

**EPIDEMIOLOGICAL HEALTH NEEDS ASSESSMENT  
FOR HEPATITIS B & C IN GLOUCESTERSHIRE**

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<b>1. Summary: Hepatitis B &amp; C in Gloucestershire</b>	
<b>Purpose</b>	This is a report for Gloucestershire County Council and the Gloucestershire Health Protection Assurance Group.
<b>Aims &amp; Objectives</b>	To ensure the local health community can base the commissioning and provision of services on local need by describing and quantifying the people with or at risk of hepatitis B and/or C in Gloucestershire.
<b>Method</b>	A review of available intelligence about hepatitis B and C in Gloucestershire
<b>Findings</b>	<p><u>Hepatitis B</u></p> <ol style="list-style-type: none"> <li>1. We can crudely estimate that in Gloucestershire there are: <ul style="list-style-type: none"> <li>• 6-7 new acute cases reported to PHE pa</li> <li>• 44-45 new acute cases pa, diagnosed and undiagnosed</li> <li>• 1,806 people living with chronic hepatitis</li> <li>• 242 people had a positive test for hepatitis B via GHNFT laboratory in 2012-13, i.e. an average of 121 pa, including some Worcestershire patients</li> <li>• 23-55 laboratory reports to PHE pa, 2005-12, of acute and chronic infections</li> </ul> </li> <li>2. Hepatology service accepts 27-55 referrals pa, 2009-2013/14.</li> <li>3. 1.7% (124) pregnant women declined hepatitis B screening in 2012, compared to 0.9% in South West (range 0.1% to 2.1%). We do not know if the women who declined are the ones most likely to have or be at risk of hepatitis B. Antenatal screening positivity appears to be 0.2%-0.3%. This equates to c15-17 women p.a., some of whom have already been diagnosed in earlier pregnancies or during other tests. This is broadly typical for the South West.</li> <li>4. Infant immunisation: broadly compliant with the Green Book, with one or two babies not receiving the full schedule. Majority of babies receive their 2<sup>nd</sup> and subsequent immunisations late. The pathway is complex. It is not yet systematic or robust.</li> <li>5. People who inject drugs: The immunisation completion rate of eligible people in treatment services is about 25% (provisional 2013/14 figures). There are data quality issues. Our rate is lower than the England rate; we do not have the statistical information to know if the difference is statistically significant.</li> <li>6. In the UK, 95% new chronic hepatitis B cases are in people who were born with the infection abroad. Local hepatology services have encouraged GP practices to screen Chinese patients in particular. There is no national screening programme as the cost-effectiveness and feasibility are unclear. We do not know if this is replicated locally or whether primary care do indeed screen Chinese or other patients.</li> </ol> <p><u>Hepatitis C</u></p> <ol style="list-style-type: none"> <li>7. We can crudely estimate that in Gloucestershire there are: <ul style="list-style-type: none"> <li>• 1,385 15-59 year olds might be living with chronic hepatitis C, if the England prevalence applies. The PHE estimate for Gloucestershire, via their commissioning tool, is 1,529, all ages.</li> <li>• 135-357 15-64 year old who inject opiates &amp;/or crack cocaine and who might have hepatitis C.</li> </ul> </li> <li>8. 78% of eligible drug treatment service users in 2013/14 had been tested for hepatitis C testing compared to 73% across England in 2012/13 as a whole. We had achieved 93% in 2012/13 so although we are likely to be performing better than England, we appear to have had a large deterioration.</li> <li>9. The local genotype profile is the same as that nationally, although the genotype of 46% of local patients was unavailable.</li> </ol>

	<p>10. The drop-out rate from treatment is low, reportedly 3%-7%. 72% of patients completing treatment had a sustained virological response.</p> <p>11. The local acute Trust does not have a fibroscanner so has to send patients out of area to comply with NICE guidance. Furthermore, a trial of expanded access to Sofosbuvir is due to start in Oxford and Birmingham. We do not yet know if or how our patients will be able to access the trial.</p>
<p><b>Recommendations</b></p>	<p><i>Local Health system</i></p> <ol style="list-style-type: none"> <li>1. Agree organisational roles and responsibilities and overarching governance arrangements and share this with staff.</li> <li>2. Agree thresholds for escalating events or poor or declining performance, particularly for hepatitis B antenatal screening and immunisation and the testing and immunisation of injecting drug users and other risk groups.</li> <li>3. Consider the feasibility of NICE recommendations (1) for monitoring via: Health needs assessment, health equity audit and clinical audits</li> <li>4. Agree information sharing arrangements.</li> <li>5. Review NICE hepatitis B quality standards published in July 2014.</li> <li>6. Agree priority of occupational hepatitis B immunisation and if any evidence is required.</li> </ol> <p><i>Providers</i></p> <ol style="list-style-type: none"> <li>1. Set up multiagency care pathway group or groups to resolve any operational issues, improve services and co-ordinate clinical audit and other monitoring.</li> <li>2. Agree multiagency clinical care pathways for hepatitis B and hepatitis C.</li> <li>3. Regular programme of clinical audit of the pathways and services against NICE guidance. Reports and action plans to be shared with Commissioners and Public Health.</li> </ol> <p><i>Commissioners</i></p> <ol style="list-style-type: none"> <li>1. Ensure sufficient volume of care has been commissioned.</li> <li>2. Ensure providers have clear, multiagency clinical pathways for all patient groups affected by hepatitis B &amp;/or C.</li> <li>3. Ensure the timeliness of hepatitis B infant immunisations improves and seek assurance of coverage of foster carers offering emergency placements.</li> <li>4. Update 2015/16 service specifications and manage performance of hepatitis B and C content in related services e.g. sexual health, HIV, substance misuse, maternity, paediatrics, medicine, and other contracts.</li> <li>5. Work with primary care providers in particular to ensure people at risk are being screened and tested as per NICE guidance (1).</li> <li>6. To specify that all providers should ensure their occupational health service achieves and reports high levels of hepatitis B immunisation and hepatitis C testing, at least be for exposure-prone staff.</li> </ol> <p><i>Public Health England</i></p> <ol style="list-style-type: none"> <li>1. <i>Knowledge and Intelligence or Field Epidemiology Teams</i> to provide annual comparative surveillance data on hepatitis B and C.</li> <li>2. <i>Health Protection team</i> to support local providers to contain cases of acute hepatitis B.</li> <li>3. <i>Screening and Immunisation team</i> to investigate hepatitis B antenatal screening with local providers to understand whether the women declining screening are also those most at risk of hepatitis B, and, to improve screening rates to at least the regional average.</li> </ol> <p><i>Public Health, Gloucestershire County Council</i></p> <ol style="list-style-type: none"> <li>1. District councils to provide annual statement of assurance about environmental risks. Real-time communication welcomed too.</li> <li>2. To consider hepatitis B and C as part of the Joint Strategic Needs Assessment. Discuss with PHE to minimise duplication.</li> <li>3. Keep aware of any progress nationally on information sharing of incidence, prevalence, positivity, hospital activity and mortality data.</li> </ol>
<p><b>Next steps</b></p>	<p>The Health Protection Assurance Group will consider this report and agree next steps including feedback to contributors.</p>

## 2. Introduction

### 2.1 This Review

This review presents the health intelligence we have about Hepatitis B and C in Gloucestershire and was compiled by the public health team in Gloucestershire County Council. Thank you to everyone who helped.

Hepatitis B and C infections are serious, not uncommon, preventable and treatable. Thus it is sensible for the local health system to review local trends and ensure any issues are identified and addressed.

There is no single, comprehensive regular report about the incidence, prevalence and outcomes for hepatitis B and hepatitis C in localities across the UK. Instead we have to consider data from a number of different sources, each with different strengths and weaknesses.

### 2.2 Hepatitis B & C

Hepatitis B, C and HIV are the most common blood-borne viruses (BBVs) in the UK, i.e. they are transmitted from person to person through blood and, more rarely, in other bodily fluids. HIV is considered in our sexual health programme and is not included in this review.

Hepatitis is inflammation of the liver. It has a number of causes including excessive alcohol, hepatitis B and hepatitis C. Some people have acute infections which clear quickly without any permanent liver damage. Other people have chronic infections which can last for many years. Chronic infections can cause scarring of the liver (cirrhosis) which can develop into liver failure or liver cancer and which can be fatal. People with untreated hepatitis C can also experience fatigue, depression and cognitive issues too.

In the UK only a small proportion of people who are infected are diagnosed and treated, for two main reasons:

- Infected individuals are often symptom-free particularly during acute infections or for the first months or years of chronic infections. So only some of those infected seek help from services.
- Those at greatest risk of infection tend to have less or more complicated contact with health services than the general population, such as people who inject drugs, people new to the UK, and men who have sex with men.

People with an untreated infection are at high risk of developing further liver disease and can also pass the infection to others. Many broader health protection measures can help to protect people from both hepatitis B and hepatitis C infections, including condom use, needles exchanges, antenatal screening, testing and treatment. These same measures help to reduce the spread of HIV too.

The National Institute of Health and Clinical Excellence (NICE) has published a number of guidelines relevant to hepatitis B and C. Some focus entirely on these infections, other guidelines apply to populations or risks related to blood-borne viruses more generally. NICE guidance is listed in **Appendix 1**. A key aim is to ensure prompt diagnosis and treatment.

There is no national screening programme for hepatitis B or C. The UK National Screening Group reviewed the evidence for a screening programme of people from ethnic groups with a higher prevalence of hepatitis B and C. They reported in 2011 and concluded that a programme was not feasible and that too little is known to be able to estimate the cost-effectiveness of it (2).

More detailed descriptions of the natural history, diagnostics and treatments for these viruses are available on-line<sup>1</sup> and are not replicated in this report except where relevant.

### **3 Report purpose and content**

#### **3.1 Aim & objectives**

This report is an epidemiological health needs assessment. It uses the information available to describe and quantify the people with or at risk of hepatitis B and/or C in Gloucestershire. To ensure the local health community can base the commissioning and provision of services on local need.

As such, this report will need to be considered alongside a range of other information, not least feedback from at-risk groups, patients and a wider range of staff about local services and resource information.

In gathering the epidemiological information, some other issues were highlighted by staff. These are noted in this report for information.

**Appendix 2** provides an overview about health needs assessment in general.

#### **3.2 Method**

This is an initial, pragmatic review of intelligence which is either already published or has otherwise been fairly straightforward to collate. All data is county-wide. District or neighbourhood-level analysis is mostly unavailable and the numbers would probably be too small to be meaningful.

The report attempts to be comprehensive, but as the infections affect many different populations, services and interventions, there will inevitably be some gaps. We would encourage further work accordingly. The need for further intelligence will be considered as part of the recommendations.

##### Key sources of information

This report mainly uses data from the following sources:

- a) Hepatitis B and C are notifiable infections. Laboratories and clinicians have to notify Public Health England's Health Protection Team of each new case. Public Health England's Field Epidemiology Service can access "CoSurv" laboratory data and report it on request to local public health teams.
- b) The sentinel surveillance study of hepatitis testing in England began in 2002, and provides further information on trends in testing, risk exposures and symptoms (3). It supplements the routine surveillance of hepatitis B and C with more detailed information from 27 laboratories from across the country. Results are available from the HPA website. Data is reported quarterly for England. The latest available data is for April to June 2011. Bristol is the only laboratory from the South West to participate and data is not available at local level.
- c) Public Health England publishes the Public Health Outcomes Framework (4), including hepatitis B immunisation of infants and under-75 mortality from liver disease. There are no specific measures for the incidence, prevalence or mortality from hepatitis B or

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<sup>1</sup> Information is available from Public Health England, via the Health Protection Agency website which is yet to be re-branded (9) (30) (31); NHS Choices(11) (29)and a variety of professional websites.

C. PHE also produce official data on antenatal screening (5) and people who use specialist drugs services (6).

- d) The microbiology and hepatology teams at Gloucestershire Hospital NHS Foundation Trust have activity and other service data.

Local Government does not have access to local mortality data or hospital activity data (hospital episode statistics). Local public health teams used to be able to access this data when they were part of Primary Care Trusts. Now that public health is in local government, this access has ceased nationally and each area, including Gloucestershire, is developing information sharing agreements.

In line with NHS guidance, any numbers less than 5 have been suppressed to protect the anonymity of patients. Any rates calculated from numbers less than 5 have been suppressed too.

### 3.3 Next steps

The Hepatitis B & C Strategy Group will consider this intelligence and agree next steps and further work, which might include none, some or all of:

- Further intelligence e.g. collection of new data or further analysis,
- Review of local commissioning strategies and policies in the context of national guidance
- Stakeholder collaboration, including commissioners, providers, clinicians, service users and populations at risk.
- Ongoing monitoring and evaluation
- Improvements in clinical practice, service delivery or commissioning
- Research

The Strategy Group will produce a brief report for the Health Protection Assurance Group. This Group needs assurance that our strategies and plans cover all the pertinent populations and interventions for BBVs and that we are doing everything reasonable to reduce the prevalence and impact of these infections.

### 3.4 Related work

The blood borne virus needs of Gloucestershire residents have not been the focus of a dedicated study or strategy. Local programmes have nevertheless included hepatitis B, C and HIV, including:

- Sexual Health Needs Assessment. The last assessment was written in 2008/9. A new version is due to be finished in Autumn 2014. It includes local HIV epidemiology, services and priorities. This review concentrates on hepatitis B & C accordingly.
- Substance misuse contract for drug and alcohol services, currently provided by Turning Point. This large contract includes the prevention, testing and treatment of service users at risk of blood borne viruses. The contract is based on local intelligence about need and demand.
- They are also a part of antenatal screening, maternity services and primary care contracts.

A quick review of the environmental health risks related to hepatitis B and C was completed earlier this year and is available separately. It describes the action District Council colleagues have taken in relation to registering businesses which offer tattooing, piercing and cosmetic implants and fillers.

Nevertheless, there is no obvious multiagency, county-wide needs assessment, strategy or detailed contracts for:

- Hepatitis B and C in general, across all risk groups and services
- Immunisation of all infants eligible for hepatitis B
- Needlestick injuries and other occupational risks
- Immigrant and travel health

This is not to ignore current organisational policies and much good work which already exists for some of these areas.

### 3.5 Review Limits

Some of the limits of this review include the following:

#### Co-infection

This report does not look at data for co-infection. It is difficult to find reliable national estimates for the number and percentage of people who have both hepatitis B and C at the same time. A review in 2008 looked at international studies that had been published until then (7) and concluded that:

- 5–20% of patients with chronic hepatitis B infection have hepatitis C (antibody positive)
- 2–10% of patients with hepatitis C (antibody positive) have hepatitis B (surface antigen positive)

It is difficult to interpret this meaningfully for Gloucestershire given the prevalence estimates for hepatitis B and C are themselves approximate

#### Populations at risk

This report considers risk factors separately e.g. transmission through injecting drug use or from pregnant woman to her baby (vertical transmission). This split is artificial. Many people will have a number of risk factors for contracting a BBV or be in touch with a number of different services.

#### Health and health services

This report is limited to the public health implications of hepatitis B and C which are, or could be, met by services which are currently commissioned. Thus it does not include the following:

- The broader determinants of health, e.g. housing, employment, education.
- Primary prevention, e.g. reducing injecting drug use or increasing condom use.
- Treatment of BBVs or their sequelae, unless it would be part of the public health response to reduce the risk of further BBV cases.
- Prevention or treatment of other conditions which increase susceptibility to hepatitis B or C e.g. Tuberculosis or STIs.
- Social care or other non-health needs
- The experience or meaning of having hepatitis B or C.

*This report will now present data for hepatitis B and hepatitis C in turn.*

## HEPATITIS B

### 4. National Context

#### 4.1 Incidence

The National Institute for Clinical and Health Excellence (NICE) reports a study by the Health Protection Agency (HPA) in 2004 which suggested there were 7.4 new diagnosed and undiagnosed infections per 100,000 in England and Wales each year (1).

The HPA have since calculated that 1.13 acute or probable acute infections per 100,000 were diagnosed in England in 2011. This rate was slightly higher for the South West region, at 1.16 per 100,000 (8).

#### 4.2 Prevalence

The World Health Organisation (WHO) estimate the prevalence of chronic infection is 0.3% in the UK (9). The HPA quote this estimate. There are further estimates of the prevalence of different stages of the natural history of hepatitis B, as summarised in **Table 1**.

**Table 1. Incidence and prevalence of hepatitis B**

	Frequency	Notes
Acute infection (2007, England & Wales)	7.4 per 100,000 pa	Many people will not be symptomatic or will have mild symptoms that they do not seek help for. Very low mortality during acute infection (<1%).
Diagnosed (2011, England)	1.13 per 100,000 pa	1.13/7.4 is equivalent to 15.27% of those infected are diagnosed.
Chronic hepatitis B i.e. detectable hepatitis B surface antigen (HBsAg) for longer than 6 months	85% of infected infants 4% of infected adults  0.3% general population prevalence	Many are not symptomatic but continue to carry the infection. Conversely, 99.7% of people infected clear the infection within 6 months
If people with chronic hepatitis B are <u>not</u> treated with antiviral medication:	8-20% get cirrhosis of the liver (10)	And of these, 5-10% get liver cancer (hepatocellular carcinoma, HCC). Conversely, 60%-90% people with liver cancer globally have underlying cirrhosis.
	1% adults get fulminant hepatitis B, an autoimmune disorder	And of these, 70% cases die from it

Sources: NICE (1), HPA (9), NHS Choices (11) and WHO (12)

#### 4.3 Risk groups

NICE states that 95% of new chronic infections in the UK occur in people who were born with the infection abroad (1) and goes on to list the other groups at greater risk of hepatitis B:

**Figure 1. Groups at increased risk of hepatitis B compared with the general UK population**

People born or brought up in a country with an intermediate or high (2% or more) prevalence of chronic hepatitis B, including all countries in Africa, Asia, the Caribbean, Central and South America, Eastern and Southern Europe, the Middle East and the Pacific Islands.

Babies born to mothers infected with hepatitis B



People who have ever injected drugs Men who have sex with men Anyone who has ever had unprotected sex, particularly: People who have had multiple sexual partners People reporting unprotected sexual contact in areas of intermediate and high prevalence People presenting at sexual health and GUM clinics People diagnosed with a STI Commercial sex workers Looked after children and young people Prisoners, including young offenders Immigration detainees Close contacts of someone known to be chronically infected with hepatitis B
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Extract from NICE public health guidance 43(1)

## 5. Applying national rates to Gloucestershire

We can apply the national rates to the local population to crudely estimate the number of new cases a year and the number of people living with chronic hepatitis B.

We might expect 44 or 45 new acute cases each year in Gloucestershire. Only some of these will present to health services, be tested, have a meaningful test result and be reported to Public Health England. Thus we would expect 6 or 7 of the 44-45 new acute cases to be reported to PHE each year.

We might expect 1,806 Gloucestershire residents to have chronic hepatitis B at any one time. These local estimates are only indicative and should be treated with caution. The figures are explained in **Table 2**.

**Table 2. Estimated incidence and prevalence of hepatitis B in Gloucestershire in 2012 by applying national rates.**

Definition (source)	Annual rate for England per 100,000 population	Estimated no. cases in Gloucestershire, 2012.
Incidence of cases reported to Public Health England -acute or probable acute infection (8)	1.13	6-7 new cases each year
	South West rate: 1.16	6-7 new cases each year
Incidence of acute hepatitis B, diagnosed and undiagnosed (1)	7.4	44-45 new cases each year
Prevalence of chronic hepatitis B (9)	300	1,806 people living in Gloucestershire with chronic hepatitis B

## 6. Local data about testing

Local data is complex too:

- We can attempt to report the number of positive test results.
- We can only estimate how many other people might be infected but have not been tested.
- There is a lag between infection and being tested.
- There are small numbers so there is a large degree of natural variation.
- The number of positive tests is affected by changes in clinical practice and service provision.
- The law restricts access to patient information about sexually transmitted infections, which can be interpreted to include hepatitis B and hepatitis C.

## 6.1 Laboratory data from Public Health England

Laboratory data available to Public Health England for analysis does not differentiate between acute and chronic cases and each patient may be tested a number of times as part of good care. PHE can simply identify the first positive hepatitis test each person had, which may have been for acute or chronic infection. PHE can exclude repeat or later tests for the same person. The microbiological definition of these reports was not known by the local epidemiological team<sup>2</sup>. Nevertheless, this is the standard way in which PHE reports this data.

Data is only available for residents who were tested in local laboratories. We do not have access to the tests completed out of area.

**Table 3** shows annual figures for the last 8 years:

- In absolute terms, the number of people testing positive is small and fluctuates. It ranged from 23 (2005 and 2007) to 55 (2010).
- In 2012, there were 51 positive laboratory reports. This compares to the 6-7 new acute or probable acute cases we might expect from national and regional rates. Thus about 45 of the cases might have been for chronic infection.
- There is a general trend of increasing numbers of reports, with an approximate doubling in the last 8 years. There seems to be an increase in positive tests from 2008 onwards. We do not know if this was because of increased or targeted testing or increased prevalence.
- Throughout this time, most reports were for 20-39 year olds and in most years, more males tested positive than females.
- The number of people under 20 who tested positive was particularly small each year, usually less than 5.
- We do not have the total number of tests analysed by the laboratories so we cannot calculate a positivity rate.

**Table 3. Laboratory reports of Hepatitis B by age group and gender**

Year	<20 years	20-29 years	30-39 years	40-49 years	50-59 years	60+ years	Females	Males	Unknown	Total
2005	<5	7	7	<5	0	<5	13	10		23
2006	<5	11	6	5	<5	0	10	17		27
2007	<5	9	9	<5	<5	0	6	17		23
2008	8	10	12	<5	5	<5	17	25	<5	43
2009	0	7	14	6	5	<5	15	20		35
2010	0	18	23	5	6	<5	20	35		55
2011	<5	12	17	10	5	<5	25	25		50
2012	<5	19	20	<5	<5	<5	17	34		51

Source: Public Health England using CoSurv laboratory data extracted 14/01/14

## 6.2 Laboratory data from Gloucestershire Hospitals NHS Foundation Trust (GHNFT)

The laboratory at GHNFT records all tests they undertake. Most of their patients are from Gloucestershire, but some are Worcestershire residents or from elsewhere. The lab system records each test. So this data has to be de-duplicated to estimate the number of people who tested positive for hepatitis B like the PHE data above.

Lab data for the two years of 2012 and 2013 is shown in **Table 4**. It is useful to give an idea of the volume of work. Antenatal tests account for half of all hepatitis B tests and GUM for

<sup>2</sup> Usually initial tests would include surface antigen, surface antibody and core antibodies

11%. The results are shown in **Table 5**. The estimated positivity rate for everyone tested is 0.9%.

**Table 4. Two year hepatitis activity, actual and de-duplicated, undertaken by Gloucestershire Hospitals NHS Foundation Trust laboratory, January 2012 – December 2013.**

	Setting			Total	Comments
	Antenatal	GUM	Other		
No. tests	15,683	3,291	12,428	31,402	
	49.9%	10.5%	39.6%	100.0%	
No. tests after de-duplication by hospital number.  Estimate for the number of unique individuals.	14,747	2,898	9,150	26,522	4,880 (31.1%) tests are likely to have been repeat tests i.e. "duplicates" for this analysis. They would
	55.6%	10.9%	34.5%	100.0%	
Tests which are likely to have been for unique individuals (%)	94.0%	88.1%	73.6%	84.5%	

Source: GHNFT laboratory data, provided May 2014

**Table 5. De-duplicated hepatitis B test results during the last two calendar years, undertaken by Gloucestershire Hospitals NHS Foundation Trust laboratory, January 2012 – December 2013**

Following all de-duplicated results:	Setting			Total	Comments
	Antenatal	GUM	Other		
No. tests de-duplicated by hospital number.	14,747	2,898	9,150	26,522	
No previous or current hepatitis B.	51	2,694	3,591	6,336	GUM patients usually considered higher risk and therefore usually screened by both tests unlike antenatal patients.
Surface antigen negative and core antibody negative	0.3%	93.0%	39.2%	23.9%	
No current hepatitis B.	14,387	29	5,187	19,603	No other markers tested. Could be core antibody positive and at risk of reactivation but risk factors from clinical information did not indicate testing.
Surface antigen negative	97.6%	1.0%	56.7%	73.9%	
<b>Infectious Hep B, acute or chronic</b>	<b>34</b>	<b>23</b>	<b>185</b>	<b>242</b>	
<b>Surface antigen positive</b>	<b>0.2%</b>	<b>0.8%</b>	<b>2.0%</b>	<b>0.9%</b>	
At risk of reactivation of hepatitis B in the event of immunosuppression	<5	145	178	324	
Surface antigen negative but core antibody positive	<0.03%	5.0%	1.9%	1.2%	
Equivocal (status not established)		7	9	17	
		0.2%	0.1%	0.1%	

Source: GHNFT laboratory data, provided May 2014

## 7. Antenatal Screening

Screening is the pro-active testing of people who otherwise have no symptoms, indications of infection or known exposure. Hepatitis B is part of the national universal antenatal screening programme.

The latest PHE report into antenatal screening (5) shows:

- *In 2012*, 1.7% of women booked into GHNFT maternity services declined hepatitis B screening (124/7,190). This was higher than the SW average of 0.9% (ranging from 0.1% to 2.1% across the different services). We do not have enough statistical information to know whether this difference is statistically significant. No further information is currently available about any trends in who declined screening or why. It will be clinically significant if the 124 women who declined are the ones most likely to have or be at risk of hepatitis B.
- *July-December 2012*, 3,305 of the 3,534 women booked into the Gloucestershire Hospitals NHS Foundation Trust maternity services were tested for hepatitis B, 93.5%. This was not as high as the South West average for 2012 as a whole (97.0%, with a range from 90.3% to 100% across the different maternity services).
- *In 2012*, the total positivity rate was 0.20%. This is similar to the 0.23% estimated from the GHNFT laboratory data for 2012-2013 (see Table 5). The regional positivity rate was 0.19%. The difference between the Gloucestershire and regional rates is small and we do not have the statistical information to know whether the difference is statistically significant.

**Table 6** shows the full figures.

**Table 6. Antenatal screening for hepatitis B in Gloucestershire and the South West, 2012.**

	Gloucestershire		South West	
	Number	Percentage	Percentage	Range
July-December 2012:				
Booked	3,534			
Tested	3,305	93.5%	97.0%	90.3% - 100%
2012 full year:				
Booked & offered	7,190			
Declined	124	1.7%	0.9%	0.1% - 2.1%
Tested	7,510 <sup>3</sup>			
New diagnosis	8	0.20% total positivity	0.19% total positivity.	0% - 0.47%
Previous diagnosis & re-screened	6			
Previous diagnosis & not re-screened	1	0.11% newly diagnosed	0.07% newly diagnosed	0% - 0.20%

Source: PHE 2013

## 8. Immunisation

The hepatitis B immunisation eligibility criteria and schedule is described in PHE guidance, known as “the Green Book” (13). Immunisation is recommended for people who are at risk, including, the following subgroups.

<sup>3</sup> This is the published figure. There is no explanation why it is not 7,065 ie 7,190 offered – 124 declined – 1 already diagnosed and not re-screened.

## 8.1 Infants at risk of exposure to hepatitis B

### National guidance

Babies born to hepatitis B positive mothers are meant to have at least 3 doses of the vaccination by their 1<sup>st</sup> birthday. Immunisation is begun at birth and continued by General Practice.

NICE (1) advises that Directors of Public Health should ensure that General Practice immunises the babies it needs to and that NHS England should complete annual audits of vaccination, including:

- Number of children receiving vaccines
- Number of doses
- Whether doses were given on schedule
- Whether babies were tested after completing the vaccination course
- The rate of vaccination failure.

NICE notes that any issues should be addressed, without making it clear who might be responsible for doing so.

### Gloucestershire performance

The Health & Social Care Information Centre reports that 7 babies were born to hepatitis B positive mothers and were due to have their 1<sup>st</sup> birthday in 2012/13 in Gloucestershire (14). 6 of these babies received at least 3 doses of the immunisation before their 1<sup>st</sup> birthday. The HSCIC are in the early stages of developing this data and describe it as “experimental” and caution against heavy reliance on it until it has been evaluated. They used data from the COVER programme and some areas were unable to submit data. Data for 2013/14 is due to be published in September 2014.

PHE published the HSCIC data as part of the Public Health Outcomes Framework<sup>4</sup> (4). In Gloucestershire in 2012/13, 85.7% eligible infants received at least 3 doses by their 1<sup>st</sup> birthday (6/7) and 71.4% received 4 doses by their 2<sup>nd</sup> birthday (5/7). The numbers are small with large confidence intervals, so we would expect the numbers to fluctuate each year.

Gloucestershire Care Services and Gloucestershire Hospitals NHS Foundation Trust have internal policies describing the care pathway for antenatal screening and any subsequent immunisation and testing.

Furthermore, there have been two recent local clinical audits:

- Whether all eligible babies have received 3 or 4 doses by their first birthday (Gloucestershire Care Services, with babies identified by maternity services, GHNFT)
- Whether all eligible babies are tested at 12 months and are seen by community paediatrics (Gloucestershire Hospitals NHS Foundation Trust)

Both audits found that babies received all immunisation doses, but mostly late and often very late.

A new local multi-agency forum has been set up to check that the current pathway is working, to iron out any areas for improvement and to help to provide assurance. The roles and responsibilities of commissioners and providers in delivering and assuring this process will be clarified too.

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<sup>4</sup> There is some inconsistency in the definition used in this data. PHOF outcome 3.03i is the percentage of eligible children receiving 4 doses of hepatitis B immunisation by their 1<sup>st</sup> and their 2<sup>nd</sup> birthday. The PHE metadata then refers to 3 doses by 1 year and 4 doses by 2 years old. The HSCIC report “at least 3 doses”. Only percentages are publicly reported in the PHOF, numbers are available from PHE data.

Many of the babies eligible for hepatitis B immunisation are involved with the Care system. This can increase the number of teams involved with their care and geographical movement. Nonetheless, with so much input, it would be hoped that immunisation could be complete and on time.

Clinicians have reported we would take a case-by-case approach if any parents declined immunisation.

Foster carers and adopters, and their families (close household contacts) should be immunised, if they offer emergency placements or if a baby has hepatitis B. We do not have any aggregated data on whether this is happening.

## 8.2 Injecting drug users

In line with the Green Book (13) and NICE guidance (1), the local drug treatment service encourages all eligible service users to be vaccinated against hepatitis B. Vaccination is provided by the service.

Public Health England publishes data for the number and percentage of drug treatment service clients who agreed to, started and completed hepatitis B vaccination, based on the National Drug Treatment Monitoring System (NDTMS).

There is an important caveat about the quality of this data. The NDTMS is not a clinical or frontline system; the only benefits are managerial, i.e. for monitoring activity and evaluating effectiveness. If drugs workers do not keep their client's status up to date on NDTMS, then the activity isn't shown. Thus more service users are likely to have agreed to vaccination, started vaccination and completed vaccination than the data shows.

### Vaccination data for service users noted to have accepted

PHE focuses their reporting on the vaccination initiation and completion of service users shown on NDTMS to have agreed to vaccination. If a service user is not flagged on the system as having accepted vaccination, then they are not included in this data.

Data for 2012/13 data is shown in **Table 7** (6). Our local performance is broadly in line with England figures, with a similar percentage of eligible service users agreeing to vaccination, slightly more starting vaccination but slightly fewer completing their course of vaccination.

**Table 7. Hepatitis B vaccination initiation and completion among adults new to drug treatment services, 2012/13.**

Adults new to treatment and eligible for hepatitis B vaccination	Gloucestershire		England
	Number	Percentage	Percentage
Agreed to vaccination	151	46%	47%
<i>Of these:</i>			
Started a course of vaccination	41	27%	23%
Completed a course of vaccination	24	16%	20%

The provisional, unpublished data for 2013/14 is similar<sup>5</sup>. The data is yet to be ratified and formally published by PHE. We cannot comment on it until it is officially confirmed.

<sup>5</sup> For Gloucestershire, 87% of the 655 people starting a new treatment "journey" were offered immunisation. Of these, 177 (27% of the 655) accepted immunisation and 185 (28%) refused. Of those recorded as accepting immunisation, 31 (17.5%) started a course of immunisation and an additional 13 (7.3%) completed a course. These latter figures compare to 20.1% and 18.7% for England, indicating we might have a high attrition rate. This was also the conclusion of the regional PHE 2014 Diagnostic Outcomes Monitoring Executive Summary(34).

### Vaccination data for all service users

Another field on the NDTMS return shows the number of all service users who have been vaccinated, irrespective of whether they are recorded on NDTMS as having agreed to it. These figures are higher: 25% (260) completed immunisation in 2013/14 (provisional figures) and 43% in 2012/13 (published data).

We have no reason or evidence to suggest anyone is being vaccinated against their will. This data completeness issue seems to be national given the England figures are similarly affected. Local commissioners and providers continue to work hard on data quality.

Theoretically it would also be possible for some service users or people who have injected drugs but who are not in services to be vaccinated via a sexual health service or their GP practice. This is unlikely to be more than a very small number.

Nevertheless, we do not have evidence of high immunisation rates locally, so there is at least an assurance and data quality issue and possibly a potential health issue.

This review has not looked to understand whether those service users not being immunised or at any different level of risk. The Specialist Hepatitis C nurse role will be able to offer hepatitis B immunisation to service users, to complement current service provision, once the PGD is approved.

### **8.3 People travelling to areas of high prevalence**

There are no routine reports about the immunisation, screening or cases among local people travelling from or to countries of high prevalence. So we do not know whether guidance from NICE (1) and Public Health England (13) are being implemented. Individual patient information is held in individual patient records in GP practices, sexual health services and in any private travel health services.

Given the NICE estimate of 95% of chronic cases are attributable to immigration and travel (1) and that there might be 1,806 people with chronic hepatitis B in Gloucestershire<sup>6</sup>, then c.1,716 of these might be attributable to immigration and travel.

A local review of how GP practices in Gloucester locality might improve their work with immigrants noted some issues that affected immunisation in general, not specific to hepatitis B. Travel interrupted immunisation schedules, different countries have different schedules and parents were often unsure of which immunisations their children have had or when (15).

### **8.4 Healthcare and other workers**

#### National data

The Health Protection Agency's 2012 report about healthcare workers with significant exposure to BBVs through work (16), states that:

- 3140 percutaneous exposures were reported between 2002 and 2011
- 8% (241) involved a patient who had hepatitis B, and 7% (203) involved a patient co-infected with a combination of two or all of hepatitis B, C &/or HIV.
- There was currently no evidence on the risk of transmission for hepatitis B from mucocutaneous exposure, i.e. transmission through the soft tissues of eyes or mouth.

National guidance from the Health Protection Agency and the Association of National Health Occupational Physicians distinguishes between clinical staff, lab staff and non-

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<sup>6</sup> If the rate for England is applied of 300 per 100,000 population, as shown in Table 2.

clinical staff who may be in contact with patients, but not usually of a prolonged or close nature. There are specific recommendations for staff undertaking “exposure prone procedures”, i.e. where staff are in contact with open tissue, usually with a sharp instrument, including surgeons, dentists, emergency department staff and midwives (17).

Immunisation is one part of a range of working practices which can reduce the risk to staff and patients. The Green Book (13) includes the following recommendation about hepatitis B immunisation:

*“...Hepatitis B vaccination is recommended for healthcare workers who may have direct contact with patients’ blood or blood-stained body fluids. This includes any staff who are at risk of injury from blood-contaminated sharp instruments, or of being deliberately injured or bitten by patients. Antibody titres for hepatitis B should be checked one to four months after the completion of a primary course of vaccine. Such information allows appropriate decisions to be made concerning post-exposure prophylaxis following known or suspected exposure to the virus.”*

Pages 85-86, Chapter 12, PHE 2013 (13)

### Local data

There are no estimates of the number of Gloucestershire staff who might be at occupational risk of exposure to hepatitis B or C. There are also no routine reports about the immunisation, screening, testing or cases among local people who might be exposed to hepatitis B through their occupation.

NHS Trusts and Local Authorities will account for many, but not all, of these staff. Occupational health services for local NHS Trusts and Gloucestershire County Council hold individual records, but the data is not aggregated or shared so that we can monitor trends locally. A very crude guess is that there might be 3,000-5,000 people in Gloucestershire employed by the NHS who should be immunised or tested for immunity. **Appendix 3** has more details.

Foster carers who offer emergency placements are also recommended to be immunised. Foster carers are advised to contact Working Well, the occupational health service for Gloucestershire Care Services, to be immunised. There is no aggregated data available to show whether foster carers are seeking and receiving immunisation.

## **9. Patients in treatment**

Hepatology services have been provided by Gastroenterology at Gloucestershire Hospitals NHS Foundation Trust since early 2013. It was previously delivered as part of sexual health services in Hope House, run by Gloucestershire Care Services.

The hepatology service sees patients from Gloucestershire and parts of Worcestershire. It has not been possible to quantify how many referrals they receive, i.e. demand for secondary care services.

Nationally, local authority public health teams are unable to access Hospital Episode Statistics, so the hepatology service has helpfully provided us with their own information. Accepted referrals are shown in **Table 8**. This represents met demand. The service accepts about 2-5 pcm for hepatitis B, albeit figures have fluctuated. The service was moved in 2012 and the number of patients has fallen. The service attributes this to a corresponding reduction in referrals received. Figures are not available for 2012 to July 2013, as the service changed organisation.



**Table 8. New patient referrals accepted by the Hepatology Service, Gloucestershire Hospitals NHS Foundation Trust, from 2009 to 19<sup>th</sup> May 2014.**

Year	No. new hepatitis B referrals accepted
2009	27
2010	58
2011	43
Aug 13 - May 14 <i>actual</i> (10 months)	22
Aug 13 - Aug 14 <i>full year estimate</i> i.e. Aug 13 - May 14 multiplied to 12 months	26

Source: Hepatology Service, GNHFT as of 19<sup>th</sup> May 2014

These figures contrast with those presented earlier in this report, i.e. the estimated:

- 6-7 people notified to PHE pa with new hepatitis B infections, if the South West rate is applied to Gloucestershire
- 44-45 people who might have new infections, diagnosed and undiagnosed, if the England rate is applied to Gloucestershire
- 242 people testing positive for hepatitis B through the GHNFT laboratory in 2012-2013, i.e. an average of about 120 pa.

The hepatology team have highlighted that there is no fibroscanner within Gloucestershire Hospitals NHS Foundation Trust. Hepatology completed a business case for Trust management earlier this year but have not yet had any feedback. NICE recommend annual fibroscans as less invasive and risky than biopsies. Scans occur in a 15 minute outpatient appointments and biopsies are day cases. Local patients currently go to Bristol or Birmingham. This is a barrier for some patients. Hepatology submitted an internal business case in March 2014. A scanner would cost £19,000 p.a. for 5 years for predicted savings of at least £76,000 pa from onsite biopsies alone. The Trust would also save recharges from out of area scans; it could be used by other specialties and it could also generate income from out of area patients. This is primarily a clinical governance or even financial matter rather than of public health, but it would nevertheless be useful for the local health system to consider.

## 10. Mortality from hepatitis B

Hepatitis B mortality data is not routinely published, nationally or locally. Analysis of mortality rates could be arranged in the future if PHE or NHS colleagues are happy to assist<sup>7</sup>.

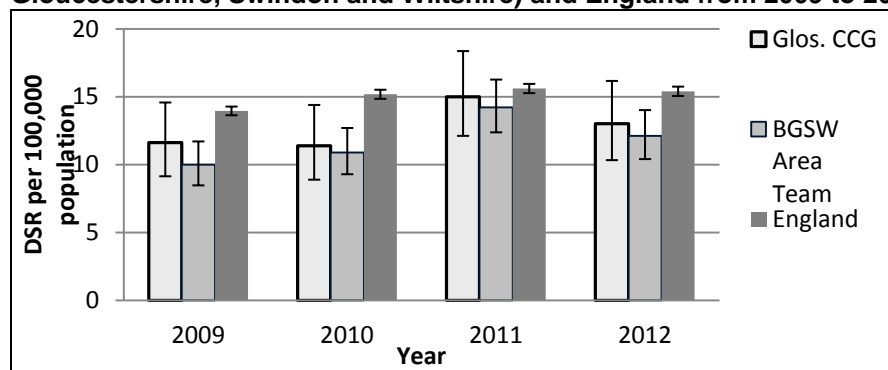
Under 75 mortality rates from liver disease from 2009-12 are available as part of the PHOF. Hepatitis B and C contribute to overall liver disease deaths, along with alcohol and other factors.

- The rate for England the rate has increased slightly and it is statistically significant.
- The rate for Gloucestershire has increased slightly but it is not statistically significant.
- The difference between Gloucestershire and England is not statistically significant.

**Graph 1** shows the comparative trend for the Area Team too.

<sup>7</sup> Even with access to the data, there is no standard definition or model for calculating mortality rates attributable to hepatitis B. The following ICD10 codes could be used to calculate the mortality rate where the primary or secondary cause of death was certified as being acute or chronic hepatitis B. It would not include those where hepatitis B was not put on the certificate: B16.0, B16.1, B16.2, B16.9, B17, B18.0, B18.1.

**Graph 1. Comparative annual directly standardised under 75 liver disease mortality rates for the registered populations of Gloucestershire, the Area Team (Bath & North East Somerset, Gloucestershire, Swindon and Wiltshire) and England from 2009 to 2012.**



## 11. Hepatitis B Key Findings

1. We can crudely estimate that in Gloucestershire there are:
  - 6-7 new acute cases reported to PHE pa
  - 44-45 new acute cases pa, diagnosed and undiagnosed
  - 1,806 people living with chronic hepatitis B
  - 242 people had a positive test for hepatitis B via GHNFT laboratory in 2012-13, i.e. an average of 121 pa, including some Worcestershire patients
  - 23-55 laboratory reports to PHE pa, 2005-12, of acute and chronic infections
2. Hepatology service accepts 27-55 referrals pa, 2009-2013/14.
3. 1.7% (124) pregnant women declined hepatitis B screening in 2012, compared to 0.9% in South West (range 0.1% to 2.1%). We do not have enough statistical information to know whether this difference is statistically significant. Nonetheless it may well be clinically significant if the women who declined are the ones most likely to have or be at risk of hepatitis B.
4. Local antenatal screening positivity appears to be 0.2%. This equates to c15-17 women p.a., some of whom have already been diagnosed in earlier pregnancies or during other tests. This is broadly typical for the South West.
5. Infant immunisation: broadly compliant with the Green Book, with one or two babies not receiving the full schedule. Infant immunisation: broadly compliant with the Green Book, with one or two babies not receiving the full schedule. Majority of babies receive their 2nd and subsequent immunisations late. The pathway is complex. It is not yet systematic or robust.
6. The immunisation completion rate of eligible people in treatment services is about 25% (provisional 2013/14 figures). There are data quality issues. Our rate is lower than the England rate; we do not have the statistical information to know if the difference is statistically significant.
7. People who inject drugs: The immunisation rate of people in treatment services is similar to that for England.
8. In the UK, 95% new chronic hepatitis B cases are in people who were born with the infection abroad. Local hepatology services have encouraged GP practices to screen Chinese patients in particular. There is no national screening programme as the cost-effectiveness and feasibility are unclear. We do not know if this is

replicated locally or whether primary care do indeed screen Chinese or other patients.

9. Mortality data is not currently available and would probably need to be negotiated from NHS commissioning colleagues or the PHE Knowledge and Intelligence Team.

## Hepatitis C

### 12. National Context

#### 12.1 Incidence

There is no simple estimate of the number of new cases per year. The annual hepatitis C report from PHE (18) estimates rates of new infections per person years. This considers how long different people have been at risk of infection, one person-year is the same as one person being at risk for a year or 2 people each being at risk for 6 months. PHE describes incidence as being stable or reducing for different risk groups “over recent years”:

*“..Preliminary data suggests that incidence of HCV infection among PWID in England, Wales and Northern Ireland during 2011- 2012 was between 7 and 20 infections per 100 person years of exposure; ... In England, infections in young adults and recent initiates to drug use suggest that incidence has remained relatively stable over recent years. Enhanced surveillance of newly acquired HCV infection in men who have sex with men (MSM) provides evidence of ongoing, but declining sexual transmission of HCV among HIV-positive MSM in England. In this population, the estimated incidence of infection has declined significantly over the last four years to 2.2 per 1,000 person years in 2012...”* p10 from Public Health England, 2013. Hepatitis C in the UK, 2013 Report.

We cannot readily interpret these person year rates for Gloucestershire.

#### 12.2 Prevalence

PHE’s most recent estimate is for 2013, when they estimated that 160,000 adults in England (0.4% of the adult population) were chronically infected with hepatitis C (18).

The genotype of the virus affects prognosis and treatment. Public Health England monitors the genotyping from 23 laboratories in England. This sentinel surveillance found 46% were genotype 1 and 43% were genotype 3 in 2008-12 (18). Genotype 1 requires 48 weeks’ treatment and all other genotypes require 24 weeks’ treatment.

There are indications that the number of people with hepatitis C is growing. PHE acknowledge that data from hospital episode statistics, death certifications and liver transplant registrations are imperfect but nevertheless useful indicators of the burden of disease. Each of these has broadly tripled in the last 13-16 years, as shown in **Table 9**.

**Table 9. Number of hepatitis C-related hospital admissions, deaths certifications and liver transplant registrations in the UK**

Indicator	Source	No.	Year	No.	Year	Increase	Time period
HCV-related end stage liver disease and hepatocellular carcinoma	No. hospital admissions, from hospital episode statistics	612	1998	2268	2011	3.7 times	13 years
	Death certifications	98	1996	381	2011	3.9 times	15 years
Liver transplant registrations with a primary code of post-hepatitis C cirrhosis	Transplant registrations	45	1996	124	2012	2.8 times	16 years Nb figures have been stable over the last 5 years

Source: Public Health England, 2013 (18)

### 12.3 Risk groups

The main risk groups for hepatitis C are shown in **Figure 2**. People who have injected illicit drugs account for the vast majority of cases: 90% of chronic infections in the UK occur in people who inject drugs or have done in the past (1). The national Unlinked Anonymous Monitoring (UAM) survey of people who inject drugs (PWID) and are in contact with specialist services suggests that, in the South West, 35% had hepatitis C antibodies, rising to 49% for England as a whole (19).

It is common for people with hepatitis C to become symptomatic or be diagnosed months or years after their drug use. There is a small risk from sharing snorting equipment too.

**Figure 2. Groups at increased risk of hepatitis C compared with the general UK population**

People who have ever injected drugs
People who received a blood transfusion before 1991 or blood products before 1986.
People born or brought up in a country with an intermediate or high (2% or more) prevalence of chronic hepatitis C. Data is incomplete, so for practice purposes this includes all countries in Africa, Asia, the Caribbean, Central and South America, Eastern and Southern Europe, the Middle East and the Pacific Islands.
Babies born to mothers infected with hepatitis C
Prisoners, including young offenders
Looked after children and young people
People living in hostels for the homeless or sleeping on the streets
HIV-positive men who have sex with men
Close contacts of someone known to be chronically infected with hepatitis C

Extract from NICE public health guidance 43(1)

### 13. Applying national rates to Gloucestershire

If the national prevalence rate is applied locally, we would expect there to be about 1,386 15-59 year olds living with hepatitis C in Gloucestershire. There would be a small number of additional cases who were under 15 and over 59 years old too.

**Table 10. Estimated incidence and prevalence of hepatitis C in Gloucestershire in 2012 by applying national rates.**

Definition (source)	Rate in England per 100,000 population	No. cases in Gloucestershire, 2012
Estimate of prevalence of chronic infection among all adults (15-59 year olds) (5)	400 (0.4%)	1,386 (Out of 346,489 15-59 year olds in total)
Estimate of prevalence of current or past infection among people who inject drugs and are in contact with specialist services, South West region	35%	250 (Out of an estimated 714 15-64 year olds in the general population who inject opiate &/or crack cocaine.) This might be 135-357 cases if the 95% CIs of the estimated no. injectors are applied

More detailed information about estimates of how many people in Gloucestershire might inject drugs or be in any other risk group is in **Appendix 4**.

PHE has constructed a spreadsheet for commissioners to estimate the local prevalence and burden of hepatitis C. The tool estimates there are 1,529 local people infected with hepatitis C, which is higher than the estimate if we simply apply the England rate. The tool

seems to have a high figure for the number of people who have injected drugs in the past (2,655), which is based on a 0.78% estimate from national household surveys. The full figures are available separately; the spreadsheet is protected and cannot be appended.

## 14. Local data

### 14.1 Laboratory data from Public Health England

Public Health England has data from local laboratories about the number of positive tests each year. PHE only count each individual once, taking the earliest test. Data is only available for residents who were tested in local laboratories. We do not have access to the tests completed out of area. This is the standard data that PHE produce; it is unclear what definitions are used.

**Table 11** shows annual figures for the last 8 years:

- In absolute terms, the number of annual laboratory reports is small and fluctuates. It ranged from 80 (2007) to 145 (2008).
- There is a general trend of increasing numbers of reports, with an increase of 32% from 2005 to 2012. Like the hepatitis B data, there is an apparent increase in positive reports from 2008, particularly in 30-49 year olds and in males. We are not clear why.
- Throughout this time, most reports were for 20-39 year olds and in most years, more males tested positive than females. Overall, there were 2.3 times as many positive results for men than women.
- The number of people under 20 who tested positive was particularly small each year, usually less than 5.

**Table 11. Laboratory reports of Hepatitis C by age group and gender**

Year	Age group (years)						Gender			Total
	<20	20-29	30-39	40-49	50-59	60+	Female	Male	Unknown	
2005	<5	17	26	24	11	<10	40	44		84
2006	<5	28	31	20	18	<5	31	70		101
2007	0	18	30	14	14	<5	25	55		80
2008	5	17	55	43	20	5	29	114	<5	145
2009	<5	24	39	44	24	<10	44	97	<5	142
2010	<5	21	40	28	18	<10	31	83		114
2011	6	21	43	41	19	9	42	97		139
2012	<5	20	36	21	20	<15	33	78		111

Source: Public Health England using CoSurv laboratory data extracted 14/01/14

### 14.2 Laboratory data from Gloucestershire Hospitals NHS Foundation Trust

If someone has a positive antibody test, they then have a PCR test. If positive, they go on to any further diagnostics and treatment if applicable. If the PCR is negative, they have another PCR test 6 months later. Only if that is also negative and their liver function tests are normal are they discharged.

GHNFT processed hepatitis C tests for approximately 10,334 people from 2012 to 2013, an average of about 100 people a week. 3.3% of people can be estimated to have tested positive. This was 14% for antenatal tests, but the numbers are very small. The figures are given in more detail in **Tables 12 and 13**.

**Table 12. Two year hepatitis C activity, actual and de-duplicated. Gloucestershire Hospitals NHS Foundation Trust laboratory, January 2012 – December 2013**

	Setting			Total	Comments
	Antenatal	GUM	Other		
No. tests	86 0.6%	1,588 11.8%	11,767 87.5%	13,441 100%	
No. tests after de-duplication by hospital number. i.e. estimate for the number of unique individuals.	85 0.8%	1,255 12.1%	8,993 87.0%	10,334 100.0%	3,110 (30.1%) tests are likely to have been repeat tests i.e. “duplicates” for this analysis.
Tests which are likely to have been for unique individuals (%)	98.8%	79.0%	76.4%	76.9%	

Source: GHNFT laboratory data, provided May 2014

**Table 13. Two year hepatitis C test results, de-duplicated estimate from Gloucestershire Hospitals NHS Foundation Trust laboratory, for tests completed January 2012 – December 2013**

Following all de-duplicated results:	Setting			Total
	Antenatal	GUM	Other	
No. tests after de-duplication by hospital number.	85	1,255	8,993	10,334
Positive	12 14.1%	31 2.5%	297 3.3%	340 3.3%
Negative	73 85.9%	1,224 97.5%	8,696 96.7%	9,993 96.7%

Source: GHNFT laboratory data, provided May 2014

### 14.3 Antenatal screening

Hepatitis C is not part of universal antenatal screening like hepatitis B is. The hepatology team are interested in developing a research proposal to include hepatitis C screening within universal antenatal screening. A mouth swab could be used, so it need not be overly invasive, and the data would help us to be clearer about our local prevalence rates and whether there are any groups currently under-represented in services.

One aim of the proposed study is to investigate the concerns of local clinicians that fewer people from Sub-Saharan Africa and Asia, regions of high prevalence, might be accessing testing and treatment services than we would expect from national figures. It would be useful to review routine data sources first.

## 15. Testing in Drug Treatment Services

There is not a national (or local) screening programme for hepatitis C and no immunisation exists either. However, anyone who has ever injected drugs is recommended to be tested for hepatitis C. Drug treatment services record the number of services users tested on the NDTMS system. Public Health England reports this data annually.

In 2012/13 Gloucestershire was far higher (better) than England, i.e. a higher percentage of people in drug treatment services who were eligible for a hepatitis C test were tested in Gloucestershire than in England as a whole (6).

Provisional data for 2013/14 is unpublished and “restricted” (20). We cannot comment on it beyond noting that it seems to have dropped from last year but is still above last year’s figure for England. The end of year and published figures might be quite different. **Table 14** shows data for both years.

**Table 14. People in drug treatment services who previously or currently inject, are eligible for a hepatitis C test, and received one**

Period Data status	Gloucestershire			England
	Number people in treatment with past or present injecting	Number of people with a hepatitis C test	Percentage of eligible clients	Percentage of eligible clients
2012/13 <i>Published</i>	Not published <sup>8</sup>	947	93%	73%
2013/14 <i>Provisional</i>	1080	839	78%	Not yet published

We do not have any data on what proportion of people in other risk groups, aside from those in drug treatment services, who are eligible for hepatitis C testing are indeed being offered and accepting testing.

## 16. Hepatology patients with hepatitis C

The Hepatology service accepts about 5-14 referrals pcm for hepatitis C. This means at least 2/3 of their caseload has hepatitis C and 1/3 or less has hepatitis B. As per the hepatitis B activity:

- the number of accepted referrals for hepatitis C have fluctuated.
- the service was disrupted in 2012 and the number of accepted patients has fallen. The service describes a corresponding reduction in referrals.

**Table 15. New patient referrals to the Hepatology Service, Gloucestershire Hospitals NHS Foundation Trust by genotype, from 2009 to 19<sup>th</sup> May 2014.**

Year	Hepatitis B	Hepatitis C	Total	Comments
2009	27	170	197	
2010	58	176	234	
2011	43	151	194	
Mid 13-Mid 14 estimate	26	62	89	based on Aug 13 - May 14 (below) multiplied to 12 months
Aug 13-May 14 Actual (10 months)	22	52	74	

The team began to keep an internal database about 10 years ago, the exact date is unknown. The database keeps track of where the patient is on the patient pathway and their genotype. A report run in May 2014 of all patients to date, shows that there have been 1,139 patients in this time, about 140 p.a. on average.

### 16.1 Genotype

Local service data includes 614 patients who had their infection genotyped. 47.6% were genotype 1 and 41.7% were genotype 3, both in line with the national figures (46% and 43% respectively). Local figures are broken down in **Table 16**.

<sup>8</sup> The published figures do not include this number, which is only included in the more detailed provisional figures provided to commissioners.



**Table 16. Hepatitis C patients of Gloucestershire Hospitals NHS Foundation Trust by genotype, from c2004 to 19<sup>th</sup> May 2014.**

Genotype	Number	Percentage	
		Of all patients	Of only those patients where the genotype is known
1	292	25.6%	47.6%
2	51	4.5%	8.3%
3	256	22.5%	41.7%
4	13	1.1%	2.1%
5	2	0.2%	0.3%
6	0	0%	0.0%
<b>Subtotal, genotype known</b>	<b>614</b>	<b>53.9%</b>	<b>100%</b>
Genotype unknown	525	46.1%	
<b>Total</b>	<b>1,139</b>	<b>100%</b>	

Source: Hepatology Service, GNHFT as of 19<sup>th</sup> May 2014

## 16.2 Treatment initiation

554 of the 1,139 patients (48.6%) have not yet attended the service sufficiently for robust assessment. Some patients take a long time to build a relationship with the team before they start assessment. Given that the data goes back for 10 years, many of these will have since moved away too.

585 patients (51.4%) started the assessment, treatment and follow-up process. Of these 67 (5.9%) are being assessed for treatment and 111 (9.8%) either cleared the virus naturally or had mild disease which, under previous NICE guidance did not warrant treatment. Under the current guidance, some of the 11 patients with subthreshold viral load would now be eligible for treatment.

Thus 407 of the 585 patients (69.6%) were suitable for treatment. In May 2014, when the data was reviewed for this report, 11 were waiting for treatment, 33 were being treated and 67 were off treatment.

**Table 17. Hepatitis C patients of Gloucestershire Hospitals NHS Foundation Trust by stage of assessment, treatment and follow-up, from c2004 to 19<sup>th</sup> May 2014.**

Treatment stage	Number	Percentage	
		Of all patients	Of only those patients where the treatment stage is known
Being assessed for treatment	67	5.9%	11.5%
Treatment not necessary, has cleared the virus	100	8.8%	17.1%
Sub-threshold, mild disease. Previous NICE guidance specified that treatment was not applicable. However, now many of these patients would now be suitable for treatment	11	1.0%	1.9%
Waiting to start treatment	11	1.0%	1.9%
On treatment	33	2.9%	5.6%
Completed treatment within last 6 months; awaiting their 6-mth PCR	67	5.9%	11.5%
Completed treatment and follow up	296	26.0%	50.6%
<b>Subtotal (treatment stage known)</b>	<b>585</b>	<b>48.6%</b>	<b>100.0%</b>
Referral accepted but assessment not yet underway	554	51.4%	
<b>Total</b>	<b>1,139</b>	<b>100.0%</b>	

Source: Hepatology Service, GNHFT as of 19<sup>th</sup> May 2014

The service has a CQUIN in 2014/15 to ensure that at least 85% patients are discussed as a team before treatment, which is being achieved.

A new Sofosbuvir expanded access programme is being trialled in Birmingham, Oxford and Bristol. Sofosbuvir has a number of advantages over existing treatments. We have not received information locally about how Gloucestershire patients can be access the treatment. A growing number of our patients are waiting to start treatment as they -and we- hope they will be able to access the trial.

### **16.3 Treatment completion and success**

The service reports that of 73 people starting treatment, 5 (7%) stopped of their own volition due to side-effects. At the time of writing, the time period for this data is unclear. More recently the service has reported a drop-out rate from treatment of only 3%.

296 patients have completed treatment and follow-up to date. Of these, 212 (71.6%) remained clear of the virus 6 months after treatment completion. The remaining 28.4% patients either did not respond to treatment or initially responded but the virus returned.

**Table 18. Hepatitis C patients of Gloucestershire Hospitals NHS Foundation Trust who completed treatment and follow-up, by outcome, from c2004 to 19<sup>th</sup> May 2014.**

Treatment outcome	Number	Percentage of those completing treatment and follow-up
Poor virological response to treatment so treatment was stopped. Will be awaiting new treatment options.	47	15.9%
Relapse, virus was undetectable but has now returned	37	12.5%
Sustained responder, PCR test post treatment at 6 mths. NB follow up continues for 2 years post-treatment	212	71.6%
<b>Total</b>	<b>296</b>	<b>100.0%</b>

Source: Hepatology Service, GNHFT as of 19<sup>th</sup> May 2014

No comparative national rates were found within the timescales of working on this report but might exist and be useful to consider.

**Table 19** on the following page gives a full breakdown of patients by stage of assessment, treatment and follow-up and genotype.

49% of patients, since the database began, have not been genotyped. It is likely to have been too early in their care and many, once they test positive, do not come back for genotyping. Furthermore, this patient group can be difficult to bleed. Genotyping is useful to determine the type and duration of treatment.

Additionally, in discussions about treatment, the hepatology team noted there is no paediatric endoscopy within Gloucestershire Hospitals NHS Foundation Trust. This review has not investigated the implications of this any further. It could usefully be considered, not least for any implications for the provision of care for other conditions too.

**Table 19. Hepatitis C patients by genotype and stage of assessment, treatment and follow-up since team database began, c2004**

Treatment stage	Definition	Genotype						Total		Subtotal of those where treatment stage known		
		1	2	3	4	5	6	Unknown	No.	%	No.	%
Referral accepted	Patient in early stages of care pathway. Not enough contact yet for assessment.	68	11	44	<5			428	<b>554</b>	48.6%	0	0.0%
Assess	Being assessed for treatment	25	<5	19	<5			18	<b>67</b>	5.9%	67	11.5%
Unsuitable	Patient has naturally cleared the virus. Treatment not necessary.	17	<5	16				65	<b>100</b>	8.8%	100	17.1%
Subthreshold	Low viral load. NICE previously recommended treatment only for moderate or severe disease.	3	<5	<5				5	<b>11</b>	1.0%	11	1.9%
Awaiting	Waiting to start treatment	7	<5	<5					<b>11</b>	1.0%	11	1.9%
On treatment		17	<5	13	<5			<5	<b>33</b>	2.9%	33	5.6%
Off treatment	Treatment completed. 6 month follow-up pending.	26	7	28	<5	<5		<5	<b>67</b>	5.9%	67	11.5%
Non-responder	Virus did not respond to treatment, treatment stopped.	38		5	<5	<5		<5	<b>47</b>	4.1%	47	8.0%
Relapse	Virus was undetectable but has now returned	19	<5	15					<b>37</b>	3.2%	37	6.3%
Sustained responder	PCR test 6 months post treatment	72	20	112	<5			<5	<b>212</b>	18.6%	212	36.2%
<b>Total</b>	<b>Number</b>	<b>292</b>	<b>51</b>	<b>256</b>	<b>13</b>	<b>&lt;5</b>	<b>0</b>	<b>525</b>	<b>1,139</b>	<b>100.0%</b>	<b>585</b>	<b>100.0%</b>
	<i>Percentage</i>	<i>25.6%</i>	<i>4.5%</i>	<i>22.5%</i>	<i>1.1%</i>	<i>&lt;0.4%</i>	<i>0.0%</i>	<i>46.1%</i>	<i>100.0%</i>			
Subtotal of those whose genotype is known	Number	292	51	256	13	<5	0	0	614			
	<i>Percentage</i>	<i>47.6%</i>	<i>8.3%</i>	<i>41.7%</i>	<i>2.1%</i>	<i>&lt;0.4%</i>	<i>0.0%</i>	<i>0.0%</i>	<i>100.0%</i>			

Source: Hepatology Service, GNHFT as of 19<sup>th</sup> May 2014

Numbers less than 5 have been suppressed to protect the anonymity of patients.

## **17. Mortality from hepatitis C**

As with hepatitis B, local mortality data is only available to NHS organisations and there is no standard model for estimating all deaths attributable to hepatitis C. However two ICD10 codes specify deaths with a primary cause of acute (B17.1) or chronic (B18.2) hepatitis C. Local NHS or PHE partners would be able to access and analyse this data for us if there was local agreement that it would be useful.

## **18. Key findings about hepatitis C**

In Gloucestershire:

12. 1,385 15-59 year olds might be living with chronic hepatitis C, if the England prevalence applies. The PHE estimate for Gloucestershire, via their commissioning tool, is 1,529, all ages.
13. 135-357 15-64 year old who inject opiates &/or crack cocaine might have hepatitis C.
14. 78% of eligible drug treatment service users in 2013/14 had been tested for hepatitis C testing compared to 73% across England as a whole in 2012/13. We do not know what percentage of other people eligible for testing have been tested, e.g. from high prevalence countries or positive for hepatitis B or HIV, and this might be difficult to monitor.
15. The local genotype profile is the same as that nationally, although the genotype of 46% of local patients was unavailable.
16. The drop out rate from treatment is low, reportedly 3%-7%. From c2004 to May 2014, the period for which we have data, 72% of patients completing treatment had a sustained virological response.
17. A trial of expanded access to Sofosbuvir is due to start in Oxford and Birmingham. We do not yet know if or how our patients will be able to access the trial.

## CONCLUSIONS & RECOMMENDATIONS

### 19. Conclusions

It is difficult to get meaningful, reliable data about hepatitis B and C. From the data we have:

- there is nothing to indicate that we have a larger disease burden than the England average.
- there is some evidence to suggest we have low hepatitis B immunisation rates. Data quality is an issue.

Overall, not enough information is yet available to give a clear account of these infections in Gloucestershire. This is a problem nationally. Data is spread across a number of organisations, the infections are complex and affect a range of subgroups. Information sharing arrangements have changed since the 2012 Health and Social Care Act too.

### 20. Recommendations

**The main recommendation is for the Health Protection Assurance Group and others to consider this data and next steps.**

When capacity allows, it would seem sensible to seek qualitative information about the experience of providing, accessing and using services from staff, at risk groups and service users. Information might already exist through service complaints and other feedback, although nothing has been available at the time of writing.

Furthermore, general recommendations for a subsequent action plan might include the following, in addition to continuing work to date, based on the experience of gathering information for this project and general good practice:

#### *Local Health system*

1. Agree organisational roles and responsibilities for hepatitis B and C and overarching governance arrangements and share this with staff.
2. Agree thresholds for escalating events or poor or declining performance, particularly for hepatitis B antenatal screening and immunisation and the testing and immunisation of injecting drug users and other risk groups.
3. Consider the feasibility of NICE recommendations (1) for monitoring hepatitis B and C via:
  - Health needs assessment
  - Health equity audit
  - Clinical auditsThese will include monitoring:
  - Number of people tested and diagnosed
  - Number of people with chronic infection who are referred to a treatment service, attend and receive treatment which complies with guidance
  - Number of people with hepatitis C who have a sustained virological response on antiviral therapy (all page 24)
4. Agree information sharing arrangements for using service and other data, particularly until PHE are able to access or report data more fully.

5. Review hepatitis B quality standards which were published by NICE in July 2014, after most of this report was written (21)
6. Agree priority of occupational hepatitis B immunisation. No evidence can currently be provided by main statutory services. The local health system will need to agree what is necessary and feasible.

#### Providers

1. To set up multiagency care pathway group or groups to resolve any operational issues, improve services and co-ordinate clinical audit and other monitoring.
2. Agree multiagency clinical care pathways for hepatitis B and hepatitis C. Flag links to HIV, Children in Care and other pathways where applicable.
3. Regular clinical audit of pathways and services against NICE guidance, including:
  - a. Screening
  - b. Vaccination
  - c. Testing and assessment
  - d. Treatment
  - e. Clinical audit reports and action plans to be shared with Commissioners and Public Health.

#### Commissioners

1. Check that sufficient volume of care has been commissioned. Continue to keep this under review as more data becomes available, e.g. via the JSNA or PHE. NICE recommend consideration of locally enhanced services  
*"...where there is a higher than average number of people at increased risk (especially areas with a large migrant population or high prevalence of people who inject drugs)"* p24 NICE 2013 (1). This report has not reviewed this information. It might apply to some of the Gloucester and Cheltenham practices.
2. Check the hepatitis B and C content in the sexual health, HIV, substance misuse, maternity, paediatrics, medicine, and other contracts. Ensure providers have clear, multiagency clinical pathways for all patient groups affected by hepatitis B &/or C.
3. Ensure the timeliness of hepatitis B infant immunisations improves and seek assurance of coverage of foster carers offering emergency placements.
  - a. Agree commissioning responsibilities for post and pre-exposure.
  - b. Support and ensure providers: collaborate and refine the pathway; proactively escalate issues and keep the pathway fit for purpose.
  - c. Ideally looking for a single, multiagency pathway and description of the clinical governance and assurance system.
  - d. Will include substance misuse services, maternity, health visiting, GP practices, child health department, Children in Care team, paediatrics, microbiology and possibly others.
  - e. Update 2015/16 and future service specifications and manage performance.
4. Work with primary care providers in particular to ensure people at risk are being screened and tested as per NICE guidance (1). This includes, but is not limited to, people from medium or high prevalence countries, men who have sex with men who are offered an HIV test and have not previously tested positive for hepatitis B antibodies, people who have ever injected drugs and anyone who tests negative but remains at risk of infection (page 17 of the guidance).

5. To specify that all providers should ensure their occupational health service achieves and reports high levels of hepatitis B immunisation and hepatitis C testing. This should at least be for exposure-prone staff in community, primary, secondary and tertiary care but would ideally cover all staff eligible via the Green Book. Minimum level to be agreed.

*Public Health England*

1. *Knowledge and Intelligence or Field Epidemiology Teams* to provide annual comparative surveillance data on hepatitis B and C.
2. *Health Protection team* to support local providers to contain cases of acute hepatitis B
3. *Screening and Immunisation team* to investigate hepatitis B antenatal screening with local providers to understand whether the women declining screening are also those most at risk of hepatitis B, and, to work to improve screening rates to at least the regional average.

*Public Health, Gloucestershire County Council*

1. District councils to provide annual statement of assurance about environmental risks. Real-time communication welcomed too.
2. To consider hepatitis B and C as part of the Joint Strategic Needs Assessment<sup>9</sup>. Data is complex and might need to be part of local information sharing agreements. It could be useful to discuss data capture, collation, analysis and reporting with PHE to minimise duplication.
3. Keep aware of any progress nationally on information sharing of incidence, prevalence, positivity, hospital activity and mortality data. Some of this has been made complicated by wider health and social care changes; access is also protected by further law where hepatitis B or C can be considered to be sexually transmitted infections.

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<sup>9</sup> NICE recommends that data should be analysed by country of origin or risk behaviour(1). However, it can be difficult to get and interpret both of these types of data.

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**NICE Guidance**

In reverse date order, most recent first. All accessed 13/01/14 or 29/05/14.

Publication date	Guidance	Link	Headlines
<b>Hepatitis B</b>			
Due July 2014	QS Quality Standards Hepatitis B	<a href="http://guidance.nice.org.uk/QSD/65">http://guidance.nice.org.uk/QSD/65</a> Page last updated 04/03/14	
Sept 2009	PH21 Reducing differences in the uptake of immunisations	<a href="http://guidance.nice.org.uk/PH21/Guidance/pdf/English">http://guidance.nice.org.uk/PH21/Guidance/pdf/English</a> Page last updated 23/12/13	
June 2013	CG165 Hepatitis B (chronic)*	<a href="http://guidance.nice.org.uk/CG165/NICEGuidance/pdf/English">http://guidance.nice.org.uk/CG165/NICEGuidance/pdf/English</a> Page last updated 09/01/14	
July 2009	TA173 Hepatitis B - tenofovir disoproxil fumarate	<a href="http://guidance.nice.org.uk/TA173">http://guidance.nice.org.uk/TA173</a> Page last updated 24/06/13	Tenofovir disoproxil is recommended as a possible treatment for people with chronic hepatitis B.
Aug 2008	TA154 Hepatitis B - telbivudine	<a href="http://guidance.nice.org.uk/TA154">http://guidance.nice.org.uk/TA154</a> Page last updated 24/06/13	Telbivudine is not recommended for people with chronic hepatitis B. Healthcare professionals should not stop prescribing telbivudine for people who were already taking it when the guidance was issued. These patients should be able to carry on taking telbivudine until they and their healthcare professionals decide that it is the right time to stop treatment.
Aug 2008	TA153 Hepatitis B - entecavir	<a href="http://guidance.nice.org.uk/TA153">http://guidance.nice.org.uk/TA153</a> Page last updated 24/06/13	Entecavir is recommended as a possible treatment for people with chronic hepatitis B.
Feb 2006	TA96 Hepatitis B (chronic) - adefovir dipivoxil and pegylated interferon alfa-2a	<a href="http://guidance.nice.org.uk/TA96">http://guidance.nice.org.uk/TA96</a> Page last updated 26/06/13	Partially updated by CG165. Recommendation 1.1 has been incorporated into NICE clinical guideline 165 as recommendation 1.5.8: Peginterferon alfa-2a is recommended as an option for the initial treatment of adults with chronic hepatitis B (HBeAg-positive or HBeAg-negative), within its licensed indications. Recommendations 1.2, 1.3 and 1.4 have been replaced by recommendations 1.5.13, 1.5.14 and 1.5.15 in NICE clinical guideline 165. Adefovir dipivoxil is no longer recommended for the treatment of chronic hepatitis B
<b>Hepatitis C</b>			
No due date given	CG Hepatitis C: diagnosis and management of hepatitis C	<a href="http://guidance.nice.org.uk/CG/Wave0/666">http://guidance.nice.org.uk/CG/Wave0/666</a> Page last updated 28/05/14	
Due Jan 2015	TA Hepatitis C (chronic) - simeprevir	<a href="http://guidance.nice.org.uk/TAG/456">http://guidance.nice.org.uk/TAG/456</a> Page last updated 31/01/14	
Nov 2013	TA300 Hepatitis C (children and young people) peginterferon alpha	<a href="http://guidance.nice.org.uk/TA300">http://guidance.nice.org.uk/TA300</a> Page last updated 14/05/14	Peginterferon alfa with ribavirin is recommended as a possible treatment for children and young people with chronic hepatitis C. Partially updates TA106 and TA75.

Publication date	Guidance	Link	Headlines
	and ribavirin		
Apr 2012	TA252 Hepatitis C (genotype 1) - telaprevir	<a href="http://guidance.nice.org.uk/TA252">http://guidance.nice.org.uk/TA252</a> Page last updated 10/01/14	NICE recommends telaprevir with peginterferon alfa and ribavirin as a possible treatment for genotype 1 chronic hepatitis C in adults with the earlier stages of liver disease (known as compensated liver disease).
Apr 2012	TA253 Hepatitis C (genotype 1) - boceprevir	<a href="http://guidance.nice.org.uk/TA253">http://guidance.nice.org.uk/TA253</a> Page last updated 07/09/12	NICE recommends boceprevir with peginterferon alfa and ribavirin as a possible treatment for genotype 1 chronic hepatitis C in adults with the earlier stages of liver disease (known as compensated liver disease).
Sept 2010	TA200 Hepatitis C - peginterferon alfa and ribavirin	<a href="http://guidance.nice.org.uk/TA200">http://guidance.nice.org.uk/TA200</a> Page last updated 20/02/14	NICE recommends peginterferon alfa (2a or 2b) plus ribavirin as a possible treatment for people with chronic hepatitis C: who have been treated previously with peginterferon alfa (2a or 2b) plus ribavirin, or with peginterferon alfa monotherapy, but their hepatitis C didn't improve, or improved but then got worse again or who also have an HIV infection. NICE also recommends short courses of treatment with peginterferon alfa (2a or 2b) plus ribavirin for people whose hepatitis C has greatly improved within 4 weeks of starting treatment and who are suitable for short treatment courses . Whether a person is suitable for a short treatment course will depend on a number of factors. Partially updates TA106 and TA75. Due for review July 2013.
Aug 2006	TA106 Hepatitis C - peginterferon alfa and ribavirin	<a href="http://guidance.nice.org.uk/TA106">http://guidance.nice.org.uk/TA106</a> Page last updated 02/04/14	This guidance has been partially updated by TA200 and TA300. Peginterferon alfa and ribavirin are recommended as possible treatments for people with mild chronic hepatitis C if they are suitable for the person and are used in these ways: A person who has mild chronic hepatitis C is offered treatment with a combination of peginterferon alfa and ribavirin. People who are not able to take ribavirin are offered treatment with peginterferon alfa on its own. The person's doctor should discuss with them whether to start treatment immediately, or to wait and only take the drugs if the disease gets worse. If the person has had treatment with peginterferon alfa (with or without ribavirin) but it has not worked after 12 weeks, they should not be offered a second course of treatment. NICE has not been able to make a recommendation about whether peginterferon alfa is suitable for people who are younger than 18 years old, or who have had a liver transplant, because there is not enough evidence.
Jan 2004	TA75 Hepatitis C - pegylated interferons, ribavirin and alfa interferon	<a href="http://guidance.nice.org.uk/TA75">http://guidance.nice.org.uk/TA75</a> Page last updated 02/04/14	This guidance replaces TA14. This guidance is extended by TA106. This guidance has been partially updated by TA200 and TA300.
Oct 2000	TA14 Hepatitis C - alpha interferon and ribavirin	<a href="http://guidance.nice.org.uk/TA14">http://guidance.nice.org.uk/TA14</a> Page last updated	Replaced by TA75.

Publication date	Guidance	Link
<b>All BBVs</b>		
Dec 2012	PH43 Hepatitis B and C: ways to promote and offer testing to people at increased risk of infection	<a href="http://guidance.nice.org.uk/PH43/Guidance/pdf/English">http://guidance.nice.org.uk/PH43/Guidance/pdf/English</a> Page last updated 09/04/13
Nov 2012	QS23 Quality standard for drug use disorders	<a href="http://publications.nice.org.uk/quality-standard-for-drug-use-disorders-qs23">http://publications.nice.org.uk/quality-standard-for-drug-use-disorders-qs23</a> Date not given for when page last updated
Nov 2011	CG132 Caesarean section	<a href="http://guidance.nice.org.uk/CG132/Guidance/pdf/English">http://guidance.nice.org.uk/CG132/Guidance/pdf/English</a> Page last updated 01/11/12
June 2010	CG100 Alcohol-use disorders: Diagnosis and clinical management of alcohol-related physical complications	<a href="http://guidance.nice.org.uk/CG100/NICEGuidance/pdf/English">http://guidance.nice.org.uk/CG100/NICEGuidance/pdf/English</a> Page last updated 17/01/11
Feb 2009	PH18 Needle and syringe programmes	<a href="http://guidance.nice.org.uk/PH18/Guidance/pdf/English">http://guidance.nice.org.uk/PH18/Guidance/pdf/English</a> Page last updated 24/01/13
July 2008	CG62 Antenatal Care	<a href="http://guidance.nice.org.uk/CG62/Guidance/pdf/English">http://guidance.nice.org.uk/CG62/Guidance/pdf/English</a> Page last updated 30/03/10
Aug 2007	PH3 Prevention of sexually transmitted infections and under 18 conceptions	<a href="http://guidance.nice.org.uk/PH3/Guidance/pdf/English">http://guidance.nice.org.uk/PH3/Guidance/pdf/English</a> Page last updated 15/01/11
Oct 2006	CG37 Postnatal Care	<a href="http://guidance.nice.org.uk/CG37/Guidance/pdf/English">http://guidance.nice.org.uk/CG37/Guidance/pdf/English</a> Page last updated 22/01/11
<b>HIV</b>		
March 2011	PH33 Increasing the uptake of HIV testing among black Africans in England	<a href="http://guidance.nice.org.uk/PH33/Guidance/pdf/English">http://guidance.nice.org.uk/PH33/Guidance/pdf/English</a> Page last updated 24/01/13
March 2011	PH34 Increasing the uptake of HIV testing among men who have sex with men	<a href="http://guidance.nice.org.uk/PH34/Guidance/pdf/English">http://guidance.nice.org.uk/PH34/Guidance/pdf/English</a> Page last updated 24/01/13
	<i>See list of technology appraisals for treatment guidance</i>	<a href="http://guidance.nice.org.uk/TA/Published">http://guidance.nice.org.uk/TA/Published</a>

## Health Needs Assessment

The Health Development Agency, later subsumed into the National Institute for Clinical and Health Excellence, defined Health Needs Assessment as

*“..a systematic method for reviewing the health issues facing a population, leading to agreed priorities and resource allocation that will improve health and reduce inequalities..”* (22).

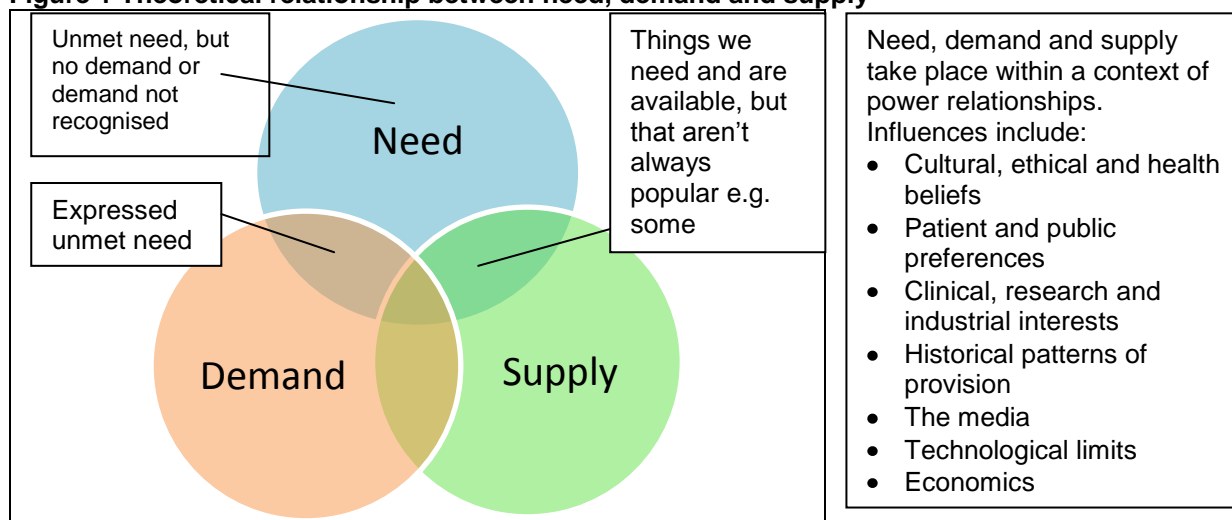
Definitions and perceptions of need vary<sup>10</sup>. Health Needs Assessments typically triangulate three approaches to reach a consensus on local need (22):

- Epidemiological – data to describe the population and the prevalence and pattern of disease.
- Stakeholder – also known as “corporate”. Feedback from stakeholders, including service users, about the experience of need and strengths and weaknesses of current provision
- Comparative – evidence from the wider research literature and similar populations or organisations.

Health Needs Assessments seek to distinguish need from demand or supply, as shown in **Figure 1**. True need can be understood as the capacity to benefit from interventions. Demand is “expressed need” and is dependent on people perceiving both that they are in need and that their needs can or should be met. Lastly, supply-led systems are dominated by what is available, potentially irrespective of what is truly useful.

If people in need do not recognise themselves as being able to benefit from healthcare then demand is low, services do not experience pressure but health outcomes can be poor.

**Figure 1 Theoretical relationship between need, demand and supply**



Adapted from Stevens, Raftery and Mant (23)

<sup>10</sup> Bradshaw (1972) defined types of need, which are commonly used in public health: normative (expert opinion), felt (personal perception), expressed (demand and service use) and comparative (benchmarking against others) (23) (28).

**Populations at risk of exposure: healthcare workers**

We do not know how many people are at risk of hepatitis B or C infection due to the nature of their work, e.g. through needlestick injuries, undertaking exposure-prone procedures or otherwise having higher risk of exposure to the infections through their work than the risk for the general public.

We know that a large number of people work in health and drugs services. Immunisation and testing is recommended for prison staff too, but the prison closed in March 2013.

**Estimates of healthcare workers**

The main public sector employers and commissioners of clinical services in Gloucestershire have provided crude estimates of how many staff might be at risk, shown in **Table 1** below.

**Table 1. Estimated number of people working in public sector healthcare in Gloucestershire and in clinical or other frontline roles which might put them at risk of exposure to blood borne viruses.**

Organisation	Estimate	Definition/Comments
Gloucestershire Hospital NHS Foundation Trust	Not known	Currently no estimate available through occupational health or emergency preparedness.
Gloucestershire Care Services	1,725	Estimate from crude breakdown of the no. people employed in different staff groups. Not all would be at risk of exposure, and some non-clinical posts could be at risk of exposure. Total of 2981 people employed including 609 AHPs, 65 medical & dental; 1517 nursing, midwifery, health visiting or HCA staff and 743 clerical or estates.
2Gether	1,070	No. frontline staff who would be offered flu immunisation
Primary care, estimate via NHS England	Not yet available	Primary care commissioning colleagues are estimating this figure for us.

There might be as many as 19,700 people working in “human health” organisations in Gloucestershire, according to the annual business register survey.

**Estimate of people employed by “human health activities”**

Business Register and Employment Survey

The only routine information about employment is the Business Register and Employment Survey. This is a national annual survey of employers and asks the number of people they employ and the main purpose of the organisation.

The Office for National Statistics collates the responses. It categorises businesses by their main purpose and uses the data to model how many people locally and nationally work in each category of business. All staff in each organisation are assigned to that business type, irrespective of the nature of their specific role.

The ONS publishes its subsequent estimates online, rounded to the nearest 100. National data is publicly available. Gloucestershire County Council has a licence to access County Council level data.

Estimate of people working in “human health activities” in Gloucestershire.

19,700 people were estimated to be working in “human health activities” in Gloucestershire in 2012, the most recent estimate(24).

This estimate includes:

- All staff irrespective of whether they are full or part time, permanent or temporary.
- All staff whether their own role is specific to health e.g. the financial teams within hospitals are included.
- Public sector, private sector and charitable organisations.
- People who live outside of Gloucestershire but who work in Gloucestershire

This estimates excludes:

- People who have a health role in organisations whose primary purpose is not health e.g. occupational health staff in a manufacturing firm.
- People who live in Gloucestershire but work in health organisations outside of Gloucestershire.

If we assume the inclusions balance the exclusions, this means that there might be up to 19,700 people in Gloucestershire who could be at occupational risk. A breakdown by subcategory of organisation purpose is shown in Table 2 below and followed by category definitions.

**Table 2. Estimated number of staff working in Gloucestershire in organisations whose main business is “human health activities”, rounded to the nearest 100.**

<b>Human health activities &amp; sub-categories</b>	<b>Estimated number of staff</b>
<b>86 : Human health activities</b>	<b>19,700</b>
<b>861 : Hospital activities</b>	<b>14,400</b>
<b>862 : Medical and dental practice activities</b>	<b>3,400</b>
8621 : General medical practice activities	2,400
8622 : Specialist medical practice activities	100
8623 : Dental practice activities	900
<b>869 : Other human health activities</b>	<b>2,000</b>

Source: Taken from Nomis on 20 June 2014. ONS Crown Copyright Reserved

The detailed category definitions from ONS are available separately.

**Populations at risk of exposure – Injecting drug use**

To help to put the following figures in context, the Office for National Statistics estimated our population to be 602,159 in mid-2012. (25).

**Injecting drug use**

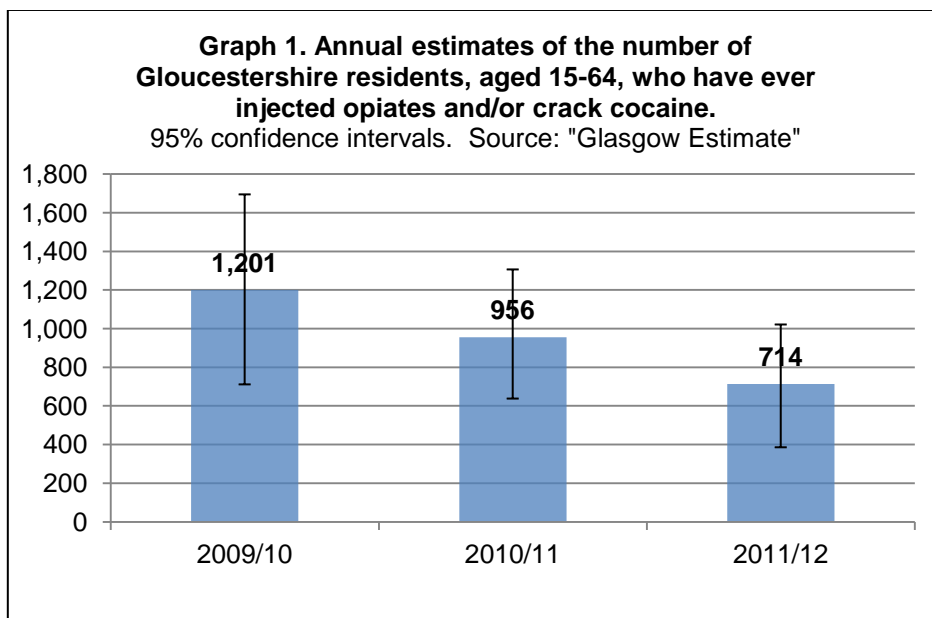
Each year Glasgow University estimates the number and rate of 15-64 year olds who are thought to have injected opiates and/or crack cocaine that year. The latest estimates are for 2011/12 (26). Taking numbers and rates in turn:

Estimated number of people who have injected drugs

According to the latest annual estimate published by PHE using NDTMS data, an estimated 714 Gloucestershire residents aged 15-64 injected opiates and/or crack cocaine at some point in their life (27). The equivalent estimate for England is 87,302. There will be an additional small number of people who inject other illicit substances, including amphetamines, melatonin and steroids, and might be vulnerable to BBVs via shared equipment.

The estimates are published with 95% confidence intervals, which show that 385-1,021 is 95% likely to include the true Gloucestershire figure. This is a large interval as the estimate is only approximate and small numbers can fluctuate greatly due to chance.

The report suggests that the number of injectors has fallen in recent years in England, the South West and in Gloucestershire. Gloucestershire's figures for the last 3 years are shown with confidence intervals in **Graph 1**.



The decrease in Gloucestershire is not statistically significant; it might be due to chance and the true figure might actually have continued or increased over this time.

Nevertheless, the local public health commissioning team has a sense that the Glasgow estimates have been higher than the true figure and also that there is likely to have been a real decrease over time too:



- Local treatment services seem to be aware of the large majority of users, for example most injectors will come into contact with the criminal justice system at some point. Local commissioners are satisfied that there are not large numbers of injectors coming through the criminal justice system who are unknown to treatment services.
- Nationally fewer young people are starting opiate or crack use so the population is an aging one and may be falling.
- Local treatment services undertook a series of data cleansing exercises in 2010-11, to remove any duplicate or erroneous entries, which is also likely to have reduced the estimate.

**Table 1. Estimated number of Gloucestershire residents aged 15-64 year who injected opiates and/or crack cocaine, with 95% confidence intervals. "Glasgow Estimate" (26)**

Year	Estimate of no. injectors	Lower 95% CI	Upper 95% CI
2009/10	1,201	711	1,694
2010/11	956	637	1,306
2011/12	714	385	1,021

Estimated proportion of people who injected drugs

The estimated proportion in Gloucestershire is lower than the estimated proportion for the South West and this difference is statistically significant.

As the numbers are small, they are reported here as per 10,000 population rather than as a percentage (/100). Gloucestershire has one of the lowest estimated rates in the South West at 18.5 per 10,000 15-64 year olds, i.e. for every 10,000 of 15-64 years we estimate that 18.5 of them injected opiates and/or crack cocaine. Estimated rates in the South West range from 67.5 in Bournemouth to 11.5 in South Gloucestershire.

The estimated rate for Gloucestershire is also lower than the estimated rate for England, but this difference is not statistically significant and our true rate could be the same or higher than the true rate for England. The estimated rate for the South West is higher than the estimated rate for England, and this difference is statistically significant.

The figures shown in **Table 2** and **Graph 2** below.

**Table 2.**

Population	Estimated prevalence of injecting per 10,000 population	Lower bound 95% CI	Upper bound 95% CI
Gloucestershire	18.48	9.97	26.42
South West	29.90	27.95	32.33
England	24.95	24.38	25.82

