

Agenda – Health, Social Care and Sport Committee

Meeting Venue:

Committee Room 3 – Senedd

Meeting date: 17 January 2019

Meeting time: 09.15

For further information contact:

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Committee Clerk

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Informal pre-meeting (09.15–09.30)

1 Introductions, apologies, substitutions and declarations of interest

(09.30)

2 Hepatitis C: Evidence session with Hepatitis C Trust

(09.30–10.15)

(Pages 1 – 36)

Rachel Halford, Chief Executive, Hepatitis C Trust.

Stuart Smith, Director of Community Services, Hepatitis C Trust.

Aidan Rylatt, Policy and Parliamentary Adviser, Hepatitis C Trust.

[Consultation Responses](#)

Research Brief

Paper 1 – Hepatitis C Trust

Break (10.15–10.20)

3 Hepatitis C: Evidence session with Royal College of General Practitioners and Royal College of Nursing

(10.20–11.05)

(Pages 37 – 40)

Dr Mair Hopkin, Joint Chair, Royal College of General Practitioners.



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Dr Peter Saul, Joint Chair, Royal College of General Practitioners.

Delyth Tomkinson, Clinical Specialist Nurse Hepatology, Cardiff and Vale University Health Board.

Lisa Turnbull, Policy and Public Affairs Adviser, Royal College of Nursing Wales.

Paper 2 – Royal College of General Practitioners

Paper 3 – Royal College of Nursing

Break (11.05–11.15)

4 Hepatitis C: Evidence session with The Blood Borne Viruses

Network

(11.15–12.00)

(Pages 41 – 60)

Dr Brendan Healy, Chair of the Blood Borne Viruses Network, Consultant in Microbiology and Infectious Diseases, National Lead for Hepatitis.

Dr Ruth Alcolado, Deputy Medical Director, Cwm Taf University Health Board.

Gavin Hardcastle, Hepatitis Clinical Nurse Specialist, Aneurin Bevan University Health Board.

Dr Chinlye Ch'ng, Consultant Gastroenterologist, Abertawe Bro Morgannwg University Health Board

Paper 4 – Brendan Healy, National Lead for Hepatitis

Paper 5 – Cwm Taf University Health Board

Paper 6 – Aneurin Bevan University Health Board

Break (12.00–12.30)

5 Hepatitis C: Evidence session with Public Health Wales

(12.30–13:15)

(Pages 61 – 69)

Dr Giri Shankar, Lead Consultant for Health Protection and Communicable Disease Control, Public Health Wales

Dr Jane Salmon, Consultant in Health Protection, Public Health Wales

Dr Jane Perrett, Lead Nurse for Health and Justice, Health Protection Programmes, Public Health Wales

Paper 7 – Public Health Wales

6 Subordinate legislation relating to health and social care

(13.15 – 13.20)

(Pages 70 – 74)

[The Adult Placement Services \(Service Providers and Responsible Individuals\) \(Wales\) Regulations 2019](#)
[Explanatory Memorandum](#)

[The Regulated Fostering Services \(Service Providers and Responsible Individuals\) \(Wales\) Regulations 2019](#)
[Explanatory Memorandum](#)

[The Regulated Advocacy Services \(Service Providers and Responsible Individuals\) \(Wales\) Regulations 2019](#)
[Explanatory Memorandum](#)

Legal Advice Note

7 Paper(s) to note

(13.20)

7.1 Dentistry in Wales: Additional information from Belgrave Dental Practice on a Prototype Dental Contract

(Pages 75 – 79)

7.2 Autism (Wales) Bill: Letter from Paul Davies AM to Chairs of Health, Social Care and Sport, Finance, and Constitutional and Legislative Affairs Committees

(Pages 80 – 86)

- 8 Motion under Standing Order 17.42 to resolve to exclude the public from the remainder of this meeting**
(13:20)
- 9 Hepatitis C: Consideration of evidence**
(13.20–13.30)
- 10 Legislative Consent Motion on Healthcare (International Arrangements) Bill: Consideration of draft report**
(13.30–13.40) (Pages 87 – 91)
- 11 Palliative Care: Consideration of draft letter**
(13.40 – 13.45) (Pages 92 – 94)

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Hepatitis C inquiry – Evidence from The Hepatitis C Trust

Background

Hepatitis C is a blood-borne virus affecting the liver. Four-fifths of those infected develop chronic hepatitis C, which can cause fatal cirrhosis and liver cancer if untreated. Around 210,000 people are chronically infected with hepatitis C in the UK¹, with 12,000-14,000 of these in Wales².

Hepatitis C disproportionately affects disadvantaged and marginalised communities, with almost half of people who attend hospital for hepatitis C coming from the poorest fifth of society, and with the latest figures showing that 50% of injecting drug users in Wales have hepatitis C antibodies³. Other groups who are disproportionately affected include homeless people and migrant communities from countries with a high prevalence of hepatitis C, such as Pakistan and Poland.

With direct acting antiviral (DAA) treatments available without restriction through the NHS in Wales, offering high cure rates with very few side effects, achieving the elimination of hepatitis C by 2030, in line with the Welsh Government's commitment, is an achievable goal. However, with Wales currently falling significantly short of its target to treat 900 patients per year, efforts to find the roughly 50% of patients who remain undiagnosed must become a public health priority to ensure the opportunity of achieving elimination is seized.

Action being taken to meet the requirements of the Welsh Health Circular and 2030 elimination target

There is some encouraging progress being made towards meeting the requirements of the Welsh Health Circular and the elimination target of 2030.

The Hepatitis C Trust welcomes the variety of community outreach pilot projects that have been trialled across Wales, including assessing the effectiveness of testing in GP clinics and within specific populations, such as image and performance enhancing drug users, the homeless community, sex workers and asylum seekers. Initiatives such as these are a valuable way of determining how to most effectively target testing campaigns. The implementation of opt-out testing in prisons has also increased testing rates, and it is to be expected that these rates will continue to increase as the policy is further embedded.

A further positive development is Public Health Wales' ongoing roll-out of a re-engagement exercise for patients diagnosed with hepatitis C in the past but never treated. As noted in the Welsh Health Circular, there is an urgent need to refer these individuals for further testing and treatment to minimise ongoing liver damage, and The Hepatitis C Trust has been pleased to contribute to planning meetings for the exercise to provide the perspective of a patient organisation.

¹ Public Health England, [Hepatitis C in the UK: 2018 report](#), August 2018

² National Assembly for Wales, [Written Assembly Questions tabled on 14 January 2015 for answer on 21 January 2015](#), January 2015

³ Public Health England, Health Protection Scotland, Public Health Wales, and Public Health Agency Northern Ireland, [Shooting Up: Infections among people who inject drugs in the UK, 2017](#), November 2018

The ambition to increase the level of testing and treatment in community pharmacies will be greatly enhanced by the recent appointment of a National Pharmacy Lead. Pharmacies are a particularly effective setting to test for hepatitis C, with many current or former injecting drug users who may not be attending substance misuse services accessing them to collect clean injecting equipment or opioid substitution therapy (OST). Increasing testing in this setting is therefore likely to lead to greater numbers of patients being diagnosed and referred for treatment.

Despite this encouraging progress, there are evidently still challenges that remain if elimination is to be achieved by 2030. Whilst some Local Health Boards are meeting their treatment targets, most are not and there is a significant shortfall in meeting the national annual target. Diagnosis and treatment rates will have to increase significantly if elimination is to be achieved by 2030.

The release of the Welsh Health Circular was a very welcome step but The Hepatitis C Trust believes this must now be followed by a comprehensive national elimination strategy, with clear targets and allocated areas of responsibility, to ensure coordination of the various actors and actions needed to achieve elimination by 2030.

With Scotland having committed to releasing a dedicated hepatitis C elimination plan in the near future and NHS England having set a more ambitious target of elimination by 2025, Wales must continue to take an ambitious approach to avoid being left behind.

Increasing awareness of hepatitis C

Knowledge and awareness of hepatitis C among the public and some health professionals remains low, reflected in the roughly 50% of undiagnosed patients and continuing stigma around the virus.

To mark World Hepatitis Day 2018, The Hepatitis C Trust commissioned a UK-wide poll of members of the public to assess awareness of hepatitis C. Despite 80% of respondents stating that they were aware of what hepatitis C is, less than 40% knew that it infects the liver, and less than 30% knew the virus is curable. Awareness of symptoms was also low, with only a third of respondents accurately identifying tiredness, loss of appetite, vomiting and abdominal pains as signs of infection, and less than half aware that symptoms are not always obvious and can go unnoticed for many years. When asked how hepatitis C is transmitted, 30% incorrectly said it was through exchanging saliva.

This lack of public knowledge contrasts markedly with awareness of HIV, which saw huge increases in public awareness following government-backed awareness campaigns and campaigning activity by high-profile individuals. The Hepatitis C Trust would like to see the Welsh Government work with other key stakeholders to develop a nationally coordinated series of local awareness-raising campaigns, including messaging tailored to specific at-risk groups highlighting transmission risks, the importance of testing and the availability of the new treatments. Increasing awareness also helps to reduce stigma, which enables people to feel more comfortable about coming forward to get tested or access treatment. With Public Health Wales implementing a patient re-engagement exercise in late 2018/early 2019 and the UK-wide Infected Blood Inquiry also due to begin hearing evidence in April 2019, a series of awareness campaigns in the first half of 2019 would be well-timed to capitalise on a window of opportunity to raise attention to hepatitis C.

Low knowledge and awareness of hepatitis C is not just an issue among the general public, with myths and outdated messages still often prevalent even among particularly at-risk groups. For example, while injecting drug users are more likely than the general population to be aware of hepatitis C, many are unaware of the availability of the newer DAA treatments, with outdated information related to the significant side effects associated with the older interferon treatments often passed on. Such misinformation can have serious consequences, with some patients choosing not to access healthcare services due to fear of the old treatments.

Peer-to-peer support and peer groups are a particularly effective way of addressing such myths and improving knowledge and awareness among at-risk groups. Peer-to-peer support involves people who have themselves had experience of hepatitis C delivering awareness-raising talks to people with backgrounds similar to their own, as well as encouraging and supporting people to access testing and/or treatment. Expanding the use of peers in Wales would be an effective way of increasing knowledge and awareness of hepatitis C among at-risk groups.

Low knowledge and awareness among some health professionals is also an ongoing issue. During interviews and focus groups The Hepatitis C Trust conducted with patients prior to the publication of our *Hepatitis C in Wales: Perspectives, challenges and solutions* report, we were told that they often encountered low levels of knowledge of hepatitis C among health professionals. While the excellent care provided by specialist hepatology teams was emphasised, patients reported less positive experiences with other health professionals, such as GPs and non-specialist nurses.

Many patients told us they had been visiting their GP for years with symptoms consistent with hepatitis C infection but had never been offered a test. Others were given incorrect advice and information, such as being told that the virus is transmitted through sexual contact, which contributed to stigma encountered by patients.

There have been various initiatives to improve this situation, with Public Health Wales carrying out valuable work to improve professional awareness, HCV Action (coordinated by The Hepatitis C Trust) holding a hepatitis C good practice roadshow for healthcare professionals in Cardiff, and the British Liver Trust running a Liver Disease Event for GPs. However, there is a need for GPs and other primary care workers to be provided with regular information about hepatitis C and presented with opportunities to undertake training on hepatitis C as part of continued professional development to ensure increased levels of awareness and knowledge.

Scope to increase community-based activity

As referred to above, a range of community outreach activity has already been rolled out in Wales, particularly in relation to testing. However, there is a need for increased community-based activity to ensure the 2030 elimination target is met.

For example, dried blood spot (DBS) testing must become routine in settings such as substance misuse services and sexual health clinics, where prevalence rates among clients are likely to be higher than among the general public. The imminent introduction of routine opt-out BBV testing in substance misuse services is a very welcome development and is a

significant opportunity to diagnose and treat more patients. However, with substance misuse services facing significant financial challenges, it is essential that the policy is adequately resourced to ensure sustainability. The Hepatitis C Trust would also encourage more frequent testing in other community-based settings, including pharmacies, homeless hostels, and mosques.

With the simplicity of the DAA treatments for hepatitis C making them highly suitable for delivery in the community, there should be a move towards treatment being made available in any setting where testing takes place. Making treatment available in settings which patients access regularly and removing the need for referral to secondary care is likely to increase treatment uptake. If elimination is to be achieved by 2030, it is essential that Local Health Boards support community outreach work by funding appropriate staffing to support the delivery of treatment in a range of community settings. Welsh Government support is also likely to be required to facilitate the delivery of treatment in certain community settings, such as pharmacies, where there are unresolved issues regarding how treatments are funded.

An increase in community-based activity can also be supported by making use of peers. Peers are well placed to deliver testing and treatment in community settings and to provide the support and encouragement needed to help patients through the care pathway. For example, between October 2017 and December 2018, The Hepatitis C Trust's Peer Support Lead in South East London made contact with 44 hepatitis C positive patients considered 'hard to reach'. Of the 44 individuals, 42 were successfully supported to engage with treatment (95%). Peer support programmes should be commissioned to take place in a range of community services to ensure this support is in place.

Long-term viability of treatment programmes

The Hepatitis C Trust welcomes the Welsh Government's commitment to providing access to DAA treatments for hepatitis C for all who need them. This approach contrasted favourably with the approach adopted in England, whereby restrictions were placed on the number of patients able to access treatment, which initially resulted in waiting lists in some areas.

However, with treatment targets not being met despite this approach, more must be done to support patients to access treatment. With the cost of DAA treatments having reduced significantly since they came onto the market, it is important that these savings are reinvested back into hepatitis C care. The Hepatitis C Trust would like to see Local Health Boards reinvesting money saved on treatment cost reductions into finding individuals living with an undiagnosed infection, providing funding for designated staff and/or peers to support the delivery of testing and treatment in community services, and ensuring adequate staffing in secondary care hepatology teams. As testing rates increase in pharmacies and substance misuse services, there is likely to be a consequent rise in referrals into treatment, which secondary care services must be prepared for.

It is also vital that Local Health Boards understand that the national hepatitis C treatment targets are a minimum which they should be aiming to exceed. Anecdotally, The Hepatitis C Trust has heard of Local Health Board Finance Directors discouraging hepatology teams

from exceeding the treatment target due to financial concerns. The Welsh Government must make it clear to Local Health Boards that this approach will result in greater financial costs to Local Health Boards in the long run and is not compatible with Wales achieving elimination by 2030. Indeed, even if the current target of 900 patients being treated per year was being met – which it is not currently – the elimination target would be missed by 18 months. At the current rate of treatment, the elimination target will be missed by a substantial distance. It is therefore essential that Local Health Boards adopt an ambitious approach to treatment, with encouragement from the Welsh Government.

The Welsh Government should also consider developing a new funding arrangement for hepatitis C treatment, which allows for a longer-term, strategic approach and incentivises case finding. With NHS England currently in negotiations with the pharmaceutical industry over a new procurement deal, there may be an opportunity for Wales to follow England's example if such a deal is agreed. The proposed funding deal in England is expected to result in longer-term budget certainty for the NHS, introduce a role for the pharmaceutical industry in finding undiagnosed patients and incentivise higher treatment numbers. There would therefore be considerable benefits to Wales in considering such an approach.

Key recommendations

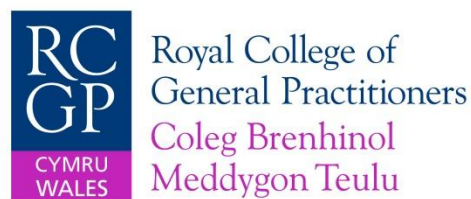
- The Welsh Government to produce a comprehensive national elimination strategy, with clear targets and allocated areas of responsibility, to ensure coordination of the various actors and actions needed to achieve elimination by 2030.
- The Welsh Government to work with other key stakeholders to develop a nationally coordinated series of local awareness-raising campaigns for hepatitis C.
- Peer support programmes to be commissioned in community services.
- GPs and other primary care workers to be provided with regular information about hepatitis C and presented with opportunities to undertake training on hepatitis C as part of continued professional development to ensure increased levels of awareness and knowledge.
- The opt-out blood borne virus testing policy in substance misuse services to be backed with adequate resource to ensure sustainability.
- The Welsh Government to work with all relevant stakeholders to facilitate the delivery of treatment in community settings, including pharmacies.
- Local Health Boards to reinvest money saved on treatment cost reductions into case finding and funding for staff personnel and/or peers to support the delivery of testing and treatment in community services.
- The Welsh Government to write to Local Health Board Finance Directors and Chief Executives to emphasise that treatment targets should be considered a minimum to

be exceeded, rather than a cap not to be exceeded.

- The Welsh Government to consider developing a new funding arrangement for hepatitis C treatment, which allows for a longer-term, strategic approach and incentivises case finding.

Further reading

- The Hepatitis C Trust, [*Hepatitis C in Wales: Perspectives, challenges & solutions*](#), October 2016.
- HCV Action, [*Summary report: Hepatitis C good practice roadshow, Cardiff*](#), December 2017.
- All-Party Parliamentary Group on Liver Health, [*Eliminating Hepatitis C in England*](#), March 2018 [focused on England but has many recommendations also applicable to Wales].



RCGP Wales response: Hepatitis C

Royal College of General Practitioners Wales welcomes the opportunity to respond to the Welsh Assembly's Health, Sport and Social Care Committee's consultation on Hepatitis C.

RCGP Wales represents a network of around 2,000 GPs, aiming to improve care for patients. We work to encourage and maintain the highest standards of general medical practice and act as the voice of GPs on resources, education, training, research and clinical standards.

The following response provides comments on the sections of the consultation we feel able to provide meaningful thoughts on. It therefore does not provide answer to each point in turn.

Point one: The action being taken to meet the requirements of the Welsh Health Circular ([WHC/2017/048\[Opens in a new browser window\]](#)) 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) No comment

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

- 2) Knowledge and awareness of the Hepatitis C virus is crucially important, not only for healthcare professionals but also for the public.
- 3) GPs are in a unique position within society to engage with groups at risk of contracting Hepatitis C infection and encourage them to get tested for the virus.
- 4) RCGP, in conjunction with the British Liver Trust, has developed a Liver Disease toolkit which provides specific guidance on Hepatitis C and its management in primary care. The toolkit is available as an online resource for primary care practitioners and is accessible [here](#).

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

- 5) RCGP Wales recognises that there is a cohort of the public who are less likely to approach their GP practice for an appointment to help with issues of addiction management, for instance prescription of Methadone. We therefore acknowledge that community pharmacies are well placed to reach these groups and promote public health messages.

Point four: The long-term viability of treatment programmes.

- 6) No comment

January 2019

Response from the Royal College of Nursing Wales to the Health, Social Services & Sport Committee's inquiry into Hepatitis C

The Royal College of Nursing Wales is grateful for the opportunity to respond to this consultation and would like to raise a number of points in relation to the inquiry:

1) *The action being taken to meet the requirements of the Welsh Health Circular and the target set by the World Health Organisation to eliminate Hepatitis B and Hepatitis C as significant public health threats by 2030*

There are several initiatives operating in Wales which are helping to meet this aim:

- The Wales Liver Disease Delivery Plan through which Health Boards aim to improve and review their liver services using six themes:
 - o Preventing liver disease & promoting liver health
 - o Timely detection of liver disease
 - o Fast & effective care
 - o Living with liver disease
 - o Improving information
 - o Targeting research
- There are highly functional blood-borne viruses (BBV) networks across Wales which have a clear national vision.
- Routine opt-out BBV screening operates across Wales. A systematic approach is also taken to BBV testing across 'at risk' population, and re-engagement for those previously diagnosed. Further investment is required in BBV teams however to ensure equitable and transparent access.
- Rates of sustained virological response (SVR) are high, with effective treatment available in tablet form – these have minimal side-effects and above a 97% chance of eradicating the disease.

2) *How the knowledge & awareness of the public and health professionals of Hepatitis C can be increased*

- Education, across the public sphere and within the health profession, is needed to help overturn negative messaging and dispel some of the myths about testing and treatment. Better education and awareness raising is also important in helping to reach those most at risk, especially the vulnerable groups such as the homeless and rough sleepers, who do not always engage with any healthcare sectors.
- Increased collaboration with a number of different services/agencies would help increase knowledge and awareness. Some of these include; correctional services, substances misuse units, asylum seeker services, community pharmacies, primary care (GP surgeries), specialist secondary care (e.g. Haemophilia unit) and tier 3 services - for example, charitable organisations.
- Health Boards should engage with and promote initiatives such as 'World

- Hepatitis Day' in conjunction with the World Hepatitis Alliance's annual themes.
- It is essential, in order to increase knowledge of health care professionals to have BBV training included in their pre & post graduate syllabus and induction for all new staff starting in all Welsh health boards.
 - Other examples of good practice which could be further invested and/or replicated across Wales:
 - Cardiff Hepatitis Support Network was launched in July 2017, providing an online information hub, along with an e-form for self-referral.
 - The Annual All Wales Hepatology Nurse Forum (AWHNF) testing and awareness raising roadshow which operates across Wales.
 - BBV training days held on a monthly basis and open to all staff across all sectors of health & social care who want to be involved in BBV testing in Cardiff & Vale.
 - All Wales Hepatology Nurse Forum annual conference, which is aimed at health professionals across Wales.
 - The Cardiff & Vale UHB Hepatitis C social media campaign #GetTestedGetCured which has been effectively supported by the Health Board's communications and media team. This is a long-term campaign which involves infographics being displayed on media screens across Cardiff & Vale UHB.
 - Increased awareness raising of BBVs amongst younger people is needed, for instance in schools, colleges and universities. This is vitally important as understanding the risks before embarking on risky behaviours may prevent the spread of infection.

3) The scope to increase community-based activity

There are many positive aspects relating to existing community-based activity such as:

- A complete map of community pharmacies across Wales that carry out needle exchange and 'Opiate Substitute Therapy' (OST) has been established. A BBV Pharmacist lead for Wales has been recruited to oversee and coordinate the national pharmacy projects in BBV screening & treatment. Cardiff have already performed some pilot projects in some community pharmacies with some positive outcomes.
- The Harm Reduction Database developed by Public Health Wales as part of their Substance Misuse Programme captures Hepatitis (BBV) activity and risks in the community. Substance misuse services are required to complete these online database forms each time a client/individual is screened for BBVs. This is an ongoing project with progress still to be made but improvements have been seen following biannual Wales network meetings.

The scope to increase community-based activity includes:

- Increasing access to portable fibroscanners; one fibroscanner is used and shared by the specialist nursing team across all the community services in Cardiff and Vale for instance. Having access to additional fibroscanners would enable more community clinics to use the technology in patient assessments.
- 'Point of care testing' (for example via Oraquick mouth swab) can enable teams

to provide Hepatitis C antibody results within 30 minutes and initiate diagnosis or further testing and treatment options where required. A virology point of care testing lead based at University Hospital Wales has been able to oversee the roll-out of the scheme across Cardiff & Vale.

- Working with homeless people, rough sleepers and other vulnerable groups such as the pilot project run in Cardiff in 2017 in conjunction with the Salvation Army & Cardiff Council night bus. A double-decker bus provided temporary shelter as well as equipment and volunteers to enable screening for BBVs and fibroscans with a view to improving liver health. Having specialist nursing teams with a presence in homeless shelters and hostels, drug and alcohol units, and prisons is also worthwhile.
- Harm reduction advice is key to the prevention of acquiring BBVs and individuals at risk should be aware that following eradication, they can be re-infected with the virus if exposed to further risks.

4) *The long-term viability of treatment programmes*

- Treatment has evolved hugely over recent years and is considered to be highly effective in the eradication of the Hepatitis C virus. There are many treatment options with Directly Acting Anti-viral (DAA) treatments all having an efficacy exceeding 97%.
- The long-term viability of treatment programmes is dependent on several factors:
 - Cross-party political support in working towards eradication 2030 must be maintained, and Welsh Government funding for BBV services, medication and awareness raising programmes are essential if the eradication target is to be met.
 - Adherence to the DAAs is imperative as the risk of treatment failure and/or developing resistance may rise in the future. This can be a challenge in small groups of patients who are already vulnerable.
 - Annual All Wales Hepatology Nurse Forum (AWHNF) to continue to provide a link between the BBV services across the health boards in order to efficiently liaise when patients geographically move between treatment centres.

About the Royal College of Nursing

The RCN is the world's largest professional union of nurses, representing over 430,000 nurses, midwives, health visitors and nursing students, including over 25,000 members in Wales. The majority of RCN members work in the NHS with around a quarter working in the independent sector. The RCN works locally, nationally and internationally to promote standards of care and the interests of patients and nurses, and of nursing as a profession. The RCN is a UK-wide organisation, with its own National Boards for Wales, Scotland and Northern Ireland. The RCN is a major contributor to nursing practice, standards of care, and public policy as it affects health and nursing. The RCN represents nurses and nursing, promotes excellence in practice and shapes health policies.

Submission of written evidence to Health, Social Care and Sport committee on Hepatitis C consultation, January 2019 by Dr 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

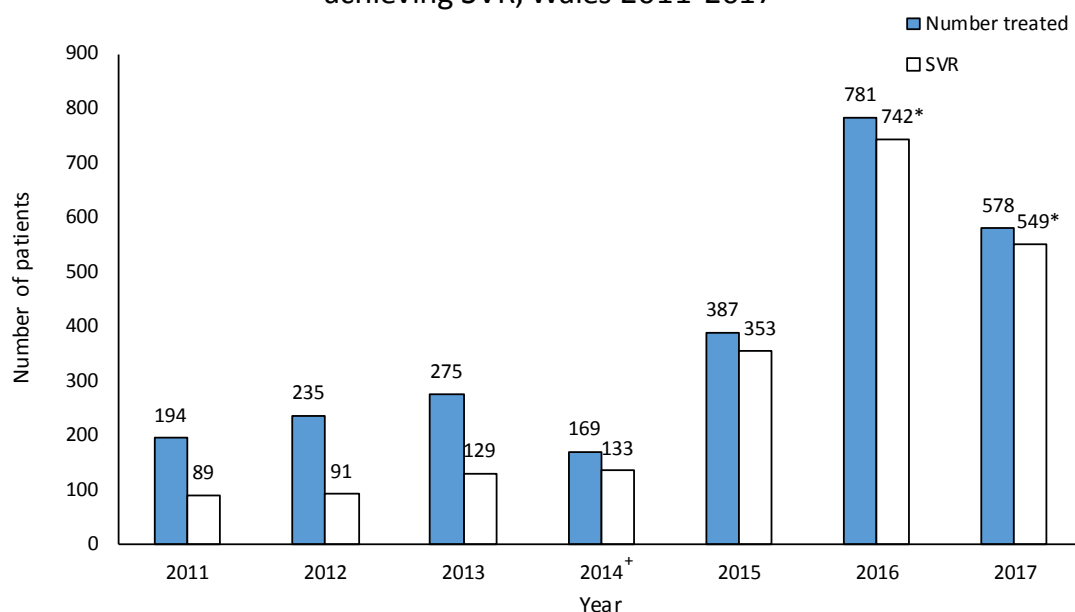
See figure 1 below for treatment and cure (SVR) rates since 2011.

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

Number of Hepatitis C patients commencing treatment and achieving SVR, Wales 2011-2017



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

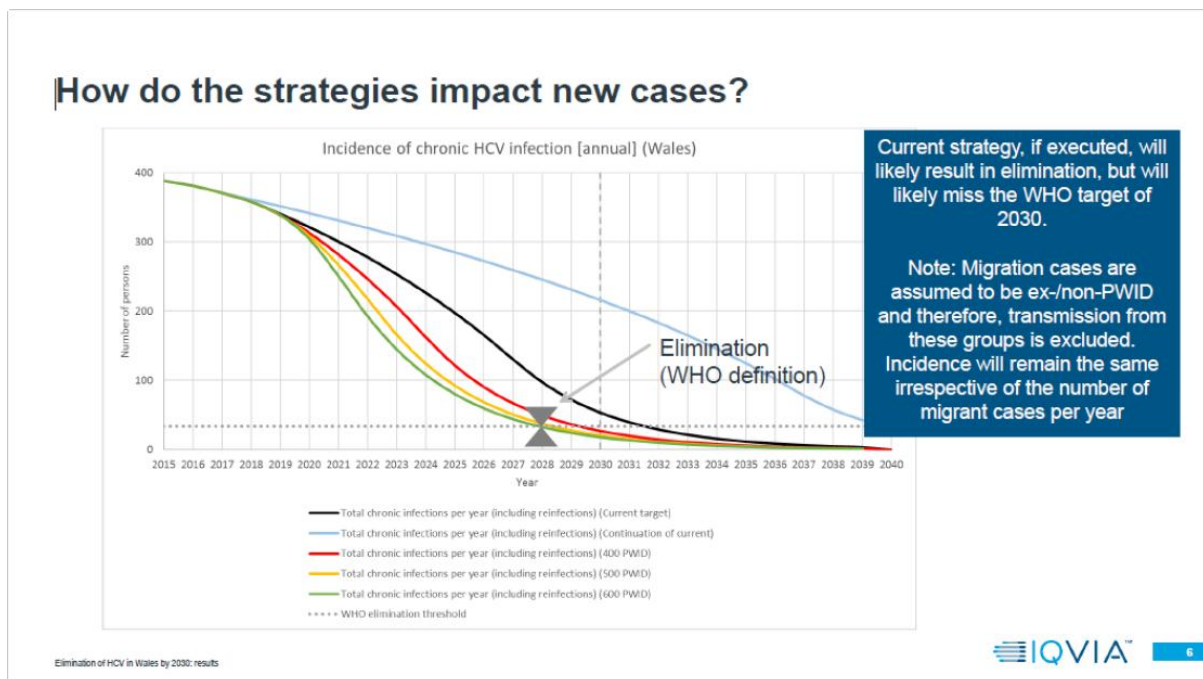
populations. The services also needed to be changed so that patients who tested positive could access treatment.

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:



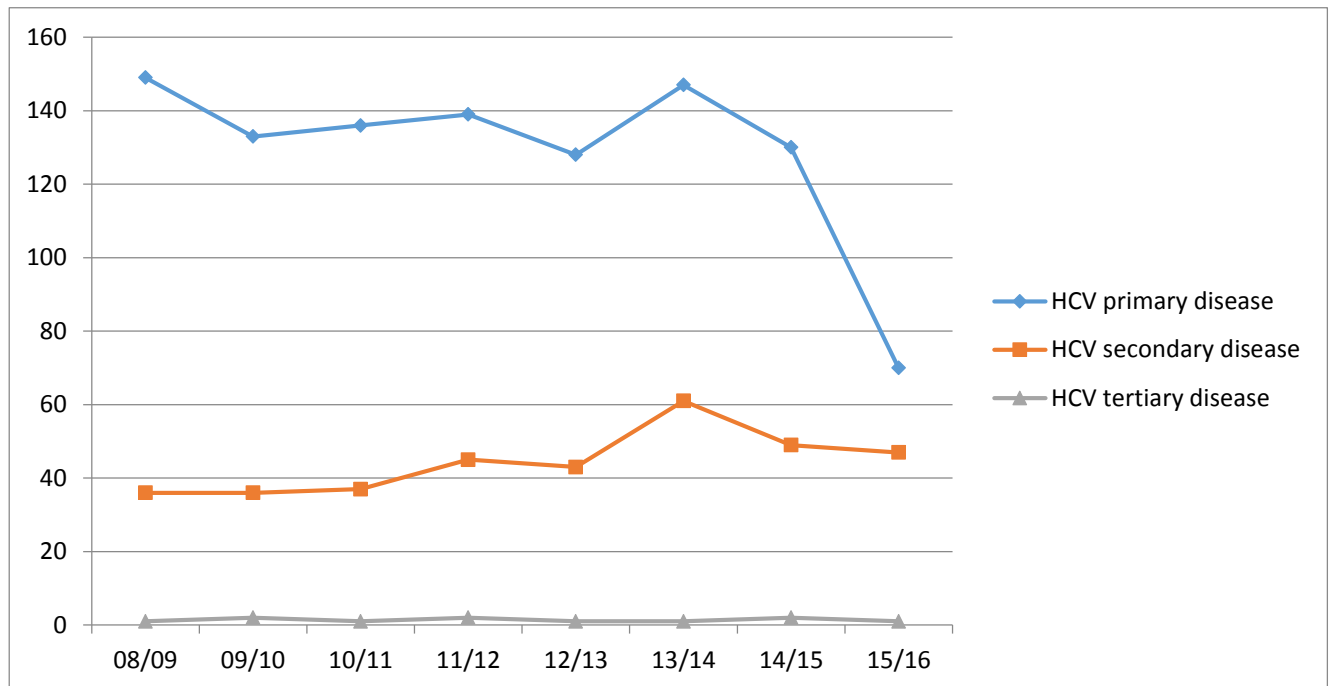
The graph demonstrates modelling of prevalence of hepatitis C in Wales based on current estimates of prevalence. The light blue line demonstrates the trajectory for elimination based on actual current treatment numbers across Wales. The black line demonstrates the trajectory of elimination based on 900 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).

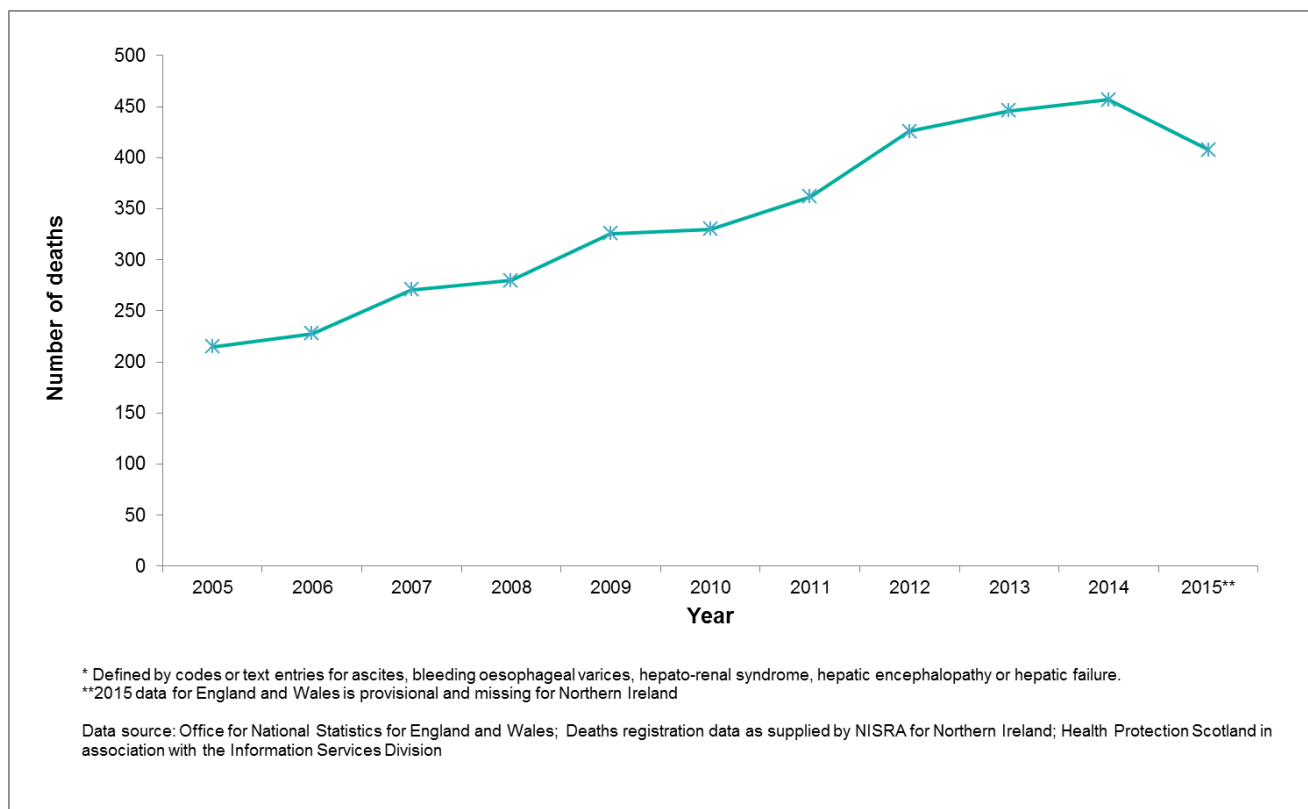
Figure 3: Patients Listed for First Liver Transplant with a Primary, Secondary and Tertiary Diagnosis of HCV 2008-2016 (UK Transplant Data)



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 / Health 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.



Cwm Taf HB response to: The Health, Social Care and Sport Committee Enquiry into Hepatitis C

Author:

██████████ Clinical Lead for CTUHB BBV Service
Deputy Medical Director CTUHB

Targeting HCV with a view to eradication in Wales

There are number of factors which will affect our ability to eradicate HCV in Wales.

- 1) Baseline prevalence
- 2) Transmission rates
- 3) Detection of new and old cases
- 4) Engagement with the treatment services
- 5) Compliance with medication

- 1) And 2) As a HB CTUHB does not have pockets of very high prevalence in the same way that some large urban areas do but we know the prevalence of disease in our actively IV drug using community is moderate (18.6%) and that if we can make inroads into treating, particularly in the active IVDU group we can make a difference to rates of ongoing transmission.

Data below is from the Harm Reduction Database 2017-18 and first two quarters of 2018/19. This shows that some HBs have particularly high levels (ABMU). Some HBs however have lower testing rates recorded on HRD and results therefore may not show prevalence accurately.

	Total individuals tested for anti-HCV	% Results Recorded (n=1,452)	% anti-HCV Reactive
ABMU	230	97.6	39.7
Aneurin Bevan	386	99.2	8.6
BCU	334	89.6	17.1
Cardiff and Vale*	38	73.2	22.2
Cwm Taf	471	93.5	18.6
Hywel Dda*	97	81.0	7.7
Powys Teaching	10	20.0	0.0
Wales	1566	92.7	18.4

2) As above

3) Detection of new and old cases:

In CTUHB since April 2018 we have had approx. 68 new referrals for patients with HCV.

35 referrals have come direct from GPs or hospital based services including GUM(2), these are people generally not actively using drugs but often being picked up due to screening for reasons for abnormal LFT.

22 are from the HB CDAT team. These people are generally people with complex MH and dependency issues who have not been able to be managed in the third sector community addiction services. Many of these patients have been seen in third sector commissioned addiction services prior to referral in to Health based CDAT services due to case complexity.

2 referrals have been from Barod, one of our community based addiction services. Given the prevalence of Hepatitis C positivity in our local IVDU population this is a very low number of referrals in the first 8 months of the financial year 18/19. Of those who are tested in community services there is a high number of HCV antibody positive people who are already know to have or have previously had HCV treated. On the HRD data base this is reflected by the high level (43%) of patients tested who are RNA negative: compared with ABMU where only 27% of the clients positive for anti HCV are RNA negative. This suggests that testing is focussing on those who have known previous disease which has been treated rather than on those who are likely to have new active disease. It is reassuring that the individuals are RNA negative and annual retesting for those continuing high transmission risk behaviours is recommended but it also suggests we are not targeting patients with risk taking behaviours who have no history of HCV.

6 referrals are through our self-referral pathway which enables friends, families and contacts of people already in our service to refer themselves in for testing and treatment.

3 were other routes including patients transferring into our HB from another HB.

Looking at the referral source it appears that we are picking up old cases opportunistically which is the majority of GP and consultant testing, the only downside of this approach is that these people are more likely to have established liver damage.

We fall down in the area of testing and referring people who are actively using drugs or are early in their engagement with community drug services. These are people who could be benefited most as not only could they be cured before they develop established liver disease from their hepatitis C. The people who are referred to the Viral hepatitis treatment services are those who have complex addictions, dual diagnosis or physical illness from their addictions who are managed by CDAT rather than community services such as Barod and whilst these patients do need to be seen they are often in a more difficult to treat category due to co-morbidities.



- 4) Engagement with treatment services is something we need to work on. Our service model of bring people to a hospital base for their first appointment results in a 50% DNA rate for first appointments and of those just over 50% DNA a second appointment which means only 74% are actually seen for a first appointment.

- 5) Compliance with treatment. Once patients are established in the service and they feel they are ready to embark on treatment compliance is good. New treatments of short duration and many fewer side effects have meant that this is no longer the issue that it has been in years gone by. We have good arrangements with pharmacy and nationally agreed drug costs so that we can ensure there is no barrier to patients receiving the most appropriate treatment.

Our target in CTUHB is to treat 85 patients in each financial year. This target is set for our population taking into account population size, and prevalence rates, if we manage to hit this target we should start to have an impact on infection rates. As we have not had enough referrals and our DNA rate is 26% we have not treated enough so far this year to be able to hit our target. We have treated 29 patients in the first 8 months of the year, leaving 56 to treat in the last 4 months of the year. We have not had enough referrals to enable us treat another 56 even if all the patients we had been referred were treated we would not hit our target of 85 for 2018/19.

Actions we are looking to take:

- 1) We in the Health based services need to work more closely with our third sector community based third sector partners to understand the barriers they are experiencing to testing and referring patients for treatment. A new service provider is being commissioned and we need to ensure close partnership working from the start of the new service.

- 2) The new opt out testing as opposed to opt in may help increase testing rates but only if we ensure tests are offered and framed in a positive light. Ensuring those offering testing have up to date information on the new treatment options is essential as treatment has changed dramatically in the past 5 years becoming much simpler, moving from injections to oral and with reduced durations of treatment.

- 3) We need to look at the model of treatment services. Whilst services are provided in local community hospitals we could look at the treatment service going to the patient rather than the other way round. For patients already engaged with health services it may be less of an issue to come up to a local DGH or community hospital but if we can increase testing



in community settings and this is the only point of contact for clients found to be positive, we may need to start looking at holding clinic consultations in community/third sector/local pharmacy/needle exchange premises. Visits to hospital bases should be kept for limited numbers of appointments where hospital based investigations are needed e.g. fixed fibroscan and only once a therapeutic relationship has been built between patient and treatment service..





Aneurin Bevan University Health Board's Evidence to the Health, Social Care and Sport Committee Enquiry into Hepatitis C

Background

Wales is signed up to a World Health Organisation global health sector strategy, which sets out to eliminate Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV) by 2030 (90% reduction in incidence and 65% reduction in mortality). New directly acting anti-viral medications have revolutionised the treatment of HCV so that the disease is now essentially curable in the early stages.

The Welsh Health Circular WHC/2017/048 outlined a series of expected measures from multiple organisations and partnerships to contribute to the elimination target:

1. Reduce and ultimately prevent ongoing transmission of HCV within Wales
2. Identify individuals who are currently infected with HCV including those who have acquired HCV outside the UK and are now resident in Wales
 - 2.1 individuals infected with HCV who were not linked to care
 - 2.2 identifying individuals infected with HCV, who have never been tested and are unaware of the infection
3. Test and treat individuals currently infected with HCV who are actively engaged in behaviours likely to lead to further transmission

The Health, Social Care and Sport Committee will be undertaking a one-day inquiry into Hepatitis C. This paper provides a written evidence to the questions raised in the Committee's terms of reference of the inquiry.

Current situation

Given the availability of the new directly acting antiviral medication in 2015, each health board was assigned treatment targets. In 2017-18, only one health board achieved the minimum treatment target with Aneurin Bevan University Health Board (ABUHB) being ranked third among all health boards. In 2018-19, only two health boards are on target whereas others are falling behind including ABUHB. Based on the current treatment numbers ABUHB is unlikely to meet the 2018-19 target. The key issue is that not enough people have been referred to our Blood Bourne Virus (BBV) service to enable the required number of Hep C cases to be treated.

The ABUHB Blood Bourne Virus (BBV) team provides treatment services across Gwent and also covers Brecon and Llandrindod Wells. The current service model includes provision of treatment clinics in both hospital and community health care settings. Regular clinics are held in the Royal Gwent Hospital in Newport, Gwent Drug and Alcohol Services (GDAS) in Tredegar, Gwent Specialist Substance Misuse Service (GSSMS) in Newport and Caldicot GP Practice. Ad hoc clinics are provided in Caerphilly, Blackwood, Ebbw Vale, Blaenavon and various GP surgeries across Gwent. The BBV team also offers an outreach service, home visits and treatment clinics in two prisons, on mental health wards, and at the Wallich drop in centre in Newport for homeless people.

The actions 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 are:

- ABUHB has been engaged with Public Health Wales led national HCV re-engagement exercise. This involves identifying and offering assessment/treatment to individuals with historical tests indicating exposure to Hepatitis C who may still be infected, but they were not linked to care.
- ABUHB has been working with GDAS to increase Blood Bourne Virus (BBV) testing. There are around 2100 patients accessing GDAS services. In 2017-18, only 18% were tested for BBV, 6% declined the offer, and 66% were not offered the BBV test. The key barrier identified for this low BBV testing was lack of Hep B vaccination for the GDAS staff. ABHUB has agreed

funding to offer Hep B vaccination to 50 staff members. This will help to increase BBV testing in GDAS in 2019-20.

- Gwent Specialist Substance Misuse Service (GSSMS) of ABUHB also offers BBV testing and Hep B vaccine to service users. However, the uptake has been very low. The BBV team have been working with GSSMS staff to identify barriers and ABUHB will be putting measures in place to increase uptake.
- People who inject drugs and the homeless population are at high risk of contracting BBV infection. However, due to the chaotic and transient nature of their lifestyles they many go untested for BBV's. ABUHB is setting up a Dried Blood Spot (DBS) Testing Incentive Scheme for service users of the Needle Exchange service in Newport and the Wallich Homeless drop in centre. The scheme is waiting for the addition of Hep C Polymerase Chain Reaction (PCR) test to the DBS test to enable a complete diagnosis.
- Gwent has an established problem of use of steroid and image enhancing drugs (SIEDs) in Gwent. To address this problem the BBV team have set up a steroid clinic. This clinic offers harm reduction advice, general health screening, ECG and BBV testing.
- ABUHB provide health care services to the two Gwent prisons. BBV testing is offered to all new prisoners. Wherever indicated HCV treatment and Hep B vaccination is offered in the prisons.
- ABUHB provides BBV treatment clinics in both hospital and community health settings across Gwent. This ensures good engagement with service users and the Did Not Attend (DNA) rate is less than 25%. The BBV team has plans to further strengthen provision of treatment clinics in community health care settings to minimise the DNA rates.
- Given the short treatment course for Hepatitis C and few side effects, the compliance with the treatment is good.

How the knowledge and awareness of the public and health professionals of the Hepatitis C virus can be increased?

- Newport has the third highest ethnic minority community behind Cardiff and Swansea. It has a population of 147,400, of these 12,900 (8.8 %) are from an ethnic minority background. In recent years, there have been a small number of projects around the UK to try to engage with the south Asian community. The projects that are integrated with the mosques seemed to bring the better results. Working in collaboration with a local GP, the ABUHB BBV Team has been running BBV awareness and testing campaign at the local mosques. Two events have been held at two mosques so far.

Further events are planned to revisit these mosques on a rolling basis twice yearly. Other communities have also expressed interest in the project.

- The ABUHB BBV team undertakes the following activities to raise BBV awareness among the professionals
 - Annual Liver Conference
 - Talks at GP annual training days
 - Training for the ABUHB clinical staff
 - Training for the GDAS and GSSMS clinical staff

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

- ABUHB is aware of developments at the national level to involve community pharmacies in BBV testing.
- There have been discussions going on locally to run a pilot project in Newport using the national service specification and protocols.

The long-term viability of treatment programmes

- The ABUHB BBV team provides the ABUHB HCV treatment service. It comprises of two full time hepatology clinical nurse specialists. A hepatology consultant supervises the clinical work.
- The funding ABUHB receives to provide a BBV treatment service is sufficient for the current number of patients being treated. However, the anticipated rise in treatment rates could pose a cost pressure and to achieve the WHO elimination target it is imperative that BBV testing and treatment services are adequately resourced to ensure long-term sustainability.

Public Health Wales' submission of written evidence to Health, Social Care and Sport committee on Hepatitis C consultation, January 2019

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 Organization (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. This goal has been incorporated into Public Health Wales' new long-term strategy to 2030 published in 2018.
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.
3. In Wales the 'Together for Health Liver Disease Delivery Plan 2015-2020' has built on the good work facilitated by the Blood Borne Viral (BBV) Hepatitis Action Plan for Wales 2010-2015. The implementation of this plan is supported by the Liver Disease Implementation Group (LDIG), which is chaired by the Executive Director of Public Health Services at Public Health Wales and includes representation from each health

board in Wales, the British Liver Trust (BLT) and the Children's Liver Disease Foundation. The LDIG identified blood borne viral hepatitis as one of the key priority areas.

4. To support taking this agenda forward the Viral Hepatitis Subgroup was established. This subgroup, chaired by the national lead for hepatitis, provides both strategic leadership and support to health boards in progressing this area of work. This subgroup includes multidisciplinary representation including representation from the Hepatitis C Trust. Epidemiological and administrative support to this group is provided by Public Health Wales.
5. This Viral Hepatitis Subgroup reports regularly to the LDIG and updates on the work of this subgroup are included in the annual statement of progress submitted by the LDIG to Welsh Government. This group has facilitated a number of developments 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.
6. The Viral Hepatitis Subgroup also helped to obtain funding and administration for a variety of projects on testing and treatment strategies for hepatitis C, e.g. funding to develop reflex Polymerase Chain Reaction (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); and the appointment of a point of care testing lead for the Wales Specialist Virology Centre to develop these services in various settings across Wales.
7. The Viral Hepatitis Subgroup also co-ordinates the collection of data to ensure appropriate governance of the national plan and feeding relevant information back to Welsh Government, health boards and other relevant stakeholders. In addition, the subgroup has been working with NHS Wales Informatics Service (NWIS) to develop a hepatitis C electronic form that will facilitate live collection of national treatment data in the future. The subgroup has also been involved in the development of an elimination model using an independent company funded through a non-restricted grant from pharmaceutical industry.

8. The Viral Hepatitis Subgroup supports the regular review of the national plan with expert advice and recommendations for development as and when appropriate. The subgroup has also been instrumental in administration of the virtual panel that enables discussion of complicated patients to ensure most appropriate treatment options are given to these individuals.

Reduce and ultimately prevent ongoing transmission of HCV within Wales

9. 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). Public Health Wales provides support to all 270 NSPs in Wales, through (as at 2017/18) the development of guidance, policy and monitoring. Statutory, voluntary and community pharmacy based NSPs all record individual activity on the Harm Reduction Database module, which provides a means of evidencing the nature and scale of injecting drug use as well as coverage of needle and syringe provision. An annual report is published by Public Health Wales to monitor progress, (available on the Public Health Wales website at <http://www.wales.nhs.uk/sitesplus/documents/888/HRD%20Report%202017-18%20-%20Final%20.pdf>).
10. In 2017/18 there were a total of 14,000 regular users of needle syringe services, and over the last five years there has been a decrease in the proportion of young people injecting drugs and accessing services, from 5.5% in 2013/14 to 2.7% in 2017/18.
11. Public Health Wales, with Welsh Government, led on a national commissioning process in 2016-17. The new NSP framework was initiated in July 2017 and has led to the introduction of 'single injection kits' in all NSPs.

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

12. With the advent of new, highly effective and well-tolerated medicines to treat hepatitis C, Public Health Wales is leading the co-ordination and implementation of a national patient re-engagement exercise. This looks to identify individuals with a historical diagnosis of Hepatitis C who, for whatever reason(s), have not completely engaged with treatment services and seeks to bring them back into the service and offer them treatment with the new therapies now available (as appropriate).
13. This work is being supported by an implementation group which includes representation from the Hepatitis C Trust, the British Liver Trust and the General Practitioners Committee (GPC) Wales in addition to every health board in Wales.
14. Using historical laboratory testing data as the starting point, work has been undertaken to identify these individuals. From Spring 2019, they will be contacted and offered the opportunity to re-engage with services and be assessed for treatment.
15. The Viral Hepatitis Subgroup has also supported a number of initiatives/pilot projects to support the identification and treatment of individuals with hepatitis C infection. This includes an evaluation of an outpatient service in one health board, and case finding in primary care in another health board. In addition, a national project and research lead for hepatitis has been appointed to help develop approaches and share learning across health boards.

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

16. Public Health Wales has developed a Harm Reduction Database (HRD) Blood Borne Virus Module, which has been implemented in all specialist substance misuse services across Wales and in a number of pilot community pharmacy sites. It is envisaged that a national roll-out across all relevant community pharmacies will commence over the next few years. Given that the prevalence and incidence of HCV infection is highest among individuals with current or historic substance misuse, it is vital that these populations are routinely tested and referred for treatment as soon as identified. The HRD blood borne virus module provides a system for recording

routine testing, in line with the implementation of routine opt-out testing in all substance misuse services in Wales

(<https://gov.wales/docs/dhss/publications/160906substance-missuse-2016-2018en.pdf>). In addition, the database enables the testing and outcome history to follow the patient wherever they are in Wales, and over time. The database provides a mechanism for screening, diagnosis, referral and treatment milestones including commencement, Sustained Virological Response (SVR) and reinfection. Public Health Wales provides an annual report on progress (available Public Health Wales website at:

<http://www.wales.nhs.uk/sitesplus/documents/888/BBV%20Annual%20report%202017-18%20FOR%20PUBLICATION.pdf>).

17. Over 1600 individuals in contact with substance misuse services were tested in 2017 and this has increased by over one third to date in 2018. However, a significant proportion of individuals remain untested and it is important that services are appropriately resourced to enable all 'at risk' clients to be tested on an annual basis.
18. In addition, Public Health Wales has supported Welsh Government in the reintroduction of a Key Performance Indicator (KPI) for all substance misuse services. This will facilitate the testing of all individuals in contact with services on at least an annual basis until no longer at risk of HCV infection. The KPI will be monitored for each site via the HRD, which ensures an individual patient record of testing, diagnosis and treatment. The system also reduces the likelihood of an individual testing reactive for HCV from being lost to services, or 'falling through the net' which has been an issue in the past.
19. Since 2010, BBV testing has become a routine part of prison health provision. In November 2016, Welsh Government issued a formal policy move to opt-out testing for blood borne viruses for all those on admission to prison. All prisons in Wales offer BBV screening although levels of delivery remain varied. Table 1 shows the number of individuals attending BBV services in each prison in Wales 2015-2017. The table demonstrates an increase in the number of men tested since November 2016 when opt-out screening was introduced. Mean prevalence of hepatitis C antibody was 10% in 2015, 7% in 2016 and 10% in 2017.

Table 1 Numbers of individuals attending Blood Borne Virus services in each prison in Wales 2015-2017

Requesting site	Individuals attending, per year			
	2015	2016	2017	Total
H. M. PRISON BERWYN	0	0	264	264
H. M. PRISON CARDIFF	238	885	1290	2413
H. M. PARC BRIDGEND	398	857	1463	2718
H. M. PRISON PRESCOED	98	114	196	408
H. M. PRISON SWANSEA	0	4	162	166
H. M. PRISON USK	70	255	71	397
Total	804	2115	3446	6366

20. All prisons in Wales offer treatment for blood borne viruses. Specialist nurses run clinics within each prison to see those testing hepatitis C antibody positive. Portable scanners used within prisons mean that in the majority of cases, individuals can transition from testing to treatment without the need to leave the prison.

21. An increase in the numbers of men screened for BBVs was evident following the introduction of the opt-out screening policy. Despite this, implementation of opt-out testing across prisons remains variable and many men appear to be untested. The setting of a staggered target for BBV screening in prisons is being considered. As yet, prisons in Wales have increased testing rates without any additional direct resource. Adequate resourcing of prisons to support continued increases in prison testing needs to be considered.

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

22. The British Liver Trust (BLT) (as part of their work with the Liver Disease Implementation Group) is working in Wales to raise public awareness of liver health, highlight the main causes of liver disease and what lifestyle choices and prevention is needed to maintain good liver health. The BLT is also delivering 'Love Your Liver' screening and scanning events throughout Wales and undertook a 'Love Your Liver' roadshow in November 2018, which saw the Mobile Scanning Unit visiting Bangor, Wrexham, Cardiff, Bridgend and Swansea.

23. As part of the BLT-funded Royal College of General Practitioners (RCGP) liver disease clinical priority programme, in July 2018, Wales hosted one of four UK regional BLT/RCGP primary care education events.
24. 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].
25. In addition, the national lead for hepatitis has led two national network meetings per year, to help share learning between teams and health boards. These were made possible through unrestricted educational grants provided by the pharmaceutical industry.
26. The BBV teams provide support to initiatives to raise awareness. These include examples such as education of primary care teams, awareness raising on World Hepatitis Day, engagement with media around awareness raising events, and a project to test and raise awareness in a mosque. However, the impact of these initiatives to date is uncertain.
27. Increasing awareness of the public and health professionals is one of the challenging areas of the elimination plan. Support for a focussed awareness-raising campaign would be welcomed. This is particularly important in finding those patients who are not easily identified (e.g. individuals from high prevalence countries, people who used to inject drugs or dabbled in early life, and those at risk through blood transfusion).

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

28. The Viral Hepatitis Subgroup of LDIG has developed a national protocol for the delivery of testing for hepatitis C in the community, which has been approved by National Pharmacy Wales.
29. With funding from the LDIG, a national pharmacy lead for hepatitis has been appointed and is now working on rolling out testing in community pharmacies. A map of all pharmacies that carry out needle exchange and opiate substitution therapy has been constructed from data extracted from the HRD and this will be used to facilitate roll-out. Funding for a pilot project to test the protocol in the live environment has been secured and will run in January 2019.
30. BBV teams from across Wales are aware of the protocol and are in position to support the roll out of testing in this environment.
31. The national pharmacist lead is now starting work on a nationally agreed treatment pathway in community pharmacy for development and roll-out in 2020.

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

32. The Viral Hepatitis Subgroup, through the national lead for hepatitis, has provided support for the national tendering process and the delivery of equitable and transparent access to treatment. This has resulted in the delivery of significant savings to the NHS in Wales through national procurement, adherence to the principles of prudent healthcare, the use of cheapest possible treatment options when appropriate, and 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.
33. The National Hepatitis C treatment pathway and treatment recommendation protocol has been developed through the coordination of the BBV network and clinical leadership.
34. Treatment programmes are currently supported by a combination of health board level BBV teams and national roles (pharmacist lead, project and research lead, point of care testing lead). The Liver Disease Implementation Group supports these national roles. 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. 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 an increase in testing in these environments is sustainable.
36. The developments to increase testing and treatment of at risk individuals needs 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.

Agenda Item 6

HEALTH, SOCIAL CARE AND SPORT COMMITTEE

LEGAL SERVICES SUMMARY OF THREE SETS OF SOCIAL CARE REGULATIONS LAID BEFORE THE ASSEMBLY:

1. The Adult Placement Services (Service Providers and Responsible Individuals) (Wales) Regulations 2019
 2. The Regulated Fostering Services (Service Providers and Responsible Individuals) (Wales) Regulations 2019
 3. The Regulated Advocacy Services (Service Providers and Responsible Individuals) (Wales) Regulations 2019
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Background

All of these Regulations are made under the Regulation and Inspection of Social Care (Wales) Act 2016 (**the 2016 Act**). Part 1 of the 2016 Act introduced a new system of regulation of care and support services in Wales, replacing the system established under the Care Standards Act 2000.

These Regulations were laid on 10 and 11 January 2019. They are affirmative resolution Regulations and the Plenary debate and vote on all three sets of Regulations has been scheduled for 22 January 2019.

The Adult Placement Services (Service Providers and Responsible Individuals) (Wales) Regulations 2019

Summary

Section 2 of the 2016 Act defines “regulated service” as including an adult placement service. Paragraph 6 of Schedule 1 to the 2016 Act defines “adult placement service” as a service carried on (whether or not for profit) by a local authority or other person for the purposes of placing adults with an individual in Wales under a carer agreement (and includes any arrangements for the recruitment, training and supervision of such individuals).

These Regulations impose requirements on service providers in relation to adult placement services, including requirements as to the standard of care and support to be provided to an individual who is placed under a carer agreement. Paragraph 6 of Schedule 1 to the 2016 Act defines “carer agreement” as an agreement for the

provision by an individual of accommodation at the individual's home together with care and support for up to three adults.

CLA reporting points

No reporting points have been included in the draft CLA report on these Regulations.

The Regulated Fostering Services (Service Providers and Responsible Individuals) (Wales) Regulations 2019

Summary

A “fostering service” is a regulated service, defined in the 2016 Act as meaning any service provided in Wales by a person other than a local authority which consists of or includes the placement of children with foster parents or exercising functions in connection with such a placement.

These Regulations impose requirements on service providers and responsible individuals in respect of fostering services. For example, the Regulations require service providers to ensure that fostering services are carried out with sufficient care, competence and skill and to take reasonable steps to ensure the service is financially stable.

CLA reporting points

The following three points are included in the draft CLA report on these Regulations. At the time of writing, the Welsh Government has not yet responded to the reporting points.

1. Standing Order 21.2(v) – that for any particular reason its form or meaning needs further explanation

The Regulations refer to “prospective foster parent” in six places. However, it is unclear what is meant by “prospective foster parent” and who is captured by the term.

The lack of clarity is of particular concern given that the term “prospective parent” applies in relation to criminal offences. For example, it is a criminal offence if a service provider fails to give a guide about the service to, among others, any prospective foster parents (see regulation 12(2)(c)(ii)).

We repeat a concern we have raised previously that absolute clarity is required when creating criminal offences.

2. Standing Order 21.2(v) – that for any particular reason its form or meaning needs further explanation

The Regulations require service providers to give various notifications. For example, service providers must notify the police of any “allegation that a child placed with foster parents has committed a serious offence” (see regulation 40(5) and paragraph 40 of Schedule 3). It is a criminal offence for a service provider to fail to do so.

However, it is unclear what amounts to an “allegation” and what amounts to a “serious offence”.

Again, we repeat our concern that absolute clarity is required when creating criminal offences.

3. Standing Order 21.2(vi) – that its drafting appears to be defective or it fails to fulfil statutory requirements

In the definition of “datganiad o ddiben” in the Welsh text, there is reference to “Reoliadau Cofrestru 2018”. However, the reference should be to “Reoliadau Cofrestru 2017”.

We note that, given the context, this error is unlikely to raise significant confusion in practice.

The Regulated Advocacy Services (Service Providers and Responsible Individuals) (Wales) Regulations 2019

Summary

These Regulations set out the regulatory requirements and related provision for providers of regulated advocacy services and for those persons who are designated as responsible individuals for such services.

These Regulations impose requirements on service providers and responsible individuals in respect of advocacy services. For example, the Regulations require service providers to ensure there are effective arrangements in place for monitoring, reviewing and improving the quality of the advocacy provided and to have policies in relation to, for example, safeguarding and staff discipline.

CLA reporting points

The following three points are included in the draft CLA report on these Regulations. The Welsh Government response to each point is included.

1. Standing Order 21.2(v) – that for any particular reason its form or meaning needs further explanation

If a responsible individual is unable to fulfil their duties, regulation 6(4)(c) requires service providers to ensure there are arrangements in place for the regulated advocacy service to comply with Part 3 to 15 of the Regulations.

However, there are also important requirements in Part 2 of the Regulations. It is unclear why regulation 6(4)(c) does not require compliance with Part 2 of the Regulations.

The same issue arises in respect of regulation 7(3)(c).

Welsh Government response to reporting point 1:

“Although many of the duties in Part 2 are of a more general overarching nature, and are therefore of more limited application in the context of interim arrangements during the temporary absence of a responsible individual (or individual provider), it is acknowledged that there may be occasions when the duties under part 2 will be of relevance and that the references in regulations 6(4)(c) and 7(3)(c) should refer to parts 2 to 15 of the Regulations. An amendment will be made at the next available opportunity.”

2. Standing Order 21.2(v) – that for any particular reason its form or meaning needs further explanation

Regulation 10 places a duty of candour on service providers – service providers must act in an open and transparent way with:

- individuals (i.e. persons for whom the service provider is providing or has provided advocacy, or for whom the service provider may provide advocacy), and
- any representatives of those individuals.

However, there is no duty to act in an open and transparent way with service commissioners (i.e. local authorities which are responsible for making arrangements with a service provider for the provision of assistance to a child or person under section 178(1) of the Social Services and Well-being (Wales) Act 2014).

We ask why there is no such duty?

Welsh Government response to reporting point 2:

“Specific consideration was given to this issue in the drafting of the regulations and to the fact that for other types of regulated service the duty of candour does apply to a service provider’s relationship with service commissioners. However for an advocacy service provider, the service commissioner is also the body against whom the child or young person wishes to make representations. In providing advocacy for a child or young person it is important that the advocacy service provider’s prime function is to represent the views of that person to the commissioning local authority. A duty to be open and transparent with the commissioning local authority might conflict with the child or young person’s instructions and conflict with this duty. For this reason service commissioners were specifically excluded from the scope of this duty for this particular type of service.”

3. Standing Order 21.2(v) – that for any particular reason its form or meaning needs further explanation

Regulation 15 requires service providers to prepare a written guide to the advocacy service. The guide must then be given to “commissioning authorities” (see regulation 15(2)(d)).

However, there is no definition of “commissioning authorities”.

The lack of clarity is of particular concern given that breach of the duty in regulation 15(2)(d) is a criminal offence, and absolute clarity is required when creating criminal offences.

Welsh Government response to reporting point 3:

“Although in the context, this is a term which is likely to be understood because in the overwhelming majority of cases services will be commissioned by local authorities, and although in our view, to the extent that there is uncertainty, a court is overwhelmingly likely to interpret the phrase in the same way, it is accepted that the clarity of the provision would be improved if the phrase “commissioning authorities” was replaced with the phrase “service commissioners”. The phrase “service commissioner” is defined in regulation 2. An amendment will be made at the next available opportunity.”

Gareth Howells
Assembly Legal Services
10 January 2019

Feedback for the Health, Social Care and Sports Committee on the impact of the General Dental “Prototype” Contract on Belgrave Dental Centre, Swansea

By Huw Hopkins B.D.S. Principal Dentist/Director at Belgrave Dental Centre and Pontardawe Dental Centre

Introduction

We have been involved in General Dental Service (GDS) contract reform at Belgrave Dental Centre since 2011. As a Dental Provider we are in an unique position within Wales in that we have two GDS contracts at two different sites, one of which is the GDS Prototype (Belgrave) and the other is the standard GDS “Unit of Dental Activity (UDA)” based contract (Pontardawe).

The background of the contract reform process has been covered in a separate document supplied by ABMU Health Board. It is a comprehensive and accurate account so I shall not duplicate its information here. I would like to thank ABMU Health Boards continued support of the Prototype Contract.

I would like to quickly outline the important issues that relate to the last two NHS Dental Services Contracts, the pre 2006 “fee per item” contract and the 2006 UDA contract.

Pre 2006 “Fee per item” Contract

Previously, under the pre-2006 “fee per item” contract NHS Dentists were paid depending on the complexity of the treatment delivered and time spent delivering those treatments to patients. There was an extensive, complicated and very prescriptive “menu” of different fees for different items of dental treatment. Long and complicated treatment plans were attributed proportionally higher fees compared to shorter, simpler treatments. There was patient registration and practices also received a separate monthly capitation payment depending on how many patients it had registered on its list. There was little in the way of payment for preventive care but there was some provision for prevention in the contract.

The Fee per item contract was far from ideal. The treatment list was vastly complex and difficult for patients to understand. High value complicated courses of treatment were sometimes delivered to patients who had a high risk of dental

carries resulting in many repeated courses of treatment that was ultimately a waste of NHS funds.

Many years of under-inflationary increases to the fees meant that dentists had to work harder and harder, see more and more patients per day as the years passed, to generate the fees that would cover their ever-increasing practice running costs. Whilst the open-ended nature of the contract allowed practices to expand when they wanted to (there was no fixed contract value for each practice) most dentists complained that they felt like they were on a treadmill, having to run faster and faster just to keep still.

2006 UDA Contract

Whilst initially the “New Contract” appeared to simplify things for both Dentists and patients it soon became apparent that the UDA contract had dramatic unintended consequences.

As dentists got paid the same for carrying out one filling as they did for twenty, most practices stopped accepting new patients as they didn't want to take the risk that the newly accepted patients needed time consuming, long treatment plans i.e. the same payment no matter how many patient visits needed to complete a course of treatment. Whilst this would be feasible if the fee was set to cover the cost of five to ten fillings, it was in reality set for roughly one and a half!

Contracts were now limited with set annual contract values for a set number of UDAs delivered. There was a dramatic variation in the UDA rate across Wales, with some Practices receiving double the UDA rate of others! Patients were no longer registered with the practice and responsibility of out of hours care was removed from practices and transferred to LHBs.

Practices would plan their expenditure for the year with regard to the total Contract Value, however failure to deliver the UDAs resulted in “claw-back” equal to the value of the undelivered UDAs. One quick and easy way to have to give a large percentage of your contract back to the Health Board is to accept new high-need patients. Many dentists feel that this is perverse, as it prevents those that need NHS dentistry the most accessing it.

The top value BAND3 course of treatment, that was meant to cover the cost of the most complex dental treatment, involving laboratory fees e.g. crowns and bridgework or CoCr dentures, was set too low to carry out all but the most simple of acrylic dentures or single crowns. This has resulted in complex or high need patients being referred to secondary care and has also de-skilled Primary Care dentists. Younger GDPs that have qualified since the UDA contract started have not had the clinical experience of many treatments that were previously regarded as pretty routine for GDS Dentists under the fee per item contract.

The impact of the Prototype Contract on Belgrave

Clinical Freedom

The working environment of the Practice was instantly transformed once the clinicians were “freed” from the constraints of the UDA. Whilst the UDA system drives clinicians to try and finish courses of treatment in the least amount of time possible the Prototype allows Dentists and their teams to exercise clinical freedom and stage treatment appropriately.

Patients that are experiencing urgent problems (e.g. dental pain) get their problems managed appropriately as a matter of urgency. With the patients consent we then build them a tailored “**Care-Pathway**” based on the patients **Risk** and **Need**, which is assessed via the ACORN template.

Patients move through the care-pathway with the aim of progressing through treatment complexity. The prototype allows proper foundations to support the patient’s journey.

The principles of Prudent Health-Care underpin the planning of treatment. No longer are complicated, expensive treatments delivered to patients who can’t maintain them. High cost treatments are delivered on patients who have lower risk of developing dental decay so that NHS funds are spent more appropriately and have the least risk of premature failure with an emphasis on quality.

Prevention

Prevention is the core to the Prototype way of working. The practice team fosters relationships with patients based on Co-production in which we motivate and support them to help maintain their oral health and progress along a **RED-AMBER-GREEN** traffic light system.

Skill Mix

The Prototype really does give the practice the freedom to utilize Dental Care Professionals (DCPs) within the practice. Dental Nurses, who have been trained to be Oral Health Educators, deliver preventive advice to patients. They also have enhanced skills that enable them to apply topical fluoride as a caries preventive measure.

Clinicians are able to delegate appropriate treatments to Dental Therapists and Dental Hygienists. All clinicians working at the top of their competency increases efficiency and enables increased capacity to see more patients.

Flexibility of services

We have the flexibility to respond to requests from the LHB to deliver targeted services within the prototype contract such as dedicated appointment slots to deliver much needed dental care to those seeking Asylum in the UK. We also deliver in-hours access sessions and offer those access patients a risk based care plan.

A Transformative effect

The Prototype really has transformed both the working environment for the staff within the practice and also the experience of patients receiving care. We would all hate to revert back to the UDA way of working. It would be devastating for the whole practice and for patients.

Since the Prototype it is not uncommon to hear the following comments from patients: -

“For the first time in 30 years I really understand how to look after my mouth”

“Having had one child with dental pain and decay, I now feel confident that I know how to look after my children’s dental health as well as my own!”

“I’m happy for you to refer me for help” (smoking cessation)

But what about the Pontardawe Practice ?

Our second practice has unfortunately been left behind with:

- UDAs
- High needs population
- Frustration attempting to treat patients based on a target, not the clinical need/risk/coproduction and prudent healthcare principles
- Staff retention issues – high turnover of Dentist performers who become disillusioned with the UDA system.
- Annual Clawback – funds being sucked out of the practice and local practice population from missing targets due to trying to treat a high needs population under UDA GDS contract and low UDA rate. Funding that would otherwise be used for capital investment/improving facilities.

However ...

Pontardawe has begun its Contract reform journey by being accepted in the WAG 2017 Contract Reform process. At present **PHASE 1** involves only a 10%

reduction in the annual UDA target. I can assure you from personal experience that this has minimal effect of the day-to-day experience of staff and patients but it is a starting point. We have implement as much of what we have learned at Belgrave as we can at Pontardawe, even though we still have to hit our UDA target. We are told that further UDA% reduction is planned for **PHASE 2** of the process but as yet no date is planned for its implementation. I can't wait until the fantastic patients and hard working staff at our Pontardawe practice sees the real benefits of a UDA free GDS contract.

Agenda Item 7.2

Paul Davies AM/AC

Aelod Y Ceidwadwyr Cymreig dros Preseli Penfro
Conservative Member for Preseli Pembrokeshire

Dai Lloyd AM

Chair, Health, Social Care and Sport Committee

Mick Antoniw AM

Chair, Constitutional and Legislative Affairs Committee

Llyr Gruffydd AM

Chair, Finance Committee

10 January 2019

Dear Chairs,

Autism (Wales) Bill

I would like to thank you and members of your committees for your detailed consideration of the Autism (Wales) Bill and your reports published on 7 December 2018. After careful consideration, I would like to take this opportunity to respond to the recommendations made in each report ahead of the Plenary debate on the general principles of the Bill on 16 January.

Health, Social Care and Sport Committee

Recommendation 8. We recommend that, if the Bill proceeds to Stage 2, an amendment should be brought forward to ensure that Judicial Review is not the only route available for individuals to assert their rights.

I accept the principle behind this recommendation, but having given careful consideration to the relevant issues, it is with much regret that I am unable to implement it at this time.

The overall purpose of this Bill is to ensure the needs of children and adults with Autism Spectrum Disorder (ASD) in Wales are met, and to protect and promote their rights. It would be of great concern to me therefore should those whom this Bill seeks to help are unable to seek appropriate remedies if their needs are not

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met. The Bill currently sets out clear duties on the Welsh Ministers and relevant bodies that enables those wishing to seek redress to do so through judicial review; however I acknowledge concerns that this is not always an easy process to navigate.

In evidence, my officials and I commented on the distinction between enforcement on the part of the Executive, and direct remedies available to the citizen. Whilst the former can be addressed in a number of ways (for example powers of direction and intervention), the options to address the latter in this type of legislation are far more limited. Financial remedies would not be appropriate in this case, and I would not want to legislate for remedies that the citizen already has the right to access (such as complaints via the existing NHS and local authority procedures, and reference to the Public Services Ombudsman). However, like the Committee, I am supportive of the aim of further enhancing the rights of the citizen to access suitable remedies where practical and, as such, have given much consideration during the development of the Bill as to how it might be amended in order to achieve this aim.

Unfortunately however, for the reasons I have outlined, I have been unable to identify a workable solution and am therefore unable to accept this recommendation at this time. That said, I remain fully supportive of the Committee's rationale in making this recommendation, and can assure Members that, should the general principles be agreed, I would be happy to work with Members, or to consider any amendments tabled during the amending periods, with the aim of strengthening the Bill in this respect.

The remaining recommendations made by the Health, Social Care and Sport Committee relate to the Welsh Government. I share the concerns raised by the Committee in its report and fully agree with the Committee that urgent improvements to ASD support services are needed.

Finance Committee

Recommendation 2. The Committee notes the miscalculation in the Regulatory Impact Assessment and recommends this is addressed, should the Bill proceed to stage 2.

Accept.

I wrote to the Finance Committee on 31 October 2018 outlining a miscalculation in the Regulatory Impact Assessment regarding the potential savings that could be made should the Bill result in a 1% reduction in ASD spend. Should the general principles of the Bill be agreed, I can confirm that the revised RIA, which will be produced following the completion of Stage 2 proceedings, will reflect the updated figure.

I share the frustration expressed by the Finance Committee around the Welsh Government's lack of co-operation with me as I sought to obtain accurate data on the current spend on ASD services across Wales. One would expect Welsh Government to collect such data so as to ensure the proper planning and delivery of its own ASD services, and I can say unequivocally that it would have enabled me to provide even greater detail around the costings for the Bill. I wholeheartedly endorse the Committee's recommendation 1 that the Welsh Government should commit to providing information to assist Members in producing accurate costs for explanatory memoranda tabled to accompany Bills introduced in accordance with Standing Order 26.91.

Constitutional and Legislative Affairs Committee

Recommendation 1. The Member in charge should table an amendment to the Bill to require that the autism strategy under section 1 of the Bill is subject to the negative procedure.

Accept.

I accept this recommendation and, should the Bill proceed to Stage 2, commit to tabling an amendment to this effect to ensure that this level of Assembly scrutiny is afforded to the strategy.

Recommendation 2. The Member in charge should discuss with the Cabinet Secretary a suitable timeframe for completion of the autism strategy and table an amendment to section 1(4) of the Bill to increase the 6 month deadline in line with those discussions.

Accept.

I am aware that the Cabinet Secretary for Health and Social Services has expressed concern around the timescale specified in the Bill for completion of the autism strategy. I am content to reconsider the timeframe and commit to working with the

Welsh Government to agree a suitable timescale and to table an amendment to the Bill to that effect.

Recommendation 3. The Member in charge should re-consider whether the remedies available to citizens under the Bill are appropriate, and if necessary, table amendments at Stage 2 to provide a more effective way of enforcing the Bill's provisions.

Accept.

This is similar to recommendation 8 made by the Health, Social Care and Sport Committee. As stated in my above response to that recommendation, I am supportive of enhancing citizen's rights under the Bill where possible, and have carefully considered all practical options to achieve the aim of strengthening the remedies available to them. Unfortunately, as I have explained, I have been unable to identify a meaningful way of amending the Bill in this respect.

However, I re-iterate my commitment to ensuring that the Bill does provide for remedial rights where practical and, as I have stated above, am happy to work with Members and other experts, or to consider any amendments tabled during the amending periods, with the aim of strengthening available remedies under the Bill.

Recommendation 4. The Member in charge should table an amendment to the Bill setting out the data that must be collected by local authorities, with the addition of a power for the Welsh Ministers to prescribe in regulations, subject to the affirmative procedure, other categories of data (in effect replicating the provision in section 6(6)(j)).

Accept.

Section 6 of the Bill sets out the specific data to be collected by NHS bodies to assist in the diagnosis and service provision for people with ASD. The specified categories of data are judged to meet the minimum requirements for satisfying the functions of diagnosis, service planning and development. This provision was informed in large part by consultation with Dr Dawn Wimpory, who manages a trial on ASD data collection for Betsi Cadwaladr UHB, and who is herself a clinical practitioner. It was further underpinned by the public consultation on this aspect of the Bill.

I acknowledge that, whilst local authorities are specified as one of the relevant bodies to whom parts of section 6 would apply, this is solely in relation to their general obligations to assist the Welsh Ministers to discharge their own data collection duties under section 6(1). The Welsh Ministers' duties are to obtain, produce and keep updated reliable data to support their functions under the Bill – and it is open to them to decide what data they must collect to achieve this. Whilst the specific data obligations placed on NHS bodies in section 6(6) of the Bill were included to address a clearly defined and pressing need, no evidence was received identifying a lacuna in relation to data collection within local authorities generally. Further, the Minister, in his evidence, pointed out that the Welsh Government already has extensive powers to collect data, and did not require further powers or obligations in this regard.

The Committee may be interested to note that the forthcoming Welsh Community Care Information System (WCCIS), which I referred to in the Explanatory Memorandum, will better enable health and social care professionals to record and share important information covering a range of activities such as community nursing, health and social care visits, mental health, learning disabilities, substance misuse, complex care needs or social care therapy.

Taking all this into consideration, I am happy to seek expert advice on the types of data that local authorities might usefully collect to assist in diagnosis and service provision, and, if appropriate, table amendments accordingly.

Recommendation 5. The Member in charge should table an amendment to section 9(1) of the Bill to remove paragraph (b) of the definition of autism spectrum disorder.

Accept.

The primary focus of the Bill is on the improvement of ASD services in Wales. However, as currently drafted, section 9(1) permits the Welsh Ministers to prescribe other neurodevelopmental disorders by regulations. This means that if future Welsh Ministers believe the provisions of this Bill should be applied to people with other neurodevelopmental disorders, they would have the power to do so.

This provision was included in the Bill as feedback from the consultation exercises I ran strongly supported the use of the WHO definition of ASD and the inclusion of

a power to specify other neurodevelopmental disorders. The rationale for including this provision was to enable the benefits of legislating for ASD to be extended to those with other conditions, however the Bill is first and foremost about the improvement of ASD services in Wales, and this is its primary focus.

I have carefully considered the rationale behind the Committee's recommendation and conclude that I am content to table the amendment necessary to implement this recommendation.

Regardless of a provision to extend the scope of this Bill to include other conditions, I believe that passing and implementing my Bill will benefit those with a wider range of conditions.

The Bill will result in the upskilling of staff who work not just with people with ASD, but people with other conditions too. The diagnostic process for autism includes consideration of related or co-occurring conditions (e.g. ADHD), necessitating skills in identifying and differentiating these other conditions. Provision in the Bill for earlier diagnosis will ensure that people receive the right help sooner, whether they have autism or another condition. In addition, improving service standards and data collection, and encouraging research and innovation, can help promote best practice across services and ensure appropriate diagnosis levels measured against relevant prevalence data.

Recommendation 6. The Member in charge should table an amendment to the Bill to enable the data collection requirements for new relevant bodies prescribed under section 9(1) to be set out in regulations subject to the affirmative procedure.

Accept.

This ties in with my response to the Committee's recommendation 4. I accept that, should it be necessary to extend the data collection requirements to include an additional body or organisation, the regulations should set out the data collection requirements on that body where expert evidence indicates this is necessary. If the general principles of the Bill be agreed, I will commit to tabling an amendment to the Bill to that effect.

I am grateful to each committee for the time you have taken to consider the Autism (Wales) Bill and your detailed reports. The aim of this Bill has always been to improve services to meet the needs of people with ASD and their families across

Wales, and I firmly believe that the measures in this Bill provide the most effective means of achieving the improvements needed.

Yours sincerely,

A handwritten signature in black ink that reads "Paul Davies". The signature is written in a cursive style with a large initial 'P' and a long, sweeping underline.

Paul Davies AM
Preseli Pembrokeshire
Leader of the Welsh Conservative Assembly Group

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Agenda Item 11

By virtue of paragraph(s) vi of Standing Order 17.42

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