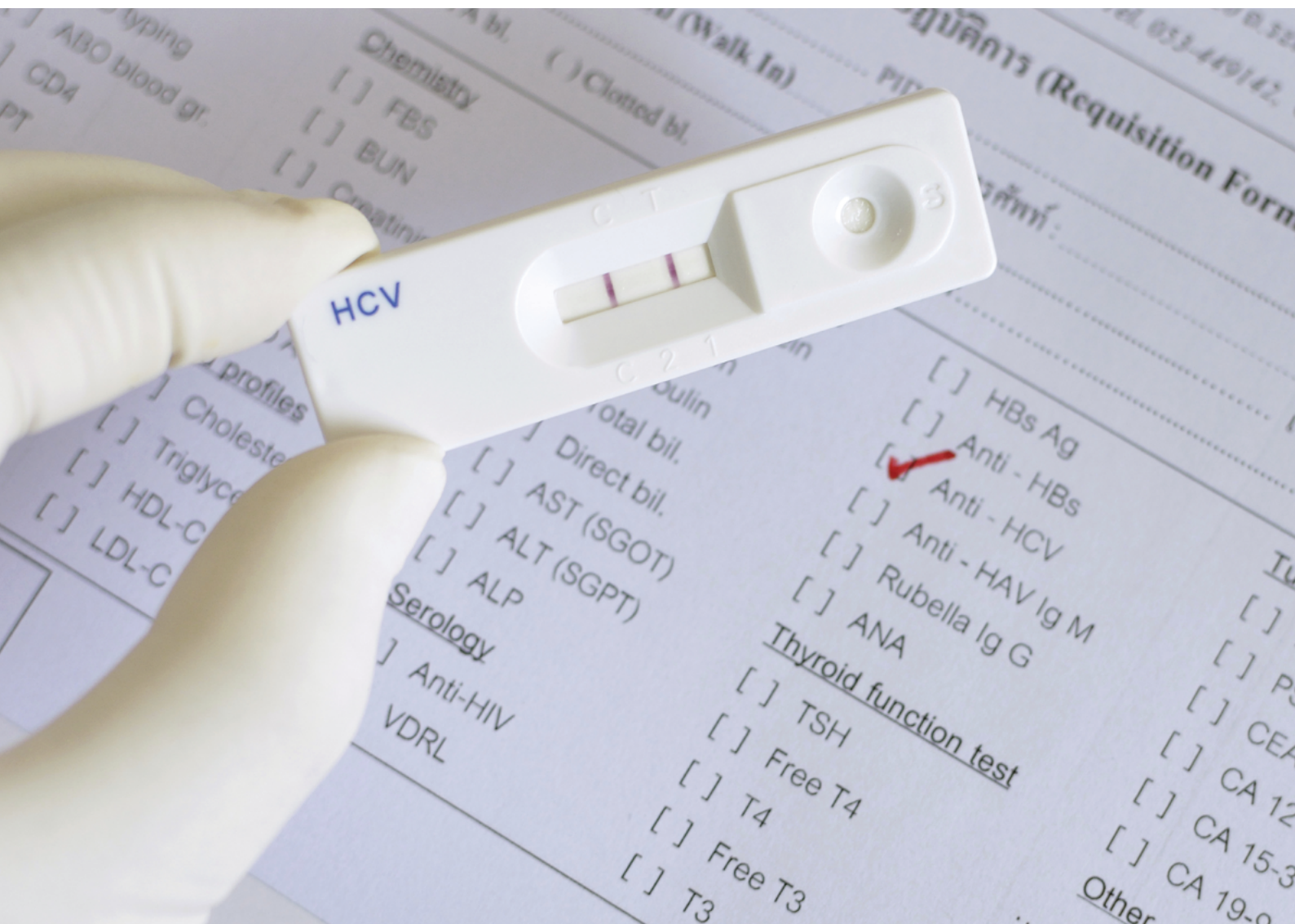


# Hepatitis C: Inequalities in Access to Medicines

Understanding the Barriers to More Effective Treatment in England



Despite being acknowledged more than 10 years ago as a growing public health problem requiring “intensified action”,<sup>1</sup> Hepatitis C (HCV) remains a significant unmet health need in England. Primarily affecting marginalised groups, shortfalls in access to HCV prevention, diagnosis and treatment persist – undermining opportunities to eradicate the disease.

As hospitalisations and deaths from HCV continue to rise, understanding the gaps and barriers to progress is essential to improving patient outcomes and “the health of the poorest, fastest”<sup>25</sup> in line with government goals.

To help inform the way forward, a study by IMS Health, based on a unique view of the HCV patient treatment journey, quantifies the current state of real-world practice and the scale of inequalities to access. At a time of major NHS reform and restructuring, its findings underscore the imperative for action to redress the balance and realise the benefits of new generation treatments.

## Global epidemic

Hepatitis C (HCV) is a serious, contagious blood-borne virus of the liver and a recognised global health problem. First identified in 1989, it is estimated to affect about 3 per cent of the world's population, representing approximately 170 million carriers.<sup>2</sup> The majority of individuals (up to 85 per cent) who are exposed to HCV develop chronic infection.<sup>3</sup>

Characteristically asymptomatic until its damage becomes severe, chronic HCV can remain undetected for many years following initial exposure. It is responsible for 27 per cent of cirrhosis cases and 25 per cent of hepatocellular carcinoma (HCC) cases worldwide<sup>4</sup> and is the most common cause for liver transplantations in Western countries,<sup>5</sup> thus imposing a substantial clinical and economic burden. Despite being preventable, treatable and curable in many cases, mortality rates among HCV patients have been found to be three times higher than those of the general population.<sup>6</sup> Between 350,000 and 500,000 deaths annually are attributable to the disease, making it one of the leading contributors to premature mortality globally.<sup>3</sup>

## Local Cinderella

In England, national estimates (2014) suggest that about 160,000 people are chronically infected with HCV, primarily genotype 1 and genotype 3.<sup>7</sup> There are wide variations in prevalence by region, with a high concentration in the North West and London.<sup>8</sup>

Currently, the most common form of transmission in England is through injecting drug use, usually via contaminated needles and syringes.<sup>9</sup> Data from Public Health England shows that about 50 per cent of people who inject drugs have chronic HCV<sup>10</sup> compared with 0.4 per cent of the general adult population.<sup>7</sup> HCV is also more prevalent among minority ethnic groups, particularly those of Eastern European origin (around 5 per cent), and prison inmates<sup>7</sup> reflecting the relatively higher level of injecting drug use in this population.<sup>11</sup>

HCV is thus primarily a disease of the disadvantaged and vulnerable, affecting some of the most socially marginalised groups in society – and the most challenging to reach.

Published data demonstrates the escalating burden of HCV in England year-on-year for nearly the last two decades and the growing impact of its major long-term sequelae. A rise described in 2009 by the Rt Hon David Cameron, MP, Prime Minister as “perhaps the most shocking...in modern disease”<sup>12</sup> has now seen the number of confirmed reports of infection increasing more than five-fold since 1996.<sup>7</sup>

“Perhaps the most shocking rise in modern disease has been Hepatitis C.”

*Rt Hon David Cameron, MP, Prime Minister*

## Good intentions, limited impact

HCV was first flagged as a growing and overlooked public health concern in England in 2002, as part of a government commitment to bring infectious diseases into the mainstream of service improvement.<sup>13</sup> Recognising a need for “intensified action to reassert control” its ‘Hepatitis C Strategy for England’<sup>14</sup> set a course for improving the effectiveness of prevention, diagnosis and treatment services. A subsequent ‘Hepatitis C Action Plan for England’ in 2004 offered a broad framework for action in four key areas: surveillance and research; awareness and diagnosis; quality of health and social care services; and prevention, with a focus on achieving better, more coordinated pathways of care.<sup>1</sup>

Since these early commitments, there have been numerous initiatives and recommendations from industry, government, the health service and charities such as the Hepatitis C Trust, which has been instrumental in laying bare ‘the uncomfortable truth’ about HCV in England.<sup>8</sup>

While there is evidence of progress in some areas, official policy undertakings have generally achieved limited success, hindered by lack of oversight, poor coordination, and the absence of mechanisms for monitoring and evaluation. As a consequence, the effective management of HCV in England remains vastly underserved:

- Only around 50 per cent of individuals living with HCV are being diagnosed<sup>8</sup>
- Just 3 per cent of those who are chronically infected are accessing potentially life-saving NICE-approved HCV medicines each year<sup>7</sup>
- A growing number of individuals are developing HCV-related end-stage liver disease (ESLD)<sup>7</sup>
- HCV-related hospital admissions and liver transplant registrations for post-HCV cirrhosis have risen year-on-year, nearly quadrupling since 1998 and 1996 respectively<sup>7</sup>
- Deaths from HCV-related ESLD and HCC have risen by more than 300 per cent since 1996<sup>7</sup>
- The absence of a national liver strategy leaves many HCV patients facing a “postcode lottery of care”<sup>8</sup>

The state of HCV practice in England rates poorly with that in other comparable countries. In a recent international comparison, the UK as a whole ranked 13 out of 14 countries studied for its low use of HCV medicines.<sup>15</sup> Among potential reasons cited in stakeholder feedback were:

- Low and patchy awareness of HCV among primary healthcare professionals and the public, including at-risk groups
- Poor access to screening and diagnostic programmes
- In England, the absence of targets in relation to HCV referrals or treatment
- Historically poor organisation of liver disease services, including detection and support
- The lag in developing and implementing national strategies for HCV compared to countries such as France, for example,<sup>15</sup> which has been found to have the highest HCV treatment rate in Europe and globally<sup>16</sup>

## Maintaining current treatment is not an option

Projections based on simulation modelling indicate that if the current level of HCV treatment coverage is maintained:

- The prevalence of HCV infection across the UK will rise from 0.44 per cent (in 2010) to 0.61 per cent in 2035<sup>17</sup>
- The number of new HCV-related ESLD and HCC cases in England will rise from 1,170 per year in 2014<sup>18</sup> to 1,650 in 2035<sup>19</sup> – an increase of more than 40 per cent
- Over 13,900 people in England will be living with HCV-related cirrhosis or HCC in 2030; more than 3,000 of these will have severe decompensated cirrhosis or HCC, potentially requiring a liver transplant<sup>7</sup>
- Deaths from HCV-related liver disease in England are likely to double by 2030<sup>20</sup>

In modelling the predicted impact of treatment on the growing HCV burden in England, Harris, et al, found that only a rapid and large increase in current levels – to almost complete coverage – can stem its rising tide in the near future; and while the introduction of more effective therapies could potentially reduce HCV incidence to 500 cases in 2030, achieving this best-case scenario would also depend on a considerable increase in treatment uptake.<sup>19</sup>

Consistent with this finding, Wedemeyer, et al, showed that although increasing treatment efficacy *only* could reduce HCV-related morbidity and mortality in England to a degree (10–20 per cent) by 2030, the reduction was significantly greater (80–90 per cent) when *more effective* treatment was coupled with *increased* treatment (and diagnosis).<sup>21</sup>

Projections thus suggest that while revolutionary advances in HCV therapy may bring the promise of better cure rates (eradication, even) with shorter regimens and fewer side-effects than older antivirals, realising their benefits will be contingent on overcoming the barriers to higher levels of treatment. This implies a deep understanding of current real-world practice in HCV and the drivers of suboptimal outcomes across the care continuum.

Current shortfalls in addressing HCV reflect gaps across the entire care pathway, exacerbated by the itinerant nature of those at greatest risk of contracting the disease.

## Addressing the gaps

Current shortfalls in addressing HCV reflect gaps across the entire care pathway, exacerbated by the itinerant nature of those at greatest risk of contracting the disease. As documented by Irving, et al, based on a case study in Nottingham, not all individuals with HCV are tested; not all who test positive are referred; not all who are referred attend their appointment; not all who attend their appointment undergo a liver biopsy; and not all who are biopsied undergo therapy.<sup>22</sup>

In investigating causal factors in variable treatment uptake, IMS Health has found that the cumulative effect of these gaps – which include failure to diagnose, varying access to specialist expertise, insufficient capacity to deliver, deficient commissioning, and variable policies – is most pronounced in HCV relative to other disease areas.<sup>23</sup>



## A real-world perspective

To date, limited data and the disparate nature of available datasets have challenged efforts to measure the true standard of HCV care in England. Researchers have underscored the urgent need for reliable and accurate information on patient referrals, treatment and outcomes in HCV, to inform the commissioning and configuration of services that can be easily accessed by those who need them.<sup>19</sup>

To help inform the way forward, IMS Health has conducted an analysis to quantify the current state of HCV management in England, specifically in relation to diagnosis and treatment. Patients newly diagnosed with HCV were identified from IMS Health's Hospital Treatment Insights (HTI), a unique dataset enabling innovative and detailed exploration of the dynamics between drug, patient and associated outcomes in the hospital environment in England.

Integrating Hospital Pharmacy Audit (HPA) information with Hospital Episode Statistics (HES) data, HTI is one of the richest data sources in this setting available, providing real-world evidence on approximately 4.1 million patients across 26 per cent of acute NHS Trusts, based on their journey through secondary care. Data is linked from 1 January 2010 to 30 June 2014 with additional HES data from 1 January 2005 and includes information on:

- Patients – core demographics through to diagnoses
- Hospitalisations – how, when and where patients are treated
- Referrals – from care settings to consultant specialty
- Treatments – including procedures and tests and their costs
- Outcomes – when and how patients are discharged and whether readmitted

As hospitalisations and deaths from HCV continue to rise, understanding the gaps and barriers to progress is essential to improving patient outcomes and “the health of the poorest, fastest”<sup>25</sup> in line with government goals.

### Methodology

Patients meeting any of the following criteria were selected for inclusion in the study:

- Diagnosed with HCV between 1 January 2005 and 30 April 2013
- Associated with a high-cost drug code covering HCV therapies between 1 January 2005 and 30 April 2013
- Dispensed the HCV antivirals ribavirin, boceprevir or telaprevir between 1 January 2010 and 30 April 2013
- Dispensed PEG-interferon between 1 January 2010 and 30 April 2013 with a diagnosis of HCV or an HCV high-cost drug code

Individuals aged 17 years or under at the later of their most recent mention of HCV or their most recent HCV therapy were excluded.

**Results**

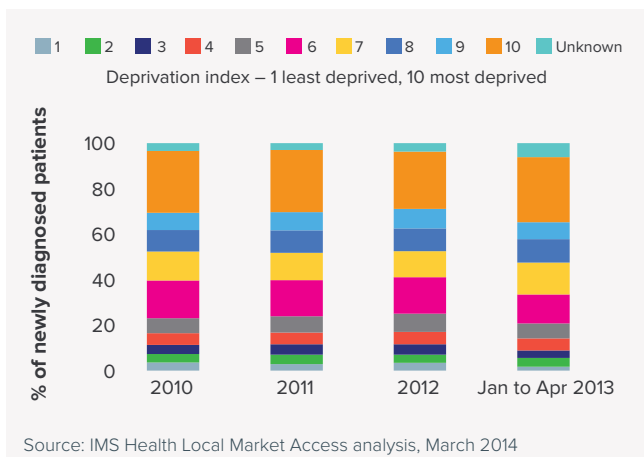
A total of 7,161 patients were identified as being first diagnosed with HCV after 1 January 2010. Analysis of this cohort provides insights into patient numbers and characteristics, treatment rates and the use of specific HCV antivirals available during the time period studied and – critically – the impact of socio-economic status.

**HCV patient demographics show a clear bias towards the more deprived.** The vast majority of HCV patients are diagnosed with chronic disease; between 60–70 per cent are male; and between 50–60 per cent are aged between 33–52<sup>i</sup> years at diagnosis. These findings are consistent over time. Notably, there is a clear bias towards the more deprived among new diagnoses as measured by the English Indices of Deprivation:<sup>ii</sup> in each year, the largest single group (20–30 per cent) comprised individuals rated with the maximum score on the scale (Figure 1).

**Treatment rates are low but have increased.** While treatment rates have remained low over time, the proportion of HCV patients treated within 12 months of diagnosis has increased markedly since 2010 (11.6 per cent versus 17.5 per cent in 2012). However, this still means that fewer than one in five patients are receiving therapy (Figure 2).

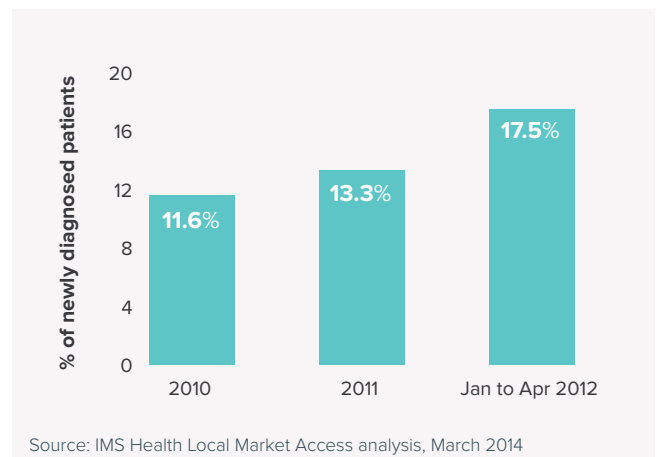
**Treatment rates are higher in the less deprived and actually falling in the most deprived patient groups.** Among patients treated within 12 months of diagnosis, treatment rates are higher in newly diagnosed males than in newly diagnosed females (although both are increasing). They are highest in patients aged 43–62 years and rising across all age groups. Surprisingly, the fastest rates of increase can be seen in the oldest patients (aged 63+ years).

**Figure 1: Proportion of newly diagnosed HCV patients by deprivation status**



There is a clear bias towards the more deprived among patients newly diagnosed with HCV. In each year since 2010, the largest single group comprises individuals with the highest deprivation score.

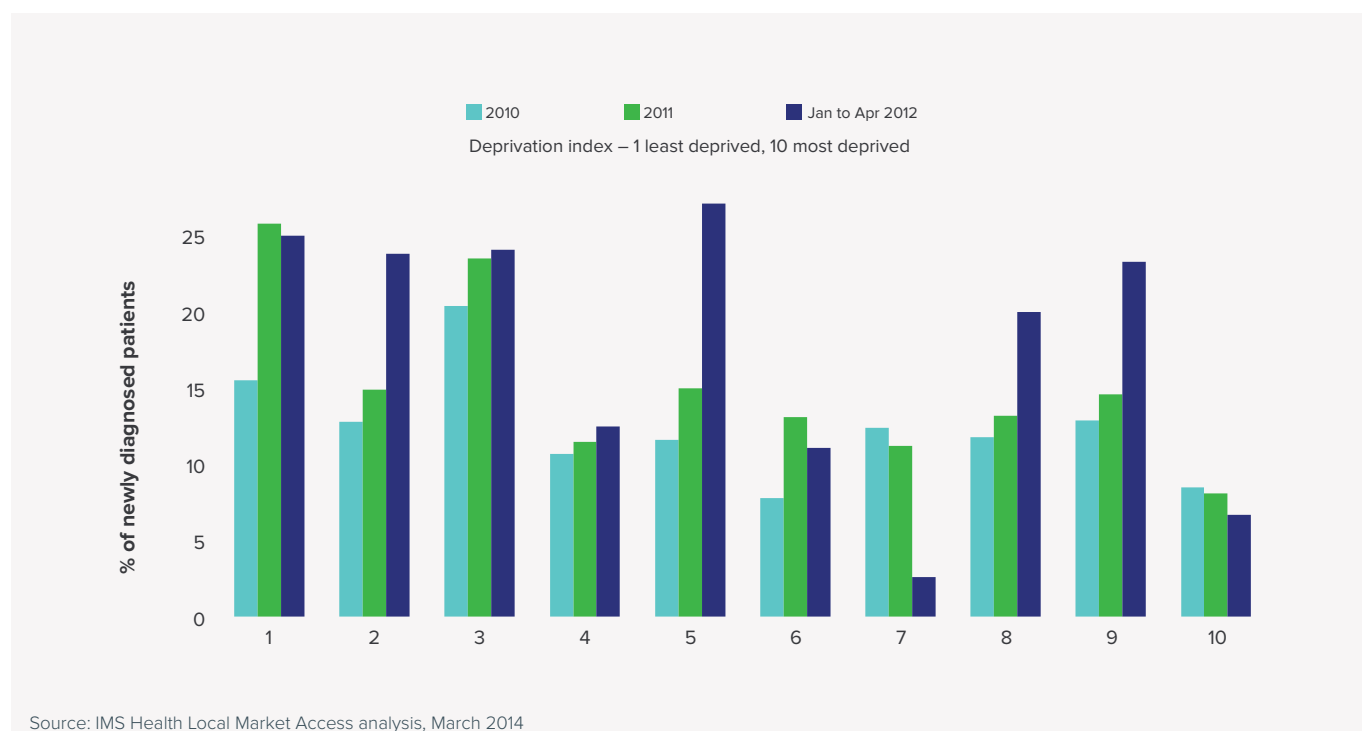
**Figure 2: Proportion of newly diagnosed HCV patients treated within 12 months of diagnosis**



Treatment rates among newly diagnosed HCV patients have increased markedly since 2010. However, they are still below 20 per cent meaning that fewer than one in five patients are receiving therapy in England.

i Reflecting HTI database age bands: 18–32 years; 33–42 years; 43–52 years; 53–62 years; 63+ years.  
 ii Department for Communities and Local Government. The English Indices of Deprivation 2010. March, 2011. Provides a relative measure of deprivation at small area level in England, ranking areas from least to most deprived across seven deprivation domains: income; employment; health & disability; education; crime; barriers to housing & services; living environment.

**Figure 3: Proportion of newly diagnosed HCV patients treated within 12 months of diagnosis by level of deprivation**



Treatment rates among newly diagnosed HCV patients vary considerably on the basis of socio-economic status, being higher in the less deprived. Furthermore, rates among the most deprived 10 per cent of patients are actually falling, underscoring the extent of inequalities in access.

Of note is considerable variation in treatment rates according to socio-economic status, with rates being higher in the less deprived and actually falling in the most deprived 10 per cent of patients: around 25 per cent of the least deprived patients who are diagnosed receive treatment but only around 7 per cent of the most deprived – despite the fact that their numbers are greater (Figure 3).

**Dual-therapy regimens dominate but use of triple therapy is increasing.** Across all years since 2010, the majority (around 60 per cent) of HCV patients receiving treatment have been prescribed a dual-therapy regimen. Reflecting the addition of new antivirals to the HCV treatment armamentarium, and based on their latest therapy to April 2013, 17 per cent of all treated patients are receiving – or have received – triple therapy.

More granular analysis shows that triple therapy is being harnessed in both previously treated and untreated patients: based on their latest therapy to April 2013, over 25 per cent of treatment non-naïve patients are receiving – or have received – triple therapy; and just under 20 per cent of treatment-naïve patients received triple therapy as their first treatment in the year to April 2013. Its use is also proportionately more likely in patients with co-morbid cirrhosis or HIV.

The evidence suggests that the inequalities in access are becoming more pronounced, with treatment rates falling in the most deprived patient groups.



**Compliance with 12-week course of therapy appears high.** The ability within HTI to track information on dispensing activity in the hospital pharmacy at the patient level over time enables a unique window on the extent to which patients adhere to their full course of treatment in this setting. This information is key to understanding the impact and potential compliance benefits of a shorter duration of therapy and/or less frequent dosing.

The protease inhibitor, telaprevir, was one of the first new direct acting antivirals to be approved – including by NICE – for their use in HCV. It is administered over a 12-week treatment period (a much shorter duration than previous therapies) in combination with PEG-interferon plus ribavirin.

A total of 163 patients were first dispensed telaprevir before 1 February 2013, the majority of whom received three or fewer prescriptions. Based on analysing quantities of drug dispensed, and assuming that all patients are instructed to take the drug as recommended (four tablets per day), the study revealed that with the exception of those receiving one or two prescriptions, these patients tend to receive a full course of therapy (average length being 8.8 weeks).<sup>iii</sup> This data demonstrates, for the first time, that the majority of patients do appear to complete the full treatment course.

A convergence of trends in HCV and in the current restructuring of health services in England make the need for action imperative. Pharmaceutical manufacturers have a key role to play.

## Conclusion

HCV has long been recognised as a disease of inequalities. Analysis of current real-world practice in England demonstrates that most new diagnoses of the disease are still among the most deprived groups in society, and equality in access to HCV medicines still does not exist in terms of socio-economic background. Indeed, the evidence suggests that the health inequalities are becoming more pronounced, with already low treatment rates falling among the most deprived groups. This clearly points to the need for more intensified action at a local level to overcome the barriers to effective diagnosis and treatment.

Implicit in the achievement of this goal is the development of new models of service delivery built around an optimised HCV care pathway focused on addressing existing shortfalls and the recognised need for services “to be more easily accessible to those who need them.”<sup>24</sup> Pharmaceutical manufacturers have a key role to play in this process through proactive outreach, engagement and collaboration with relevant stakeholders in NHS England to facilitate pathway development and the optimal use of their drugs, based on robust evidence of outcomes and deep insight into local payer and provider perspectives.

A convergence of trends in HCV and its projected future consequences, in its medical management with breakthrough treatments, and in the current restructuring of health services in England make the need for action imperative. With “improving the health of the poorest, fastest” at the heart of NHS reform,<sup>25</sup> a legal onus on CCGs to reduce healthcare inequalities with respect to access and outcomes,<sup>26</sup> and the prevention of premature mortality from liver disease part of the overarching vision for public health,<sup>27</sup> there is now both impetus and opportunity to drive this forward.

<sup>iii</sup> Calculated by dividing total number of tablets dispensed by four to reach number of days of therapy dispensed and converting this into weeks.

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## United Kingdom

210 Pentonville Road  
London N1 9JY  
United Kingdom

## HQ

83 Wooster Heights Road  
Danbury, CT 06810  
United States

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