TACKLING THE PROBLEM OF HEPATITIS C, SUBSTANCE MISUSE AND HEALTH INEQUALITIES: A CONSENSUS FOR LONDON

The London Joint Working Group for Substance Misuse and Hepatitis C (LJWG)

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EXECUTIVE SUMMARY

Aims
This document represents a call to action from experts in the fields of addiction and hepatitis in London. It provides a framework with which to address the epidemiological, clinical and financial challenges presented by current rates of hepatitis C among people who have injected drugs and sets out solutions in the form of a blueprint for local commissioners.

Findings
Against the backdrop of a radically changing healthcare environment and increasingly limited resources, mortality associated with liver disease is rising dramatically in the UK. This stands in stark contrast to the four other major causes of death in this country, which affect fewer people at a later age than ever before, while liver disease affects growing numbers of increasingly younger people.

The cost to the NHS of liver disease is already at least £500m a year, and is rising by 10% annually. The main causes of liver disease are alcohol abuse, obesity and viral hepatitis. Of these, hepatitis C is the factor most amenable to intervention, through prevention strategies focused on education and awareness, and medical interventions with cost-effective, NICE-approved treatments.

In London an estimated 34,000 people with a history of injecting drugs have hepatitis C - yet only about 800 people (2%) a year receive treatment. Not only does this represent a major health inequality but it is also a false economy in terms of NHS resources. Current service provision is disjointed and patchy, so much so that even where individual services are performing well, gaps in the wider provision needed to treat drug users with hepatitis C continue to undermine their progress.

Action needs to be taken now to avert a major public health crisis. Education and awareness must be improved among workers and service users in drug services, prisons and other services in London. Integrated care pathways must be implemented to support access to treatment for larger numbers of people with hepatitis C and a history of injecting drugs. We believe this is the only way to address a significant health inequality and prevent a massive future burden of disease in London.

Recommendations
Our key requirements and recommendations are set out in terms of prevention, diagnosis, treatment and data collection for each type of service that impacts on the patient’s journey. The emphasis is on education and training, and on the need for integration and collaboration across drug and specialist hepatitis treatment services, public health, prisons and primary care.

Drug services
- Every patient attending a drug service in London should be tested for blood borne viruses (BBVs) and, if negative, repeat tested every 6 months. A baseline target of 90% should be adopted in all drug services.
- Every patient attending a drug service in London should be vaccinated against hepatitis A and B. A baseline target of 90% uptake should be adopted in all drug services.
- Every hepatitis C RNA-positive patient should be referred to a specialist treatment service for assessment, and provided with support to attend if required. Current substance misuse in itself is not a barrier to hepatitis C treatment.
- Every drug worker should have a clear basic knowledge of hepatitis C, (through completing the RCGP Certificate in the Detection, Diagnosis and Management of Hepatitis B and C in Primary Care, or an equivalent qualification).
- Consistent harm reduction advice and education should be provided through all services working with drug users, including all needle exchange services.
- Every local drug service centre should have a nominated person responsible for liaising with hepatitis treatment centres, prisons and primary care.

Specialist hepatitis treatment services
- Every hepatitis C treatment centre should have a nominated person responsible for liaising with local drug services, prisons and primary care.
- Everyone referred to specialist services should be assessed for treatment. Current substance misuse in itself is not a barrier to treatment, though other factors will influence whether treatment is initiated. These factors should be recorded to inform ongoing improvements in services and patient support.
- Potential alternatives to treatment in the hospital setting should be formally assessed, and nurse-led outreach services should be established wherever possible.
- Data should be collected on an ongoing basis to capture:
• Total number of drug users and non-drug users referred for assessment.
• Total number of drug users and non-drug users offered treatment.
• Barriers to treatment (where treatment is assessed as inappropriate at present or is declined by the patient).
• Adherence and outcomes, e.g. sustained viral response (SVR) rates in individual patients and the link with adherence to treatment.
• Patients should have access to mental health support before and during hepatitis C treatment.

Directors of Public Health
• Every public health locality should have a multi-sector working group responsible for ensuring people who use drugs have access to a robust pathway from testing to specialist treatment services. The group should include specialists in public health, viral hepatitis, substance misuse and mental health as well as GPs and support workers.
• The use of DBS (dry blood spot) testing or Point of Care (Rapid) Testing should be available in as many services working with people who use drugs as possible.
• Data on prevalence and incidence – among both drug users and non-drug users – should be collected on an ongoing basis.

Primary Care
• Every clinical commissioning group should have a nominated lead for hepatitis C and substance misuse.
• Every hepatitis C RNA-positive patient should be referred to a specialist treatment service for assessment, and provided with support to attend if required. Current substance misuse in itself is not a barrier to hepatitis C treatment.
• At least one GP in every practice should have a basic knowledge of hepatitis C, (through completing the RCGP Certificate in the Detection, Diagnosis and Management of Hepatitis B and C in Primary Care, or an equivalent qualification).
• GP practices should implement strategies to search patient records for indications of substance misuse and invite all identified to be screened for BBVs.

Prisons
• Every prisoner in London should be tested for BBVs at their initial health assessment. A baseline target of 90% should be adopted in all prisons.
• Every prisoner in London should be vaccinated against hepatitis A and B. A baseline target of 90% should be adopted in all prisons.
• Every hepatitis C-RNA positive patient should be referred to a specialist treatment service for assessment, and provided with support to attend if required. Current substance misuse is not a barrier to hepatitis C treatment.
• Patients on antiviral treatment should not have their therapy interrupted due to incarceration, transfer or release from prison. Health records should move with the prisoner and maintenance of hepatitis treatment and/or opioid substitution therapy (OST) planned in advance with receiving services.
• Every prison officer should be provided with sufficient training to maintain a clear, basic knowledge of hepatitis C.
• Consistent harm reduction advice and education should be provided through all services working with prisoners, including harm reduction advice after release.
• Every prison should have a nominated staff member responsible for liaising with primary care, public health, drug services and hepatitis treatment centres.
INTRODUCTION

“Current practice, with treatment of a ... minority of HCV-infected patients, will scarcely affect the future burden of this disease.”
Health Protection Scotland¹

It is widely recognised that socially excluded and vulnerable groups, such as people who use drugs, can find it difficult to navigate traditional referral pathways in order to access secondary and tertiary care services. This may be due to chaotic lifestyles, fear of being judged, and difficulties in dealing with authority. In London, as many as 34,000 people with a history of injecting drugs are estimated to have hepatitis C, yet only about 800 a year are being treated (see Figure 1). We believe that not enough is being done to integrate health, addiction and other services to provide the support this vulnerable group needs, so people are simply falling through the gaps. This represents a major health inequality that must be addressed.

Figure 1. Estimated proportion of people treated compared with estimated number of people with HCV and a history of IDU in London. Source: LJWG

People who inject drugs are the group most at risk of acquiring hepatitis C. If left untreated, hepatitis C can lead to cirrhosis, cancer, liver failure and the need for transplantation. A cost-effective, NICE-approved treatment for hepatitis C is available, which will cure most people. Treatment not only benefits overall health and outcomes, but may also positively affect a person’s recovery from substance misuse. Treatment in this patient group is also a very effective way of reducing the spread of the virus.

Models developed by Health Protection Scotland (HPS) show that large numbers of people need to be treated in order to prevent an epidemic of severe liver disease, which is both extremely debilitating and potentially fatal for individuals, and enormously costly to the NHS.¹

London faces particular challenges due to the size, diversity and often transient nature of its population, as well as the disjointed nature of existing service provision. Many affected people are unaware they have the virus, as it can remain asymptomatic for many years. If rates of diagnosis and treatment are not improved soon we will see a dramatic increase in hepatitis C-related liver cirrhosis in the next 10-20 years in London. However, effective treatment delivered in the context of integrated and supportive care pathways would cure the majority of people infected, prevent these long-term clinical consequences and save at least £600m of NHS resources over the same period.

The London Joint Working Group for Substance Misuse and Hepatitis C (LJWG) was formed in October 2009, by expert clinicians and patient advocacy and voluntary sector leads. Its aim was the development of an integrated plan that would drive improvements in the prevention, diagnosis, treatment and outcomes of hepatitis C in people who use drugs, and reduce the spread of the virus. A stakeholder conference was held at King’s College, London, in October 2010, and this consensus document is the result. The guidelines have been developed by the LJWG in consultation with
experts in a range of disciplines, including clinical practice, policy development, community liaison, treatment research and development, and service user experience from across the UK. They represent a statement of current best practice from opinion leaders and practitioners and should be considered as a blueprint to enable government, NHS London (and any successor agency), national and local commissioners, clinical commissioning groups, clinicians and providers to deliver effective, integrated services in London for the treatment of hepatitis C in people who use drugs. It should also be considered as a template for service development in other areas.

It is not clear at the time of writing who will be accountable for the delivery of these standards of care following the dissolution of NHS London. We envisage that the responsibilities of the London Specialised Commissioning Group will transfer to the NHS Commissioning Board. In the meantime, the Chief Executive of the NHS Commissioning Board should assume responsibility.

**METHODOLOGY**

The process of developing the consensus is outlined briefly here. We hope the methodology can be used as a template, enabling other parts of the country to replicate the process and apply it to their own service provision.

Our starting point was to review current service provision and its limitations. A conference held in October 2010 brought stakeholders together to share best practice from London and other parts of the UK, and plan a London strategy to join up existing services, improve access to treatment, tackle health inequalities and reduce the spread of the hepatitis C virus (HCV). Ideas and conclusions from the conference were developed into a draft consensus, which was distributed for consultation to a wide range of stakeholders, whose valuable perspectives were incorporated to produce this final consensus document.

The next phase will involve developing implementation plans for the recommendations, and identifying and engaging with clinical commissioning groups and others responsible for ensuring they are put into practice following the dissolution of NHS London. A second conference is planned for November 2011, to build an effective implementation plan linked to deliverable outcomes. The goal is to reduce liver-related mortality in drug users by developing a comprehensive London-wide service based on the consensus recommendations. It will provide consistency and excellence in hepatitis C treatment for people who use drugs, resulting in improved care and outcomes.

**Stages in developing and implementing a consensus**

- Bring together interested experts
- Identify the problem and its causes
- First stakeholder conference to consider ideas and conclusions for consensus
- Develop consensus document in consultation with a wide range of stakeholders
- Second conference to build implementation plan
- Measure implementation and deliverable outcomes

**EPIDEMIOLOGY**

London is the largest city in the European Union, with a population estimated at 7.8 million in 2010, and it continues to grow and change. It is one of the most ethnically diverse cities on the planet, with 29% of the population classified as non-White, and many of them coming from parts of the world with a high prevalence of HCV. Furthermore, many marginalised individuals may feel drawn to the anonymity such a large city offers.

According to the National Treatment Agency, nearly 35,000 people accessed structured treatment for problem drug use in the London region last year – more than 80% related to heroin or crack cocaine use. Many more have yet to access services. Studies show that within 5 years of beginning to inject, 50-80% of injecting drug users (IDUs) are infected with hepatitis C. This represents a large pool of infected individuals – many asymptomatic and undiagnosed – capable of transmitting the virus to others and carrying on the epidemic. Many others will have stopped using drugs but may still be infected.

London also houses over 7,000 prisoners and young offenders. Australian studies have suggested that up to a third of prisoners are confirmed HCV-positive, though no such studies have been carried out in the UK.

Half of England’s rough sleepers are in London. Many use drugs and alcohol, as well as having other mental and physical health problems, and very poor outcomes: a homeless drug user admitted to hospital is seven times more likely to die over the next five years than a housed drug user admitted with the same medical problem.
THE SCALE OF THE PROBLEM

Liver disease in England

Deaths due to liver disease have been increasing in the last 30 years, in contrast to other major causes such as heart disease, stroke, respiratory disease and cancer (see Figure 2). Liver disease is now the fifth most common cause of death, and rates of liver-related mortality in England have been rising compared to other European countries, which have been falling. In 2009 we surpassed the EU average (see Figure 3). Moreover, liver-related deaths occur at an earlier age (average 59 years and falling) compared to the other major causes (average 78-84 years and rising). The cost to the NHS of liver disease is at least £500m a year, and is rising by 10% annually.

The causes of this epidemic of liver disease are alcohol abuse, hepatitis B and C, fatty liver disease linked to obesity, and cancer as a result of all of these. Tackling lifestyle factors such as drinking and obesity is a massive and long-term public health task, requiring political will, policy initiatives like minimum alcohol pricing, and huge resources in terms of public awareness campaigns and effective, wide-ranging national and local strategies. Viral hepatitis, on the other hand, which accounts for around 20% of the disease burden, is largely treatable. Hepatitis B and C can be cured in the majority of patients with cost-effective, NICE-endorsed treatments, and prevented through education and the provision of effective needle and syringe services; hepatitis B can also be prevented through vaccination programmes.

“Out of the main causes of liver disease – alcohol, obesity, and viral hepatitis – hepatitis C is the one bit that is actually solvable in a reasonable amount of time. We could all but eradicate hepatitis C in England within the next 30 years, and make a huge dent in the prevalence in a reasonably short time, if there are clear directions to local NHS on how to go about it in a way that is easy to action.”

The Hepatitis C Trust

Hepatitis

Figures from the Health Protection Agency (HPA) estimate that around 53,000 people living in London have hepatitis C. Of these, only 7,386 are known to have been diagnosed. A significant proportion of undiagnosed individuals are likely to be former or current injecting drug users. Such high numbers of undiagnosed and untreated patients will constitute a significant burden of disease in the medium and long term.

The incidence of hepatitis C is rising annually, and by far the greatest risk factor is injecting drug use; over 90% of people diagnosed with HCV have a history of injecting drugs. Statistical models predict that hepatitis C infection in the UK is likely to increase by almost 40% between 2010 and 2015. It is estimated that 15-20% of people with hepatitis C will develop cirrhosis after 20 years (30% after 30 years) and each year, up to 5% of those will develop primary liver cancer. Hepatitis C is the commonest indication for liver transplantation. Costs for transplantation and immunosuppressant drugs and monitoring are extremely high, and the future cost to London for failing to address the issue now has been estimated by the LJWG to be at least £600 million over the next 10-20 years. Figure 4 puts this projection into context, showing the large increase in hepatitis C-related cirrhosis and cancer cases expected in the next few years in England. According to The Hepatitis C Trust, the economic burden to the NHS could be up to £8 billion over the next 30 years.
Drugs and the risks of spreading hepatitis C

According to the British Crime Survey 2009-2010, an estimated 3% of Londoners use Class A drugs (a category that includes heroin, cocaine, ecstasy and crack cocaine). Many people take more than one drug and may also be on OST at the same time.

The most frequently reported substances taken by adults who are in a treatment programme in London are:

- Heroin – 29%
- Crack cocaine – 10%
- Crack cocaine and heroin – 41%
- Cocaine – 7.5%
- Benzodiazepines – 0.6%
- Amphetamines – 0.6%
- Hallucinogens – 0.2%
- Ecstasy – 0.1%

Sharing needles and other injecting paraphernalia is most commonly associated with the transmission of BBVs including hepatitis C, although sharing cocaine straws and crack pipes can also spread these viruses. While the remit of this document is confined to hepatitis C among people who use drugs, it is worth highlighting that other forms of transmission are also on the increase in London. Rates of hepatitis C infection are high in migrants from Asia, North and sub-Saharan Africa, and Eastern Europe, and the virus may have a different epidemiological profile in these populations. Hepatitis C infection among men who have sex with men (MSM) is also known to be increasing through sexualised drug taking, and the emergence of tattoo parties among young people is another potential source of concern. Of course there is some overlap between the profiles of these populations. For example, hepatitis treatment services in London are noting an increase in patients from Eastern Europe who also have a history of injecting drugs.

Treatment for hepatitis C

A cost-effective, NICE-approved treatment that can eradicate the virus in 40-80% of infected individuals for a fraction of the cost of a liver transplant is readily available. In spite of this, only around 800 Londoners per year – about 1.5% of the HPA-estimated total infected in the capital – receive treatment. Furthermore, the fraction of active or recent injecting drug users treated is small.

Health Protection Scotland (HPS) used modelling to plan a public health response to hepatitis C: the model established that the number of former drug users developing HCV-related decompensated cirrhosis in Scotland was predicted to double between 2000 and 2020, and the authors concluded that “current practice, with treatment of a relative minority of HCV-infected patients, will scarcely affect the future burden of this disease.” The number of people treated needs to increase significantly in order to prevent high levels of severe disease in the long term.

There is an increasingly compelling argument that treatment in this population is prevention. Modelling from Bristol shows that, with relatively modest levels of treatment, hepatitis C prevalence amongst active injecting drug users could be substantially reduced, even taking into account the risk of re-infection (see Figure 5). Thus, antiviral treatment of people who still actively inject could play a significant role in reducing the burden of hepatitis C – both in public health
and economic terms. Furthermore, a recent study demonstrated similar response rates (57%) to antiviral therapy in active injectors and non-injectors.

CURRENT PRACTICE

Hepatitis treatment services

The management of hepatitis C has historically been based mainly in academic units and large teaching hospitals. However, there have been attempts in recent years to establish treatment centres in local hospitals, GP surgeries, drug treatment units and prisons, to make it easier for vulnerable and socially excluded people to access treatment in places they feel comfortable. The emphasis on outreach has increased, as has the role of the voluntary sector in identifying and referring patients. Ongoing audit plays an important part in ensuring that provision of outreach services does not affect safety standards, quality of care or patient outcomes.

Funding remains a key challenge, as fragmented services across London all compete for both central (DH) and regional (Primary Care Trust, Local Authority) resources to fund their activities. Given that budgets are limited, and unlikely to increase in the next few years, it is all the more important to ensure existing services are delivered as cost-effectively as possible. At present, there is no overall policy underpinning hepatitis C services throughout London, and the structures in place vary considerably from area to area. Most service provision in the capital involves a combination of consultant-led care at large teaching hospitals, supported by Clinical Nurse Specialists (CNS) who follow up treatment and train GPs and other treatment centre staff, aided by the voluntary sector in outreach clinics, prisons and treatment units. Clinical teams in East London have found that basing a BBV CNS in the same location as drug treatment works well, taking services to where the patients are, and not expecting them to find and attend a completely different site, among non-drug-using patients, where they may experience or perceive stigma.

However, the lack of a unifying structure and strategy means that quality of care received by hepatitis C patients can vary greatly. London's network of hepatitis C services is complex, currently comprising:

3 NHS Mental Health Trusts
15 NHS Foundation Trusts
40+ substance misuse services
21 NHS Trusts
8 prisons
7 major hepatitis C treatment units
31 PCTs
Many smaller local treatment centres

Figure 6 illustrates the range of services available, but also highlights the lack of systemic co-ordination. Current service configuration leads to constraints that make no sense to patients: while depression is a recognised side effect of antiviral treatment, for example, the hospital specialist cannot prescribe a course of anti-depressants during a treatment review (because the cost will not be covered by the tariff), but must write to the GP making a recommendation instead.

Figure 6. London's network of services

Similarly, intra-hospital referrals – which could save the patient time, inconvenience and worry – are not allowed, and must be done through the GP.

"The lack of joined-up service provision across primary and secondary care is causing a lack of adequate treatment, with patients bouncing from service to service."

Stakeholder feedback
The service structure we recommend is illustrated in Figure 7, where all the different strands of London’s hepatitis C services are brought together to maximise clinical effectiveness and cost-effectiveness, and ensure consistency of care and standards.

Treatment options
Antiviral treatment for hepatitis C consists of self-administered weekly subcutaneous injections of pegylated interferon and twice daily oral ribavirin for 24-48 weeks. Complete clearance of the virus occurs in 40-80% of individuals, depending on a number of factors including age, gender, race, human and viral genetics, BMI and stage of liver fibrosis. The side effects of treatment are not insignificant and may include depression, mood swings and irritability, lethargy, fevers, thyroid dysfunction, rashes and anorexia. In addition, the treatment may have a marked effect on blood count, with anaemia, low white blood cells and platelets a common observation. These side effects can seriously impair day-to-day function, and patients undergoing treatment are placed under close supervision and frequent monitoring by a CNS who is supported by specialists in hepatology, gastroenterology, infectious diseases and psychiatry. People who use drugs often lack a robust support network, and issues with housing or relationships can disrupt their treatment. Education, peer support and buddy schemes can all be helpful, and should be developed by treatment centres in collaboration with local primary care and drug treatment services.

Commissioners need to be aware that the first generation of directly acting antiviral agents are now licensed, improving treatment options for patients, while adding a layer of complexity and specialisation to antiviral treatment. While they may well offer an improved outcome to a number of patients, this comes at a cost – both financial and in terms of additional side-effects and drug-drug interactions. A clear set of guidelines should be in place to ensure that the latest treatment can be delivered efficiently to all those who are likely to benefit from it.

Addiction services
There are numerous strands to the current provision of addiction services in London. Over recent years, addiction services have moved away from acute secondary care units and into the community, with community-based services and satellite clinics run by drug workers who are integrated into their GP surgery’s clinical team. This allows for the provision of a more holistic service. The present structure of addiction services in London is based mainly around NHS community drug teams, GPs, prison health services, and non-statutory or voluntary sector teams.

Funding for London addiction services is a combination of central (primarily DH but also the Home Office and Ministry of Justice) and local funding (from PCTs, local authorities, criminal justice agencies and voluntary sector donations). Treatment services in London provide harm reduction advice and counselling, psycho-social interventions such as contingency management and behavioural therapy, detoxification and pharmacotherapy including OST. It is worth noting that the interval between the onset of a drug misuse problem and accessing treatment can be several years, and patients can feel a considerable degree of ambivalence towards their therapy.

The role of OST in antiviral therapy
Antiviral treatment for hepatitis C is a major undertaking, and the instability often found in the lives of people who use drugs should not be underestimated – a range of problems from housing issues to relationship breakdowns will all play...
a part in disrupting treatment progress. It is not unusual in this patient population to find a preference not to know their hepatitis C status, and educating patients about the advantages of diagnosis and treatment is a necessary part of any service.

Consideration should be given to all factors that can increase the chances of success before embarking on treatment. Psycho-social support, psychiatric assessment, treatment for alcohol dependence, housing support and appropriate OST should be considered. Ongoing drug use should not be considered a barrier for antiviral therapy. Research demonstrates that people who are actively using drugs can and should be successfully treated for hepatitis C in the community.\textsuperscript{16} Indeed, current guidelines from NICE and AASLD recommend treatment for this population.\textsuperscript{12,17} Furthermore, undergoing treatment for hepatitis C can be a marker for recovery, helping people break with the past and put risk-taking behaviours and their drug-taking lifestyle behind them.

Current evidence supports the stabilisation of patients with OST using methadone, buprenorphine (Subutex), or buprenorphine-naloxone (Suboxone) as a prelude to antiviral treatment. OST has become a widely accepted treatment for people with opioid dependency.\textsuperscript{16} Methadone has been the mainstay of treatment since the 1960s, and is effective in blocking the effects of opiate withdrawal and to some extent deterring intravenous heroin use. Buprenorphine is a long-acting partial agonist available since 1995, which has been shown to achieve similar outcomes to methadone with fewer drug–drug interactions,\textsuperscript{19} which may be of particular benefit to patients undergoing antiviral therapy. The combination of buprenorphine with naloxone may confer an additional benefit, since the naloxone component deters intravenous use.\textsuperscript{20}

The World Health Organisation suggests the choice between buprenorphine and methadone should be based on clinical assessment and experience.\textsuperscript{16} NICE suggests the decision should be made case by case, taking into account individual history, commitment to long-term therapy and an estimate of risks versus benefits.\textsuperscript{21} Other issues that should be considered are drug–drug interactions, safety in overdose, ease of withdrawal, clear-headedness, and the potential for diversion and misuse. OST with either agent reduces the cost of opioid dependence to the public by reducing illicit drug use, criminal activity and morbidity and mortality.\textsuperscript{21} OST should be provided in combination with psychological support, to increase the likelihood of a successful outcome.\textsuperscript{21}

The potential benefits of OST are therefore two-fold: it can help patients stabilise their lives, and can thereby also help them accept and deal with both BBV testing and antiviral therapy.\textsuperscript{18,21} For these reasons, it is important to maintain effective levels of OST during hepatitis C treatment, and so close liaison between drug services and hepatitis treatment services is vital.

### Abstinence-based therapy

Under the present Government there has been a shift of emphasis towards abstinence-based recovery. This requires some extra precautions for those taking antiviral therapy. The physical and mental side-effects of interferon and ribavirin, together with the possible psychological trigger of injecting, have the potential to provoke relapse into drug use. A series of Department of Health-funded workshops for hepatitis and addiction nurses on this issue in 2003/4 produced a consensus document suggesting that those less than a year into abstinence-based recovery were likely to be unsuitable for treatment because of the risk of relapse. The consensus also suggested types of extra support to offer these patients.\textsuperscript{22}

### Alcohol

Many individuals with hepatitis C are misusing alcohol. It has been demonstrated beyond doubt that alcohol has a synergistic effect with hepatitis C in progressing hepatic fibrosis. It is essential therefore that a holistic approach is taken, and alcohol issues are addressed at the same time as assessing and treating hepatitis C, where necessary involving third-party agencies. While ongoing alcohol misuse is not an absolute contraindication to treatment, it can affect compliance with hepatitis C therapy and make interpretation of surrogate biochemical markers more difficult, thereby compromising the eventual outcome. More importantly, it is illogical to attempt to eradicate one factor while ignoring the other, if the long-term goal of improving hepatic health is to be achieved.

### LEARNING FROM THE EXPERIENCE OF OTHERS

#### Scotland

In 2005 Health Protection Scotland (HPS) estimated 37,500 people in Scotland had chronic hepatitis C. Funded by the Scottish Government, the Hepatitis C Action Plan was launched in 2006, and following data gathering and needs assessment work, set out 34 actions, which are monitored by HPS.

The major public health goal is to significantly increase treatment numbers in order to prevent huge numbers progressing to liver failure, which is debilitating and potentially fatal for the patient and extremely expensive for the NHS to manage. In order to achieve this increased uptake in therapy, and bearing in mind that people who use drugs may be reluctant to engage with health services for a range of reasons (absence of symptoms, poor communication between health worker and patient, fear of diagnosis, stigma and the presence of ongoing drug, alcohol, or mental health problems), service development in Scotland has focused on making it easier for the at-risk community to access testing and treatment. Managed Clinical Networks (MCNs) have been developed to facilitate communication between primary and secondary care. Open referral systems can be accessed by drug workers, prison nurses, midwives, social workers,
and homeless workers. Nurse-led and outreach clinics have been established, and shown to be effective, and dry blood spot testing has been rolled out. Rates of testing, diagnosis and treatment have increased.

Greater Manchester

The Greater Manchester Hepatitis C Strategy was published in 2006, following a needs assessment that estimated prevalence to be around 20,000. Calculations showed the estimated cumulative cost to the NHS in 20 years’ time in terms of associated liver disease to be £360m if the issue was not addressed, compared with a cost of £158m for treatment.

Local Directors of Public Health, Finance and Commissioning were lobbied to acknowledge the issue and provide the resources to tackle it, and all 10 PCTs in Greater Manchester agreed to provide a total of £1.4m in order to escalate local testing, treatment and prevention services. A full time programme manager was appointed, and there is a commitment from the PCTs to increase funding year on year if the strategy proves effective and antiviral drug costs are reduced.

Good communication is at the centre of the strategy. Also crucial is an effective BBV prevention network (including needle and syringe programmes), prison in-reach and community outreach programmes, and training local drug workers in both awareness of hepatitis and the use of dry blood spot testing.

As in Scotland and elsewhere, effective interlinking of different services is being shown to maximise the chances of success in reaching and engaging patients, while drug procurement initiatives with pharmaceutical companies are reducing drug costs.

The PREVENT project

The PREVENT project aims to improve the provision of BBV services to patients in treatment for substance misuse in North West London, and is a collaboration between a number of organisations including:

- Central North West London NHS Foundation Trust
- The Hepatitis C Trust
- Imperial College NHS Trust
- Chelsea and Westminster NHS Foundation Trust
- Health Protection Agency
- North West London Sexual Health Network
- Patient representatives

The project covers approximately 20 substance misuse services across North West London and focuses on three areas: BBV screening, HBV vaccination, and referral to specialist services for hepatitis and HIV.

PREVENT is a quality improvement project attempting to develop more efficient services by examining the process of delivery. The first step was to identify barriers to BBV testing and treatment. Focus groups were set up to look at specific parts of the patient journey, and the results used as the starting point for service improvement.

PREVENT is now testing the service improvements using the Plan, Do, Study, Act (PDSA) methodology. Examples of PDSA cycles include testing the impact of generalist versus specialist BBV workers. Once a particular service improvement has been identified, it is then tested in another part of the service to see if it is successful in the new setting. In this way, improvement is disseminated through the organisation.

The findings of the PREVENT project will be published in full in Spring 2012.

The experience of service users

Understanding the experience of patients is crucial to help achieve continual improvement. Patient focus groups in the PREVENT project revealed the following views, which are due to be published shortly:

Factors affecting attendance at BBV screening and HBV vaccination sessions

- Convenience. Easy access is crucial; particular factors include the location and convenience of services. HBV vaccination appointments are most likely to be attended if connected to the regular drug treatment service.
- Remembering appointments. Appointment reminders by phone, text or email are very helpful.
- Current drug and alcohol use. This strongly predicts non-attendance, but a targeted and intensive approach, such as motivational interviewing and contingency management (e.g. voucher reinforcement) can help.
- Mental health. Co-morbid mental health problems also predict non-attendance. Again, a more targeted and intensive approach, particularly contingency management, is recommended.
- Physical health and wellbeing. Poor physical health and drug/sex-related practices considered as placing the patient at risk are strong motivations for seeking BBV screening.
• Needles and blood taking. Patients described poor venous access and euphoric recall as two reasons for avoiding BBV screening. A strong preference was expressed for dry blood spot testing.

Factors affecting hepatitis C treatment
• Engaging in hepatitis C treatment. Patients described the decision to undertake hepatitis C treatment as complex and difficult. Important factors included the quality of information provided, particularly relating to side effects.
• Support during treatment. Convenience of services was felt to be important. Link nurses offering practical and emotional support were highly valued. Services which were flexible and responsive were felt to achieve better results.

A FUTURE SERVICE MODEL FOR LONDON

It is clear that London faces a particular and sizeable challenge. Unless education and screening are improved, and services configured to allow large numbers of patients to be treated for hepatitis C, we face a significant burden of disease in the next 20 years. There are excellent models and examples of good practice we can learn from, such as Scotland, Greater Manchester and PREVENT. There are already innovative outreach programmes in London such as the East London service, which have fed into the development of this consensus document. Looking to the future, we describe the service model that should be implemented across the whole of the capital.

Key principles of an effective integrated strategy for London
The long-term aim of the London strategy is to reduce liver-related mortality in people who use drugs; late diagnosis of hepatitis C (i.e. with cirrhosis) in this population is a key indicator. In developing recommendations for an integrated London strategy to achieve this aim, and considering their implementation in the wider healthcare environment, the following areas need to be considered:
• Needs assessment and cost analysis.
• Development of integrated care pathways with clearly defined roles and responsibilities.
• Patient-centred and coordinated service provision, with specialist hepatitis treatment services available in the community.
• Robust data collection and outcomes measurement, linked to Payment by Results.
• A pan-London commissioning strategy.

Key requirements
1. Prevention
• Awareness and education for both workers and service users in all healthcare environments, particularly those serving at-risk populations, such as drug treatment services, prison services, needle exchange services, homeless health.
• Effective needle exchange services with opening hours to suit patients.
• Expert OST service provision combined with consistent harm reduction advice and education.
• All patients engaging with drug treatment services in London should be tested for BBV unless they opt out.
• All patients engaging with drug treatment services in London should vaccinated against hepatitis B unless they opt out.
• Rates of BBV testing and hepatitis B vaccination should be included in Payment by Results targets.
• Patients should have informed discussions with health professionals about risks pre- and post-testing.
• Physical harm reduction measures should be considered, including treatment for alcohol misuse, with therapies such as acamprosate and naltrexone, as recommended by NICE for moderate to severe alcohol dependence.

2. Diagnosis
• At-risk groups should be approached and educated to encourage acceptance of BBV testing.
• Patient education leaflets about treatment should be developed and provided in appropriate language.
• Patients should have informed discussions with health professionals about risks pre- and post-testing.
• Expert phlebotomy services, or access to dry blood spot testing, should be available.
• Laboratory services should automatically undertake an HCV RNA test when the HCV antibody is positive and issue the combined result to minimise NHS workload, inappropriate and costly referrals to specialist services, and inconvenience to the patient.
• RNA testing should be available to primary care services across London and not be dependent on referral to hepatology services.
• Results should be available within a week, interpreted with clarity, appropriate for each patient.
• Clear referral pathways should be established, with arrangements for interactive community-specialist review of problematic clinical cases.

3. Treatment
• Shared care in a community environment or outreach service improves patient engagement, and maximises the chance of a successful outcome. Locating hepatitis treatment services in the same place as drug treatment services should be considered.
• Individualised, patient-centred treatment should be provided by a multi-disciplinary team linking appropriate resources such as psychiatric assessment, psycho-social support, treatment for alcohol dependence, housing support and OST.
• A robust administrative infrastructure should enable timely clinic appointments, clearly communicated to patients and carers.
• Appointments for antiviral therapy should be coordinated with OST appointments, and phone, email or SMS reminder messages used.
• There should be a clear patient visit schedule, and afternoon clinics should be available for those on supervised OST.
• Non-invasive methods of liver fibrosis assessment (Fibroscan™) should be available.
• There should be rapid turnaround of viral tests (within a week).
• Patient education leaflets about treatment should be developed and provided in appropriate language.
• Appropriate information should be provided to patients and carers, via timely letters.
• There should be effective signposting to support groups, buddying schemes, peer education groups and other relevant services.

4. Data collection
Data collection as per the Scottish Hepatitis C Action Plan should also be an important element of an effective hepatitis C strategy for London in order to assess the public health need, plan and commission services, and assess the effectiveness of treatment strategies. The following information should be collected as part of an essential data set:
• Number of tests offered
• Number of tests performed
• Number of positive results
• Number of patients referred to secondary care
• Number of patients offered treatment
• Number of patients starting treatment
• Number of patients completing treatment
• Number of patients with SVR
• Data should be collected on the reasons patients decline testing or treatment
AN EFFECTIVE LONDON HEPATITIS C CARE PATHWAY FOR PEOPLE WHO USE DRUGS

“All primary care organisations in England and Wales should ensure that integrated pathways of care are available for patients with hepatitis C (ideally coordinated through a clinical network).”

HPA: Hepatitis C in the UK – 2009 report

Patients should be at the centre of the care pathway. A holistic approach should be taken, developing joined-up services that make it easier for vulnerable people to access high-quality treatment, care and support. The success of the pathway depends on high levels of awareness among workers in services looking after at-risk populations, clear guidance on what to do, and good communication between services.

Before implementing the care pathway, consideration should be given to practical issues such as making sure the first visit to the clinic is positive, and how to follow up people who fail to attend their appointments.

Screening, diagnosis and referral

Screening
National and international guidelines recommend that people at risk of being infected and who could benefit from knowing their hepatitis C status should be offered a test. Every patient attending a drug service in London should be tested for BBV unless they opt out. If people decline testing, it should be offered again in three months. The risks of HIV co-infection should be considered, and all HIV-positive people should be offered a HCV test. Vaccinations for hepatitis A (HAV) and B (HBV) should be given.

BBV testing at needle exchange services is also very effective, as this may be the patient’s first point of contact. Surrey, East London & the City, Kingston, Wandsworth and Haringey PCTs all currently fund BBV testing in community pharmacies with needle exchanges.

Testing for antibodies can be carried out by either taking venous blood (using DBS or venepuncture) or with oral fluid testing kits. Blood tests are the gold standard and should be used in preference to oral tests as the sensitivity and specificity of oral tests are lower than blood tests. Those testing positive for antibodies should have their sample tested for hepatitis C RNA to confirm whether they are currently infected.

Diagnosis
Laboratory services should be set up to enable the RNA and antibody results to be given to the patient at the same time, and the results should be given in the context of a post-test discussion with a health professional. If the result is negative, the discussion should include the result and the accuracy of testing, and the recommendation that if recent exposure to the virus has occurred they should be retested in 6 months. If positive, information about the disease and treatment options should be given, to enable the patient to make a decision about treatment. Consistent harm reduction advice should be reinforced regardless of the test result.

The patient should be referred to a hepatitis specialist service for assessment, ideally located in the community. If the patient is not suitable for treatment, or declines treatment, they should be placed on yearly follow-up at the hepatitis C clinic.

Specialist care should be provided for all patients with chronic hepatitis C, and not restricted to potential candidates for antiviral therapy. Specialist clinics are a source of useful information on health promotion and methods of avoiding secondary transmission of the virus.

Referral
Patients should be referred to an experienced hepatology team (including a clinical lead in viral hepatitis, a specialist nurse, a specialist voluntary sector practitioner, and a pharmacist with knowledge of the relevant medications) who will provide information about hepatitis C and the treatments available so that the patient can make a decision on whether to start antiviral therapy. All patients have the right to high quality care regardless of lifestyle, and ongoing use of drugs or alcohol should not be a barrier to treatment.

The specialist team should assess each patient’s suitability for treatment, including a mental health assessment, and identify and address individual support needs. The success of treatment relies on adherence, and the ability of the patient to complete treatment can be improved with careful planning. All patients should be reviewed by a CNS before starting treatment.

A pre-treatment discussion should include the length and likely outcomes of treatment depending on viral genotype, the potential side effects and their management, information about the natural progression of hepatitis C and factors that affect it, and advice on preventing transmission to others. The review should also describe the monitoring protocol and make sure the patient is able to commit to it.
Other important patient-centred discussions should take place, such as a suitable start date that takes into account any imminent family, housing or employment issues, and education on the safe storage and disposal of medications and equipment. Storage may be an issue in the case of people who are homeless, or live in hostels, and needs to be considered.

2. Treatment
During treatment patients should have a regular review with a CNS or Specialist Practitioner. They should be shown how to administer their interferon injections, have side-effects monitored, and have the opportunity to discuss any problems. Changes to dosing will be reviewed by the CNS and the consultant.

Ongoing peer support and education should be aimed at encouraging and supporting patients to live healthy lives and engage in less risky behaviours. It should include access to support groups (including HIV groups if appropriate), information on lifestyle changes and harm reduction advice, as well as peer education and volunteering opportunities. Outreach support by specialist nurses should be considered, for example within addiction services. It may be easier to manage mental health and behavioural issues in this setting than in a hospital environment. Every effort should be made to ensure that patients undergoing treatment in prison continue their treatment uninterrupted, and that provision is made for continuity of care on release or transfer to another prison.

3. Long-term Care
Aftercare and ongoing support should be in place to manage any long-term residual effects after antiviral treatment. Patients who have an SVR should be referred back to their GP or drug treatment service for the management of any persistent symptoms caused by treatment. GPs may be unaware of the potential for post-antiviral treatment effects, some of which can be significantly debilitating. Follow-up care for patients with these symptoms should be available. Patients who do not have an SVR should be monitored on a regular basis by the hepatitis treatment service and offered re-treatment or new therapies as appropriate. It is imperative not to lose contact with these patients. Patients with evidence of cirrhosis should continue with long-term follow up for hepatocellular cancer (HCC) surveillance.
Figure 8. London Hepatitis C integrated care pathway for people who use drugs
RECOMMENDATIONS FOR THE INTEGRATION OF HEPATITIS C SERVICES IN LONDON FOR PEOPLE WHO USE DRUGS

Recommendations
Our key requirements and recommendations are set out in terms of prevention, diagnosis, treatment and data collection for each type of service that impacts on the patient’s journey. The emphasis is on education and training, and on the need for integration and collaboration across drug and specialist hepatitis treatment services, public health, prisons and primary care.

Drug services
- Every patient attending a drug service in London should be tested for blood borne viruses (BBVs) and, if negative, repeat tested every 6 months. A baseline target of 90% should be adopted in all drug services.
- Every patient attending a drug service in London should be vaccinated against hepatitis A and B. A baseline target of 90% uptake should be adopted in all drug services.
- Every hepatitis C RNA-positive patient should be referred to a specialist treatment service for assessment, and provided with support to attend if required. Current substance misuse in itself is not a barrier to hepatitis C treatment.
- Every drug worker should have a clear basic knowledge of hepatitis C, (through completing the RCGP Certificate in the Detection, Diagnosis and Management of Hepatitis B and C in Primary Care, or an equivalent qualification).
- Consistent harm reduction advice and education should be provided through all services working with drug users, including all needle exchange services.
- Every local drug service centre should have a nominated person responsible for liaising with hepatitis treatment centres, prisons and primary care.

Specialist hepatitis treatment services
- Every hepatitis C treatment centre should have a nominated person responsible for liaising with local drug services, prisons and primary care.
- Everyone referred to specialist services should be assessed for treatment. Current substance misuse in itself is not a barrier to treatment, though other factors will influence whether treatment is initiated. These factors should be recorded to inform ongoing improvements in services and patient support.
- Potential alternatives to treatment in the hospital setting should be formally assessed, and nurse-led outreach services should be established wherever possible.
- Data should be collected on an ongoing basis to capture:
  - Total number of drug users and non-drug users referred for assessment.
  - Total number of drug users and non-drug users offered treatment.
  - Barriers to treatment (where treatment is assessed as inappropriate at present or is declined by the patient).
  - Adherence and outcomes, e.g. SVR rates in individual patients and the link with adherence to treatment.
- Patients should have access to mental health support before and during hepatitis C treatment.

Directors of Public Health
- Every public health locality should have a multi-sector working group responsible for ensuring people who use drugs have access to a robust pathway from testing to specialist treatment services. The group should include specialists in public health, viral hepatitis, substance misuse and mental health as well as GPs and support workers.
- The use of DBS (dry blood spot) testing or Point of Care (Rapid) Testing should be available in as many services working with people who use drugs as possible.
- Data on prevalence and incidence – among both drug users and non-drug users – should be collected on an ongoing basis.

Primary Care
- Every clinical commissioning group should have a nominated lead for hepatitis C and substance misuse.
- Every hepatitis C RNA-positive patient should be referred to a specialist treatment service for assessment, and provided with support to attend if required. Current substance misuse in itself is not a barrier to hepatitis C treatment.
- At least one GP in every practice should have a basic knowledge of hepatitis C, (through completing the RCGP Certificate in the Detection, Diagnosis and Management of Hepatitis B and C in Primary Care, or an equivalent qualification).
qualification).

- GP practices should implement strategies to search patient records for indications of substance misuse and invite all indentified to be screened for BBVs.

Prisons

Every prisoner in London should be tested for BBVs at their initial health assessment. A baseline target of 90% should be adopted in all prisons.

Every prisoner in London should be vaccinated against hepatitis A and B. A baseline target of 90% should be adopted in all prisons.

Every hepatitis C-RNA positive patient should be referred to a specialist treatment service for assessment, and provided with support to attend if required. Current substance misuse is not a barrier to hepatitis C treatment.

Patients on antiviral treatment should not have their therapy interrupted due to incarceration, transfer or release from prison. Health records should move with the prisoner and maintenance of hepatitis treatment and/or opioid substitution therapy (OST) planned in advance with receiving services.

Every prison officer should be provided with sufficient training to maintain a clear, basic knowledge of hepatitis C.

Consistent harm reduction advice and education should be provided through all services working with prisoners, including harm reduction advice after release.

Every prison should have a nominated staff member responsible for liaising with primary care, public health, drug services and hepatitis treatment centres.

Conclusion

Hepatitis C is a major public health issue currently facing the UK, and the situation in London is of particular concern. In terms of the liver disease epidemic, it is the most tractable problem, with cost-effective treatments available, yet many vulnerable patients fall through the net in London for want of effective planning and joined-up service provision. For this reason a multi-disciplinary group of experts convened to explore ways to address this problem. The first output of this group was a pan-London stakeholder conference, from which this consensus has been developed. It outlines a clear series of actions, each of which will have an individual effect on this problem, but which all together will provide a very significant impact on the seemingly inexorable rise in hepatitis C-related liver disease. The consensus will now be turned into an action plan to enable this outcome.

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Glossary of acronyms

AASLD: American Association for the Study of Liver Diseases
BBV: blood-borne virus
BMI: body mass index
CNS: Clinical Specialist Nurse
DAT: Drug and Alcohol Team
DBS: Dry blood spot (test)
DLA: Disability Living Allowance
DNA: Did Not Attend
DH: Department of Health
HBV: hepatitis B virus
HCC: hepatocellular carcinoma
HCV: hepatitis C virus
HIV: human immunodeficiency virus
IDU: intravenous (or injecting) drug user
LFT: liver function test
LJWG: London Joint Working Group for Substance Misuse and Hepatitis C
NICE: National Institute for Health and Clinical Excellence
OST: opioid substitution therapy
PCT: Primary Care Trust
RNA: ribonucleic acid
SVR: sustained virological response

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