment. Liver specialist nurse clinics were set up in local GP

practices to maximise convenience for patients. Of the 180 who agreed to an appointment, 88 have already attended, 46 are pending, and 46 have not attended. 68 of the 88 (77%) have either commenced treatment, or have a treatment start date. Patients reported that they felt empowered, valued, and 'not forgotten' by the re-engagement process.

Offering HCV testing to PWID attending pharmacies, NHS Lothian and NHS Fife

NHS Tayside trained pharmacy assistants at six community pharmacies to conduct Dried Blood Spot (DBS) testing, salivary testing, and carry out patient discussion. Of 143 eligible patients offered a test, 43 accepted, and 12 were positive. NHS Lothian trained harm reduction workers at four pharmacies and offered tests over a six-week period. Of 83 people who inject drugs (PWID) who attended, 49 accepted a test, but <5 were positive. Both interventions were considered to be acceptable to patients, and pharmacy and harm reduction workers were able to correctly administer and interpret the test.

Offering HCV testing at a General Practice, NHS Tayside

NHS Tayside conducted a case-finding exercise in a deprived area of Tayside during 2011. An initial READ code search was used to identify patients with a history of drug dependence. Although 300 patients were identified, many were using sleeping tablets or other non-illicit drugs. After cross-referencing with practice records and the methadone list, there were 86 individuals who could be offered a test. These patients were flagged on the electronic records system in the practice, and were invited for testing when they turned up for other appointments. Many patients attended the practice routinely as the drug worker was based in the practice. Patients were offered a brief pre-test discussion and testing, plus HBV vaccination: 75 people were tested, and six new diagnoses were made.

Opt-out HCV testing in the prison, NHS Ayrshire & Arran and NHS Grampian

NHS Ayrshire & Arran has conducted opt-out testing in the prison setting since 2013. Prison paperwork has been altered to facilitate a BBV risk assessment to take place at prisoner reception. All prisoners are subsequently booked in for an appointment with the BBV nurse (unless they refuse at reception) and can then choose whether they wish to attend. During 2017, 1,185 offers were made, 905 appointments were attended, 228 BBV tests were conducted, and 10 new HCV diagnoses were made. The appointment is also a chance to offer advice and screening on sexual health.

NHS Grampian has offered opt-out testing since 2015. A testing appointment is offered at reception, and if accepted the test takes place the next day at the GP practice. However, wording on the reception paperwork is complex and testing is not considered a priority. DBS is now being introduced as an alternative.

Testing drive in drug service, NHS Greater Glasgow & Clyde

NHS Greater Glasgow & Clyde has conducted a testing drive led by medical and nursing staff in Community Addictions teams, mostly using DBS. The proportion of clients accepting a test has been more than 98% for the last three years.

Testing interventions for Black Minority Ethnic (BME) groups

NHS Lothian and NHS Highland have offered testing in a number of outreach sites, including mosques, lunch clubs, community projects, and local restaurants. The initiatives were successful in

finding cases of HBV, but no cases of HCV were identified. NHS Tayside conducted testing initiatives at Mosques and a Pakistani Women's Centre: 170 people were tested, and 5 (2.9%) were HCV PCR positive.

Hospital case-finding, NHS Ayrshire and Arran

Hospital case-finding has been taking place in Ayrshire and Arran since January 2018. A Specialist BBV nurse conducts rounds of all medical and surgical wards and offers patient reviews and informal staff education. In four months the nurse has seen 76 patients, of whom 17 were known to be HCV positive and were re-engaged in care, and a small number of new diagnoses have been made.

Reporting and monitoring, NHS Greater Glasgow & Clyde

NHS Greater Glasgow & Clyde have been reporting testing rates back to Community Addiction treatment (CAT) services. All CAT teams have reported an increase in the proportion of people tested since the start of monitoring in 2016, with a total of 1,208 people diagnosed in 2017.

4.2. Novel approaches to testing rapid literature review

Two separate reviews of the evidence were conducted: one on Dried Blood Spot (DBS) tests, and one on Point of Care (PoC) tests. The two reviews updated the recent systematic review on DBS and PoC tests conducted by Coats et al [Coats 2015].

The DBS review identified four studies, three of which were conducted in a Scottish setting. Radley et al reported test uptake (among eligible PWID) of 30% in six pharmacies trained to offer DBS testing, compared to 13% uptake in thirty pharmacies that were not DBS trained [Radley 2017]. McLeod et al reported a three-fold increase in testing and a 12-fold increase in positive cases in drug services following the introduction of DBS testing nationally [McLeod 2014]. A study using record linkage to follow patients after diagnosis reported lower rates of HCV treatment initiation among the DBS-diagnosed population, although this may reflect the predominance of DBS use among the PWID population [McAllister 2014]. A study conducted in public venues (including Birmingham PRIDE, festivals, pubs and clubs) reported that 212 people accepted a test: a number of HIV and HBV diagnoses were made but only a single case of HCV was detected [Flavell 2014]. The Coats et al review also identified six studies of DBS: five studies reported evidence that DBS testing increased test uptake, and one study reported that DBS increased the number of HCV diagnoses.

Two studies on PoC testing were identified. An RCT in France offered either PoC or standard HCV testing for people attending inner-city safety-net clinics. People attending the clinics were mainly migrants from high prevalence countries. In the PoC arm, 98% of people received their results, and 90% were linked in to care, compared to 64% and 83% respectively in the standard testing arm. The other PoC study was conducted in a Swiss OST clinic and reported that the proportion of their 631 clients who had never been tested reduced from 24% before compared to 2% after the introduction of PoC testing [Bregenzer 2017].

Box 3: Health Board activity on novel approaches to testing

Use of Dried Blood Spot (DBS) testing in NHS Tayside

NHS Tayside has introduced DBS into third sector, outreach, and pharmacy settings. Approximately 1,500 tests have been conducted, of which 30% were positive. 70% of those diagnosed have been able to access care.

Use of rapid HCV tests in NHS Ayrshire and Arran

A pilot of rapid testing for HCV was rolled out in April 2018. Tests can be conducted using either a salivary test or finger stick – depending on patient choice and the setting where the test takes place. In the pilot phase community health additions nurses were trained to deliver testing, but the next phase will involve training non-clinical staff, including peers. The new test has re-energised staff and made testing available in a broader range of settings, for example homeless hostels. Over thirty tests have been conducted in the first few weeks of the pilot, with many clients reporting that they had not been tested for a number of years. Rapid testing also offers the potential for significant cost-savings compared to DBS.

4.3. Awareness-raising rapid literature review

Eight studies of HCV awareness-raising interventions were identified. There were two studies of mass media campaigns; one from Australia, and one from the USA at the time of the birth cohort screening recommendation. The Australian study reported on a mass media campaign using radio and TV advertising. The authors reported small improvements in public knowledge but limited impact on attitudes. The impact on HCV testing, diagnosis, and access to care were not assessed [Smith 2006]. In the USA, a campaign to support the new birth cohort policy led to an additional 200,000 hits on the Centers for Disease control website, but impact on knowledge, attitudes, and treatment uptake were not assessed [Jorgensen 2016].

Two studies examined GP awareness-raising interventions. One study [McLeod 2017] reported minimal differences in GP testing practice before and after targeted awareness-raising activities. Helsper et al reported a 3.0-fold increase in testing and a 1.7 fold increase in diagnosis after an awareness-raising campaign and GP education, although the absolute number of tests and diagnoses was very small [Helsper 2010].

Box 4: Health Board activity on HCV awareness-raising

Local awareness-raising in NHS Forth Valley

Forth Valley BBV MCN have conducted an awareness-raising campaign via local radio (seven different 25 second clips featuring real patients talking about their experience of treatment, with a consistent strap-line) local newspapers (patient stories), and posters and leaflets provided in tattoo parlours, betting shops, GP surgeries, drug services, homeless accommodation, and pharmacies. All campaigns used the same 'hotline' number for patients to access testing and care. Most patients who called the hotline were fitted in for appointments within two weeks of calling.

Social media campaign in NHS Lanarkshire

NHS Lanarkshire used Facebook, Instagram, Twitter, and Snapchat to raise awareness of HCV, and achieved 15,548 clicks through to their local BBV website. Lanarkshire highlighted the importance of using click-bait and videos to arouse interest, and to make local references ('Listen up Lanarkshire!') and use local branding.

4.4. Access to care rapid literature review

Sixteen studies of DAA treatment in community settings were identified; three from Australia, three from Canada, two from the UK, and eight from the USA. Treatment interventions were diverse, and included treatment in primary care, community pharmacies, OST clinics, needle exchange programmes, and tele-health. All sixteen studies measured treatment uptake; three reported increased uptake at the community compared to the hospital site. Fifteen studies measured treatment effectiveness, with SVRs appearing to be similar at community and hospital sites, although formal meta-analysis is awaited.

A systematic review of community-based treatment was published in the PEG/RBV era [Wade 2016], which included thirteen studies of a variety of interventions, including telehealth, treatment in primary care, OST clinics, and needle exchange programmes. Six studies measured treatment uptake; three reported increased uptake at the community site, two found similar uptake rates between sites, and one found decreased uptake at the community site. Nine studies measured SVR, of which four reported higher SVRs in the community, four reported similar SVRs, and one found inferior SVRs in the community compared to the hospital site. Most studies had very small numbers of patients, and statistical significance testing was not done.

In summary, the evidence suggests that community-based treatment is feasible and achieves similar or slightly improved uptake and SVRs compared to treatment offered in a hospital setting.

Box 5: Health Board activity on HCV access to care

Testing and assessment hotline in NHS Forth Valley

NHS Forth Valley has a dedicated direct number for the HCV team, which they use on all promotional resources and correspondence. The line is manned Monday to Friday, and patients can self-refer for testing or treatment, even if they have previously defaulted. Patients are slotted in quickly by over-booking and making use of DNA appointments.

Offering treatment in drug services, NHS Greater Glasgow & Clyde

NHS Greater Glasgow & Clyde conducted a six-month pilot of a consultant outreach clinic at a community addictions treatment centre. Of the 26 patients appointed, 23 have attended a consultant assessment and 12 have commenced treatment. Previously, this cohort had failed to attend a total of 139 HCV appointments. Another site in Glasgow compared HCV treatment in hospital and drug use clinic settings. 60% of patients appointed to the hospital site disengaged or

were lost to follow-up, compared to 0% in the drug use clinic.

Offering treatment in IEP sites, NHS Tayside

People who inject drugs (PWID) are being actively recruited to a study in NHS Tayside offering treatment at a number of IEP sites. After 30 months of a 60-month study, 80 participants have commenced HCV therapy, with an overall SVR rate of 90.5%.

4.5. Reflection on the evidence base for developing recommendations

Overall the evidence base was weak, from both published literature and evidence of best practice. Much of the published literature focused on 'near outcomes', e.g. awareness of HCV or uptake of testing, as opposed to longer-term and patient-important outcomes such as diagnosis and access to care. While there was extensive evidence of innovative activity in case-finding and access to care at Health Boards, many initiatives had not been formally evaluated or were still in progress. The expertise of SLWG members and the wider stakeholder group was therefore key in the development of the recommendations.

5. Recommendations

5.1. General principles

The SLWG agreed the following general principles in developing the recommendations:

- The importance of the full care pathway, from prevention to testing, treatment, and care.
- Reducing barriers to care, particularly for service users who may have experienced stigma in accessing health services in the past.
- Offering patients a choice: some patients value the anonymity of a hospital or specialist setting, whereas others value the convenience of community settings.
- Offering both social and biomedical HCV interventions. Some patients may engage with social support only, but subsequently engage with treatment once support is in place.
- However, social issues should not preclude treatment for those willing to commence, bearing in mind that DAA therapy is straightforward and in most cases requires minimal healthcare intervention.
- BBV should be considered as a core part of the work of services that look after those at highest risk, including Drug Use services and IEP.

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- BBV should be considered as a core part of the work of services that look after those at highest risk, including Drug Use services and IEP.

Recommendations on case-finding

1. HCV testing should be opt-out at services used by groups at highest risk of HCV, including Drug Use services, specialist IEP services, prisons, asylum services, and homeless/crisis services.
2. Drug Use services must offer all service-users (including OST clients) HCV testing at their initial assessment, and annually thereafter. Testing should be offered more frequently if there has been an episode of risk. The requirement to offer opt-out testing should be written into contracts (or equivalent agreements or understandings) with providers of these services, with reference to the Health Board targets outlined in 5.1.
3. All pharmacies that dispense OST or provide injecting equipment must either offer HCV testing, or have a clear pathway in to testing, treatment, and care. All relevant staff must be confident to provide basic information on BBV issues.
4. BBV MCNs should support GPs to offer testing to those who are at increased risk of HCV, in particular current and former People Who Inject Drugs (PWID). READ codes and OST prescription lists in primary care should be used to identify patients at risk.
5. BBV MCNs should support the development of HCV testing opportunities for: people born or brought up in geographical areas of high HCV prevalence, people admitted to medical or mental health facilities with risk factors for HCV, and all persons found to have a raised ALT.
6. As part of the existing NHS Education for Scotland programme, there should be online training available for professionals on HCV testing, treatment, and care.

Recommendations on novel approaches to testing

7. The gold standard for testing is venepuncture analysed by conventional technology. Dried Blood Spot (DBS) testing can be used where venepuncture would not be feasible or venepuncture skills are not available, for example non-clinical staff, outreach settings, or for those with difficult venous access.

8. Pilots of Point of Care (PoC) testing, self-testing, and other novel testing approaches should be performed to evaluate the impact on access to treatment and care. All testing approaches should be developed in partnership with laboratories to ensure appropriate quality control.

Recommendations on awareness-raising

9. There should be local awareness-raising campaigns about the risks of HCV, test availability, and the effectiveness of new therapies, using conventional and social media approaches. Awareness-raising should be led by Public Health departments and delivered in partnership with services used by people at increased risk of HCV.*
10. BBV MCNs should facilitate education and training for all primary and secondary care health practitioners to raise awareness of HCV and local treatment and care pathways. MCNs should ensure that staff working in services used by people at increased risk of HCV * are appropriately trained to conduct testing, offer advice on treatments, and support patients into care.

Recommendations on access to care

11. BBV MCNs must ensure that all testing venues or testing initiatives either provide treatment at the testing venue, or have a clear pathway in to care. Care pathways must be designed to minimise or remove barriers to providing HCV treatment.
12. BBV MCNs are required to conduct a look-back exercise at least once every three years (and ideally more frequently) to re-engage those who have previously been diagnosed and/or referred to services, but who have never been treated.
13. HCV treatment and care services should accept referrals from patients, peers, and third sector partners, in addition to referrals from healthcare practitioners.
14. HCV treatment should be provided in a variety of locations close to the patient, and must be available in all appropriate Drug Use services (excluding for example drug crisis services or third-sector providers). Treatment may be provided by in-house staff or specialist in-reach services.
15. If appropriate to facilitate access to care, patients should be offered a choice of support, which could include peer, third sector, NHS, or partnership providers.

* Services used by people at increased risk of HCV:

Drug Use services, IEP services, asylum services, sexual health services, homeless/crisis services, GPs in areas of high HCV prevalence, peer support or drug recovery services, criminal justice and detention facilities.

Recommendations for further research

There were a number of interventions that were considered to be of possible benefit, but had insufficient evidence to support a recommendation. These interventions are

recommended as pilots or areas of further research, which could be adopted by single health boards or regions and evaluation findings shared nationally.

16. A feasibility study of identifying people at risk from national or local OST or drug addiction records should be conducted.

17. A pilot study should be conducted to assess the feasibility and effectiveness of birth cohort testing in areas of deprivation.

18. A pilot study should be conducted to assess the feasibility and effectiveness of Drug Use and IEP services working with existing clients to identify partners, friends, or associates who are in a risk group and could be offered a test.

6. Implementation and monitoring

6.1. Implications of the recommendations for services

Implementing the recommendations will require close partnership working between BBV MCNs and ADPs, as well as Drug Use services, Community Pharmacy, General Practice, and third sector organisations. There are likely to be a number of training needs arising from the recommendations, particularly for staff who only deal with BBV issues as part of a wider role, for example Community Pharmacists and GPs.

6.2. Recommendations for monitoring

The recommendations require robust monitoring to ensure that Scotland stays on track to deliver elimination of HCV. Existing measurement and reporting structures should be used to minimise additional workload and prevent duplication. It is recommended that MCNs are responsible for the collation of data for reporting to their local Clinical and Executive leads, and ultimately to the national SHBBV Executive leads group.

1. BBV MCNs should monitor and feed-back on a quarterly basis to relevant services on the number of tests, and the number of positive tests conducted. The number of positive tests should be presented against the estimated number of people still to be diagnosed with HCV in the respective Health Board area.

Suggested testing targets for services used by those at highest risk (Drug Use services, IEP services, and prisons) are:

- iii) 90% of clients ever had a test
- iv) 80% tested within the preceding 12 months

It is recognised that individual Health Boards will have different capabilities in terms of data availability and accuracy, and that estimates may be required.

2. BBV MCNs should monitor the number of HCV treatment initiations on a quarterly basis to ensure they are on track to meet their local Health Board targets set by Scottish Government.

3. BBV MCNs should undertake appropriate investigation and action if the above testing, diagnosis, and treatment targets are not met.

4. BBV MCNs should report biannually on their progress to the national SHBBV Executive leads group.

7. Conclusions

Scotland is in an ideal position to take advantage of the HCV therapeutic revolution, and has the leadership, will, and service infrastructure to deliver HCV elimination. The next phase will be challenging, not least because of the size of the undiagnosed and diagnosed untreated population; but thanks to strong leadership and dedication from people of all positions – political, professional and patient – Scotland is ready to take the next step in combating HCV. These recommendations offer a comprehensive and practical approach to HCV diagnosis and treatment at Boards, including a number of recommendations for further research or pilots and a proposal for monitoring that utilises existing HCV reporting structures. Effective implementation and monitoring of these recommendations should set Scotland well on course for HCV elimination in the coming decade.

8. References

- Aspinall EJ, Doyle JS, Corson S, Hellard ME, Goldberg D, Nguyen T et al. Targeted hepatitis C antibody testing interventions: a systematic review and meta-analysis. *European Journal of Epidemiology*, 2015; 30: 115-29
- Bottero J, Boyd A, Gozlan J, Carrat F, Nau J, Pauti MD et al. Simultaneous Human Immunodeficiency Virus-Hepatitis B-Hepatitis C Point-of-Care Tests Improve Outcomes in Linkage-to-Care: Results of a Randomized Control Trial in Persons Without Healthcare Coverage. *Open Forum Infectious Diseases*, 2015.
- Brady JE, Liffmann DK, Yartel A, Kil N, Federman AD, Kannry J et al. Uptake of Hepatitis C Screening, Characteristics of Patients Tested, and Intervention Costs in the BEST-C Study. *Hepatology*, 2017; 65: 44-53
- Bregenzer A, Conen A, Kunchel J, Friedl A, Eigenmann F, Naf M et al. Management of hepatitis C in decentralised versus centralised drug substitution programme and minimally invasive point-of-care tests to close gaps in the HCV cascade. *Swiss Medical Weekly*, 2017; 147: 14544
- Coats JT, Dillon JF. The effect of introducing point-of-care or dried blood spot analysis on the uptake of hepatitis C virus testing in high-risk populations: A systematic review of the literature. *International Journal of Drug Policy*, 2015; 26: 1050-5
- European Association for the Study of Liver Disease. Recommendations on Treatment of Hepatitis C, 2018. *Journal of Hepatology*, 2018
- Flavell S, Davison C, Anderson N, Burbidge N, Atabani S, Taylor S et al. Dried blood spot testing: an alternative to point-of-care testing in public venues? *Sexually Transmitted Infections*, 2014; 91:2
- Harris M, Rhodes T. Hepatitis C treatment access and uptake for people who inject drugs: a review mapping the role of social factors. *International Journal of Drug Policy*, 2013; 10: 7
- Helsper CW, Janssen MP, van Essen GA, Croes EA, van der Veen C, de Wit AG et al. Effectiveness and cost-effectiveness of nationwide campaigns for awareness and case finding of hepatitis C targeted at people who inject drugs and the general population in the Netherlands. *International Journal of Drug Policy*, 2017; 47: 117-125
- Jorgensen C, Carnes CA, Downs A. "Know more Hepatitis:" CDC's National Education Campaign to Increase Hepatitis C Testing Among People Born Between 1945 and 1965. *Public Health Reports*, 2016; 131:29-34
- Litwin AH, Smith BD, Drainoni ML, McKee D, Gifford AL, Koppelman E et al. Primary care-based interventions are associated with increases in Hepatitis C virus testing for patients at risk. *Digestive and Liver Disease*, 2012; 44: 497-503
- McAllister G, Innes H, McLeod A, Dillon JF, Hayes PC, Fox R et al. Uptake of hepatitis C specialist services and treatment following diagnosis by dried blood spot in Scotland. *Journal of Clinical Virology*, 2014; 61:359-64
- McLeod A, Weir A, Aitken C, Gunson R, Templeton K, Molyneaux P et al. Rise in testing and diagnosis associated with Scotland's Action Plan on Hepatitis C and introduction of dried blood spot testing. *Journal of Epidemiology and Community Health*, 2014; 68:1182-8
- McLeod A, Cullen BL, Hutchinson SJ, Roy KM, Dillon JF, Stewart EA et al. Limited impact of awareness-raising campaigns on hepatitis C testing practices among general practitioners. *Journal of Viral Hepatitis*, 2017; 944-954

Merchant RC, Baird JR, Liu T, Taylor LE, Montague BT, Nirenb. Brief Intervention to Increase Emergency Department Uptake of Combined Rapid HIV and Hepatitis C Screening Among a Drug Misusing Population. *Academy of Emergency Medicine*, 2014; 21: 752-767

Merchant RC, DeLong AK, Liu T, Baird JR. Factors Influencing Uptake of Rapid HIV and Hepatitis C Screening Among Drug Misusing Adult Emergency Department Patients: Implications for Future HIV/HCV Screening Interventions. *AIDS Behaviour*, 2015; 19: 2025-35

National Institute for Clinical Excellence. Hepatitis B and C testing: people at risk of infection, 2012. NICE, UK. Accessed online May 2018, URL: <https://www.nice.org.uk/guidance/ph43>

Norton BL, Southern WN, Steinman M, Smith BD, DeLuca J, Rosner Z et al. No differences in achieving Hepatitis C Virus care milestones between patients identified by birth cohort or risk-based screening. *Clinical Gastroenterology and Hepatology*, 2016; 14: 1356-60

Radley A, Melville K, Tait J, Stephens B, Evans JMM, Dillon JF. A quasi-experimental evaluation of DBS testing through community pharmacies in the Tayside region of Scotland. *Frontline Gastroenterology*, 2017; 8:221-228

Reilley B, Leston J, Hariri S, Neel L, Rudd M, Galope M et al. Birth Cohort Testing for Hepatitis C Virus—Indian Health Service 2012–2015. *Morbidity and Mortality Weekly Report*, 2016; 65: 467-469

Scottish Intercollegiate Guidelines Network. Management of hepatitis C. SIGN, 2013. Accessed online May 2018, URL: <http://www.who.int/hepatitis/publications/hepatitis-c-guidelines-2016/en/>

Southern WN, Norton N, Steinman M, DeLuca J, Drainoni ML, Smith BD et al. A Birth-cohort testing intervention identified Hepatitis C Virus infection among patients with few identified risks: a cross-sectional study. *BMC Infectious Diseases*, 2015; 15: 553

Smith BJ, Bauman AE, Chen J, Loveday S, Costello M, Mackie B et al. Hepatitis C in Australia: impact of a mass media campaign. *American Journal of Preventive Medicine*, 2006; 31: 492-498

Wade A, Veronese V, Hellard ME, Doyle JS. A systematic review of community based hepatitis C treatment. *BMC Infectious Diseases*, 2016; 16:202

World Health Organisation, 2016. Combating Hepatitis B and C to reach elimination by 2030. Geneva, 2016. Accessed online, 2nd July, URL: http://apps.who.int/iris/bitstream/handle/10665/206453/WHO_HIV_2016.04_eng.pdf;jsessionid=D33D4650D9A74BCCCC3E1A44BC7D41EC?sequence=1

World Health Organisation. Guidelines for the screening, care and treatment of persons with chronic hepatitis C infection. WHO, Geneva, 2016. Accessed online May 2018, URL: <http://www.who.int/hepatitis/publications/hepatitis-c-guidelines-2016/en/>

9. Appendices

Appendix 1: Terms of reference of Short Life Working Group



1. **Title:** National short life working group on case-finding and access to treatment and care for Hepatitis C (HCV)
2. **Accountable to:** HCV Treatment and Therapies group
3. **Scope:** To bring together partners from NHS, Health and Social Care Partnerships, and the third sector to agree recommendations for best practice on:
 - New case-finding for HCV
 - Re-engagement in care for people with HCV who are lost to follow-up
 - HCV care pathways/models of care for those diagnosed and re-engaged in careWith the aim of eliminating HCV as a cause of advanced liver disease in Scotland
4. **Out of Scope:** HCV screening in pregnancy, dialysis, or fertility clinics
5. **Chairs:** John Dillon, Esther Aspinall
6. **Secretariat:** Chris Biggam
7. **Remit of Group**
 - To review current evidence on HCV awareness-raising, case-finding, re-engagement, and access to care, to include:
 - Analysis of testing, diagnosis, and uptake of treatment and care in Scotland, by age, risk group, disease stage, setting, and Health Board, using the Scottish testing, diagnosis, and clinical databases
 - Review published evidence on HCV awareness, case-finding and re-engagement initiatives, to include birth cohort screening, dried blood spot testing, point of care and opt-out testing, case-finding in hospital or community settings, and the development of care pathways after a positive test, with a focus on the DAA era.
 - Review published evidence on treatment delivered in community/outreach, General Practice, and hospital settings, with a focus on the DAA era.
 - Review of best practice on awareness-raising, case-finding, re-engagement, and models of treatment and care in Scotland, with a focus on the DAA era.
 - Review of current national and international HCV guidelines on HCV testing, case-finding, re-engagement, and models of treatment and care, with a focus on the DAA era.
 - To plan a national stakeholder event with invited speakers and to present the findings of the group and endorse recommendations for action.
 - To produce a final report for circulation to local and national networks, to include a review of current activity and evidence, and the agreed recommendations for action.

- To plan and make recommendations to the HCV Treatment and Therapies group on follow up actions to support implementation of recommendations by Boards

8. Meetings: Approximately four meetings over the period November 2017 to July 2018

9. Deliverables:

- Stakeholder event during May-June 2018
- Written summary report for circulation to local and national networks by July 2018.

10. Membership

- Prof John Dillon (Co-Chair) – Consultant Hepatologist and BBV Clinical Lead, NHS Tayside
- Dr Esther Aspinall (Co-Chair) – BBV Executive Lead, NHS Ayrshire and Arran/Senior Clinical Research Fellow, GCU/HPS
- Mr Chris Biggam (Secretariat) – Research Advisor, Glasgow Caledonian University
- Dr Andrew Fraser (Advisory role - developing recommendations) - Consultant Gastroenterologist and BBV Clinical Lead, NHS Grampian
- Ms Anne Eriksen – BBV Executive Lead, NHS Tayside
- Mr Allan McLeod - Epidemiologist, HPS
- Dr Amanda Weir - Statistician, HPS
- Dr David Campbell - GP Partner, NHS Ayrshire and Arran
- Mr Charles Gore - Director, Hepatitis C Trust
- Dr Rory Gunson – Consultant Clinical Scientist, NHS Greater Glasgow & Clyde
- Dr Trina Ritchie - Lead Clinician, Glasgow Alcohol and Drug Recovery Services
- Mr Leon Wylie – Hepatitis Scotland/Scottish Drug Forum
- Dr Stephen Barclay – Consultant Hepatologist, NHS Greater Glasgow & Clyde
- Ms Lisa Allerton – MCN Manager, NHS Grampian
- Ms Hilda Stiven – Senior Health Policy Officer, NHS Lothian
- Dr Jose Fernandez – Consultant in Infectious Diseases, NHS Ayrshire and Arran
- Mr Andrew Radley – Consultant in Public Health Pharmacy, NHS Tayside
- Dr Wendy Beadles – Consultant in Infectious Diseases, NHS Highland
- Dr Jenny Wares – Consultant in Public Health Medicine, NHS Highland
- Mr Mark Steven – Team Leader, SHBBV Development Team, NHS Fife

11. Draft agenda plan

Meeting 1: November 2017

- Review and agree purpose, ToR, membership, and timetable for action
- Where are we? Review of national testing, diagnosis, and treatment uptake data, review existing activity at Health Boards/Third Sector and agree invitations for speakers at meetings
- Approach to the evidence: choose questions for rapid review, agree approach and template
- Event planning and discussion

Meeting 2: March 2018 - Focus on awareness-raising and case-finding

- Presentations on best practice from Boards and discussion (awareness-raising, case-finding)
- Presentations on rapid evidence reviews and discussion (awareness-raising and case-finding)
- Review relevant national and international guidance
- Review all evidence presented to the group and agree draft recommendations to take to event

Meeting 3: March 2018 - Focus on access to care

- Presentations on best practice from Boards and discussion (access to care)
 - Presentations on rapid evidence reviews and discussion (access to care)
 - Review relevant national and international guidance
 - Review all evidence presented to the group and agree draft recommendations to take to event
- Event planning and discussion

Meeting 4: June/July 2018

- Event de-brief, finalise recommendations, agree report

Appendix 2: SLWG members: declarations of conflict of interest

Stephen Barclay has received speaker fees from AbbVie and Gilead, participated in advisory boards for AbbVie, BMS, Gilead, and MSD, and is a co-recipient of departmental grants from AbbVie and Gilead. John Dillon has received personal and departmental funds from AbbVie, Gilead, MSD, BMS, Roche, and Janssen. Ann Erikson has acted in an advisory role for the International Symposium for Hepatitis Treatment among substance users (INHSU) HCV Education Programme. Jose Fernandez has received sponsorship to attend EASL meetings in 2016 and 2017 from Gilead. Charles Gore has received organisational support for the Hepatitis C Trust from AbbVie, Gilead, and MSD. The Hepatitis C Trust is an advocacy organisation. Andrew Radley has received research funding from Gilead and Roche, provided paid consultancy to AbbVie, and received support from Gilead to attend EASL conferences in 2016 and 2018. Trish Tougher is a board member of the Scottish Drugs Forum.

Lisa Allerton, Esther Aspinall, Wendy Beadles, Chris Biggam, David Campbell, Elizabeth Dickson, Andrew Fraser, Rory Gunson, Allan McLeod, Wendy Mitchell, Trina Ritchie, Mark Steven, Hilda Stiven, Jenny Wares, Amanda Weir, and Leon Wylie have no conflicts of interest to declare.

Appendix 3: Review of national and international guidance, May 2018

Testing

- ❖ Targeted testing
 - PWIDs
 - Should be tested routinely and voluntarily.
 - If HCV antibody negative should be tested annually.
 - Detained/secure settings
 - People entering or transferring between prisons should be tested for BBV
 - Prisons should have access to DBS for people whom venous access is difficult.
 - Drug treatment services
 - Drug treatment services should have access to DBS
 - Specialist phlebotomy services to encourage HCV treatment particularly in PWIDs
 - Other targeted populations: From countries of medium or high prevalence identified in primary care when joining GP, blood/tissue donors, patients on dialysis, people with persistently elevated ALT, people who are HIV positive, people who have had a sexual partner or household contact who is HCV positive, people who have had tattoos or body piercing in circumstances where infection control procedures are deemed to be suboptimal, healthcare professionals performing exposure prone procedures.
- ❖ Testing at alternative sites/community testing
 - This could include primary care, sexual health clinic and mobile street clinics.
 - DBS convenient and cost effective in accessing targeted populations
 - DBS and POC testing can be used to facilitate HCV screening and improve access to care
- ❖ People with ongoing risk should be tested annually
- ❖ People with positive antibody, but negative RNA testing should have repeat RNA testing at 3 months

Diagnosis

- ❖ Laboratory services
 - Can support the range of samples used for HCV testing e.g. DBS and venepuncture samples
 - Automatically test samples that are positive for HCV antibody for HCV RNA, or send samples to a referral laboratory.
 - Results within 2 weeks of testing
- ❖ Diagnostic tests should be performed on serum or plasma where possible
 - The OraQuick test can be used in place of existing serum antibody tests.

Diagnostic tests

- ❖ Anti-HCV antibodies are the first line diagnostic test for HCV
- ❖ HCV RNA should be used to screen for suspected acute infection or immunocompromised patients.
- ❖ Positive antibodies should be confirmed with HCV RNA
- ❖ HCV core antigen can be used in place of HCV RNA
- ❖ The HCV genotype and sub-genotype must be identified prior to treatment initiation.

Case Finding

- ❖ Screening strategies should be defined according to local epidemiology
- ❖ Screening for HCV is based on the presence of antibodies.

Treatment models

- ❖ National elimination plans require the development of economic partnerships and planning to expedite unrestricted access to treatment.
- ❖ HCV treatment should be delivered by an MDT with experience in HCV
- ❖ DAAs would be easier to use in the community/outreach settings

- ❖ PWIDS:
 - People with HCV and stable on drug treatment should be treated
 - Active drug users should be engaged to address healthcare needs and risk reduction.
 - Treatment should be considered on an individualised basis
- ❖ Prison inmates should be treated by HCV service in-reach
 - Efforts should be made to ensure continuation of treatment in the case of release/transfer

Appendix 4: National Stakeholder event report

Thursday 24 May 2018; 10am-4pm; CoSLA Conference Centre, Verity House, Edinburgh

Meeting notes

1. Welcome

Meeting began at 10am. Professor David Goldberg (Consultant Epidemiologist, Health Protection Scotland) welcomed participants and thanked Professor Sharon Hutchinson, Amanda Burrige, Dr Hamish Innes, Dr Esther Aspinall and Professor John Dillon.

2. Introductions and purpose of the day

Gareth Brown (Head of Blood, Organ Donation and Sexual Health, Scottish Government) gave a welcome address on behalf of the Scottish Government. Noted that while Scotland has perhaps slipped from our position at the forefront of Hep C elimination, we continue to have the will and the tools for elimination, including some of the best professionals working in the field and great relationships with patients and patient groups. Gareth wished the delegates luck for the day ahead.

3. The global perspective: elimination strategies around the world, where does Scotland stand?

Professor Jeff Lazarus (ISGlobal & Hospital Clinic, University of Barcelona) spoke about the elimination challenge around the globe and Scotland's position in leading elimination. Jeff said that in his view, many people were still looking to Scotland as leaders in Hep C elimination, however he acknowledged that Scotland was not currently on the list of nine countries considered to be 'on track' for Hep C elimination by 2030. Jeff noted that there was still time to change this, if the will was there.

Jeff encouraged delegates to consider whether they thought elimination was possible by 2025, and to consider in which populations we could eliminate Hep C in today if challenged. Jeff recapped on the global attention (and political will) on Hep C elimination beginning in 2006, culminating in the World Health Assembly Resolution (2014) and first World Hepatitis Summit (Glasgow, 2015). Jeff outlined the Global Health Sector Strategy HCV targets and spoke about the example of Spain, using a people-centric health system-approach to progress towards Hep C elimination.

Jeff said that Scotland had a number of the key factors in place to achieve Hep C elimination (e.g. a capable and sizeable workforce working in Hep C research, diagnosis, care provision and treatment; established systems and infrastructure for testing provision; budgets for testing and treatment). Jeff emphasised the importance of raising awareness of national Hep C elimination strategies with everyone in the chain. Jeff noted that many countries progressing towards Hep C elimination had attributed part of that progress to establishing good relationships with the pharmaceutical industry, to negotiate down the cost of Hep C treatment.

Jeff encouraged delegates to be creative in their approaches to testing, underlining the importance of eliminating late presentation and encouraging delegates to consider how we might test / screen possible Hep C patients in non-hospital settings according to patient groups. Jeff emphasised that multiple models of Hep C care are needed to address the needs of different patient groups.

Jeff said that Hep C elimination is a daunting thought for any health system. It's challenging, costly and complex and necessitates bold choices. In conclusion Jeff encouraged delegates to consider the benefits of a micro-elimination approach, considering 'low hanging fruit' or 'easy wins' (easy to reach patient groups, either in terms of geography or particular circumstance).

4. The Scottish perspective: epidemiology, the challenge ahead.
Professor David Goldberg (Consultant Epidemiologist, Health Protection Scotland) welcomed participants, reporting generally good news on up-scale of treatment. David noted that if we can continue to keep up our efforts by meeting or exceeding our diagnosis and treatment targets, elimination of Hep C (defined as reducing the number of patients diagnosed and in treatment to less than 5,000) is achievable between 2025 and 2030.
5. The patient and advocacy perspective: patient and peer.
Leon Wylie (Lead Officer, Hepatitis Scotland) shared patient perspectives which emphasised some good and bad news stories in terms of patient experiences in diagnosis and access to treatment. The patient stories Leon shared with delegates emphasised the need to break down the barriers or blockages that sometimes exist between testing and diagnosis, and between diagnosis and treatment.
6. Evidence review on case-finding.
Dr Esther Aspinall (Consultant in Public Health Medicine, NHS Ayrshire & Arran; and Senior Clinical Research Fellow, Glasgow Caledonian University) and Allan McLeod (BBV Epidemiologist, Health Protection Scotland) introduced details of a rapid evidence review on Hep C case-finding.
7. Recommendations and digi-voting: case-finding.
Professor John Dillon (Professor of Hepatology and Gastroenterology Ninewells Hospital and University of Dundee & Honorary Consultant, NHS) chaired this recommendations and digi-voting section, with input from a guest panel (panel membership below)

The short life working group had – ahead of the national event – come up with a series of suggested recommendations on Hep C case finding. At this point, the delegates were each asked to vote using a digital keypad on the priority they would give to each recommendation (on a four-point scale: High priority, Medium priority, Low priority, Not a priority). Delegates were free to challenge wording, give suggestions for amendments, or free to speak in support of each recommendation as these arose.
8. Evidence review on novel approaches to testing.
Elizabeth Dickson (EUPHEM Fellow, Health Protection Scotland) and Dr Esther Aspinall introduced details of a rapid evidence review on novel approaches to Hep C testing. Emma Walker (SHBBV Programme Manager, NHS Ayrshire & Arran) presented on rapid Hep C testing initiative in A&A.
9. Recommendations and digi-voting: novel approaches to testing.
Professor John Dillon chaired this recommendations and digi-voting section, with input from a guest panel (panel membership below)

The short life working group had – ahead of the national event – come up with a series of suggested recommendations on novel approaches to Hep C testing. At this point, the delegates were each asked to vote using a digital keypad on the priority they would give to each recommendation (on a four-point scale: High priority, Medium priority, Low priority, Not a priority). Delegates were free to challenge wording, give suggestions for amendments, or free to speak in support of each recommendation as these arose.
10. Evidence review on awareness-raising.
Dr Esther Aspinall and Allan McLeod presented information from their rapid evidence review on Hep C awareness-raising.

11. Recommendations and digi-voting: awareness-raising.

Peter Bramley (Consultant Gastroenterologist, NHS Forth Valley) chaired this recommendations and digi-voting section, with input from a guest panel (panel membership below)

The short life working group had – ahead of the national event – come up with a series of suggested recommendations on novel approaches to Hep C testing. At this point, the delegates were each asked to vote using a digital keypad on the priority they would give to each recommendation (on a four-point scale: High priority, Medium priority, Low priority, Not a priority). Delegates were free to challenge wording, give suggestions for amendments, or free to speak in support of each recommendation as these arose.

12. Evidence review on access to care.

Dr Andrew Radley (Consultant in Public Health Pharmacy, NHS Tayside) and Dr Esther Aspinall presented information from rapid evidence reviews concerning access to Hep C treatment / care. Pauline Dundas (BBV Clinical Nurse Specialist, NHS Grampian) presented on a recent re-engagement project in NHS Grampian.

13. Recommendations and digi-voting: access to care.

Professor David Goldberg chaired this recommendations and digi-voting section, with input from a guest panel (panel membership below)

The short life working group had – ahead of the national event – come up with a series of suggested recommendations on access to Hep C treatment / care. At this point, the delegates were each asked to vote using a digital keypad on the priority they would give to each recommendation (on a four-point scale: High priority, Medium priority, Low priority, Not a priority). Delegates were free to challenge wording, give suggestions for amendments, or free to speak in support of each recommendation as these arose.

14. The challenge ahead: how should we respond to the challenge ahead?

Professor John Dillon walked delegates through the key activities required for Hep C elimination in Scotland by 2030 and emphasised the need for creative approaches, including targeted and micro-elimination in pockets / population groups / geographies / communities wherever appropriate. John highlighted many initiatives taken in NHS Tayside towards the micro-elimination of Hep C. John emphasised that – as per evidence presented throughout the day - increased testing and diagnosis in previously undiagnosed patients will be key in driving elimination – driving the simple message: ‘Get tested, get treated, get cured’. John gave the vote of thanks and closed the event at 3.45pm.

Panel membership:

Case-finding

Prof John Dillon – BBV Clinical Lead, NHS Tayside (Chair)

Dr David Campbell, GP partner, NHS Ayrshire and Arran

Dr Erika Peters, Consultant in Infectious Disease, NHS Greater Glasgow & Clyde

Jacqui McGinlay, Senior Addictions Nurse, NHS Greater Glasgow & Clyde

Andrew Radley, Consultant in Public Health Pharmacy, NHS Tayside

Novel approaches to testing

Prof John Dillon – BBV Clinical Lead, NHS Tayside (Chair)

Dr Rory Gunson – Consultant Biochemist, NHS Greater Glasgow & Clyde

Mina O’Hara – Lead BBV nurse, NHS Lothian

Claire Fuller – Programme Manager, Waverley Care

Awareness-raising

Dr Pete Bramley – BBV Executive Lead, NHS Forth Valley (Chair)

Dr Stephen Barclay – BBV Clinical Lead, NHS Greater Glasgow & Clyde

Petra Wright - Hepatitis Trust

Allan McLeod – BBV Epidemiologist, Health Protection Scotland

Dr John Logan – BBV Executive Lead, NHS Lanarkshire

Access to care

Prof David Goldberg, Consultant Epidemiologist and BBV Lead, Health Protection Scotland (Chair)

Dr Stephen Barclay – BBV Clinical Lead, NHS Greater Glasgow & Clyde

Donna Thain – BBV Coordinator, NHS Tayside

Rachel Halford – Chief Executive, Hepatitis Trust

Grant Sugden - Chief Executive, Waverley Care