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Y Pwyllgor Iechyd, Gofal Cymdeithasol a Chwaraeon
Ymchwiliad i Hepatitis C
HSCS(5) H05
Ymateb gan Brendan Healy National Lead for Hepatitis

National Assembly for Wales
Health, Social Care and Sport Committee
Inquiry into Hepatitis C

Evidence from Brendan Healy National Lead for Hepatitis

This submission is provided to the Committee through my role as National Lead for Hepatitis, which I am commissioned to provide by the Liver Disease Implementation Group at the request of Welsh Government. The views expressed in this submission are my own and reflect opinions formed as a result of that position. They do not necessarily reflect the views of my employing organisation (Public Health Wales) or any other organisation that I work for (Cardiff and Vale University Health Board and Abertawe Bro Morgannwg University Health Board).

Current situation

See figure 1 below for treatment and cure (SVR) rates since 2011.

Prior to 2014 patients were treated with a combination of drugs called pegylated interferon (which had to be given by injection) and ribavirin. This treatment was difficult to take and had low cure rates of 40-80% in the small number of people who could tolerate it. Treatments using directly acting antiviral medications without the need for interferon have been available since 2015. These treatments are all in tablet form, are easy to take, well tolerated, can be taken by almost all people infected with hepatitis C and have high cure rates (>90% in all patients and >95% in most patients). In 2015, patients with the most advanced disease were treated with directly acting antivirals using a Welsh Government central fund. In 2016, patients that were accessing care, most of whom had been accessing care for some time, were treated (i.e. backlog of patients waiting for treatment was cleared). From 2017 onwards, the number of patients being treated reflects the number of patients being diagnosed and treated each year.

SVR = Sustained Virological Response which is an undetectable viral load in the blood taken 12 weeks after treatment has been completed which equates to a cure.

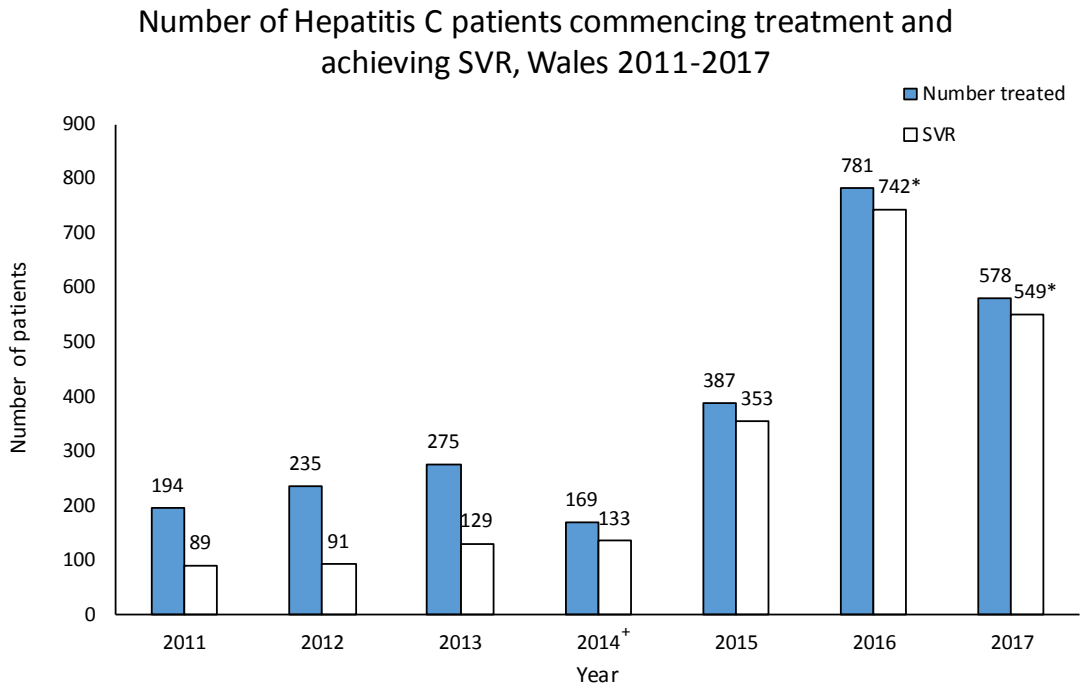

Figure 1

Notes on interpretation

I. Data obtained from health board returns. Data are unavailable for one health board in 2014+

II. Data collection systems have been under development and therefore figures should be interpreted with caution, and may be subject to change. It is possible that some individuals may have been counted more than once.

III. Year of SVR (sustained virological response) may not be the same as year of starting treatment for years 2011 to 2014.

IV. *SVR in 2016/2017 is estimated based on 2015 SVR rates. Work on the exact SVR for those years is currently underway.

Each Health Board was assigned a minimum treatment target at the end of 2015. This target was based on data available at that time which was used to predict the approximate prevalence of infection in each area and to provide treatment targets that would facilitate equitable and transparent access to treatment across Wales. The Viral Hepatitis Subgroup of the Liver Disease Implementation Group (LDIG) is aware that these figures will need to be refined when a more robust estimate of prevalence becomes available. The group anticipates being able to recalculate these minimum treatment targets at the beginning of 2020 when data from increased testing in the prisons, community pharmacies and drug and alcohol services is available. Delivery of increased testing in these environments is critical in facilitating a refinement of these figures and a refinement of the elimination modelling, which is currently based on data that may not accurately depict the current situation in Wales.

Attainment of minimum treatment targets:

Year 2017/2018

In 2017/2018 only one Health Board achieved the minimum treatment target. This was to be expected as there was a requirement for Health Boards to change the way the services were being run in order to meet the target. Health Boards had to change services to increase testing in at risk populations. The services also needed to be changed so that patients who tested positive could access treatment.

Year 2018/2019

Only two Health Boards are on target to treat the recommended minimum number of patients that need to be treated per year to achieve elimination. If the current trajectory (based on end of November figures, two thirds of the way through the year) is maintained, 638 patients will be treated by year-end (262 patients short of the minimum target).

Modelling (provided by an independent company funded by a pharmaceutical company), based on the most up to date data, suggests that if we treated 900 patients per year we would miss the WHO elimination date of 2030 by 1-2 years. Based on the current treatment numbers (2015/16 and 2016/17) elimination would not be achieved until 2040 (see figure below). It is imperative, therefore, that the number of at risk individuals being tested and treated is increased rapidly if elimination is to be achieved. This requires investment in a number of services and for Health Boards and BBV teams from each Health Board to work together to ensure that the teams in each area are appropriately resourced to deliver the necessary increase in testing and treating.

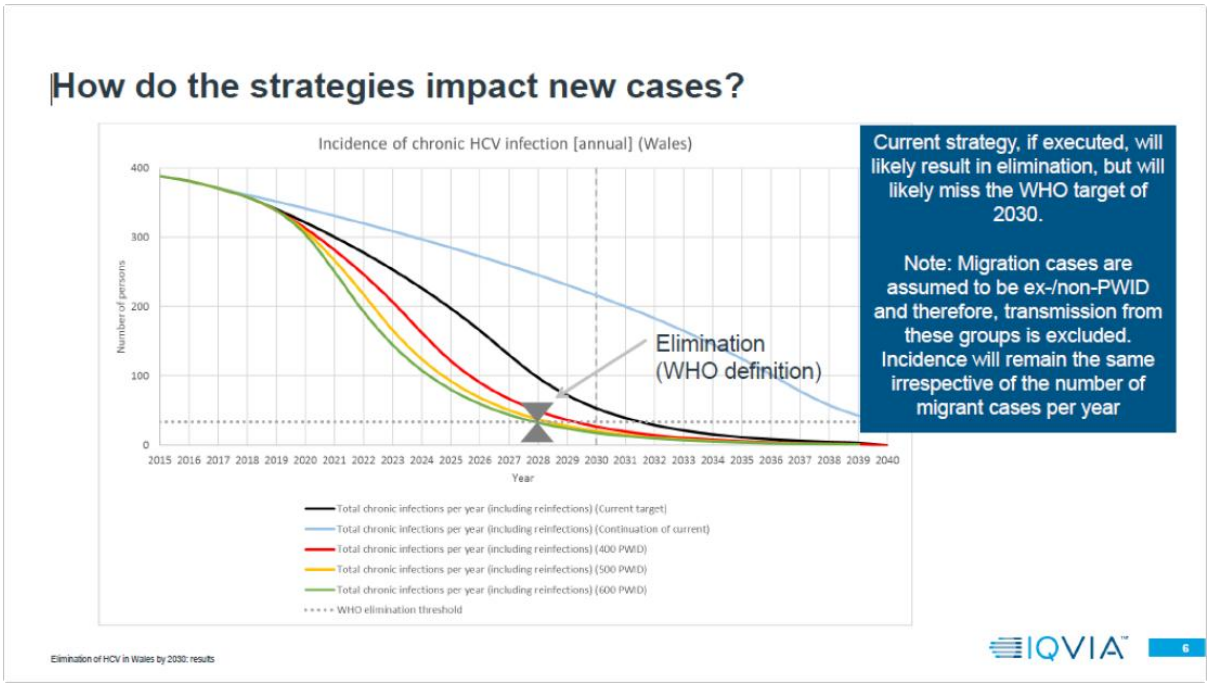

Figure 2

The graph demonstrates modelling of prevalence of hepatitis C in Wales based on current estimates of prevalence. The light blue line demonstrates the trajectory for elimination based on actual current treatment numbers across Wales. The black line demonstrates the trajectory of elimination based on 900 patients in Wales receiving treatment each year (current minimum target). The other lines demonstrate the trajectory for elimination if the number of people who are injecting drugs is altered within the model. Because people who inject drugs are responsible for most of the ongoing transmission of hepatitis C, treatment in this group has the potential to increase the speed with which elimination can be achieved without altering the overall annual treatment numbers. It also has the potential to reduce the overall number of people that need to be treated to achieve elimination and reduce the total cost of the programme as a result.

The treatment programme in Wales has delivered significant clinical success which will be cost saving to NHS Wales in the long run because patients who have been cured of hepatitis C will not then develop hepatitis C related liver disease which is costly to manage (for example through the costs of the management of liver failure and liver transplantation - which is also a scarce and precious resource). Cure rates in the region of 95% were achieved in 2015, which is at least equivalent to other major international centres. Data on cure rates for 2016 – 2018 will be available in 2019 (work ongoing currently).

National (UK) statistics demonstrate that the new medications are having a significant impact on the outcomes of advanced liver disease – namely the reduced demand on liver transplantation and reduction in the number of hepatitis C related deaths (see graphs below).

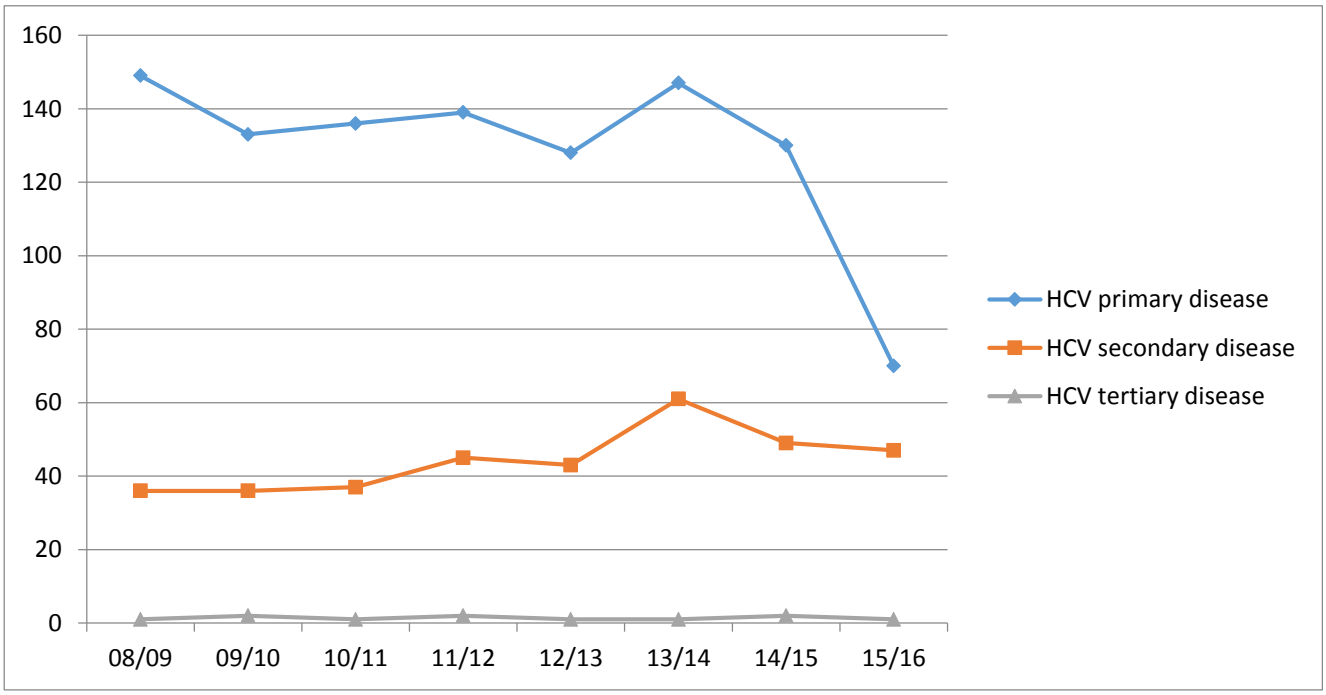

Figure 3: Patients Listed for First Liver Transplant with a Primary, Secondary and Tertiary Diagnosis of HCV 2008-2016 (UK Transplant Data)

This graph demonstrates that the number of people requiring a Liver transplant for hepatitis C (where hepatitis C is the main cause of liver disease – "HCV primary disease") dropped significantly following the introduction of directly acting antiviral agents. In this year, it most likely reflected treatment of patients with advanced disease who improved following treatment and could be delisted as a result. As liver transplant is a precious resource, this reduction in demand is a very positive outcome of the new treatments.

In the graph there is no change in the number of patients requiring liver transplantation where hepatitis C is not the main cause of liver disease ("HCV secondary disease" and "HCV tertiary disease") suggesting that this decline in the need for transplantation in the "HCV primary disease" group is related to treatment with the directly acting antiviral agents.

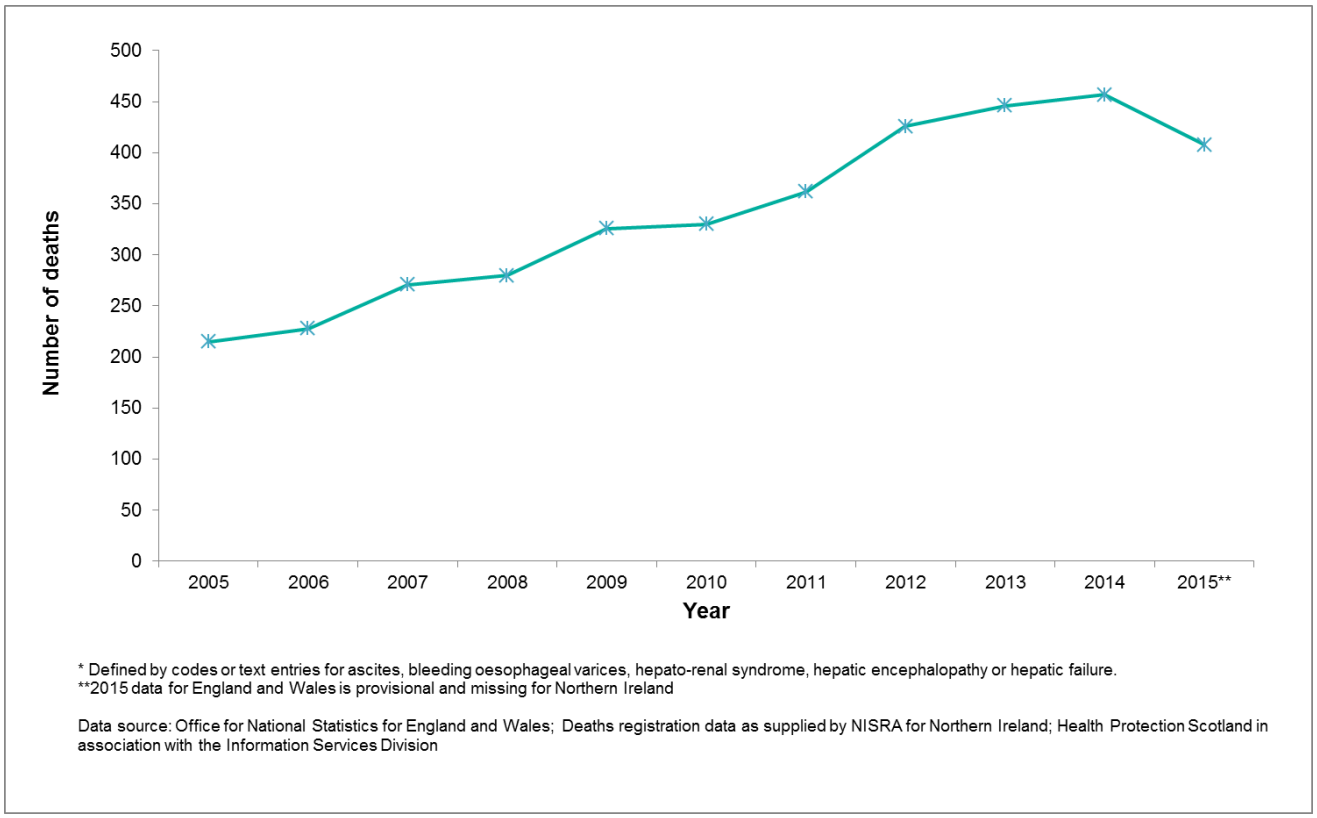

Figure 4: Death certificates with HCV

The National (UK) figures for deaths caused by hepatitis C as listed on death certificates also fell in 2015 following the introduction of the directly acting antiviral treatments. This is another positive sign that the treatments are having a beneficial effect at a national level.

Section 1: The action being taken to meet the requirements of the Welsh Health Circular (WHC/2017/048) published in October 2017 and subsequently meet the World Health Organization target to eliminate Hepatitis B and Hepatitis C as significant public health threats by 2030.

1. The World Health Organisation (WHO) has announced a global health sector strategy on viral hepatitis which sets out to eliminate hepatitis B (HBV) and hepatitis C (HCV) as significant public health threats by 2030. The WHO target is a 90% reduction in occurrence of new cases (incidence) and 65% reduction in death (mortality) due to hepatitis B and C by 2030. Wales is signed up to this strategy.

2. The Welsh Health Circular (WHC/2017/048, issued in October 2017) highlights the three key areas where action is needed in Wales to progress toward the 2030 elimination target. Those three areas are:-
    a. Reduce and ultimately prevent ongoing transmission of HCV within Wales;
    b. Identify individuals who are currently infected with HCV including those who have acquired HCV outside the UK and are now resident in Wales; and
    c. Test and treat individuals currently infected with HCV who are actively engaged in behaviours likely to lead to further transmission.

Reduce and ultimately prevent ongoing transmission of HCV within Wales

3. Over 90 per cent of ongoing transmission of hepatitis C is via injecting drug use. As such, the most effective way of reducing transmission is through a reduction in the number of individuals injecting and through provision of effective needle and syringe programmes (NSPs).

4. Reduction in HCV in these individuals is reliant on increased testing in appropriate settings (prisons, drug and alcohol services, needle exchange services, opiate substitution services, criminal justice services, third sector agencies, community pharmacies). Testing rates in all of these settings is currently sub-optimal. Work is being carried out to improve uptake of testing in these settings (e.g. community pharmacy national specification for testing, testing now a key performance indicator (KPI) for drug and alcohol services, catch-up vaccination for hepatitis B of staff who will be involved in testing, opt out in prisons). However, these initiatives need to be matched by an appropriate investment in the services so that they have sufficient staff and equipment to facilitate testing of all at risk clients.

5. Once tested positive individuals need to be able to access treatment. Each Health Board needs to have a robust mechanism in place that enables individuals to access treatment easily. This will most likely be provided by secondary care services. All Health Boards (except Powys) have a Blood Borne Virus team that delivers treatment for hepatitis C. Treatment and

management of hepatitis C in Powys is supported by the Blood Borne virus teams of neighbouring Health Boards. It is imperative that these teams are appropriately resourced so that they are able to deliver treatment to positive individuals in a setting that they are willing and able to access. This will most likely be in the community where they are already accessing another service (e.g. community pharmacy, drug and alcohol services, needle exchange services, prison etc.). I think the BBV teams in all Health Boards require some investment to ensure that they have the appropriate staff in place to enable this to happen.

6. Treatment in community pharmacy setting is another means for achieving this aim. Work will start on a specification for this in the near future. This work is being carried out by the National Pharmacy Lead for BBV. This post is funded until 2020 through Liver Disease Implementation Group money. The delivery and roll out of a specification for treating in community pharmacies is complicated. For this to be achieved the funding for this post needs to run beyond 2020. Some of the decisions in relation to delivering treatment in this setting will need to be made at senior level and so engagement from individuals in a variety of settings is required to achieve this goal (e.g. Health Board finance directors, Senior Pharmacy staff at National level, Community Pharmacy Wales).

7. Delivery of appropriate harm reduction services is also a key component of the elimination strategy. It will reduce the number of people that require treatment, will reduce the risk of re-introduction of the infection once the prevalence has been significantly reduced, will reduce the risk of transmission of resistant virus and have other health benefits by preventing transmission of other infections. These services therefore require appropriate investment / funding. The Viral Hepatitis Subgroup of the Liver disease Implementation Group works with the Substance Misuse Programme, Health Protection, Public Health Wales in this regard and strategy in this context is taken forward by them in conjunction with relevant individuals in Welsh Government. Substance Misuse Area Planning Boards / Heath Boards should have in place appropriate, comprehensive and effective harm reduction groups and local action plans, in line with the Welsh Government strategy, accompanying substance misuse treatment frameworks and best practice guidance.

Identify individuals who are currently infected with HCV including those who have acquired HCV outside the UK and are now resident in Wales

8. Public Health Wales with the Viral Hepatitis Subgroup of the Liver Disease Implementation Group is leading the co-ordination and implementation of a national patient re-engagement exercise. This work is looking to identify individuals with a historical diagnosis of Hepatitis C who, for whatever reason(s), have not completely engaged with treatment services and is seeking to bring them back into the service. The yield from this strategy is yet to be determined but pilot work has suggested that a high return in

percentage terms is unlikely. Further work to try and identify individuals on this database at ongoing risk will probably be required.

9. Testing and treating patients at high risk of infection and at high risk on onward transmission is the first priority of the BBV subgroup. As such most work to date has concentrated on identifying infected individuals through testing in settings that provide services to individuals who inject drugs (see section above for more detail). Testing and treating individuals in this setting is the fastest way to reduce the overall prevalence, will be the key to achieving WHO elimination targets and will reduce the overall cost of reaching the elimination target (each individual successfully treated can reduce the overall number of individuals that need treatment as onward transmission is prevented). Success in this regard is being monitored through the harm reduction database. Measures in place to increase testing in these groups include the KPI for drug and alcohol services, opt out in prisons, national specification for testing in community pharmacies. As previously mentioned this needs to be matched with services that are able to offer treatment to these individuals when identified as positive.

10. Strategies to identify positive individuals from high risk countries, those that injected in the past but are no longer accessing services and those with other risk factors are not yet well established. There is still uncertainty with regards to the best way to identify these people and further work will be required on this in due course. It is the intention of the Viral Hepatitis Subgroup to turn its attention to these groups of people once the testing and treating of people in high risk groups already accessing services as outlined above is operating successfully. That said work has been carried out in asylum services and testing is now routinely offered to individuals accessing these services. Work is also being carried out to encourage testing of at risk pregnant women. It is yet to be determined whether targeted testing can be effective in this setting. I understand that previous attempts at targeted testing in this environment (e.g. HIV) were not successful. Some pilot work of testing individuals and raising awareness in individuals from high risk countries has also been carried out.

Test and treat individuals currently infected with HCV who are actively engaged in behaviours likely to lead to further transmission

11. As previously mentioned the three main areas of development in this regard relate to opt out testing in prisons (testing has increased from approximately 8% to 32% as a result), development of a KPI for drug and alcohol services related to BBV testing and development of a national specification for testing in community pharmacies.

12. All of these developments now need to be made operational and it is the appropriate investment and adequate resourcing of services that will make this possible.

13. Development of appropriate services to facilitate treatment of positive individuals identified in these settings is also required with adequate

resourcing for medication should the number of patients accessing treatment dramatically increase. As previously mentioned this requires development of the BBV teams in secondary care to ensure treatment is delivered at the point of need and engagement from senior members of the Health Board such as the Finance Directors to ensure budgeting and adequate allocation of funding is achieved.

Developments so far

14. In my role as National Lead for Hepatitis I have worked with members of Public Health Wales, Welsh Government colleagues, other members of the BBV network, the Liver Disease Implementation Group, the microbiology / virology laboratory Cardiff, the National Point of Care testing lead, in developing roles, services and protocols to support elimination. Most of this work is carried out through the Viral Hepatitis Subgroup of the Liver disease Implementation Group.

15. The following has been delivered

- Appointment of a National Pharmacy Lead for Hepatitis (funding secured to 2020)
- Appointment of a National Project and Research Lead for Hepatitis (funding secured to 2020)
- Appointment of a National Point of Care Testing Lead (funding due to expire 2019)
- Development of a national protocol for testing for hepatitis in a community pharmacy setting
- Obtaining funding to develop reflex PCR testing from dried blood spot tests that will facilitate and increase speed of access to a confirmed diagnosis which in turn can speed up access to treatment in some settings (e.g. community pharmacy)
- Funding, and administration for a variety of projects on testing and treatment strategies for hepatitis C
- Development of a protocol and plan including administrative support for delivery of a programme designed to re-engage patients with hepatitis C that may have been lost to follow-up or may never have been offered treatment for hepatitis C (e.g. diagnosed when no treatment was available historically)
- Development of the national Hepatitis C treatment pathway and treatment recommendation protocol.
- Co-ordination of the blood-borne virus network.
- Running of two national network meetings per year made possible through unrestricted educational grants provided by pharmaceutical industry.

- Development of an elimination model using an independent company funded through non restricted grant by pharmaceutical industry
- Support for the national tendering process
- Delivery of equitable and transparent access to treatment.
- Construction of a map of all community pharmacies involved in provision of opiate substitution and needle exchange services
- Administration of the virtual panel that enables discussion of complicated patients to ensure most appropriate treatment options are given to these individuals
- Administration and collection of national figures on treatment numbers on a monthly basis
- Reporting of appropriate statistics on a regular basis to Welsh government, health boards and national bodies as appropriate
- Development of a hepatitis C electronic form that will facilitate live collection of national treatment data in the future
- Working with other agencies as appropriate to develop and support increased testing and treatment in a variety of settings including prisons, drug and alcohol services, third sector services and community pharmacies
- Regular reports of activity and routine reporting to the Liver Disease Implementation Group
- Collection of data to ensure appropriate governance of the blood borne virus section of the National Liver plan
- Regular review of the national plan for elimination with expert advice and recommendations for development as and when appropriate.
- Delivery of significant savings to the NHS in Wales through national procurement, adherence to the principles of prudent Healthcare, use of cheapest possible treatment options when appropriate, taking senior decisions to delay treatment in patients who could afford to wait for newer cheaper options in the early days of management of hepatitis C.
- Significant savings were delivered through a number of strategies that include strong clinical leadership, prudent use of available medications, national procurement and use of home care. In 2017 Wales was shown to have the lowest acquisition costs in the UK for the new hepatitis medications as a result of these factors.

16. From October 2015 to 2017 the total saving to NHS Wales are estimated to be of the order of £29 Million, with £15.9 Million of this realised through direct

action of the BBV group (home care delivery of medication and holding patients back for treatment). Breakdown of savings:

- National procurement – significant savings against list price - £6M in 2015/2016, £8.5M in 2016/2017, Total £14.5M
- Use of home care – £2.5M in 2015/2016, £2.3M in 2016/2017, Total £4.8M
- Prudent prescribing – use of cheapest appropriate product – savings in 2015 £2M, 2016 £5M, Total £7M
- Prudent prescribing – in 2016 patients with a certain genotype (genotype 3) disease that could wait were held back for treatment early in the financial year until a newer cheaper alternative became available – £3.1M (204 patients treated with the cheaper medication @ £15,623 saving per patient)
- This figure does not include further savings achieved in 2017-2018 when treatment of patients with a certain genotype (genotype 3) infection who were willing and able to wait were delayed until a cheaper alternative became available, delivering a saving of approximately £13,000 per patient.

Section 2: How the knowledge and awareness of the public and health professionals of the Hepatitis C virus can be increased.

17. Increasing awareness of the public and health professionals is one of the most challenging areas of the elimination plan.

18. The British Liver Trust (BLT) (as part of their work with the Liver Disease Implementation Group) is working in Wales to raise public and professional awareness of liver health including the need for at risk individuals to be tested and treated.

19. In December 2017, a good practice hepatitis C roadshow was held in Cardiff. This event was organised by HCV Action and Public Health Wales, and aimed to bring together professionals working with hepatitis C in a variety of contexts, identify challenges and solutions for tackling hepatitis C locally, and showcase and share examples of good practice in prevention, testing, and treatment. The summary report from the roadshow is available on the HCV action website at http://www.hcvaction.org.uk/resource/summary-report-hepatitis-c-good-practice-roadshow-cardiff-december-2017 [accessed 27/12/2018]

20. In addition, I have organised with the blood borne virus network national network meetings (two in 2018 and two planned for 2019), to help share learning between teams and health boards. These were made possible

through unrestricted educational grants provided by the pharmaceutical industry.

21. Local education and awareness raising is currently dependent on the enthusiasm and work of the local BBV teams. Whilst there has been some success in this regard, it is fair to say that public awareness raising / advertising is not the skill set of these teams.

22. To date the following local awareness raising initiatives have been carried out (list not exhaustive)

    - Education of primary care teams
    - Awareness raising on World Hepatitis Day
    - Engagement with media when Hepatitis C is in the news
    - Support for Hepatitis C awareness raising events
    - Project to test and raise awareness in a mosque

23. Impact of these initiatives is uncertain but there is no evidence of a significant impact so far.

24. Consideration should be given to ways in which awareness raising could be increased although I also appreciate that this is not as easy to achieve as it sounds. In this particular instance targeted messaging is required.

25. Consideration could be given to using learning from other Public Health Campaigns such as the stop smoking campaign but we may require a very different approach to public messaging and engagement to that which has been used previously because the individuals at risk of hepatitis C infection come from groups in society that may not respond to traditional methods.

26. Consideration should be given to funding a focussed awareness raising campaign designed to specifically target the groups in society who are at risk of infection. A campaign of this sort could be particularly important in finding patients who are not easily identified (e.g. individuals from high prevalence countries, people who used to inject drugs or dabbled in early life but are no longer accessing support services, those at risk through blood transfusion etc.).

Section 3: The scope to increase community-based activity e.g. the role of community pharmacies.

27. I have worked with the Viral Hepatitis Subgroup of the Liver Disease Implementation Group, Community Pharmacy Advisor, Lead Pharmacist - Community Pharmacy & Primary Care, CTUHB, other BBV pharmacy colleagues, the Chief Pharmaceutical Officer for Wales and Community Pharmacy Wales to develop a national specification for delivery of testing for hepatitis C in the community pharmacy setting. The specification has now been approved by National Pharmacy Wales.

28. The National Pharmacist for Hepatitis C was appointed in October 2018. He has been involved in the completion of the national specification and is now working on rolling out testing in community pharmacies across Wales (making the specification / service operational).
29. Funding for a pilot project to test the protocol in the live environment has been secured and will run in January.
30. Blood borne virus teams from across Wales are aware of the protocol and are in position to support the roll out of testing in this environment.
31. A map of all pharmacies that carry out needle exchange and opiate substitution therapy has been constructed from data extracted from the Harm reduction database and this will be used to facilitate roll out. This has been provided by the Head of Substance Misuse Programme, Health Protection, Public Health Wales.
32. The National Pharmacist for Hepatitis C is also tasked with developing a national specification for treatment of positive patients in the community pharmacy setting. There are a number of hurdles to overcome in relation to this development. Earliest start date for this specification is 2020. Development of this specification requires engagement and support from a number of key decision makers including Health Board Finance Directors and senior members of the pharmacy teams in both secondary care and the community.

Section 4: The long-term viability of treatment programmes.

33. Treatment programmes are currently supported by a combination of Health Board level Blood Borne Virus teams and national roles (National Pharmacist, National Lead for Hepatitis, National Project and Research Lead, National Point of Care Testing Lead).
34. The national roles are supported by the Liver Disease Implementation Group. Funding for those roles is uncertain beyond 2020. At the current trajectory elimination will not be achieved until after 2030. If testing and treating is to be up-scaled to the point that elimination by 2030 is to be achieved then it is imperative that these roles are sustained beyond 2020.
35. Funding for treatment is currently secured through Health Boards. However, as treatment numbers increase this could create a cost pressure. If elimination is to be achieved it is imperative that Health Boards support treatments of hepatitis C and do not put any cap on treatment numbers at any stage.
36. Blood borne virus teams are variably resourced across Wales. It is imperative that all Health Boards ensure that their BBV teams are adequately resourced to deal with the challenge of elimination and this includes sufficient staff to support testing and treating in the community setting. As National Lead for Hepatitis, I am concerned that the BBV teams are not sufficiently resourced in this regard at this time.

37. There are many developments designed to increase the testing of at risk individuals and link them to care (e.g. increased testing in prisons, drug and alcohol services, third sector agencies, community pharmacies). It is imperative that these initiatives are appropriately resourced so that the increase in testing in these environments is sustainable.

38. The developments to increase testing and treatment of at risk individuals need to be appropriately matched with investment to promote harm reduction messages to reduce the risk of re-infection and make the delivery of elimination as cost effective as possible.