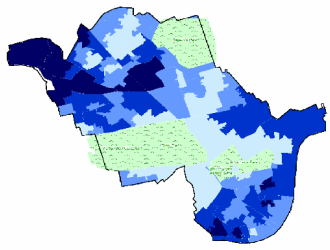
Westminster's

Joint Strategic Needs Assessment

Hepatitis C

May 2010

Amina Aitsi-Selmi
Specialty Registrar
Toni Williams
Public Health Programme Manager
NHS Westminster



Westminster City Partnership

This document contributes to Westminster's JSNA

Contents

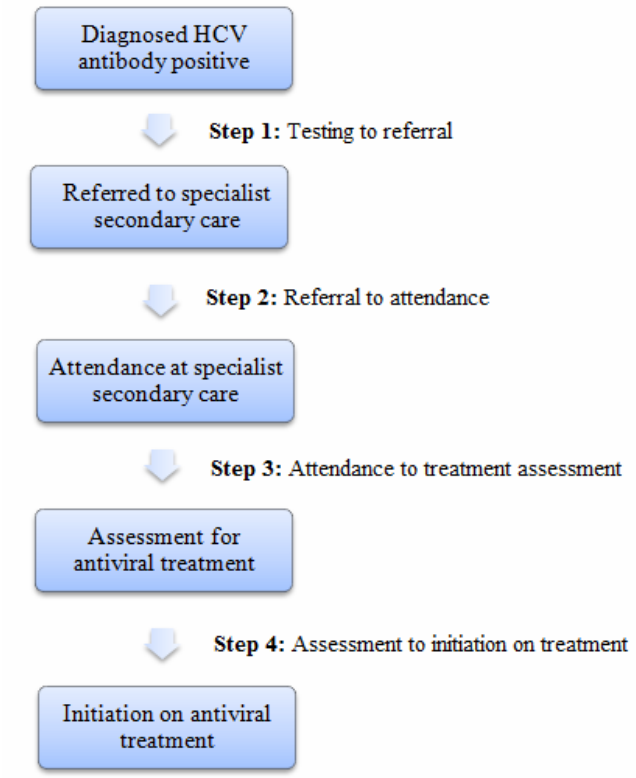
1: Introduction

This needs assessment, which is part of Westminster's Joint Strategic Needs Assessment Rolling Programme, considers the population of Westminster infected with hepatitis C.

Hepatitis C virus is a blood-borne virus that infects liver cells, resulting in a slowly progressing chronic disease. Since its identification in 1989 (Choo *et al*, 1989), hepatitis C has become an increasingly important public health issue. Hepatitis C is considered by many to be one of the most serious and significant public health risks of our generation.

This needs assessment focuses on the main stages of the patient management process (figure 1.1) and considers each stage in turn; (i) testing and diagnosis of infection, (ii) referral to specialist services and (iii) the management and treatment of patients with chronic hepatitis C infection. Although it is recognised that the prevention of hepatitis C infection is exceptionally important, it is beyond the scope of this needs assessment and will be considered in a separate, more detailed piece of work.

Figure 1.1: Summary of the patient management pathway



Source: Williams (2008)

Specifically this needs assessment aims to:

- Estimate the burden of disease by modelling the prevalence and incidence of hepatitis C in Westminster;
- Describe the long term impact of hepatitis C in Westminster
- Describe the patient management pathway from testing and diagnosis to referral to specialist care and management and treatment;
- Understand the number of individuals progressing through the patient pathway;
- To identify gaps in the current patient management pathway and identify points on the pathway where patients 'drop off' (attrition);
- To better understand reasons for attrition and barriers to care;
- Present evidence of the most effective way to overcome attrition, barriers to care and promote progression through the patient care pathway leading to initiation of antiviral therapy;

This needs assessment was overseen by the Westminster Hepatitis C Needs Assessment Steering Group, a multidisciplinary group including local clinicians, Westminster Drug and Alcohol Action Team, GPs and Public Health.

2: What is the issue and why is it important?

Key Messages:

- **Large numbers of people are thought to be chronically infected with hepatitis C;**
- **Many infected individuals remain undiagnosed;**
- **Infection is primarily associated with intravenous drug users, a typically marginalised and hard to reach population;**
- **Hepatitis C infection is associated with substantial morbidity and mortality that is increasing with time, with increasing health costs to individuals and financial costs to the NHS;**
- **A clinically and cost effective treatment is available, however, too few people have benefited from treatment;**
- **Westminster is performing poorly in tacking the problem of hepatitis C.**

Hepatitis C is a complex and increasing public health problem, as is recognised in the national Hepatitis C Strategy for England (Department of Health, 2002). In England, although the overall prevalence is low compared to some countries, large numbers of people are thought to be chronically infected with hepatitis C, with the number of people chronically infected thought to exceed 200,000.

Although large numbers of people are infected, because the infection is largely asymptomatic, many individuals remain undiagnosed and are, therefore, unable to benefit from treatment or unaware that they may need to modify their lifestyle to reduce the speed of progression of liver disease.

In England, hepatitis C infection is primarily associated with intravenous drug users (IDU), a typically marginalised and hard to reach population that experiences significant health inequalities. This poses significant challenges to health services to engage with individuals to enable appropriate care to be delivered.

However, it is important to recognise that hepatitis C infection is not just associated with injecting drug use. In some countries the prevalence of hepatitis C is particularly high because of the re-use of syringes and needles

for medical treatment and vaccinations. It is important that these routes of transmission are considered locally because Westminster has an ethnically diverse population and is likely to have a larger population of persons from countries where the prevalence of hepatitis C is high, than other areas.

Hepatitis C is an issue in Westminster for all of the reasons outlined above, however, it is likely that because Westminster has a higher number of injecting drugs users, a large migrant population from areas of high hepatitis C prevalence and a large homeless population, that the number of people chronically infected and the burden of disease associated with hepatitis C will be larger than in other areas.

Hepatitis C infection is associated with substantial morbidity and mortality. Accordingly, not only are there significant health costs to individuals but there are financial costs to the NHS associated with hospital inpatient admissions and liver transplants.

If nothing is done the situation will worsen. The associated health and financial costs associated with hepatitis C are increasing and are expected to rise significantly in the future; not only are the numbers of people chronically infected increasing, but the length of time people have been infected for is increasing. As a result, the number of people with complications associated with hepatitis C infection is increasing.

Despite the fact that a clinically and cost effective treatment is available and recommended by NICE and the fact that significant numbers of cases of cirrhosis and liver failure could be prevented, only small numbers of patients have benefited from antiviral treatment in England.

A number of service reviews conducted by bodies such as the All Party Parliamentary Hepatology Group and the Healthcare Commission/National Treatment Agency suggest that Westminster is failing to adequately tackle the hepatitis C epidemic. Furthermore, local anecdotal evidence suggests that although positive developments have been made with regards to identifying IDUs with hepatitis C, pathways into specialist care and treatment are inadequate and poorly understood. Accordingly, for these reasons and those discussed above, tackling the hepatitis C epidemic should be a commissioning priority for Westminster.

3: What is hepatitis C?

Key Messages:

- **Hepatitis C is a virus that infects liver cells;**
- **Infection is usually persistent resulting in a slowly progressing chronic disease;**
- **A clinically and cost effective treatment is available, however, too few people have benefited from treatment.**

3.1 What is hepatitis C?

Hepatitis C virus is a blood-borne virus that infects liver cells, resulting in a slowly progressing chronic disease. Since its identification in 1989 (Choo *et al*, 1989), Hepatitis C has become an increasingly important public health issue. Hepatitis C is considered by many to be one of the most serious and significant public health risks of our generation.

Large numbers of people are infected; worldwide an estimated 180 million people are infected with hepatitis C, with higher rates of infection in the developing world (World Health Organisation, 2006). Not only are considerable numbers of people infected worldwide, but hepatitis C is associated with substantial morbidity and mortality that is increasing with time.

In the UK, hepatitis C is primarily associated with intravenous drug use (IDUs), a typically excluded and hard to reach population. Hepatitis C is often referred to as a 'silent epidemic' as many who are infected are unaware of it. However, a cost effective treatment is available and is recommended by the National Institute for Health and Clinical Excellence, however, to date too few people have benefited from treatment.

3.2 Routes of transmission

Hepatitis C is transmitted primarily through direct contact with infected blood. In developing countries, re-use of syringes and needles for medical treatment and vaccinations is still a well documented mode of hepatitis C transmission. Although these factors are not commonly associated with hepatitis C transmission in developed countries, it is important that they are considered with regards to the Westminster population. Westminster has an ethnically diverse population and is likely to have a larger population of persons from

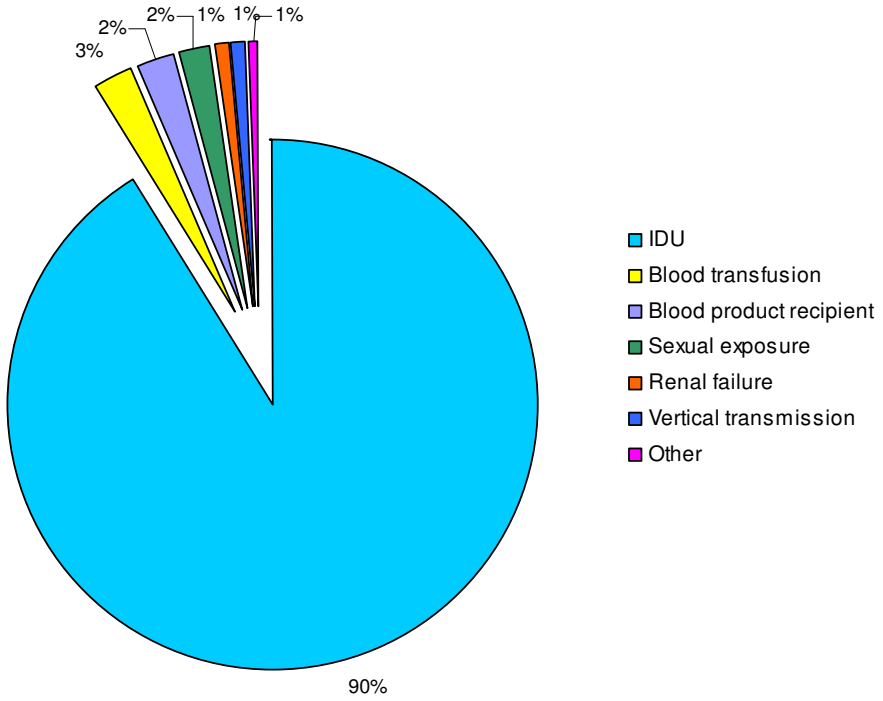
countries where the prevalence of hepatitis C is high (where these methods of transmission account for a large number of infections) than other areas.

In developed countries, transmission mainly occurs through IDU (via the sharing of needles, syringes and other injecting paraphernalia), accounting for more than 90% of infections in England (Department of Health, 2002).

Prior to the introduction of heat treatment of blood factors in the late eighties and blood donor screening in 1991, the receipt of contaminated blood/blood products was a risk factor for hepatitis C infection (Makris *et al*, 1993). With the onset of nucleic acid testing, risk of hepatitis C infection is now one in two million (Goldberg & Anderson, 2004).

Less reported routes of transmission in England include vertical transmission, occupational exposure, tattoo and body piercing, household items such as toothbrushes and razors and sexual exposure (Department of Health, 2002).

Figure 3.1: Routes of transmission in England



Source: Health Protection Agency

3.3 Natural history

3.3.1 Acute infection

Hepatitis C infection follows exposure to the hepatitis C virus, with anti-hepatitis C antibodies produced within two to three months and viral RNA detectable within one to three weeks of infection. In most cases this initial

stage of infection is asymptomatic; however, a small proportion of cases experience clinical symptoms (Seef, 2002).

The incubation period from time of exposure to onset of acute infection is approximately seven weeks (Seef, 2002).

Following acute infection, viral RNA is either cleared spontaneously (10-20% of cases) or persists (80-90% of cases), establishing a slowly progressing chronic disease (Seef, 2002) (figure 3.2).

3.3.2 Chronic infection

Chronic hepatitis C infection is characterised by mildly elevated alanine aminotransferase (ALT) and inflammation of the liver, although often infection remains asymptomatic. The spectrum of disease ranges from mild to moderate hepatitis, progressing first to compensated and in some, to decompensated liver cirrhosis before end stage liver failure; additionally hepatocellular carcinoma may develop (Seef, 2002).

(i) Mild to moderate hepatitis

Mild and moderate hepatitis can be asymptomatic, but can also result in non-specific symptoms as well as reduced quality of life and extrahepatic manifestations (Seef, 2002).

(ii) **Severe hepatitis**

Cirrhosis results in the liver no longer functioning as it should, leading to sequelae such as impaired blood clotting, jaundice, ascites, hepatic encephalopathy and variceal bleeding. Cirrhotic individuals are also at increased risk of developing hepatocelluar carcinoma.

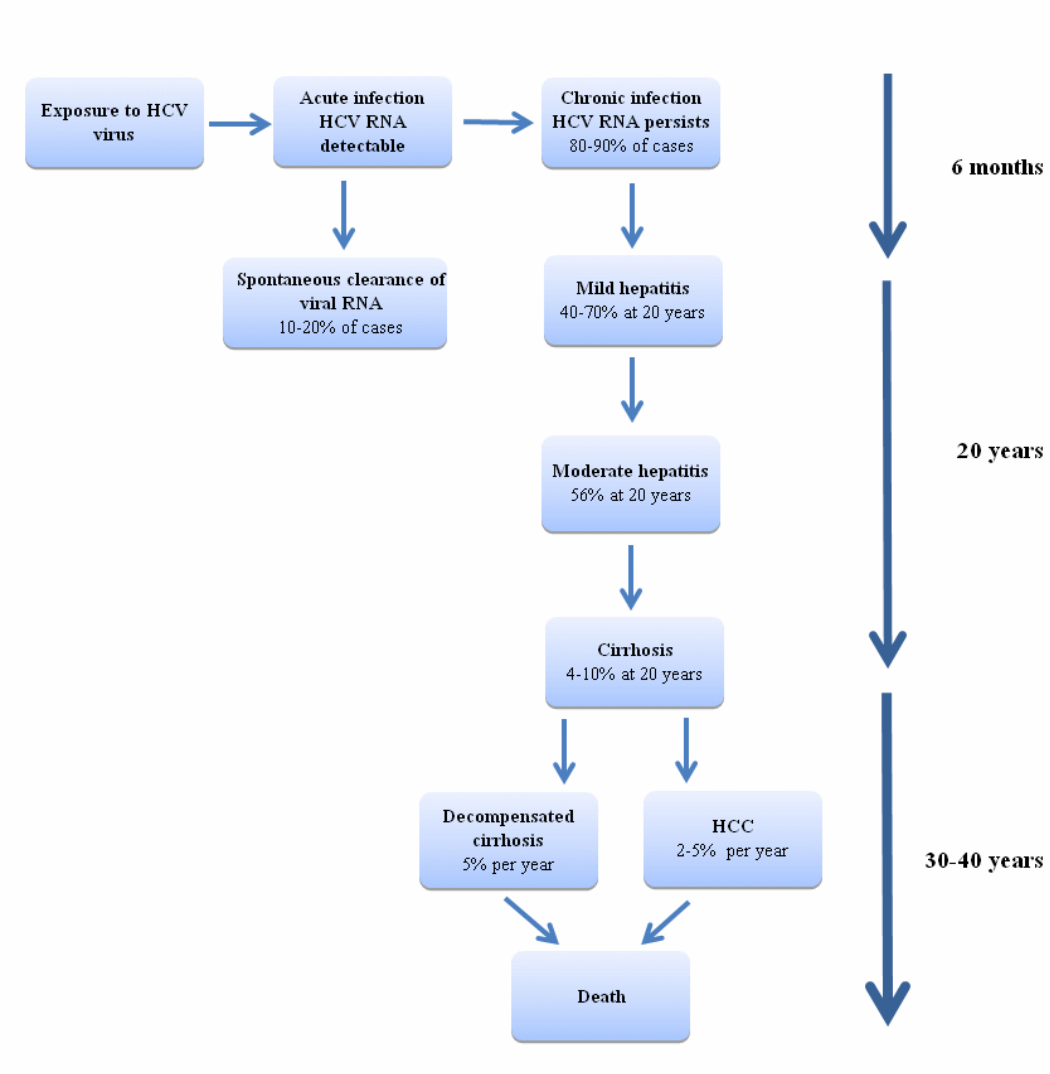
(iii) Rate and determinants of disease progression

It is estimated that the proportion of individuals progressing to cirrhosis within 20 years of infection is between four and ten percent, with two to four percent of individuals who have developed cirrhosis going on to develop hepatocellular carcinoma (Seef, 2002).

The factors associated with rapid development of severe liver disease have been described (Seef, 2002):

- Male sex
- Alcohol consumption of >50g per day
- Aged over 40 years at time of infection
- Co-infection with human immunodeficiency virus (HIV) or hepatitis B (HBV).

Figure 3.2: Natural history of Hepatitis C



Source: Seef (2002)

3.4 Morbidity and mortality

Hepatitis C infection is associated with substantial morbidity and mortality and can lead to cirrhosis of the liver, which itself can progress to liver decompensation, end stage liver disease, hepatocellular carcinoma and eventually lead to a need for liver transplantation.

3.5 Treatment

Pegylated interferon and ribavirin is the current recommended treatment for chronic hepatitis C infection. Following the NICE guidance (NICE, 2006) and the Health Technology Assessment (Shepherd *et al*, 2007), the use of

pegylated interferon and ribavirin is now recommended for treatment of mild, moderate and severe liver disease (excluding very severe liver disease).

Depending on the strain of infection (known as genotype) length of treatment can range from 24 weeks to 48 weeks, although some guidance is beginning to emerge around treatment begin administered for only 12 weeks (when patient show an early viral response). Furthermore, it should be noted that antiviral therapy is not easy, it is associated with a number of side effects including depression, skins problems and flu-like symptoms amongst many others.

Therefore, not only must patients undergoing antiviral therapy be committed to treatment for a relatively long period of time, but they must be well and stable enough to manage the potential side effects that may present. Given the vulnerability and coexisting morbidities of the population in Westminster most likely infected with hepatitis C, this presents challenges.

4: Expected numbers by time person place

Key Messages:

- **The prevalence of hepatitis C in Westminster is between 1.1% and 1.5% - this is three times the national average;**
- **Prevalence of hepatitis C is highest amongst IDUs;**
- **The annual incidence hepatitis C in Westminster is around 46 cases per 100,000 population, equivalent to 108 newly diagnosed cases per year;**
- **The majority of people diagnosed with hepatitis C in Westminster are men from White ethnic groups, however, a relatively large proportion of persons diagnosed in originate from Europe and South East Asia;**
- **Persons with hepatitis C often have co-morbidities such as mental health problems and addiction problems and some may be co-infected with HIV and/or hepatitis B.**

4.1 Prevalence of hepatitis C

Prevalence is a measure of the total number of cases in a defined population. The World Health Organisation estimates that 3% of the world's population is chronically infected with hepatitis C (WHO, 2006). The prevalence varies geographically; in Egypt it is thought to be as high as 18% (WHO, 2000), whereas in developed countries it is much lower; for example, in England and Wales, 0.4% of the population is estimated to be chronically infected (Health Protection Agency, 2008).

4.1.1Prevalence of hepatitis C in Westminster

The Health Protection Agency (HPA) has produced a model to provide local prevalence estimates. Based on the HPA model, an estimated 2647-3,618 people in Westminster are infected with hepatitis C; this is equivalent to a prevalence of between 1.1% and 1.5%, which is three times the national average. Assuming that 20% of people clear the infection spontaneously, it is estimated that between 0.9% and 1.2% of the Westminster population has active or chronic hepatitis C infection (equivalent to between 2,238 and 2,894 individuals) (see Appendix A for detailed calculation).

Table 4.1: Number of people infected with hepatitis C in Westminster by infection group

	Prevalence	Number of people hepatitis C positive
Hepatitis C positive IDU	55%	1,039 - 2,010
Hepatitis C positive ex-IDU	29%	1,232
Hepatitis C positive non-IDU	0.12%	211
Hepatitis C positive born overseas	1%	240

Source: HPA

Prevalence of hepatitis C is highest amongst IDUs. Those starting to inject are likely to be exposed to hepatitis C relatively soon after initiation and, therefore, should be a key target group for preventative initiatives, for example, outreach, safer injection advice, needle exchanges, substitution access and access to voluntary confidential diagnostic testing for hepatitis C.

4.2 Diagnosed cases in Westminster

Local data from a large acute hospital trust shows that between 1990 and 2009, 708 individuals have been diagnosed with hepatitis C. This is likely to be an underestimate of the number of people diagnosed in Westminster, as other laboratories will also be diagnosing cases.

In order to better understand the number of persons in Westminster diagnosed with hepatitis C infection, data should routinely be collated from St Mary's Hospital, St Thomas' Hospital, University College Hospital and Chelsea and Westminster Hospital.

4.3 Incidence of hepatitis C in Westminster

Incidence is a measure of the number of new cases in a population over a defined period of time. Ascertaining the incidence of hepatitis C in Westminster is problematic, because hepatitis C infection is usually asymptomatic, persons are often not diagnosed at the time of infection, but instead at a later date. As a result, the incidence of hepatitis C can only be calculated for newly diagnosed cases (as opposed to newly acquired infections). It should be noted that this will not be an accurate reflection of current infection rates as diagnostic practices will affect this.

Given the difficulties in ascertaining incidence, we have drawn upon a range of data sources to provide a local estimate of incidence.

The World Health Organisation estimates that the UK has one of the highest incidence rates of hepatitis C in Europe at 16/100,000 per year (2007). However, analysis of the number of cases detected by the Imperial College Hospitals Trust laboratory (one of the main diagnostic laboratories in Westminster) suggests that the annual incidence is closer to 24 per 100,000.

Based on an estimated 3,000 people infected with hepatitis C in Westminster, it is estimated that 210 new cases of hepatitis C should be identified each year in Westminster; this is equivalent to a much higher annual incidence of 90 per 100,000

Table 4.2: Estimated incidence of hepatitis C in Westminster

	Annual incidence per 100,000	**Number of cases diagnosed per year**
WHO estimate	16 per 100,000	37
Laboratory data based estimate	24 per 100,000	54
HPA commissioning based model estimate	90 per 100,000	210
Combined estimate	46 per 100,000	108

Source: WHO, Imperial College Healthcare Trust, HPA and Westminster Hepatitis C Needs Assessment Steering Group

Taking all data sources into account, an annual incidence of 46 per 100,000 (or 108 newly diagnosed cases per year) is thought to be a realistic estimate of the incidence of hepatitis C in Westminster.

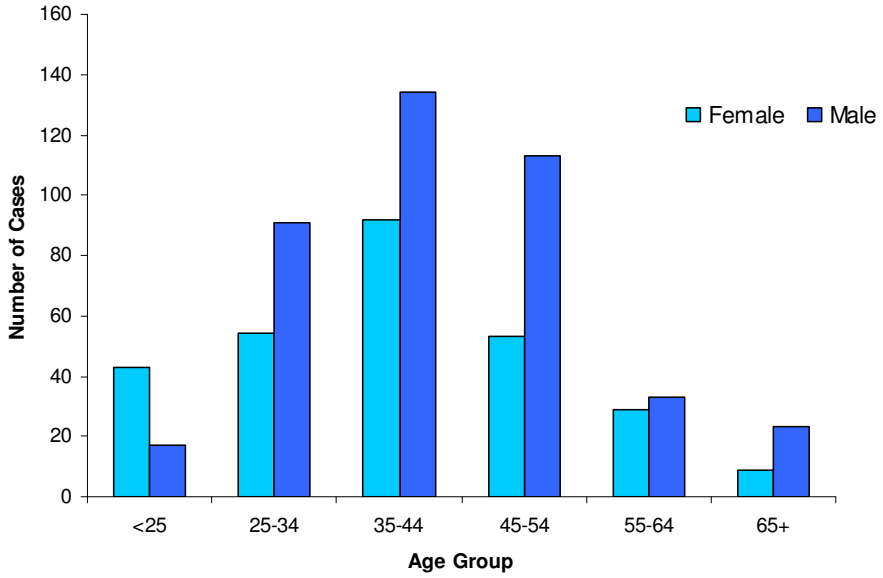
4.4 What are the characteristics of people with hepatitis C in Westminster?

Given the large undiagnosed hepatitis C population, it is difficult to accurately describe the characteristics of those persons with hepatitis C in Westminster. However, inferences can be drawn from the laboratory data of people testing positive and data from the published literature. It should, however, be noted that the characteristics of those persons who are infected but not diagnosed will not be represented in this dataset.

(i)Age, sex and ethnicity

Almost 60% of those diagnosed with hepatitis C in Westminster were men (this is slightly lower than the national proportion of 68%), with the majority of cases aged between 35 and 54 years old.

Figure 4.1: Age and sex distribution of hepatitis C diagnosed persons in Westminster: Imperial College Healthcare Trust 1990-2009



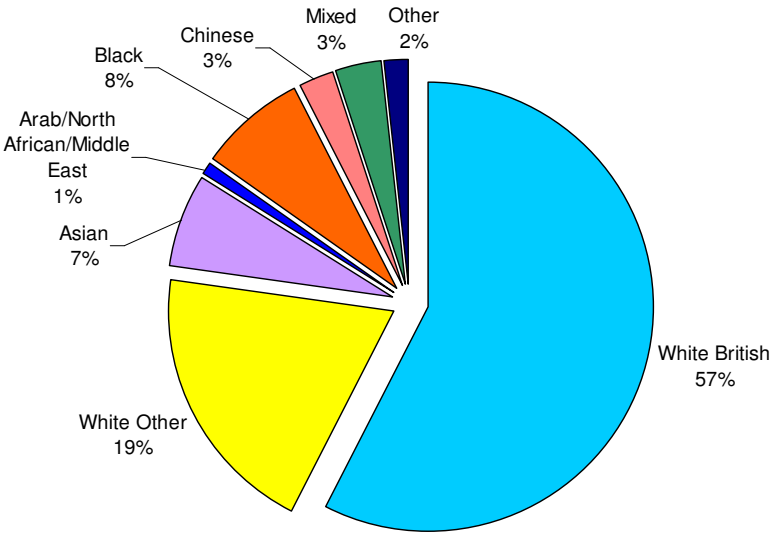
Source: Imperial College Healthcare Trust

Of the 708 cases diagnosed, ethnicity was recorded for 124 cases; the majority of cases were from White British or White Other ethnic groups (figure 4.2). This is largely as expected given the ethnic mix of the Westminster population, however, persons from White Other ethnic groups appear to be slightly overrepresented, whereas persons from White ethnic groups are underrepresented. This might suggest that persons from White British ethnic groups are less likely to be diagnosed positive with hepatitis C – most likely because they are not presenting for testing.

Because of the large amount of missing data relating to ethnicity and because of the relatively large proportion of cases reported as White Other, Mosaic Origins was used to try to ascertain the geographic region of origin of the diagnosed cases.

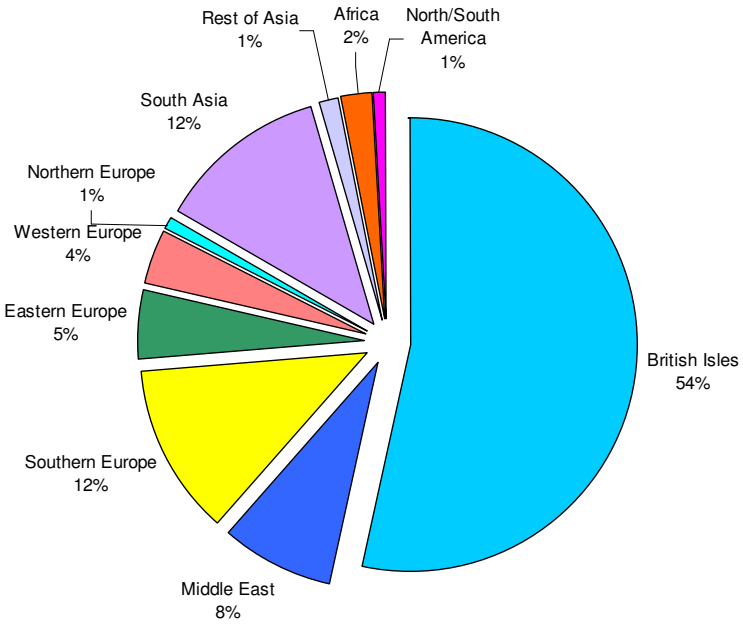
Analysis using Mosaic origins shows that a relatively large proportion of persons diagnosed in Westminster originate from Europe and South East Asia.

Figure 4.2: Ethnic distribution of hepatitis C diagnosed persons in Westminster: Imperial College Healthcare Trust 1990-2009



Source: Imperial College Healthcare Trust

Figure 4.3: Geographical region of origin of hepatitis C diagnosed persons in Westminster: Imperial College 1990-2009



Source: Imperial College Healthcare Trust and Mosaic Origins

(ii) Co-infection

Co-infection with either hepatitis B virus (HBV) or HIV is associated with more rapid development of severe liver disease. Of the 708 individuals who tested positive for hepatitis C, 265 had also undergone a diagnostic test for HBV infection. Of these, 14 tested positive for recent HBV infection (identified by testing positive for HBV surface antigen). This is equivalent to an HBV co-infection prevalence of 5% and is consistent with the literature (Williams, 2008).

HIV data was not available from the Imperial Healthcare diagnosis data, however, a recent review of the literature estimates that the prevalence of hepatitis C amongst persons with HIV is between 10% and 40% (there are currently no estimates pertaining to the proportion of persons with hepatitis C who are HIV positive). In a recent study of describe the characteristics of hepatitis C infected patients attending a specialist liver clinic in Scotland, between 8% and 13% of patients were HIV and hepatitis C positive (Williams, 2008).

(iii) History of psychiatric illness

Given that persons with a history of substance misuse constitute a large proportion of those persons infected with hepatitis C, it is likely that mental health problems will be relatively common in the hepatitis C infected population in Westminster. In the absence of local data, published data from Scotland was drawn upon; an estimated 26% of persons with hepatitis C are likely to have either a history of psychiatric illness. Applying this to the Westminster population suggests that 941 local people with hepatitis C also have a mental health problem.

Table 4.3: Estimated number of persons with co-morbidities

	Prevalence amongst Hepatitis C positive persons	**Estimated number of people in Westminster**
HBV co-infection	5%	181
HIV co-infection	8%-13%	289-470
Psychiatric illness	26%	941
Alcohol use	58%	2,098

Source: Williams (2008) and Imperial College Healthcare Trust

(iv) History of alcohol use

Evidence from the published literature suggests that alcohol use amongst persons with hepatitis C is high. In a recent Scottish study, 58% of persons with hepatitis C attending a specialist liver centre were drinking more than 21 units of alcohol per week (the majority were drinking more than 50 units of alcohol).

The co-morbidities described above have all been identified as factors that may affect the management of persons with hepatitis C infection and in some studies they have been shown to be significant barriers to care and initiating on antiviral treatment (Williams, 2008).

5: Burden of disease associated with hepatitis C

Key Messages:

- **The number of people with hepatitis C related complications is increasing and is expected to continue to increase unless the number of people receiving antiviral treatment significantly increases;**
- **Hepatitis C associated hospital inpatient admissions are rising and have doubled in England over the last ten years;**
- **The number of liver transplants required as a result of hepatitis C infection is increasing – numbers in England have also doubled in the last ten years;**
- **Hepatitis C related mortality is increasing – latest available data shows that there were 7 deaths in 2008/09 in Westminster.**

Hepatitis C infection is associated with significant morbidity and mortality and is a recognised cause of end stage liver disease and hepatocellular carcinoma. The burden of disease in Westminster is now beginning to be realised in terms of hospital admissions for hepatitis C related end stage liver disease, liver transplantation and hepatitis C related deaths.

If current levels of antiviral therapy are maintained, the number of liver failures associated with hepatitis C is expected to increase. However, evidence from Scotland shows that by significantly increasing current treatment levels, thousands of individuals can be prevented from progressing to end stage liver disease and liver failure (Hutchinson *et al*, 2006).

5.1Decompensated liver disease

Limited robust data is available describing the number of people in Westminster with hepatitis C infection who have end stage liver disease. However, national data clearly shows that the number of people with hepatitis C related end stage liver disease and/or hepatocellular carcinoma (cancer of the liver) is increasing.

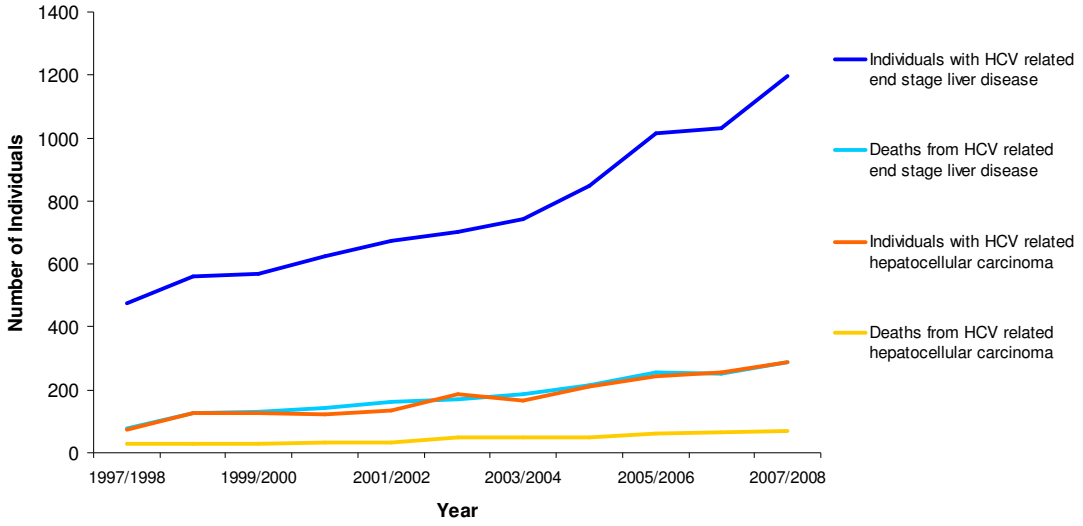
5.2 Hospital admissions

Between 2005 and 2008, 53 people with a diagnosis of hepatitis C recorded were admitted to hospital as a result of liver decompensation in Westminster. The actual number is, however, likely to be much higher because coding may not have been complete on the Secondary User Service Data interrogated

here. The majority of admissions were men aged 40 years and over; this is unsurprising given the characteristics of those known to be infected with hepatitis C.

Given the small numbers and likely under-recording in Westminster, it is difficult to analyse local time trends. However, analysis of national data shows a clear increase in the number of hospital admissions associated with hepatitis C, from approximately 5,000 episodes per year in 1997/98 to 18,000 episodes per year in 2007/08. This increase is likely to continue in the future.

Figure 5.1: Number of individuals with hepatitis C who have end stage liver disease and/or hepatocellular carcinoma and deaths from these conditions: England 1997/1998-2007/2008



Source: Health Protection Agency

5.3 Transplants

Between 1996 and 2008 there has been a large increase in hepatitis C related disease requiring transplantation; in 1996 10% of first liver transplants in England were associated with hepatitis C infection – this rose to 21% in 2008 (Health Protection Agency, 2008). In 2008/09, 6 Westminster residents received a liver transplant, at an estimated annual cost of approximately £426,000. This is likely to increase in the future as more people develop advanced liver disease.

5.4 Deaths

Figure 5.1 shows that number of deaths associated with hepatitis C in England is increasing. Latest available data for Westminster shows that there

were seven deaths in 2007/08. This figure is likely to increase in the future as the current cohort of patients ages and their disease progresses, unless they are successfully treated.

6. Testing and diagnosis

Key messages:

- **A large proportion of individuals with hepatitis C remain undiagnosed- most are current or former IDUs or people who have moved to Westminster from high prevalence countries;**
- **Considerable developments have been made in establishing testing services in drug/alcohol service settings;**
- **However, the greatest opportunity for hepatitis C testing exists in general practice, however, anecdotal evidence suggests that little testing is occurring in general practice settings.**

6.1 Why is testing important?

Published research shows that the majority of persons chronically infected with hepatitis C remain undiagnosed – a large proportion of these individuals are persons who have a history of injecting drug use, but who no longer inject or migrants who have moved to Westminster from countries of high prevalence. If those persons are to benefit from antiviral therapy, a diagnosis must be made so that a referral to specialist care can be made.

Furthermore, testing also has an important role in prevention; the process of testing, including pre and post test counselling, may be used to raise awareness of hepatitis C infection and educate individuals about how the virus is transmitted and how individuals can avoid contracting it and passing it on to others. Accordingly, hepatitis C testing services should be widespread and easily accessible to persons at risk of hepatitis C infection, to enable persons to access testing and advice.

Understanding of current testing practices in Westminster is incomplete and, therefore, a range of UK based studies have been drawn upon to draw inferences on likely testing patterns in Westminster.

6.2 Who should be tested?

Current national and international guidelines recommend that individuals who have an excess risk of being infected and who would benefit from knowing their hepatitis C status should be offered a hepatitis C test.

The Scottish Intercollegiate Guidelines Network (SIGN) Guideline recommends that the following groups should be tested for hepatitis C:

Table 6.1: Hepatitis C testing recommendations

Should be tested for hepatitis C	Should be offered an hepatitis C test
Blood/tissue donors	Patients with other unexplained persistently elevated alanine aminotransferase
Patients on haemodialysis	People with a history of IDU
Healthcare workers who intend to pursue a career in a speciality that requires them to perform exposure prone procedures	People who are HIV positive
	Recipients of blood clotting factor concentrates prior to 1987
	Recipients of blood and blood components before September 1991 and organ/tissue transplants in the UK before 1992
	Children whose mother is known to be infected with hepatitis C
	Healthcare workers following percutaneous or mucous membrane exposure to blood which is, or is suspected to be, infected with hepatitis C
	People who have received medical or dental treatment in countries where hepatitis C is common and infection control may be poor
	People who have had tattoos or body piercing in circumstances where infection control procedure is, or is suspected to be, suboptimal
	People who have had a sexual partner/household contact who is hepatitis C infected

Source: SIGN

The National Institute of Health and Clinical Excellence are currently developing a clinical guideline for hepatitis B and hepatitis C testing; this guideline is expected to make recommendations around who should be tested for hepatitis C. Accordingly, the recommendations of this guideline should be considered for implementation in Westminster.

6.3 Testing in Westminster

Hepatitis C testing in Westminster is available in a range of settings, including:

- General practice

- GUM clinics
- Drug/alcohol services

(i) General practice

The greatest opportunity for hepatitis C testing exists in general practice, however, anecdotal evidence suggests that little testing is occurring in general practice settings.

Quantitative data pertaining to hepatitis C testing in general practice settings in Westminster is not available and, therefore, it is unclear how much testing is occurring in general practice settings.

Sentinel surveillance by the Health Protection Agency shows that the number of people tested in general practice settings is increasing (between 2007 and 2008 there was a 13.4% increase in the number of individuals tested for hepatitis C, (Health Protection Agency 2009)), however, evidence from elsewhere in the UK, suggests that testing activity remains relatively low.

The Scottish needs assessment found that:

- Approximately 95% of GPs in Scotland did not diagnose a single case of hepatitis C in 2006;
- Fewer than one in five general practices actively seeks out patients with risk factors for hepatitis C;
- Difficulties in taking blood for hepatitis C testing from persons who had injected drugs and the often long interval between blood taking and a result being available were barriers to testing uptake – IDUs regularly fail to return to receive the results of their test (Scottish Government, 2008).

A number of substance misuse shared care GP surgeries in Westminster are offering dried blood spot testing as part of a pilot programme to increase the number of IDUs (particularly those with poor venous access) being tested for hepatitis C.

(ii) Genitourinary medicine (GUM) clinics

Hepatitis C testing is available in GUM settings. In Westminster (and Central London) there is good provision of GUM services, with Westminster residents predominantly accessing 56 Dean Street, St Mary's Hospital and Mortimer Market.

Although we cannot quantify exactly how many hepatitis C tests are occurring in GUM clinic settings, data is available describing the number of positive tests. Data for 2009/10 shows that relatively few diagnoses are made in GUM settings; in 2009/10 8 hepatitis C diagnoses were made at 56 Dean Street.

GUM clinics provide anonymous testing for individuals; whilst this may be appealing for the presenting individual, from a service point of view, anonymity presents a barrier to sharing information. This is particularly a problem for a population where a multidisciplinary integrated care approach is essential for successful access to treatment services.

(iii) Westminster Blood Borne Virus Service

The Westminster Blood Borne Virus Service, which was established in 2008, is a partnership between Westminster Drug Project, Central and North West London NHS Foundation Trust and the Hungerford Drug Project (HDP) and aims to improve the detection of blood-borne viruses, prevent the long term sequalae associated with blood-borne viruses and prevent onward transmission of blood-borne viruses by screening problematic drug users.

The service has agreed targets for testing with NHS Westminster; the target is to test 118 clients each quarter. There are no targets regarding detection rate, although this could encourage more effective targeting of patients.

The service offers dried blood spot testing; this is beneficial as it addresses the problem of poor venous access amongst drug users and tests can be conducted by a wider range of staff. It is useful for both identifying new cases of blood borne viruses and also for the regular blood borne virus tests for those persons at high enough risk to warrant monitoring through repeat testing.

Dried blood spot testing has been shown to be an effective method of blood borne virus testing and is comparable to wet blood testing in terms of sensitivity and specificity.

Between April 2008 and March 2009, 443 service users were screened (83% of all service users). 160 people were found to be hepatitis C positive, equivalent to a prevalence in the screened population of 36%.

The acceptance of a hepatitis C test was generally high across all locations, with the exception of King George's hostel.

It should be noted that the 160 newly diagnosed cases of hepatitis C by the Blood Borne Virus Service in 2008/09 is higher than the estimated incidence of hepatitis C in Westminster as a whole (46 cases per 100,000 population). This suggests that current estimates of incidence of hepatitis C in

Westminster are inaccurate. Further, more robust estimates are, therefore, needed. Routine monitoring of laboratory and Westminster Blood Borne Virus Service data should be undertaken to monitor local incidence trends.

Table 6.2: Westminster Blood Borne Virus Service: hepatitis C testing activity

April 2008 - Mar 2009	Number service users	Total screened	Uptake of testing (%)	Hep C +ve	Prevalence (%)	95% CI lower limit	95% CI upper limit
Total Westminster	532	443	83	160	36.1	31.6	40.6
WDP	59	59	100	15	25.4	14.3	36.5
WTC	36	30	83	10	33.3	16.5	50.2
HDP	81	80	99	35	43.8	32.9	54.6
King George's Hostel	50	32	64	13	40.6	23.6	57.6

Source: Westminster Blood Borne Virus Service

Although, relatively large numbers of problematic drug users are being screened by the service, the prevalence of hepatitis C amongst the screened population (36%) is currently below the level deemed cost-effective by the Health Technology Assessment Council (68%). The reasons for this are difficult to ascertain but at first glance it could be suggested that it is a result of suboptimal targeting strategies. However, it should be noted that some people will be tested on more than one occasion and that one of the aims of the service is to provide repeat testing to persons who continue to inject drugs so that any newly acquired infections are picked up as soon as possible, minimising onward transmission. In order to better understand testing practices, data collection should be expanded so that 'repeat tests' can be identified.

(iv) Hospital inpatient settings

Hospital inpatient settings are likely to represent another place where hepatitis C testing may be occurring, however, it is unclear what level of activity is currently occurring.

6.4 How do we increase the uptake of testing?

In order to determine how best to increase the uptake of hepatitis C testing in Westminster, the published literature was reviewed to identify the most cost effective approaches to testing.

The cost effectiveness of different approaches to hepatitis C screening was the subject of two recent Health Technology Assessments (Health Protection Scotland, 2008). These assessments found that:

- Universal screening of hepatitis C in GUM clinics was not cost effective[1];
- Testing persons with a history of IDU in GUM clinics was cost effective;
- There was evidence to support offering hepatitis C testing to new prison inmates aged between 25 and 39 years old;
- Targeted screening of IDUs in general practice and drug/alcohol service settings were found to be the most cost effective approaches.

Table 6.3: Cost effectiveness of hepatitis C testing in different settings

Setting	Hepatitis C test offered to:	Hepatitis C prevalence	£/QALY *	Cost effective
GUM	All attenders	1.5%	£85,000	No
	Past IDUs	49%	£27,000	Yes
Prison	New inmates	16%	£20,000	Yes
General practice	IDUs	49%	£16,500	Yes
Drug/alcohol services	IDUs	68%	£17,500	Yes

Source: Health Protection Scotland

(i) General practice

The greatest opportunity for increasing the uptake of hepatitis C testing and reducing the proportion of hepatitis C infected individuals who are

[1] A approach to screening was considered cost effective if the quality adjusted life year gained was below the £30,000 threshold recommended by NICE

undiagnosed lies within general practice settings – this is one of the most cost effective settings for screening IDUs and also provides an opportunity to identify immigrants from high prevalence countries. Accordingly, new approaches are needed to improve current levels of testing, particularly for current and former IDUs. The introduction of a locally enhanced service should be considered to develop and improve services including hepatitis C testing.

Studies undertaken in Glasgow suggests that a targeted approach to hepatitis C testing in general practice settings (one which focuses on persons aged 30 and over who have ever injected drugs) is most effective. This approach generates the highest test uptake and yield of positivity among persons who have discontinued or are near to discontinuing injecting drugs (Anderson *et al*, 2008 and Health Protection Scotland, 2008).

Given the barriers to testing in general practice settings previously described (for example, poor venous access), innovative approaches may be needed to increase the uptake of testing in former and current IDUs. The shared care pilot which is currently being undertaken in Westminster, examining the feasibility of offering dried blood spot testing in general practice settings, should be monitored and any recommendations considered for wider implementation to increase the uptake of hepatitis C testing in general practice settings.

Data collection needs to be improved to better understand testing practices in Westminster and to monitor the impacts of any initiatives to improve the uptake of hepatitis C testing in general practice settings. Accordingly, NHS Westminster needs to work with local testing laboratories to agree and formalise data reporting arrangements.

In addition to providing financial incentives to improve and increase the uptake of hepatitis C testing in general practice settings (and ultimately reduce the proportion of hepatitis C infected individuals who are undiagnosed), it is likely that awareness raising activities and training for primary care stakeholders will be needed to improve knowledge and awareness of hepatitis C.

(ii) GUM

There is no evidence to support universal screening in GUM clinic settings. There is however, evidence that persons with a history of IDU should be offered hepatitis C testing and accordingly, all persons with a history of IDU presenting to GUM clinics should be offered a test for hepatitis C.

(iii) Drug/alcohol services

As is highlighted above, targeted testing of IDUs in drug/alcohol service settings is cost effective (if the prevalence is high). Current data suggests that the Westminster Blood Borne Virus Service is not cost effective, however, this is most likely associated with the way in which data is collected (see previous).

The latest Health Protection Agency report on hepatitis C recommends that the high rate of testing in those attending specialist services for drug users be maintained. Accordingly, the Westminster Blood Borne Virus Service should work to ensure current high levels of testing are maintained.

Because of the large proportion of current and former IDUs who have been infected with hepatitis C and remain undiagnosed, it is important to better understand testing activity in drug/alcohol services. Accordingly, monitoring information should be expanded to include:

- Reasons for refusing an hepatitis C test (for those who decline an hepatitis C test);
- Historical tests.
- Follow up actions, including onward referrals.

(iv) Prisoners

Although the testing of new prison inmates was found to be cost effective, this has not been further considered in this needs assessment as there are no prisons in the City of Westminster.

(v) Pharmacies

There are 13 pharmacies in Westminster that offer needle exchange and 28 substitute prescribing pharmacies. None of these pharmacies currently offers hepatitis C testing, however, in line with the Health Protection Agency's recommendation to make testing for hepatitis C widespread, the option of providing testing in such pharmacies should be explored.

(vi) Awareness raising

Finally, it is important to note that any approach to trying to reduce the proportion of persons with undiagnosed hepatitis C infection is likely to require some level of awareness raising around the issue of hepatitis C, to encourage individuals to come forward for testing.

7: Referral and attendance at specialist services

Key messages:

- **Referral pathways into specialist services are unclear and inconsistent;**
- **The number of persons with chronic hepatitis C in Westminster referred to specialist care is sub-optimal following a positive diagnosis;**
- **Once referred a significant proportion of individuals fail to attend any appointments in specialist settings suggesting that the current configuration of services does not meet their needs;**
- **Furthermore, once engaged with specialist services, the rates of attrition are high, with individuals found to be highly mobile and difficult to retain in follow up.**

7.1 Why is referral important?

The Hepatitis C Strategy for England (Department of Health, 2002) states that there should be clear pathways of referral to hepatitis C specialists for persons infected with hepatitis C. Referral to specialist care is important not only for initiation of antiviral therapy, but specialist clinics are often a source of information for patients and relatives, including health promotion, information around the prevention of onward transmission of the virus and advice around behaviours likely to speed up the progression of disease.

The Hepatitis C Action Plan for England recommends that there should be clear pathways into specialist care. Furthermore, pathways should include medical and social care needs, encompassing testing, referral and appropriate access to the whole range of treatment services (Department of Health, 2004).

7.2 Who should be referred?

There are no clear guidelines in England around who should be referred to specialist care, however, the SIGN guideline published in Scotland makes some clear recommendations that can be taken forward in Westminster. SIGN recommends that referral to specialist care should be considered for all patients with active hepatitis C (i.e. are hepatitis C PCR positive) and not restricted to potential candidates for antiviral therapy. Specifically SIGN recommends that:

- Individuals, including IDUs, diagnosed with chronic hepatitis C should be offered integrated multidisciplinary care as it can maximise their uptake of, and retention in, services;
- Patients with acute hepatitis C infection should be referred to specialist care immediately (as treatment given during the acute phase is more likely to be successful);
- Current IDUs infected with hepatitis C should not be excluded from consideration for hepatitis C clinical management, including antiviral therapy, on the basis of their injecting status;
- All patients should be referred to a setting that periodically assesses the state of infection and the progression of liver disease, to determine if further interventions or therapies are needed.

7.3 Referrals in Westminster

7.3.1 The referral pathway

There is currently no agreed and consistent referral pathway in place in Westminster; accordingly, in line with the Hepatitis C Strategy for England and Action Plan, formal referral arrangements need to be established.

There are a number of referral routes to specialist services in Westminster (figure 7.1) including through GPs, mental health services, homeless hostels and drug /alcohol services amongst others. Being able to access referral to specialist services in Westminster through numerous referral routes is encouraging, however, anecdotal evidence suggests that poor awareness of referral arrangements and the absence of a formal referral pathway (including criteria for referral) means that some persons do not get offered a referral to specialist care (even though they may potentially benefit from referral), and some people that are referred get bounced between a number of services before finally being referred to the appropriate specialist service.

As the majority of testing activity for hepatitis C in Westminster is occurring in drug/alcohol service settings (Westminster Blood-Borne Virus Service), it is useful to look at referral processes in place in drug/alcohol services in more detail (figure 7.2).

Figure 7.1: Referral pathways in Westminster

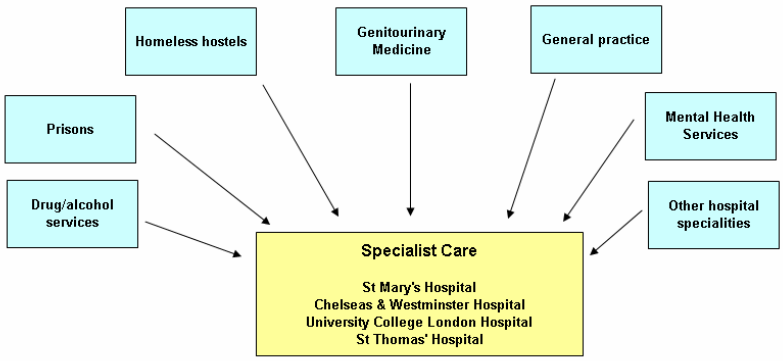
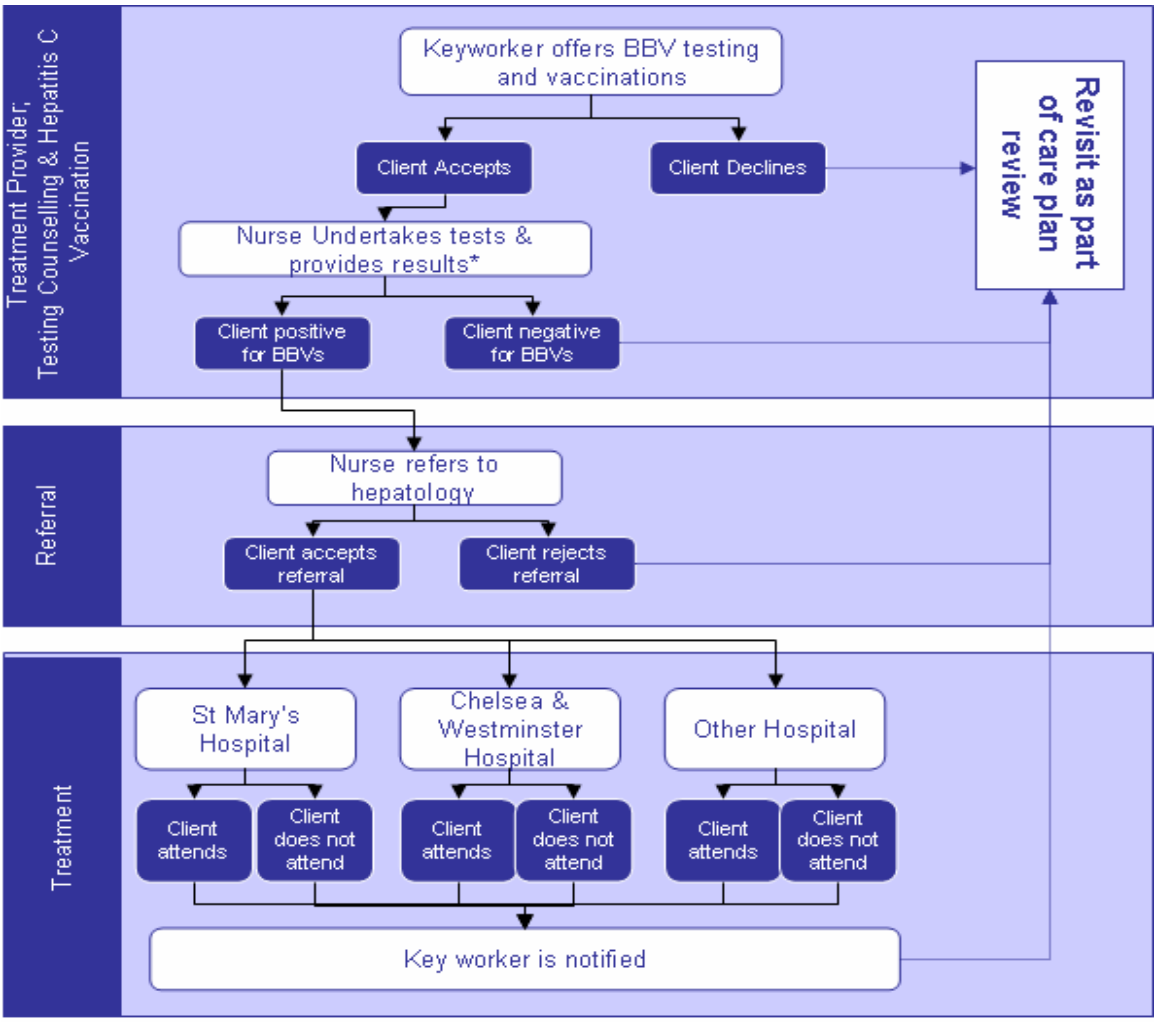


Figure 7.2: Patient pathway for hepatitis C positive individuals accessing drug/alcohol services in Westminster



* 4 WTC nurses provide backfill if needed

Increasing the points and methods of access to testing is in line with national recommendations, however, the expansion of testing services beyond conventional clinical settings also prevents challenges.

Although on paper, referral arrangements appear clear, anecdotal evidence suggests that the referral pathways are inadequate, routes of entry into specialist services are unclear and, accordingly few clients are accessing specialist services. Furthermore, the support structures in place around the diagnosis process are unclear, a gap which is further compounded where clients are not registered with a GP. Anecdotal evidence also suggests that this tends to stop some clients from engaging effectively with specialist services. Additionally a diagnosis of hepatitis C without a clear integrated route into specialist services can lead to distress for clients.

Stakeholders expressed some concerns regarding information governance and service quality issues and stressed that the following should be adhered to at all times:

- Clinical staff performing the diagnostic test should be sufficiently trained to provide pre and post test counselling and to deal with laboratory results;
- Clinical staff performing the diagnostic test should have an adequate understanding of hepatitis C treatment protocols, success rates and side effects as well as referral routes into specialist services;
- Clinical information should be handled by clinical staff only.

The Wilson-Junger criteria describe a number of key requirements that an effective targeted screening programme should meet, however, the current system in place is unlikely to fulfil these criteria for the reasons outlined above. Accordingly, the Wilson-Junger criteria should be considered when developing improved and formalised integrated referral pathways.

7.3.2 How many people have been referred to specialist services in Westminster?

Overall it is unclear what proportion of Westminster residents with chronic hepatitis C infection are referred on to specialist services, however, the stakeholder survey shows that there is wide variation between settings, with drug/alcohol services referring a large proportion of hepatitis C positive individuals and GPs referring a much smaller proportion.

Studies in Scotland and in Trent suggest that only around 51% of persons diagnosed with chronic hepatitis C infection are referred to specialist care (Williams, 2008) – this is low. Given these patterns of referral across the rest

of the UK, it is likely that the number of persons with chronic hepatitis C in Westminster referred to specialist care is sub-optimal and accordingly, the number of persons benefiting from referral to specialist services needs to be improved.

7.4 Barriers to referral

Semi-structured interviews with stakeholders were undertaken to better understand referral patterns in Westminster. A number of barriers to being successfully referred to secondary care (defined as patient referred and attended on at least one occasion) were identified. These included a number of patient and health professional factors:

- Patient choice;
- Clinical contraindication;
- Administrative problems booking and confirming appointment (see later section on non-attendance);
- Chaotic lifestyle of the patient;
- Patient believes they are unsuitable for treatment;
- Patient fears side effects of treatments.
- Lack of training of staff to deal with health issues;
- Poor awareness of who is appropriate for referral.

The Trent Study (Irving *et al*, 2006) also indentified a number of factors associated with non-referral upon a positive diagnosis. These included:

- < 45 years old;
- Male;
- Diagnosis made by prison;
- Diagnosis made by drug/alcohol services.

7.5 Attendance at specialist services

Not all patients who are referred to specialist care actually attend their appointment – healthcare professionals involved with managing hepatitis C infected persons describe great difficulties in getting and keeping individuals engaged with specialist services.

Non-attendance of patients has been described as one of the major barriers to antiviral therapy (Foster *et al*, 1997 and Hutchinson, 2007). If Westminster is to increase the number of patients benefiting from antiviral therapy, it must increase the number of patients progressing through the patient management pathway and being assessed for suitability for treatment.

Analysis of St Mary's cohort of hepatitis C infected patients suggests that approximately 18.6% of appointments are not attended (DNA), with persons from the UK and Asia having the highest rates of DNA.

A systematic review of the literature identified additional factors associated with non-attendance. These include:

- Being male;
- Younger age;
- Lower socio-economic status;
- Increased wait for appointment;
- Being unemployed;
- Increased severity of disease;
- Increased impairment of social functioning (Williams, 2008).

The high attrition rates in secondary care of individuals with hepatits C is well documented in the literature (Hutchinson, 2007), with hepatitis C patients found to be highly mobile and difficult to retain in follow up. Published studies suggest that approximately 50% of new patients default their initial appointment (Hutchinson, 2007). This suggests that hospital based care is not acceptable or easily accessible to many individuals.

Accordingly, innovative approaches and new models of care are needed to improve the accessibility of specialist services and encourage individuals to engage in the first instance and also to maintain follow up as required.

Community based approaches should be explored to engage hard to reach individuals; shared care across the primary-specialist interface and delivery of specialist services in the community (for example, through nurse led outreach) should be considered. Although current evidence does not support significant benefits of widespread shared care for chronic disease management (Smith *et al*, 2007), there is not published evidence regarding its benefits with regards to the management of hepatitis C infected persons – this approach could be piloted in Westminster.

Community outreach clinics for the management of persons with hepatitis C are beginning to be established across the UK. There use is supported by recent initiatives which have increased the number of patients attending specialist appointments and also the number of patients initiated on treatment (Catt, 2008).

The All Party Parliamentary Hepatology Group describes the benefits of devolving some care to community based settings including:

- Expanding the capacity available to manage individuals with hepatitis C;
- Giving individuals more choice and control regarding where they access services;
- Delivering care closer to home

It is important to make the distinction between providing care and ongoing management of hepatitis C in the community and also providing antiviral therapy in community settings. The All Party Parliamentary Hepatology Group primarily focuses on delivering antiviral therapy in the community, however, Westminster is not yet at a stage where this would be feasible and should first consider the development of community outreach clinics for persons requiring specialist care, but who are not undergoing antiviral treatment.

For those persons where hospital based care is acceptable, additional support and information may be needed to support patients through assessment and management of their hepatitis C. Such ways this may be provided include:

- Buddying schemes to accompany persons to appointments;
- Peer support;
- Adequate information at the point of referral;
- Friendly, non judgemental staff;
- Text reminders (for those persons with mobile phones);
- Improving patient transport services.

The Westminster Hepatitis C Needs Assessment Steering Group also suggested that administrative services could have a dedicated administrator to focus on managing the appointments of vulnerable groups.

It has also been suggested that appointment systems may have their own intrinsic deficiencies that make them inadequate for dealing with the specific

needs of persons with hepatitis C; accordingly, persons with complex needs may miss appointments for reasons outside of their control. For example, if persons are homeless (or frequently move around) they may not receive their appointment or letters via post. Additionally, anecdotal evidence suggests that a large number of appointments (for hepatitis C and other specialities individuals may be required to attend), may lead to appointment fatigue.

8: Treatment, care and support

Key messages:

- **There is a clinically and cost effective treatment for hepatitis C recommended by NICE;**
- **However, insufficient numbers of hepatitis C infected persons are benefiting from antiviral treatment;**
- **White, male IDUs are underrepresented amongst those patients attending specialist care and receiving antiviral therapy – the population most affected by hepatitis C;**
- **Many of the individuals infected with hepatitis C also have complex addiction, health and social care needs that pose a significant challenge to ongoing management and initiation of antiviral therapy.**

8.1: Treatment

A clinically and cost effective treatment is, however, available and is recommended by the National Institute for Health and Clinical Excellence (NICE, 2006), however, too few people have benefited from treatment.

8.1.1 Provision of antiviral treatment in Westminster

Insufficient numbers of hepatitis C infected persons are receiving antiviral treatment. Latest available data for the two main providers of specialist care for hepatitis C suggests that around 80 Westminster residents are initiated on treatment each year. Considered in the context of (i) annual numbers of hepatitis C related end stage liver disease having more than doubled in the last ten years in England (ii) low historical numbers of people receiving antiviral treatment (iii) 160 individuals diagnosed last year by the Westminster Blood Borne Virus Service alone, and (iv) a number of new infections occurring annually among IDUs, the number of individuals undergoing antiviral treatment is insufficient.

8.1.2 Who has undergone antiviral treatment in Westminster?

Analysis of the characteristics of individuals initiated on antiviral therapy at either St Mary's Hospital or Chelsea & Westminster Hospital (between 2007 and 2009) showed that:

- The mean age at treatment initiation was 54 years old;

- 47% of patients resided in the most deprived areas of Westminster;
- 33% of patients treated were from White Other ethnic groups, whilst only 20% were from White British ethnic groups

The latter observation was corroborated by the Steering Group who noted that patients seen in clinic and receiving treatment were not representative of patients who have hepatitis C (mainly White, male IDUs).

Data linkage studies show that approximately 8% of individuals who had new patient appointments between September and March 2009 have received antiviral therapy. For most patients there was a time lag between first appointment and initiation of therapy (average time lag of 7-12 months). This is unsurprising and most likely results from patients requiring monitoring, preparation and stabilisation prior to commencing treatment.

8.1.3 Barriers to treatment and ongoing management

Local stakeholders identified a number of barriers to commencing antiviral therapy, (many of which were also identified as barriers to regular attendance and follow up), as well as a number of drivers helping patients progress towards antiviral therapy (table 8.1).

Locally, homeless persons also identified a number of barriers to treatment. These included:

- Poor explanation of test results;
- Language barriers;
- Lack of understanding of the treatment pathway;
- Fear of side effects
- A belief that current injectors will not be treated;
- A belief that an asymptomatic state does not require treatment;
- Need for alcohol/drug detoxification plans to be linked to the hepatitis C management plan.

Table 8.1: Drivers and barriers to receiving antiviral treatment

Drivers for receiving antiviral treatment	Barriers to receiving antiviral treatment
Good, multidisciplinary working relationships	Booking system errors such as appointment sent out late, wrong address
Support systems such as buddy schemes, text service reminders	Booking system that does not take into account complex needs
Non-judgemental environment	Chaotic lifestyles
Patient is able to book their own appointment at a time convenient to them	Patient Choice
Patient is stable both clinically and socially	Currently injecting
New treatments being available through clinical trials	Psychiatric comorbidities
	Lack of multidisciplinary structures to support complex needs

Source: Stakeholder survey and Steering Group

8.2 Management and support

As described previously, hepatitis C is primarily associated with IDUs, a typically excluded and hard to reach population of patients with multiple health and social care needs. Therefore, it is unsurprising that a lack of integrated multidisciplinary care to support complex needs is seen as a significant barrier to treatment (and also progression through the patient management pathway).

Accordingly, there should be strong links between social care, addiction services, mental health services, primary care, dietetics, homeless hostels and specialist services, as it is not possible to manage and treat individuals without considering individual's wider health, social care and drug/alcohol needs.

It is also important to recognise the role of the voluntary sector in providing information and support to persons with hepatitis C.

In some areas Managed Clinical Networks involving health, social care and voluntary sector input have been established to provide integrated

multidisciplinary care. Whilst this may not be the chosen way forward for Westminster, improved support, communication and clear referral routes between services are needed at the very least.

In addition to the population requiring support through the treatment process, it is important to consider those persons who are not treated (either because they choose not to be or because of contraindications) and those persons who have been treated but who have not responded. There are no clear guidelines around effective practice for monitoring and advising persons who are not candidates for treatment or have received unsuccessful treatment, however, the SIGN Guideline (2006) suggests that the following represent good practice:

- Patients should be encouraged to continue attending follow up clinics for review in order to monitor their condition and discuss new therapies as they emerge;
- Patients should have access to counselling and specialist nurse services to provide support on lifestyle issues relating to hepatitis C.

Clear guidelines are needed in Westminster around the best ways to manage and support such populations. Currently it is unclear how many persons have been unsuccessfully treated or are unsuitable for treatment and, accordingly, such information should be routinely collected.

9: What does this mean for Westminster?

Key Messages:

- **Widespread access to testing for high risk groups will reduce the proportion of hepatitis C infected individuals who are undiagnosed;**
- **Effective support structures and referrals protocols will increase the number of hepatitis C infected individuals accessing multidisciplinary care and support;**
- **Accessible and acceptable specialist services and better treatment pathways will increase the number of hepatitis C infected persons who undergo antiviral treatment and clear their infection and thus reduce the numbers of infected persons who develop severe hepatitis C related liver disease;**
- **Pathways and services must be tailored to be accessible and acceptable to those in highest need in Westminster;**
- **Action across the entire patient pathway must be coordinated to have the biggest impact.**

9.1 The Case for Change

Although large numbers of people are thought to be chronically infected with hepatitis C, many infected individuals remain undiagnosed. Those persons who are not aware of their infection do not realise what steps they should be taking to reduce the progression of hepatitis C and prevent onward spread of the virus. Furthermore, only a small proportion of those persons who could benefit from treatment are receiving treatment.

Accordingly, there are five key issues that Westminster must address if it is to tackle the hepatitis C epidemic and achieve good health outcomes for persons infected with hepatitis C:

- There should be widespread access to testing for high risk groups and the testing methods used should be acceptable to high risk groups, for example, oral fluid and dried blood spot testing for persons with poor venous access;

- There should be effective support structures in place to support the diagnosis and referral process, particularly for those persons not registered with a GP;
- There should be appropriate and effective referrals to specialist services with clear routes of entry into specialist services;
- There should be accessible and acceptable specialist services, particularly for the IDU population;
- There should be better pathways for treatment and support for the multidisciplinary needs of persons infected with hepatitis C.

Understanding the local context of hepatitis C in Westminster is essential in addressing the key issues outlined above. The differing needs of (i) the large number of injecting drug users (ii) the large homeless population and (iii) the large immigrant population in Westminster should be considered when developing pathways and services if they are to be accessible and acceptable to those in greatest need.

Action is needed across the entire patient pathway. Improvements of one element will have little impact without other upstream or downstream changes; for example, increased testing and diagnosis could potentially cause more stress to an individual if appropriate referral pathways are not in place and acute providers do not have sufficient capacity to treat increasing numbers of individuals diagnosed. Likewise, increasing the capacity of acute providers to treat patients and improve multidisciplinary care to effectively support individuals through treatment will have minimal impact if patients are not being supported to access specialist care.

Accordingly, a coordinated approach to change is needed, one that plans appropriately for the likely impacts of the implementation of recommendations. The retention of the Hepatitis C Needs Assessment Steering Group is, therefore, essential to maintain links between services and oversee the actions that arise as a result of this needs assessment.

9.2 The impact of change

9.2.1 Workforce

This needs assessment has highlighted many areas of action around the testing and care of persons chronically infected with hepatitis C and, accordingly has made recommendations about changes in the way in which services should be delivered. If successful, the result of such change will see an increasingly number of people infected with hepatitis C identified requiring management, support and treatment. This is likely not only to affect

drug/alcohol services and GPs, but also specialist services as numbers referred increase. This will impact mainly on providers in acute hospital settings, particularly in terms of capacity. Accordingly, NHS Westminster should work with local providers to monitor the capacity of local service providers to manage persons with hepatitis C to ensure adequate and high quality service provision.

Specialist workforce models have been developed for the management of persons with hepatitis C in specialist services (it is estimated that one WTE nurse specialist is needed to manage 300 hepatitis C patients a year and one WTE consultant for 900 patients). These models should be considered when workforce planning.

9.2.2 Cost

Increasing the number of people in Westminster undergoing antiviral therapy will not only have implications for the local workforce, but will also have cost implications. The average cost of treating a person with hepatitis C is £6,246 for 24 weeks of treatment and £12,714 for 48 weeks of treatment (length of treatment will depend on the strain of virus). This however, is a spend to save as increasing the uptake of antiviral therapy will prevent hospital admissions associated with decompensated liver disease and liver transplants as a result of hepatocellular carcinoma and liver failure.

9.3 Local indicators of success

It is essential that any actions to improve the diagnosis, treatment and care of persons with hepatitis C in Westminster as a result of the recommendations of this needs assessment are appropriately monitored. Not only will this provide a better understanding of the state of the hepatitis C epidemic in Westminster, but it will enable effective evaluation of current services and pathways.

Given the main issues highlighted in this needs assessment, key local indicators of success will include:

- The number of people diagnosed with hepatitis C (chronic and acute);
- Proportion of people diagnosed with chronic hepatitis C who enter specialist care
- The number of people with chronic hepatitis C in specialist care who are eligible for antiviral therapy;
- The number of people with chronic hepatitis C who receive antiviral therapy

- The proportion of people with chronic hepatitis C who complete their course of antiviral therapy and for those that do not complete reasons for non-completion
- The proportion of people who receive antiviral therapy who achieve a sustained viral response

9.4 Information gaps

Information systems at present are not optimal for the adequate monitoring of the hepatitis C epidemic in Westminster. The Health Protection Agency recommends that all primary care organisations should have mechanisms in place to obtain reliable data on the number of patients referred, seen and treated for hepatitis C (Health Protection Agency, 2009). Accordingly, Westminster needs to work with local acute providers to establish data sharing arrangements for this data.

In addition to establishing data sharing arrangements with acute providers, data sharing arrangements should be established with local laboratories so that the number of people being diagnosed hepatitis C positive can be monitored and the characteristics of those persons diagnosed better understood.

9.5 Further work

This needs assessment represents the first comprehensive review of the patient management pathway of persons with hepatitis C infection in Westminster. However, it is important that this initial work is built upon in the future as services develop. Areas of further work include a more detailed analysis of persons attending specialist services, including examining sustained viral response rates and current stage of disease of infected individuals as well as looking at length of duration of infection. This will help to better understand the current state of the hepatitis C epidemic in Westminster.

10: Recommendations

Improving hepatitis C services in Westminster and ultimately improving access to treatment requires improvements along the entire patient pathway including: testing practices, referral and appointment making, communication, as well as sustained network and capacity development. It also requires tailoring services to the needs of specific groups such as the homeless.

Identification

Ex-IDUs and other risk groups not in contact with substance misuse services require improved detection and referral through GP practices.

- Implement an awareness raising campaign (leaflets/posters, etc) that is non-stigmatising and does not associate hepatitis C directly with intravenous drug use but with a variety of routes of transmission as well as past drug use (including non-injecting drug use such as cocaine snorting);
- Include promotional materials on other BBVs to increase understanding around other health risks associated with hepatitis C;
- Incentivise GPs to enhance targeted screening in general practice settings;
- Support GPs, DAAT and other community stakeholders to work towards developing multidisciplinary teams to manage hepatitis C patients and work with hospital specialists to develop outreach clinics hosted in GP practices.

Ex-IDUs on substitute treatment and current injecting drug users require support from key workers and other trained staff working in drug projects or homelessness services to help clients understand the importance of safer injecting and their behaviours and how they are linked to blood borne viruses.

- Routine monitoring of demographic and epidemiological data from BBV testing locations to better identify any areas of unmet need;

- Incorporate the workload of buddy systems to provide support during attendance of appointments in workforce planning.

Testing and diagnosis

- The BBV service should ensure a suitable governance framework is in place before further expanding its testing facilities. In order for testing to be cost-effective structures should be in place to adequately manage the additional number of new cases detected especially as they have complex needs spanning several services;
- Improve cost-effectiveness of targeted screening by encouraging closer work between the BBV service and general practices, for example by supporting services within general practice. Targeting could be made more efficient through closer monitoring of risk factors and tailoring of the screening programme towards those at higher risk;
- Staff carrying out testing should be trained in pre- and post-test counselling and be able to explain the referral route and implications of treatment (with the aid of written material and leaflets). They should also be able to support the patient in preparing for treatment by providing information on the management of substance misuse, psychiatric co-morbidities, psychological issues and how to access NHS services to address any health problems. This is best done in collaboration with a GP;
- Support services such as counselling are needed to help individuals come to terms with their diagnosis and understand the likely future impact of their diagnosis – these services should be available within current testing settings.

Referral Pathways

- There should be a clear and consistent referral pathway into specialist care developed and implemented across Westminster;

- Increase GP registrations and strengthen links between DAAT services and shared care GPs specialised in the provision of service to the vulnerable groups
- Work with specialist centres through specialist nurses in developing training opportunities and referral links
- Develop care plan protocols for DAAT clients. These can be used as a basis for comprehensive good quality referrals to GPs and specialists
- Improve appointment attendance by continuing to implement buddy systems;
- Strengthen communication lines through regular multidisciplinary meetings between stakeholders along the referral pathway
- Work through practice based commissioning groups to explore and deliver new models of care with an outreach component. This should involve DAAT services as well as hostels. Consider incorporating these plans in broader plans for polyclinics;
- Consult users and patient advocacy groups in service development

Treatment care and support

- Ongoing support needs to be built into care management plans, focusing not only on BBV treatment but harm reduction and other underlying issues identified at first stage of access;
- Consistent and easy to read information should be available to all persons tested for BBVs;
- Training is needed for third sector staff regarding information around BBVs and what a positive diagnosis means, harm reduction and treatment pathways;
- Integrated working and information sharing between DAAT services and health providers is needed to coordinate the care of individuals with BBVs and manage their co-morbidities;
- Implement rapid access to specialist assessment through improved appointment systems. This may involve specialised commissioning of administrative services in hospitals and may include designation of

specialised administrative staff to deal with referrals for vulnerable hepatitis C patients, as this may involve extra tasks such as checking of contact details, chasing up of patients who do not follow up on the appointment making and sending reminders in writing of through use of mobile phone technology if patient consent has been obtained;

- There should be strong links between social care, addiction services, mental health services, primary care, dietetics, homeless hostels and specialist services;
- Clear guidelines are needed in Westminster around the best ways to manage and support those persons who are not treated (either because they choose not to be or because of contraindications) and those persons who have been treated but who have not responded.

Overall service

- Retain the steering group as a basis for a Westminster hepatitis C network
- Within the Westminster hepatitis C network begin working towards:
    - Developing a Westminster wide protocol and template for referral of cases from the community;
    - Work to address referral issues or 'plug holes' in referral pathways. These should include a 'referral triangle' of 1) DAAT/drug projects/homeless hostels with clinical staff, 2) GPs and 3) staff from treating centres in hospitals;
    - Continue strengthening the hepatitis C care pathway and exploring the most cost-effective manner of engaging and treating vulnerable clients;
    - Explore how to increase the detection rate for targeted screening in DAAT services and compare this with testing strategies in GP practices;
- Offer training support on a regular basis by specialist hospital staff to staff in hostels/drug projects;

- Work with the Royal College of GPs to design and provide training through an accredited module (c.f. Substance Misuse Management module which has been deemed very popular with GPs) to improve awareness and understanding of hepatitis C management and treatment;
- Link obesity and alcohol abuse services to hepatology services as obesity and alcohol abuse may need to be managed prior or alongside HCV treatment. Similarly, link in with HIV and hepatitis B services as there is significant overlap;
- Strengthen information and monitoring systems both in primary care and in specialist settings as well as in DAAT services to include information on the following: age, sex, postcode, ethnicity, homeless status, IDU/ex-IDU, mental health diagnosis, co-infection; likely route of transmission; duration of injection and age at first use; estimated date of infection; clinically relevant outcomes such as sustained viral response if laboratory data is available, complications, treatment regimen, reasons for discontinuing treatment. At the pathway level, the number of referrals made and the number of referred patients treated should be recorded;
- Develop data recording mechanisms within the new substance misuse service to identify repeat patients;
- The BBV service must ensure sensitive clinical information is handled appropriately and systems are in place to notify the proper Public Health Officer as required by law (c.f. Public Health act);
- Set Westminster wide targets e.g. for improved detection rates but also for referral and treatment to match those of other regions like Scotland.

11: References

All Party Parliamentary Hepatology Group. Discussion paper on the best location for treatment of hepatitis C [Online] Available at: http://www.hepctrust.org.uk/OneStopCMS/Core/CrawlerResourceServer.aspx?resource=4A2ED985-D2F7-4B8B-9798-1E9136B4DAD9&mode=link&guid=635a5c77d3864352a780dc3496b522a0 [accessed 21/04/2010]

Anderson EA, Mandeville R, Hutchinson SJ, Cameron SO, Mills PR, Fox R, Ahmed S, Taylor A, Spence E & Goldberg DJ (2008). Evaluation of a general practice based hepatitis C virus screening intervention. *Scottish Medical Journal*. In press

Catt J (2008). Community Outreach Service [Online] http://www.nhs.uk/livewell/hepatitisc/pages/bestpractice.aspx [accessed 09/03/2010]

Choo QL< Kuo G, Weiner AJ, Overby LR, Bradley DW & Houghton M (1989). Isolation of cDNA clone derived from a blood-borne non-A, non-B viral hepatitis genome. *Science* 244 359-362.

Department of Health (2002). Hepatitis C Strategy for England. London. Department of Health. Available at: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4009316

Department of Health (2004). Hepatitis C Action Plan for England. London. Department of Health. Available at: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4009316

Foster GR, Goldin RD, Main J, Murray-Lyon I, Hargreaves S & Thomas HC (1997). Management of chronic hepatitis C: clinical audit of biopsy based management algorithm. *British Medical Journal* 315 453-458.

Goldberg D & Anderson E (2004). Hepatitis C: who is at risk and how do we identify them? *Journal of Viral Hepatitis* 11 (Suppl 1) 12-18.

Health Protection Agency (2008). Hepatitis C in the UK: 2008 report. London. Health Protection Agency. Available at: http://www.hpa.org.uk/web/HPAweb&HPAwebStandard/HPAweb_C/1228810569993

Health Protection Agency (2009).Hepatitis C in the UK: 2009 report. London. Health Protection Agency. Available at: http://www.hpa.org.uk/web/HPAweb&HPAwebStandard/HPAweb_C/1259152221168

Health Protection Scotland (2008). Needs assessment of hepatitis C testing, treatment, care and support services in Scotland: overview report. Glasgow. Health Protection Scotland

Hutchinson SJ, McIntyre PG, Molyneaux P, Cameron S, Burns S, Taylor A & Anderson E (2006). Hepatitis C virus infection in Scotland: epidemiological review and public health challenges. *Scottish Medical Journal* 51 (2) 8-15

Hutchinson SJ (2007). 'Needs assessment of hepatitis C testing, treatment, care and support services in Scotland' presented at the Hepatitis C Action Plan for Scotland:Stakeholder Conference. Edinburgh 12th October 2007.

Irving WL, Smith S, Cater R, Pugh S, Neal KR, Coupland CA et al (2006). Clinical pathways for patients with newly diagnosed hepatitis C – what actually happens. *Journal of Viral Hepatitis* 4 264-271

Makris M, Garson JA, Ring CJ, Tuke TW, Tedder RS & Preston FE (1993). Hepatitis C viral RNA in clotting factor concentrates and the development of hepatitis in recipients. *Blood* 81 1898-1902

National Institute for Health and Clinical Excellence (2006). Peginterferon alpha and ribavirin for the treatment of mild chronic hepatitis. London. National Institute for Health and Clinical Excellence. Available at: http://www.nice.org.uk/nicemedia/pdf/TA106guidance.pdf

Scottish Intercollegiate Guidelines Network (2006). *SIGN Guideline 92, Management of Hepatitis C: A national clinical guideline*. Edinburgh. Quality Improvement Scotland. Available at: http://www.sign.ac.uk/pdf/sign92.pdf

Seef LB (2002). Natural history of chronic hepatitis C. *Hepatology* 36 S35-S46.

Scottish Government (2008). Hepatitis C Action Plan for Scotland Phase II: May 2008 to March 2011. Edinburgh. Scottish Government. Available at: http://www.scotland.gov.uk/publications/2008/05/13103055/17

Williams T (2006). Management of Hepatitis C at a tertiary referral centre (unpublished)

World Health Organisation (2006). Innovative vaccine research, viral cancer and hepatitis C. [Online]. Available at:

http://www.who.int/vaccine_research/disease/viral_cancers/en/index2.html
[accessed 02/02/2008]

Appendix A: Determining the prevalence of hepatitis C in Westminster

Population category	Lower estimate	Higher estimate
Estimated number of IDUs (Home Office)	890	-
Estimated number of IDUs adjusted	1,888	-
Estimated number of IDUs from the National Drug Treatment Monitoring System	-	522
Estimated number of IDUs from the National Drug Treatment Monitoring System – adjusted for IDUs not in contact with the service	-	3,654
Prevalence of hepatitis C in IDU population	55%	55%
Estimated number of IDUs infected with hepatitis C	**1,039**	**2,010**
Estimated number of previous IDUs	4,238	4,238
Prevalence of hepatitis C in previous IDUs	29%	29%
Estimated number of previous IDUs infected with hepatitis C	**1,232**	**1,232**
Estimated number of non- IDUs	176,214	176,214
Prevalence of hepatitis C in non-IDUs	0.12%	0.12%
Estimated number of non-IDUs infected with hepatitis C	**211**	**211**
Estimated number of people born in high prevalence countries	24,000	24,000
Prevalence of hepatitis C in high prevalence areas	1%	1%
Estimated number of persons from high prevalence areas infected with hepatitis C	**240**	**240**
Total number of people ever infected with hepatitis C	**2,647**	**3,618**
Total number of people chronically infected with hepatitis C	**2,118**	**2,894**

Adjustment and assumptions that were made include:

- Updating the Westminster population estimates using the latest Office of National Statistics (2008) mid year estimates;
- For the lower estimate, the estimated number of IDUs was based on an adjusted Home Office estimate from 2004/5. For the higher estimate was based on the National Treatment Agency estimates, applying assumptions about the number of IDUs not in contact with services from the Glasgow model;
- Including all migrants in the calculation for cases coming from high prevalence countries, assuming that most migrants will come from countries where the prevalence is higher than in the UK. This included 24,000 migrants;
- 20% of all new antibody positive infections clear spontaneously and do not require further medical follow up.

Appendix B: Wilson- Junger Criteria

The Wilson-Jungner criteria for appraising the validity of a screening programme

1. The condition being screened for should be an important health problem
2. The natural history of the condition should be well understood
3. There should be a detectable early stage
4. Treatment at an early stage should be of more benefit than at a later stage
5. A suitable test should be devised for the early stage
6. The test should be acceptable
7. Intervals for repeating the test should be determined
8. Adequate health service provision should be made for the extra clinical workload resulting from screening
9. The risks, both physical and psychological, should be less than the benefits
10. The costs should be balanced against the benefits

World Health Organisation 1968

Criteria for appraising the viability, effectiveness and appropriateness of a screening programme 2003

The condition

1. The condition should be an important health problem.
2. The epidemiology and natural history of the condition, including development from latent to declared disease, should be adequately understood and there should be a detectable risk factor, disease marker, latent period or early symptomatic stage.
3. All the cost-effective primary prevention interventions should have been implemented as far as practicable.
4. If the carriers of a mutation are identified as a result of screening the natural history of people with this status should be understood, including the psychological implications.

The test

5. There should be a simple, safe, precise and validated screening test.
6. The distribution of test values in the target population should be known and a suitable cut-off level defined and agreed.
7. The test should be acceptable to the population.

8. There should be an agreed policy on the further diagnostic investigation of individuals with a positive test result and on the choices available to those individuals.

9. If the test is for mutations the criteria used to select the subset of mutations to be covered by screening, if all possible mutations are not being tested for, should be clearly set out.

The treatment

10. There should be an effective treatment or intervention for patients identified through early detection, with evidence of early treatment leading to better outcomes than late treatment.

11. There should be agreed evidence-based policies covering which individuals should be offered treatment and the appropriate treatment to be offered.

12. Clinical management of the condition and patient outcomes should be optimised in all healthcare providers prior to participation in a screening programme.

The screening programme

13. There should be evidence from high-quality randomised controlled trials that the screening programme is effective in reducing mortality or morbidity. Where screening is aimed solely at providing information to allow the person being screened to make an 'informed choice' (for example, Down's syndrome and cystic fibrosis carrier screening), there must be evidence from high-quality trials that the test accurately measures risk. The information that is provided about the test and its outcome must be of value and readily understood by the individual being screened.

14. There should be evidence that the complete screening programme (test, diagnostic procedures, treatment/intervention) is clinically, socially and ethically acceptable to health professionals and the public.

15. The benefit from the screening programme should outweigh the physical and psychological harm (caused by the test, diagnostic procedures and treatment).

16. The opportunity cost of the screening programme (including testing, diagnosis and treatment, administration, training and quality assurance) should be economically balanced in relation to expenditure on medical care as a whole (ie value for money).

17. There should be a plan for managing and monitoring the screening programme and an agreed set of quality assurance standards.

18. Adequate staffing and facilities for testing, diagnosis, treatment, and programme management should be available prior to the commencement of the screening programme.

19. All other options for managing the condition should have been considered (for example, improving treatment and providing other services), to ensure that no more cost-effective intervention could be introduced or current interventions increased within the resources available.

20. Evidence-based information, explaining the consequences of testing, investigation, and treatment, should be made available to potential participants to assist them in making an informed choice.

21. Public pressure for widening the eligibility criteria for reducing the screening interval, and for increasing the sensitivity of the testing process, should be anticipated. Decisions about these parameters should be scientifically justifiable to the public.

22. If screening is for a mutation, the programme should be acceptable to people identified as carriers and to other family members.