The Hepatitis C Coalition is a group of leading clinicians, patient organisations, professional groups, industry and other interested parties committed to the reduction of morbidity and mortality associated with hepatitis C and its eventual elimination.

The Coalition welcomes the opportunity to contribute to the Health Committee’s consideration of public health since April 2013. In this period, the treatment and service landscape for hepatitis C has undergone significant change alongside the reforms to public health planning and funding systems. As such, hepatitis C presents a strong case study of where the reforms to public health have delivered well and less well.

This submission provides background information about hepatitis C before considering how the reforms to public health systems have affected the associated services. An assessment of the advantages and disadvantages of the new system to date is then provided, before turning to the opportunities ahead and the merits of hepatitis C as a case study for the Committee to consider in further detail.

**Executive summary**

- Hepatitis C is a viral infection which affects some of the most marginalised groups in society, including many infected by the contaminated blood scandal. It is a leading cause of liver disease and liver cancer and can be transmitted through blood-to-blood contact.
- Since April 2013, responsibility for hepatitis C services has been split between a range of local and national organisations, diminishing coherence and co-ordination in efforts to tackle the disease.
- The advent of curative treatment presents an unprecedented opportunity to leverage the public health system to generate a substantial reduction in health inequalities and move towards the elimination of hepatitis C as a public health threat, matching the commitment of the Scottish government.
- While there have been some successes in the monitoring of services since April 2013, major improvements will be needed in the years ahead.
- First and foremost, publication of the Improvement Framework first announced by Public Health England in July 2014 is an urgent priority.
- Hepatitis C would be a strong case study for the Committee to consider as part of its inquiry.
About Hepatitis C

Hepatitis C is a viral disease which affects the liver. It can go undetected for years, during which time it can cause significant damage and can lead to liver cirrhosis (scarring), liver cancer and death.

It is one of the major causes of deaths from liver disease, which is the only one of the UK’s five ‘big killers’ where mortality rates are on the rise.

Hepatitis C is a blood-borne virus, contracted through blood-to-blood contact. Key routes for transmission include: injecting drug use, blood transfusions prior to 1991, unsterile tattoo equipment, unsterile medical and dental equipment particularly during travel to high prevalence countries, and high-risk sexual activity.

In 75% of cases, hepatitis C virus will persist in the body for many years - this is known as chronic hepatitis C infection. The speed of disease progression is variable and, in many cases, individuals do not know that they are infected. This has led to hepatitis C being termed ‘the silent killer’. Half of people who inject drugs who are infected with hepatitis C are unaware of their infection status.

Left untreated, patients will develop liver cirrhosis and require lifelong monitoring for the development of liver cancer. As the disease progresses, patients may require a liver transplant. Untreated patients can also continue to transmit the virus. In the most serious cases, chronic hepatitis C infection will lead to liver failure and death.

Prevalence

Estimates suggest that around 160,000 people are chronically infected with the virus in England. Currently, only around 3% of people with the virus receive treatment each year and this in combination with poor rates of diagnosis contributes to rising mortality, high burden of disease and widening health inequalities, as hepatitis C disproportionately affects marginalised groups.

Changes in treatments

Older medicines for hepatitis C required long durations of treatment of 48 weeks with severe side-effects. This treatment consisted of weekly injections of pegylated interferon in addition to orally administered ribavirin. Side-effects see most patients experiencing flu-like symptoms for the duration of treatment in addition to fatigue, nausea, anaemia, insomnia, weight-loss, and rashes. Older treatments were successful in around 70 – 80% of patients who completed their course, however due to the profile of side-effects, some patients were not able to complete the course of treatment.

Newer treatments, often referred to as direct acting antivirals, achieve cure (sustained virological response) in over 90% of patients. These oral medicines require shorter treatment durations and have very few side effects. NICE has been evaluating these new medicines, the first all-oral version of which will be available to all patients on the NHS from February 2016 following a positive NICE appraisal. Others will then become available throughout the year.
**Hepatitis C service commissioning since April 2013**

The NHS reforms of April 2013 saw the division of responsibilities for hepatitis C services between a number of different organisations. As a public health condition with relatively high per capita costs being met by specialised commissioning, hepatitis C is relatively unusual in spanning a large number of different commissioners.

There has been significant local and national confusion about hepatitis C commissioning responsibilities. This has led to unnecessary local anxiety about meeting treatment costs, despite these being covered nationally by NHS England.

Broadly speaking, the commissioning arrangements are as follows:

- **Local Authorities** – responsible for prevention and awareness raising
- **Clinical Commissioning Groups** – responsible for identification of disease (testing)
- **NHS England specialised commissioning** – responsible for costs of treatments and associated services
- **NHS England health and justice** – responsible for costs within prison services
- **Public Health England** – produces national guidance and annual report on ‘Hepatitis C in the UK’.

Other organisations are also involved in services for people with hepatitis C, including drug and alcohol centres.

Given the different points of entry to hepatitis C service pathways, the split between commissioners can be problematic. The below diagram seeks to demonstrate the different commissioners involved in different hepatitis C service pathways.

---

**Assessment of hepatitis C service standards**
Since April 2013 the new NHS and public health structures have failed significantly to improve treatment rates or outcomes for people with hepatitis C.

This is due in some part to the impact of delays in the NICE process on securing access to new, transformative and curative medicines for patients with hepatitis C. Related guidance mandating access to the full range of new drugs is now due to come into force from February 2016. The challenge will then be whether the new system architecture can seize the opportunity presented by this advance in medical science to cure more people of the virus and move towards its elimination as a major public health threat.

Successes since April 2013

- **New treatments becoming available**: the growing availability of a new generation of curative, orally-administered hepatitis C medicines heralds a new opportunity for patients with the disease. Limited early access was granted to critically ill patients but there were delays to enabling full access to others infected with the virus.

- **Operational Delivery Networks launched**: NHS England launched new ODNs to ensure specialist oversight of hepatitis C services. This sees multidisciplinary teams examine cases, with treatment then delivered in hub and satellite sites. The networks were launched in August 2015.

- **Public Health England’s Hep C in the UK report**: Public Health England has continued to produce well-evidenced reports on the state of hepatitis C services, emphasising its broader importance as a major public health challenge in addition to its impact on individual patients.

- **Opt-out testing in prisons**: NHS England’s health and justice team has worked with colleagues within the prison estate and Public Health England to roll-out a programme of opt-out blood-borne virus testing in prisons. This is not yet in all prisons but, in future, should yield rewards as diagnosis rates for hepatitis C increase.

- **Commitment to a partnership approach**: officials from the Department of Health, NHS England, Public Health England, the third sector and others have convened on a regular basis since April 2013 in recognition of the fragmented responsibilities for different elements of hepatitis C services within the system. They have agreed on a partnership approach, best embodied in the development of a national improvement framework for hepatitis C in England.

Challenges since April 2013

- **Lack of strategic direction**: the fragmentation of the hepatitis C pathway has meant that no single organisation can set or implement a clear strategic direction or ambition for hepatitis C services as a whole. Given the opportunities now on the horizon, it would seem important for this to be addressed.

- **Delays to improvement framework**: an improvement framework for hepatitis C in England has been seen as a key means of achieving greater collaboration and coherence for hepatitis C services by guiding local authorities, local commissioners and others within a national plan.
However, its publication has been serially delayed, despite assurances from the Minister for Public Health, NHS England and others since the announcement of the framework by Public Health England in July 2014.

- **Low testing rates:** there remains local ambiguity on where responsibilities and costs for hepatitis C services will be met in the system. As a result, testing and referral rates require substantial improvements. Research from Public Health England suggests that the rate of testing for hepatitis C has stabilised since 2008. The report states that this could be because the ‘easy-to-reach’ population has now been tested, suggesting that public health services are failing to reach out to those most likely to suffer from inequalities.

- **Issues with data collection:** Public Health England and others have been working on a dataset which would allow for more detailed monitoring of the impact of treatments with a view to a more sophisticated understanding of the prevalence, impact and trends of hepatitis C infection. These have not yet been introduced, with ongoing discussions between providers and NHS England taking place.

- **Public health cuts:** reductions in the public health budget this financial year are likely to affect many of the preventative steps which local authorities should be taking to address hepatitis C infection rates. In particular, the future viability of drug and alcohol centre provision is likely to be placed into doubt.
Hepatitis C as a case study for the public health system

The Hepatitis C Coalition strongly believes that hepatitis C services would be an excellent case study for the Health Committee to consider as part of its inquiry into public health since April 2013.

Hepatitis C would warrant consideration as a case study on the following grounds:

**Public health importance:** Hepatitis C is a major cause of liver disease – the only one of the “five big killers” with rising mortality rates in the UK. It is also the most amenable to treatment amongst the causes of liver disease mortality. The Department of Health highlights this in its strategy, ‘Living Well for Longer: preventing premature mortality’ and measures the under 75 mortality rate from preventable liver disease in its Public Health Outcomes Framework. The further transmission of the hepatitis C virus represents a challenge for public health into the future unless action can be taken to reduce its prevalence and prevent onward transmission.

**Health inequalities impact:** hepatitis C disproportionately affects poorer and more vulnerable groups in society. It is particularly prevalent in people who inject drugs, as well as the prison and homeless population. There is also a disproportionately high prevalence within minority ethnic communities, particularly South Asian communities. Several thousand people have been diagnosed or potentially infected as a result of the contaminated blood scandal.

**Community concerns:** since the implementation of structural changes following the Health and Social Care Act, there has been little change in the rates of testing and treatment of hepatitis C in England. This lack of progress has been noted in the foreword to Public Health England’s annual reports on Hepatitis C in the UK, which notes: “In an era of curative treatments and prevention options, we must question whether this is acceptable.”

**Topicality:** the opportunity created by new cost-effective medicines could shift the public health landscape, reducing premature mortality due to liver disease and addressing a range of health inequalities. NHS England has prioritised hepatitis C in its planning guidance for the next financial year. The crucial implementation phase will be a test to the whole public health system over the next few months. In England, if advances in treatments are matched by improvements in service delivery and 14,700 patients are treated each year, modelling work has shown that hepatitis C would be eliminated as a public health threat by 2030. Scotland announced its commitment to the elimination of Hepatitis C as a public health threat in September 2015.

**Demonstration of system performance to date:** given the involvement of a wide range of different local and national commissioning organisations in delivering the associated services, hepatitis C is an efficient lens through which to assess the performance of many of the new parts of the NHS and public health system.

*14 December 2015*