



An audit of Strategic Health Authority  
hepatitis C governance

16<sup>th</sup> July 2009



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## 1. Abbreviations

APPHG	All-Party Parliamentary Hepatology Group
BBV	Blood Borne Virus
DH	Department of Health
FOI	Freedom of Information
GP	General Practitioner
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
HPA	Health Protection Agency
HPS	Health Protection Scotland
IDU	Injecting Drug User
MCN	Managed Care Network
NHS	National Health Service
NICE	National Institute for Health and Clinical Excellence
NPHSW	National Public Health Service for Wales
PCT	Primary Care Trust
QIS	NHS Quality Improvement Scotland

## 2. Acknowledgements

The Hepatitis C Trust would like to thank Roche for allowing the inclusion of new data showing the implementation of NICE guidance on hepatitis C treatment. The Trust would also like to thank the All-Party Parliamentary Hepatology Group for allowing the inclusion of findings from their reports *Divided Nations*, *Location, Location, Location* and *A Matter of Chance*.

### 3. Executive summary

Deaths caused by hepatitis C, a cancer-causing infectious blood-borne virus, are rising, contributing to a national liver health crisis. Liver disease is the fifth biggest killer in the UK and the UK is the only developed country where liver disease is on the rise. This poor performance on liver disease can be explained in part by the failure to successfully address hepatitis C, which is both treatable and preventable.

In 2004 the Department of Health published the Hepatitis C Action Plan for England, which set out actions on surveillance, research, increasing awareness and prevention and improving service quality for patients. However, there is concern, most recently expressed by the All Party Parliamentary Hepatology Group in its report, *Divided Nations: Tackling the hepatitis C challenge across the UK*, that there is a lack of implementation of the Action Plan because of poor governance arrangements, monitoring and evaluation<sup>1</sup>.

Our audit of Strategic Health Authorities (SHAs) shows that 70% of SHAs are failing to oversee the implementation of the Action Plan, despite the fact that responsibility for oversight is placed with them in the Action Plan. Some are not aware of any local arrangements in place to deliver the Plan. Furthermore, there is absolutely no mechanism for checking that SHAs have been performing their oversight role.

This lack of oversight has allowed inaction and complacency on hepatitis C at every level of the health service: most PCTs have not implemented the Department of Health's *Hepatitis C Action Plan for England*<sup>2</sup> and NICE recommended treatment is being grossly underused across the country<sup>3</sup>.

As a result we are facing a silent epidemic of hepatitis C: over 100,000 patients remain undiagnosed<sup>4</sup>; too few of those diagnosed are receiving the recommended treatment; and there are worrying regional variations in hepatitis C healthcare and delivery of treatment across the country. Of particular concern is the number of new infections each year – more than five times the number of people being successfully treated – indicating that prevention methods are not working. Clearly, the management of hepatitis C is out of control.

Hepatitis C is a national public health problem and gaining control of it will require central direction and leadership – something which this report reveals is singularly lacking. Poor oversight on hepatitis C delivery has resulted in significant regional variations in treatment and, unless a new national strategy is adopted, the postcode lottery of hepatitis C care will persist and preventable deaths will continue. Urgent action is now needed by the Department of Health to address this growing public health crisis.

#### The Hepatitis C Trust calls for:

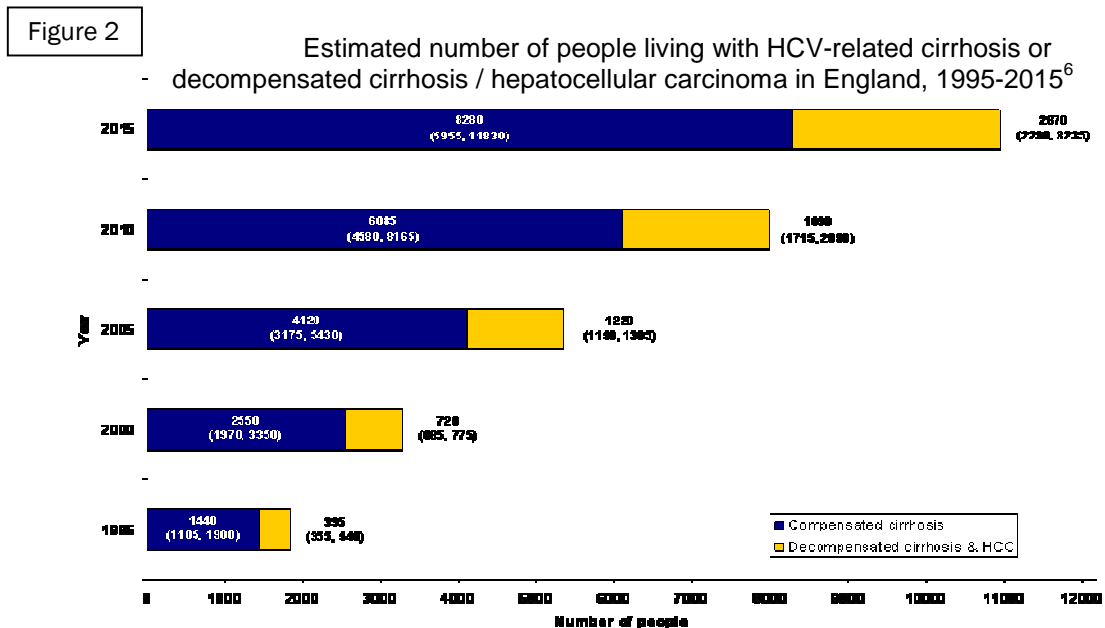
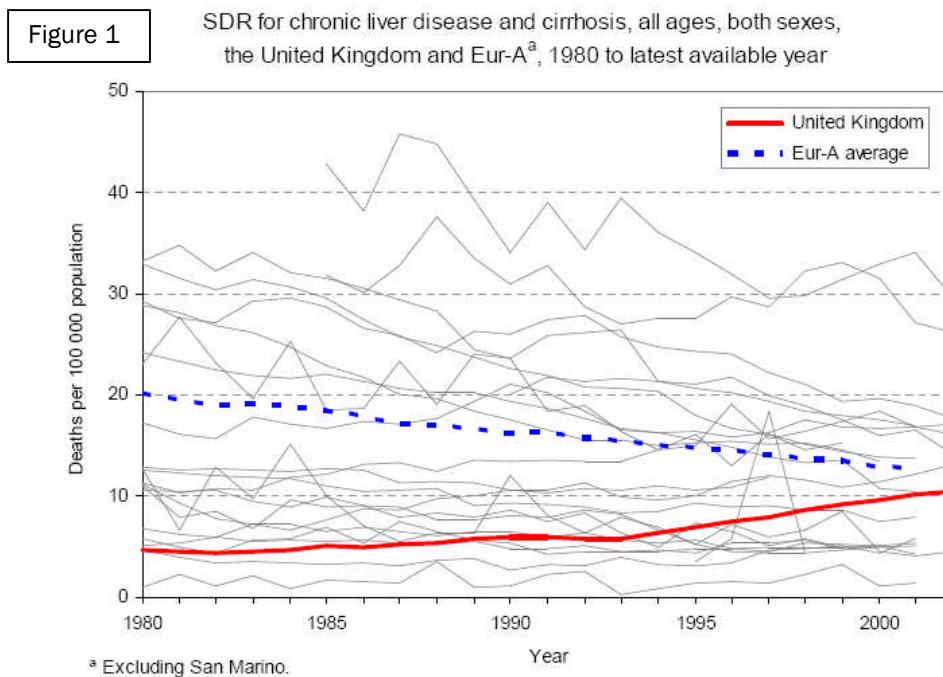
1. **A national liver czar** responsible for driving forward improvements in liver services, particularly hepatitis C.
2. **A national liver strategy** to address the growing crisis of liver disease, with clearly defined actions for addressing hepatitis C.
3. **A robust governance structure** to oversee the monitoring, benchmarking and evaluation of actions for hepatitis C by all levels of the NHS. These should be reported annually in the HPA report on hepatitis C.
4. **A review of the implementation of NICE treatment** and an audit of the barriers to achieving the recommended treatment uptake levels.

## 4. Background

### a. About hepatitis C

Hepatitis C is a cancer-causing infectious blood borne virus that is undiagnosed in the majority of the 250,000 to 466,000 people infected in the UK.<sup>5</sup> The virus is preventable and can be successfully treated and cured in around half of patients, averting complicated and costly health interventions and avoiding premature death.

Overall, deaths from liver disease are declining in Europe. In contrast, the UK already faces an increasing mortality rate (see figure 1). A major contributory factor has been the increase in cirrhosis and in decompensated cirrhosis and liver cancer (hepatocellular carcinoma), which is projected to continue rising sharply over the next six years in the absence of “increasing diagnosis and treatment for infected individuals” (see figure 2).



Unless urgent action is taken to improve the rates of diagnosis and treatment, the prevalence of hepatitis C will continue to rise, resulting in ever increasing costs for the NHS and an unacceptable number of deaths which could have been prevented.

## **b. Current policy on hepatitis C**

The Department of Health responded to the public health challenge of hepatitis C with a 'Hepatitis C Strategy for England' in 2002 and then published a 'Hepatitis C Action Plan for England' in 2004, which detailed a series of actions for Primary Care Trusts (PCTs) and NHS Hospital Trusts to address hepatitis C in their local areas.

The Action Plan tasked Strategic Health Authorities with ensuring that local NHS arrangements were in place to deliver a number of improvements<sup>7</sup>, including:

- Commissioning of specialised hepatitis C services for their patient population
- Development of hepatitis C clinical networks
- Access to accredited laboratory services with appropriate hepatitis C tests and services
- Development of local hepatitis C protocols between primary and secondary care
- Sufficient numbers of appropriately skilled staff to deliver hepatitis C service improvements
- Multi-agency arrangements for hepatitis C prevention through Drug Action Teams
- Strengthened harm reduction services associated with injecting drug use
- Adoption of rigorous infection control precautions in NHS organisations
- Promotion and audit of good infection control practice in cosmetic piercing businesses

The National Institute for Health and Clinical Excellence (NICE) has recommended that combination therapy with peginterferon alfa + ribavirin should be used to treat people aged 18 years or older who have mild to severe chronic hepatitis C, if they are suitable for the individual.<sup>8</sup>

## **c. Effectiveness of current efforts to tackle hepatitis C**

Unfortunately, evidence suggests that the Department of Health's Action Plan has failed to successfully address the increasing problem of hepatitis C:

- Many PCTs have failed to implement the Action Plan effectively. An audit in 2008 found that half of PCTs were only partially implementing the Action Plan and in 15% of PCTs there was minimal implementation or none at all.<sup>9</sup>
- Even the most conservative estimates of prevalence show that half of the people living with hepatitis C in the UK are still undiagnosed.<sup>10</sup>
- Levels of public awareness of hepatitis C remain low (a poll in 2007 found that just 29% of the general public think that they know a great deal or a fair amount about hepatitis).<sup>11</sup>
- Too many primary care professionals are not equipped with the skills needed to make accurate diagnoses of hepatitis C, let alone to provide patients with comprehensive support and advice on managing their condition.<sup>12</sup>

The result is that England lags behind other countries in its efforts to tackle hepatitis C. A recent report by the APPHG, *Divided Nations: tackling the hepatitis C challenge across the UK*, highlighted the importance of monitoring and of having clear measures of accountability to ensure effective implementation of prescribed actions. It found that the lack of monitoring and governance arrangements in the Action Plan for England had hampered implementation and contrasted this with the robust governance structures set out in the Action Plan for Scotland.<sup>13,14</sup>

#### **d. Report rationale**

Although PCTs were tasked with implementing much of the Action Plan, SHAs were given the primary oversight responsibility:

*“Strategic Health Authorities will ensure that local NHS arrangements are in place to achieve the objectives of these [Prevention and High Quality Health and Social Care Services] action areas.”<sup>15</sup>*

In spite of this, the Department of Health has not published any analysis of the effectiveness of SHAs in discharging these responsibilities. Therefore the Hepatitis C Trust determined to audit SHA performance on hepatitis C, using the Freedom of Information Act 2000.

Given that hepatitis C is a virus that can be eradicated in the majority of patients, thereby halting and in some cases reversing liver disease as well as preventing onward transmission, the Trust also decided to look at levels of treatment across the country. To assist in this research we were given access to Roche’s recent data and research on treatment rates.

#### **e. Report methodology**

The Hepatitis C Trust submitted 17 separate requests to each of the 10 SHAs in England, seeking information on how they had discharged the responsibilities set out for them in the Action Plan. The full list of requests is included in Annex 1. The actions that these are based on are included in Annex 2.

The SHAs were given a score between 0 and 3 for each question as follows:

- 0 = no action, monitoring or oversight
- 1 = demonstrated awareness of action being undertaken by another body
- 2 = stated action, monitoring or oversight
- 3 = evidenced action, monitoring or oversight

Therefore every SHA was awarded a mark out of 51 which was then converted into a percentage score. It is important to note that SHAs are not required to respond to Freedom of Information Requests in a set format. Therefore the resultant scores and analysis are The Hepatitis C Trust’s interpretation of the information provided by SHAs. The variation in quality, format and substance of the responses received highlights the need to develop a standard performance monitoring template for hepatitis C so that patients, policymakers and the public are able to effectively hold the NHS to account for its performance in tackling this critical public health issue.

Data on drug utilisation collected by IMS Health and supplied to the Hepatitis C Trust by Roche, as well as information from the HPA on rates of diagnosis and estimates of prevalence, have been used to develop a picture of the extent to which health services are successfully treating people infected with hepatitis C. Further information on the methodology used is included in Annex 3.

The way in which the Health Protection Agency diagnosis data is collected and reported means that it is only possible to provide an accurate breakdown to Government Office of the Region level. These regions are broadly contiguous with Strategic Health Authority boundaries.

**5. Results of the audit of Strategic Health Authorities**

The audit reveals significant variations in the extent to which SHAs are fulfilling the responsibilities set out for them in the Action Plan:

Strategic Health Authority	Percentage score	Level of oversight
South East Coast *	0 % *	Very poor
North East	12 %	Very poor
London	16 %	Very poor
South West	18 %	Very poor
Yorkshire and The Humber	20 %	Very poor
South Central	27 %	Poor
North West	33 %	Poor
West Midlands	55 %	Fair
East Of England	59 %	Fair
East Midlands	92 %	Excellent

<p>Key:</p> <ul style="list-style-type: none"> <li>• Excellent oversight of implementation of the Action Plan ..... 91-100</li> <li>• Very good oversight of implementation of the Action Plan ..... 81-90</li> <li>• Good oversight of implementation of the Action Plan ..... 61-80</li> <li>• Fair oversight of implementation of the Action Plan ..... 41-60</li> <li>• Poor oversight of implementation of the Action Plan ..... 21-40</li> <li>• Very poor oversight of implementation of the Action Plan ..... 0-20</li> </ul>
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*\*South East Coast SHA re-submitted their audit form and related data after the initial publication of these results. Their new score is 92%.*

The responses from the SHAs revealed that there is confusion about the role that SHAs should play in supporting the NHS in improving hepatitis C services, with several SHAs not even aware that they are mandated to ensure the Action Plan is implemented. For example, South East Coast SHA has not made any attempt to monitor hepatitis C, simply stating that ‘NHS South East Coast does not hold any of the information you requested’.

This lottery of oversight may be an important factor in the extreme variations which exist between PCTs on hepatitis C diagnosis and treatment rates.

Beneath the headline findings from the SHA audit, worrying inequalities emerge in many areas of provision:

**Assessing health needs**

In order to ensure that services are in place to address the needs of hepatitis C in a region, a SHA should assess the health needs of the local population and the existing service provision. East Midlands SHA has done extensive work auditing the existing provision of hepatitis C services and assessing the needs of the local population through a regional hepatitis C virus group and the development of a regional strategy. However, Yorkshire and Humber, North East, London, South East, South West and North West SHAs have not conducted any assessment of hepatitis C provision or the needs of their populations and are therefore not aware of the health needs of their areas. This is concerning as, without a full understanding of the needs of hepatitis C in a region, SHAs will have a limited ability to ensure that services are developed to address gaps in provision or areas of poor performance.

## **Commissioning**

Commissioning good quality and appropriate services for hepatitis C is key to delivering improved health outcomes in hepatitis C. The Action Plan tasks SHAs with ensuring that NHS arrangements are in place for commissioning the specialised hepatitis C services needed for their patient population. However, only East Midlands, West Midlands and East of England SHAs have provided any direct oversight of commissioning in their areas. Several of the SHAs simply state that commissioning is a PCT responsibility and do not appear to be aware of their oversight responsibilities set out in the Action Plan (detailed in annex 1).

## **Prevention**

With new infections of hepatitis C estimated at 12,995 per year nationally (see annex 4), all parts of the NHS should work together locally to prevent further infections in order to minimise the disease burden in the future. However, only East Midlands, West Midlands and the East of England SHAs have ensured that local NHS arrangements are in place for drug action teams to develop multi-agency working for the prevention of hepatitis C. Further, six of the SHAs have not ensured that local NHS arrangements are in place in order for the National Treatment Agency, Drug Action Teams and HM Prison Service to review and strengthen harm reduction services for the prevention of transmission associated with injecting drug use.

## **Prison health**

The last Department of Health survey of blood borne viruses in prisons showed that 7% of prisoners are infected with hepatitis C.<sup>16</sup> Prisons therefore represent an important opportunity to diagnose and treat patients and to prevent further transmissions. However only three SHAs (East Midlands, South West and East of England) had directly communicated with HM Prison Service in the past three years.

## **Workforce planning**

The Workforce Directorates in six of the ten SHAs have not worked with Care Group Workforce Teams to ensure that there are enough appropriately skilled hepatitis C staff in their region. Perhaps this is unsurprising given that only five SHAs had estimated the prevalence of hepatitis C in their area and only three knew the number diagnosed and could therefore know the level of staffing required.

## **Local protocols**

For the successful management of hepatitis C, patients must be diagnosed and referred to secondary care for further assessments, treatment and care. However, the poor diagnosis rates and low treatment levels detailed in section 6.a below indicate that this is not happening successfully in most SHA areas. This may be in part due to a lack of SHA oversight of the development of local protocols: the audit revealed that only Yorkshire and Humber, East Midlands and West Midlands had assessed the effectiveness of local protocols between primary and secondary care.

## **Laboratory Services**

Over half (six out of ten) of the SHAs have not made any attempt to ensure local NHS arrangements are in place for delivering access to accredited laboratory services. Although The Hepatitis C Trust is unaware of any current problem in accessing accredited laboratory services, an unpublished survey carried out by the Trust revealed widely varying times for the delivery of

test results. In some cases simple antibody tests took two months or more, an unacceptable and bitterly resented wait for patients. The Trust has also received reports of incorrect virus genotyping, an uncommon but nevertheless extremely concerning event, potentially leading to incorrect duration of treatment and consequently greatly reduced chances of virus eradication.

### **Performance oversight**

The lack of performance management of hepatitis C in many areas of the country is exemplified by the fact that only four of the ten SHAs had directly communicated with their constituent PCTs regarding hepatitis C in the last three years. North East, London, South East Coast and South Central SHAs have not had any communication with their PCTs regarding hepatitis C in the last three years, and Yorkshire and Humber and South West SHAs were aware only of indirect communications from other NHS organisations about the virus – they had not communicated with PCTs themselves.

The fact that only three of the ten SHAs scored over 33% in this audit shows the lack of performance oversight being conducted. This makes it all the more important that we develop an accurate means of understanding what is happening at a PCT and NHS trust level. This report has demonstrated the need for further detailed monitoring and auditing of hepatitis C provision at all levels of the NHS.

6. The Impact on patients

a. Delivery of treatment

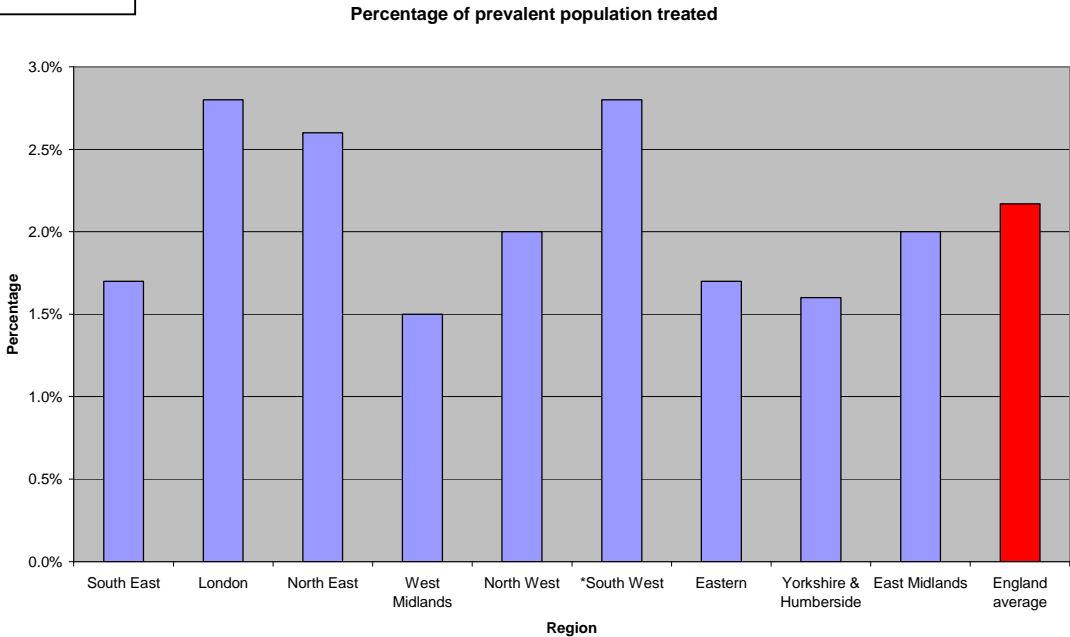
Many patients can be successfully treated for hepatitis C, enabling the virus to be eradicated from their body. Since 2000 NICE has given clear recommendations on treatments for hepatitis C on several occasions giving explicit and positive endorsement for the treatment of mild to severe hepatitis C. <sup>17</sup>

The current NICE endorsed standard of care for the management of chronic hepatitis C is pegylated interferon and ribavirin combination therapy. NICE guidelines indicate that in 2006, from a baseline of 41%, the proportion of diagnosed patients accessing treatment should be up to 60%.<sup>18</sup>

However, in 2007 only 29% of diagnosed patients were treated with NICE approved antiviral therapy. The headline figure masks the significant variations in treatment levels between regions, where treatment ranges from 16% to 57% (see annex 5).

Further, there are significant variations in the numbers of patients who have been diagnosed in each area. When assessing the estimated prevalent population infected with hepatitis C, no SHA area manages to treat more than 3% of their infected population in a year (see figure 2).

Figure 2



Note: information on South Central SHA is captured in both the South East and South West HPA regions.

b. Mortality

Deaths, transplants and hospital admissions for HCV-related end stage liver disease are rising: deaths in England attributable to hepatitis C have doubled in the past 10 years<sup>19</sup> and the number of people with HCV-related cirrhosis is expected to more than double to 8,280 by 2015.<sup>20</sup>

Health Protection Scotland undertook research into projected deaths from hepatitis C in order to estimate how many patients should receive treatment if they were to flatten the rising mortality curve. Based on this research, the Scottish Government has set targets to increase the number of people receiving treatment from 450 to 2,000 per year by 2011. Comparable research has not been conducted for the patient population in England, but extrapolating from the Scottish research on a population size basis indicates that England should be treating around 20,000 people per year in order to flatten the mortality curve.

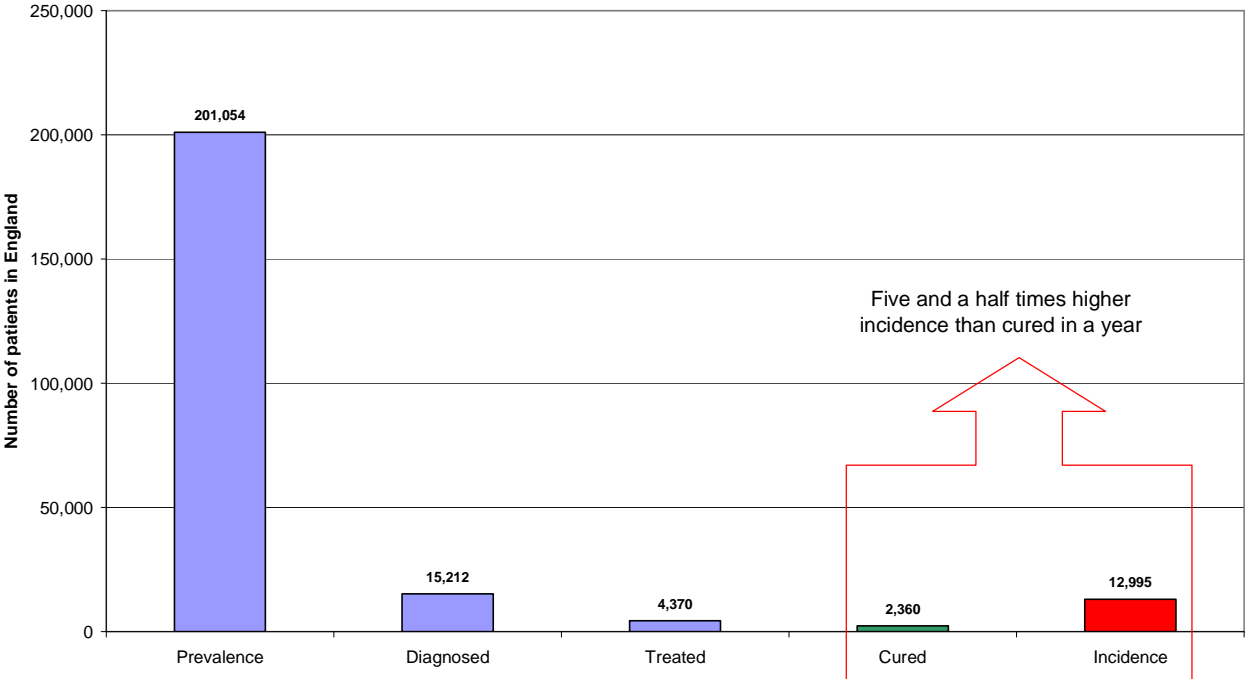
At present around 5,000 people are receiving treatment in England per year. Quadrupling the number of people currently being treated would require significant improvements in diagnosis, care and support for hepatitis C patients.

**c. Incidence**

The poor treatment rates, coupled with an incidence of around 12,995 new infections per year (see annex 4), means that hepatitis C is a significantly escalating problem in England. Many more people are contracting hepatitis C each year than are being cured, as shown in the figure 3.

Figure 3

Hepatitis C Patient Flow: incidence vs. prevalence and numbers diagnosed, treated and cured annually<sup>21</sup>



Note: Figure for prevalence is HPA estimate and is significantly lower than other estimates. Figure for annual diagnosis is new HPA estimate and is higher than laboratory reported cases

To estimate the incidence rates across the country, we used a standard variable of 6.46% (the total estimated annual incidence of 12,995 as a percentage of the total HPA estimate of prevalence in England of 201,054). This indicates that there are huge regional variations in numbers of new infections per year (see annex 6 for the breakdown), with new infections in London as high as 3,345 per year.

## 7. Lessons from other models of governance

It is clear from the findings of our audit that there is a need for significant improvements to the structures in place in the NHS to oversee and implement the Hepatitis C Action Plan. A recent report by the APPHG identified that England has much to learn from the Scottish model of governance.<sup>22</sup>

Each organisation involved with implementing the Action Plan for Scotland has a well-defined role and is directly accountable to the Scottish Government through clear reporting and governance structures. The Action Plan initiates local networks for the planning, implementation and audit of services, as well as national networks so that best practice and progress on delivery of the Action Plan can be shared.

The implementation of the Action Plan for Scotland is monitored locally and information is fed into Health Protection Scotland. To ensure this process is consistent and well managed, a Project Management approach has been employed. An Action Plan Governance Board, run by HPS and comprising representatives of lead organisations, will facilitate and co-ordinate the reporting process. The Scottish Government is establishing an Action Plan Advisory Board to advise on progress with, and issues concerning, Action Plan delivery.

These actions are intended to ensure the successful delivery of the Action Plan for Scotland. It highlights the deficiencies in the approach to governance in the Action Plan for England, given the evident confusion about SHAs' role in overseeing PCT implementation.

There is a clear need for a more robust strategy in England which learns from Scotland's experience and prevents England falling further behind in addressing hepatitis C. A clearer governance structure will help drive implementation, help identify problems and help spread best practice.

A national liver strategy, co-ordinated by a national liver czar, would address these deficiencies for hepatitis C in England. It could tackle the issues relating to all forms of liver disease, including prevention, awareness, diagnosis, treatment, workforce and research. In particular, it would ensure that hepatitis C services are configured and delivered effectively through robust structures for monitoring, evaluation and governance.

## 8. Recommendations

Given these findings, the Hepatitis C Trust recommends:

1. A national liver czar responsible for driving forward improvements in liver services, particularly hepatitis C.
2. A national liver strategy to address the growing crisis of liver disease, with clearly defined actions for addressing hepatitis C.
3. A robust governance structure to oversee the monitoring, benchmarking and evaluation of actions for hepatitis C by all levels of the NHS. These should be reported annually in the HPA report on hepatitis C.
4. A review of the implementation of NICE treatment and an audit of the barriers to achieving recommended treatment uptake levels. This should examine potential reasons why treatment rates appear to be significantly below predicted levels, including missed opportunities for referral, capacity challenges, commissioning policy, levels of professional awareness and patient support.
5. A hepatitis C reporting template should be developed to facilitate effective performance management at a SHA and PCT level by bringing together information on service quality and appropriate benchmarking.
6. SHA clinical directors should urgently assess the extent to which their local health economy is effectively tackling hepatitis C and develop a local action plan to address any shortfalls.
7. SHAs with particularly poor rates of treatment of the diagnosed population should enter into urgent discussions with commissioners and providers about how this issue could be addressed.
8. Given the disparity between recorded diagnoses and estimated prevalence, efforts should be redoubled to raise awareness of hepatitis C with both the public and health professionals. To this end, missed opportunities to diagnose hepatitis C (e.g. through the misreading of blood test results) should be treated as a patient safety issue.

### **Action 3: High-quality health and social care services**

*Key issue: High-quality services for the assessment and treatment of all patients with hepatitis C needs to be co-ordinated and accessible across the country.*

#### **Ongoing actions**

Chief Executives of Primary Care Trusts and NHS Hospital Trusts should be able to demonstrate that there are adequate services and partnerships at local level to enable models of best clinical practice to be followed, as set out in the *Hepatitis C Strategy for England*, including:

- commissioning specialised services for hepatitis C needed for their patient population, in line with the specialised services national definition;
- the development of clinical networks for the assessment and treatment of patients with hepatitis C, including the provision of services for particular groups of patients, such as those with hepatitis C/HIV co-infection, patients with haemophilia, children and those who may experience social exclusion, such as prisoners and injecting drug users;
- access to accredited laboratory services able to provide the appropriate diagnostic tests, histopathology services specialising in liver histology, and radiology services suitable for the diagnosis, monitoring and management of patients with liver disease;
- the development of local protocols between primary and secondary care centres to ensure patient pathways for both medical and social care that encompass testing, referral and the whole range of treatment services, including appropriate access to liver transplantation services;
- Care Group Workforce Teams, the Workforce Review Team and the National Workforce Programme Board will work with Strategic Health Authority Workforce Directorates and Workforce Development Confederations to develop arrangements that take account of the need to ensure that the NHS has enough appropriately skilled staff in the future to deliver service improvements to patients with hepatitis C infection.

#### **New actions**

**Strategic Health Authorities will ensure that local NHS arrangements are in place to achieve the objectives of this action area.**

## Action 4: Prevention

**Key issue:** *There is evidence of ongoing transmission of hepatitis C, particularly among injecting drug users. Prevention efforts need to be intensified to reduce the spread of hepatitis C in at-risk populations.*

### Ongoing actions

- Drug Action Teams will develop local multi-agency arrangements for hepatitis C prevention, which link into other related areas such as sexual health and drug misuse.
- The NTA, Drug Action Teams and the Prison Service will review and strengthen, where necessary and appropriate, harm reduction services for the prevention of hepatitis C transmission associated with injecting drug use. These services, in line with best clinical practice as set out in the *Hepatitis C Strategy for England*, to include:
  - provision of needle, syringe and other injecting equipment exchange services in the community;
  - safe disposal of used needles and syringes;
  - provision of outreach and peer education services;
  - provision of specialist drug treatment services;
  - provision of information and advice about hepatitis C and other blood-borne viruses and the risks of injecting drugs (including stopping injecting, the risks of sharing injecting equipment and avoiding initiating others); and
  - provision of disinfecting tablets throughout the prison estate.
- All NHS organisations will minimise the risk of hepatitis C transmission within health care settings by the adoption of rigorous standard (universal) infection control precautions, occupational health checks for staff and effective management of occupational blood exposure incidents.
- Local Authorities will continue to work with NHS organisations to promote and audit good infection control practice in cosmetic skin piercing businesses, to provide information to the public about the potential health risks and how to choose a reputable business.

### New actions

- The Department of Health will develop health promotion information explaining the risks of injecting drugs and how to avoid hepatitis C and other blood-borne viruses to give to all young people entering juvenile and young offenders' establishments and to other offenders.
- The Department of Health will work with stakeholders to provide information about avoiding hepatitis C infection abroad, including information for people from minority ethnic groups visiting their countries of origin.
- The NTA will develop proposals to carry out a national audit of needle exchange schemes, which will be used to inform future provision of harm reduction services for injecting drug users.
- **Strategic Health Authorities will ensure that local NHS arrangements are in place to achieve the objectives of this action area.**

## **Annex 2: Audit questions sent to Strategic Health Authorities (by Freedom of Information request)**

1. Please confirm or deny that your Strategic Health Authority has audited the provision of hepatitis C services since 1 July 2006.
  - 1a. If confirmed, please supply the audit.
2. Please confirm or deny that you have communicated with your constituent Primary Care Trusts since 1 July 2006 on the provision of hepatitis C services.
  - 2a. If confirmed, please supply all communications.
3. Please confirm or deny your Strategic Health Authority has communicated with HM Prison Service since 1 July 2006 on the provision of hepatitis C services.
  - 3a. If confirmed, please supply all communications.
4. Please confirm or deny that your Strategic Health Authority has ensured local NHS arrangements are in place to commission specialised services for hepatitis C.
  - 4a. If confirmed, please supply details of the arrangements.
5. Please confirm or deny that your Strategic Health Authority has estimated the prevalence pool of people with hepatitis C in your area.
  - 5a. If confirmed, please supply the estimate.
6. Please confirm or deny that your Strategic Health Authority has estimated the number of people diagnosed with hepatitis C in your area.
  - 6a. If confirmed, please supply the estimate.
7. Please confirm or deny that your Strategic Health Authority is aware of the number of people treated for hepatitis C in your area in the year 2007/8.
  - 7a. If confirmed, please supply the number.
8. Please confirm or deny that your Strategic Health Authority has assessed the needs of the local population for hepatitis C services.
  - 8a. If confirmed, please supply the assessment.
9. Please confirm or deny that your Strategic Health Authority has ensured that local NHS arrangements have been made to develop clinical networks for the assessment and treatment of patients with hepatitis C, including the provision of services for particular groups of patients.
  - 9a. If confirmed, please supply details of each clinical network.
10. Please confirm or deny that your Strategic Health Authority has ensured local NHS arrangements are in place for delivering access to accredited laboratory services suitable for the diagnosis, monitoring and management of patients with liver disease since 2006.
  - 10a. If confirmed, please supply details.
11. Please confirm or deny that your Strategic Health Authority has ensured local protocols have been developed between primary and secondary care centres for treatment services for hepatitis C.
  - 11a. If confirmed, please supply details.
12. Please confirm or deny that your Strategic Health Authority has assessed the effectiveness of local protocols between primary and secondary care centres for treatment services for hepatitis C.
  - 12a. If confirmed, please supply the assessment.
13. Please confirm or deny that your Strategic Health Authority Workforce Directorate has worked with Care Group Workforce Teams, the Workforce Review Team and the National Workforce Programme Board to ensure that the NHS has enough appropriately skilled staff to deliver hepatitis C services and service improvements.
  - 13a. If confirmed, please supply details.
14. Please confirm or deny that your Strategic Health Authority has ensured that local NHS arrangements are in place for Drug Action Teams to develop multi-agency working for hepatitis C prevention.
  - 14a. If confirmed, please supply details.
15. Please confirm or deny that your Strategic Health Authority has ensured that local NHS arrangements are in place in order for the National Treatment Agency, Drug Actions Team and HM Prison Service to review and strengthen harm reduction services for the prevention of hepatitis C transmission associated with injecting drug use.

15a. If confirmed, please supply details.

16. Please confirm or deny that your Strategic Health Authority has put in place local NHS arrangements to minimise the risk of hepatitis C transmission within health care settings.

16a. If confirmed, please supply details.

17. Please confirm or deny that your Strategic Health Authority has ensured that local NHS arrangements are in place for working with local authorities to promote and audit good infection control practice in cosmetic skin piercing businesses.

17a. If confirmed, please supply details.

### Annex 3: Calculations to determine treatment by Government Office of the Region

#### Percentage of patients eligible for and participating in treatment

	Baseline value	Minimum value	Maximum value
Percentage of patients eligible for treatment <sup>9</sup>	70%	54%	85%
Percentage of patients participating in treatment <sup>9</sup>	58%	50%	70%
% of diagnosed patients receiving treatment	41%	27%	60%

#### Patients treated in 2007

IMS Hospital Pharmacy Data was taken for 2007 for all pegylated interferons by Region<sup>10</sup>. The number of treated patients was then calculated based on the average number of units used per patient per year (This figure was calculated on the basis of the split of genotype<sup>8</sup>, length of treatment for each genotype<sup>12</sup> and an estimate of compliance by genotype.)

#### Regional breakdown of treatment

Region	% of diagnosed patients treated <sup>#</sup>	% of NICE TA106 baseline	% of NICE TA106 maximum	Rank
South East	57.0%	140%	96%	1
London	41.5%	102%	70%	2
North East	38.6%	95%	65%	3
West Midlands	26.7%	66%	45%	4
North West	26.6%	65%	45%	5
*South West	24.4%	60%	41%	6
Eastern	19.5%	48%	33%	7
Yorkshire & Humberside	19.0%	47%	32%	8
East Midlands	15.8%	39%	27%	9
<b>England</b>	<b>29%</b>			
<b>England - NICE Baseline</b>		<b>41%</b>		
<b>England - NICE Maximum</b>			<b>60%</b>	

<sup>#</sup>Patients treated in 2007 as a proportion of those diagnosed in 2006

\*Levels of under-reporting of diagnosis were not available for the South West so the National average was used

#### Patients cured in 2007

The number of patients cured in 2007 is generated from the treated population and the Sustained Virological Response rate (54%) from a pivotal clinical trial within the SPC (Study NV15801)<sup>12</sup>. Based on this estimation, only 2,360 patients achieved a cure in 2007.

#### Annex 4: Calculations to estimate annual HCV incidence<sup>23</sup>

##### *New infections based on immigration & emigration.*

An estimate of new infections can be calculated based on immigration and emigration movements and the associated HCV prevalence.

<u>Immigration &amp; emigration</u>			
	Number	HCV prevalence	HCV cases
Emigration in 2006 <sup>13</sup> (England & Wales)	371,000	0.40%	1,479
Immigration in 2006 <sup>13</sup> (England & Wales)	545,000	(See below)	10,686
<b>New cases in 2006</b>	<b>9,207</b>		
<u>Immigration into England &amp; Wales by WHO region</u>			
	Number	HCV prevalence <sup>14</sup>	New cases
Africa	41,000	5.30%	2,173
Americas	36,000	1.70%	612
Eastern Mediterranean	20,000	4.60%	920
Europe	307,000	1.03%	3,162
South East Asia	96,000	2.15%	2,064
Western Pacific	45,000	3.90%	1,755
<b>Total</b>	<b>545,000</b>		<b>10,686</b>

##### *New infections based on new intravenous drug users (IDUs)*

An estimate of incidence from new IDUs can be calculated via the following:

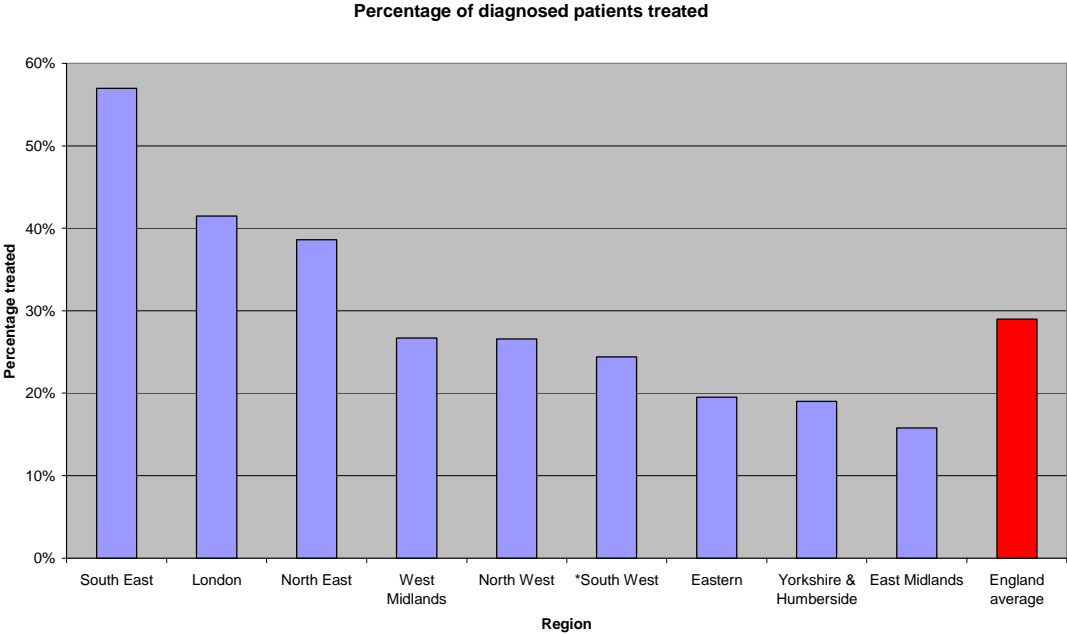
<u>IDUs</u>	
Total IDUs <sup>15</sup>	140,000
% new users <sup>16</sup>	12.3%
New users	17,220
Prevalence in new users <sup>15</sup>	22%
<b>New user incidence</b>	<b>3,788</b>

##### **Estimated HCV incidence in England = 12,995**

This estimate takes no consideration of new infections from current IDUs, or the general population and therefore represents a very conservative view of new infections per year.

**Annex 5: Regional implementation of NICE HCV guidance**

In 2007 only 29% of diagnosed patients were treated with NICE approved antiviral therapy. The headline figure also masks the significant variations in treatment levels between regions, where treatment ranges from 16% to 57% as shown in the graph below:



*Note: information on South Central SHA is captured in both the South East and South West HPA regions.*

It is worth noting that, although East Midlands scores highly on the audit on discharging its responsibilities under the Action Plan, this does not translate into high levels of treatment for its diagnosed population. While East Midlands SHA should be congratulated for its high score in overseeing PCT implementation of the Action Plan, it is concerning that PCTs in the East Midlands area are not treating an appropriate proportion of diagnosed patients. It seems likely that a significant number of these diagnosed patients are falling out of the system, and further investigation is needed into the reasons for this.

Conversely, although PCTs in the South East region treat a high proportion of their diagnosed population, the overall rate of diagnosis is very poor. This may be explained by abject levels of oversight provided by the SHA.

## Annex 6: Regional incidence statistics

Region*	Prevalence	% of National prevalence	Average Incidence** (%)	Calculated Incidence***
Eastern	14703	7.3	6.46	950
London	53145	26.4	6.46	3435
South East	23341	11.6	6.46	1509
South West	17304	8.6	6.46	1118
West Midlands	18670	9.3	6.46	1207
North West	29505	14.7	6.46	1907
Yorkshire and Humberside	22130	11.0	6.46	1430
East Midlands	14994	7.5	6.46	969
North East	7262	3.6	6.46	469
England	201054	100	6.46	12995

\* South Central SHA was not established until 1<sup>st</sup> July 2006 and therefore is not included in HPA data

\*\* The estimated HCV incidence in England is 12,995, and this figure as a percentage of the total prevalence in England (201,054) is 6.46%. This percentage can then be applied to all of the regional SHAs.

\*\*\*  $\frac{\text{Prevalence}}{100} \times \text{Average Incidence} = \text{Calculated Incidence}$

## References

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- <sup>1</sup> *Divided Nations: tackling the hepatitis C challenge across the UK*, London: APPHG, 2009
- <sup>2</sup> *Location, Location Location: An Audit of Hepatitis C Healthcare in England*. London: APPHG, 2008
- <sup>3</sup> *Hepatitis C in England: an analysis of the implementation of NICE guidance on the treatment of hepatitis C*, London: Roche Products Ltd, 2009
- <sup>4</sup> *Hepatitis C in the UK: Annual Report 2008*. London: Health Protection Agency, December 2008
- <sup>5</sup> The HPA estimate there are around 250,000 people in the UK infected with hepatitis C (*Hepatitis C in the UK: Annual Report 2008*. London: Health Protection Agency, December 2008) although some estimates show the prevalence as much higher; up to 466,000 in the UK (*Losing the fight against hepatitis C*. London: The Hepatitis C Trust and the University of Southampton, 2005)
- <sup>6</sup> *Hepatitis C in England: The Health Protection Agency Annual Report*, London: Health protection Agency, 2007
- <sup>7</sup> *Hepatitis C Action Plan for England*. London: Department of Health, July 2004, p.13 and p.14
- <sup>8</sup> NICE guidance TA106 (2006) and TA75 (2004)
- <sup>9</sup> *Location, Location Location: An Audit of Hepatitis C Healthcare in England*. London: APPHG, 2008
- <sup>10</sup> *Hepatitis C in the UK: Annual Report 2008*. London: Health Protection Agency, December 2008
- <sup>11</sup> The FaCe It awareness campaign found that: "Analysis in 2007 of the campaign's effectiveness demonstrated that following the first three years of the campaign, 29% of the general public said that they know a great deal or a fair amount about hepatitis compared with only 15% in 2003" (Quoted in *Improving public awareness of viral hepatitis and other key health concerns*, London: APPHG, 2007)
- <sup>12</sup> GP survey, May 2008 conducted by ICM research, published by Roche Products Ltd, and quoted on Sky News: <http://www.hepctrust.org.uk/news/2008/August/Thousands+at+risk+of+deadly+virus+as+GPs+misread+hepatitis+C+test+results.htm>
- <sup>13</sup> *Divided Nations: tackling the hepatitis C challenge across the UK*, London: APPHG, 2009
- <sup>14</sup> See the *Hepatitis C Action Plan for Scotland, Phase II: May 2008-March 2011*, Edinburgh: Health Protection Scotland, May 2008, p.26-27
- <sup>15</sup> *Hepatitis C: Action Plan for England*, London: Department of Health, 2004, pp.13-14
- <sup>16</sup> Government response to Parliamentary Question on 22 July 2008: <http://www.theyworkforyou.com/wrans/?id=2008-07-22e.221199.h> (accessed 30.06.09)
- <sup>17</sup> NICE, TA14, TA75, TA106
- <sup>18</sup> NICE TA 106 Costing Template. Sensitivity Analysis <http://www.nice.org.uk/guidance/TA106/costreport/xls/English>
- <sup>19</sup> *Hepatitis C in the UK: Annual Report 2008*. London: Health Protection Agency, December 2008: Graph on p.58 shows that deaths more doubled between 1997 and 2007
- <sup>20</sup> *Hepatitis C in England: The Health protection Agency Annual Report*, London: Health Protection Agency, 2007
- <sup>21</sup> *Hepatitis C in England: an analysis of the implementation of NICE guidance on the treatment of hepatitis C*, London: Roche Products Ltd, 2009
- <sup>22</sup> *Divided Nations: tackling the hepatitis C challenge across the UK*, London: APPHG, 2009
- <sup>23</sup> Calculations from *Hepatitis C in England: an analysis of the implementation of NICE guidance on the treatment of hepatitis C*, London: Roche Products Ltd, 2009