Confronting the silent epidemic: a critical review of hepatitis C management in the UK

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Islands of outstanding clinical and public health practice in the UK demonstrate that with adequate resources, imaginative thinking, robust leadership and major input from the third sector (such as the UK Hepatitis C Trust), the seemingly tortuous patient journey for those with lifestyle issues can be completed very successfully.

Professor David Goldberg of Hepatitis Scotland

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The National Health Service (NHS) in the UK is going through a period of radical change. The restructuring of the commissioning frameworks and the overhaul in the way healthcare services are delivered are already impacting on the way different health conditions are managed. It is likely that the management of well known, well understood diseases may be prioritised during this period of change. But what of conditions that already represent great challenges for the health service? What will happen with conditions like hepatitis C?

Hepatitis C, often described as a “viral time bomb” and “silent epidemic”, can lie dormant for many years before manifesting as chronic liver disease, cirrhosis or even liver cancer.1 The World Health Organization estimates that about 150 million people are chronically infected with the virus across the world,2 and it remains a significant health problem in the UK where the most recent national estimates suggest that at least 216,000 people are chronically infected with hepatitis C.3

At the heart of the problem is awareness – over half of those with the virus do not know that they are infected. Initially, for most people, there are no discernible symptoms and those that are present do not always lead to a clear diagnosis of hepatitis C. Despite the availability of effective treatment strategies and programmes across the UK, there has been a 300 per cent rise in hepatitis C deaths from related end-stage liver disease or liver cancer.1 It is for this reason that Government policy and increased public awareness is needed to help bring about action to halt this disease.

Although the challenges we face in the management of this debilitating, but completely treatable and controllable disease are well documented, diagnosis and treatment rates are dishearteningly low when compared to other European countries and patients are suffering unnecessarily as a result. But rather than accepting the failings in our services from the evidence available, we should see the changing health landscape and commissioning framework as an opportunity to tackle the burden of hepatitis C. The previous practice of waiting to treat patients until their disease had progressed meant that in the long-term, the resources used to manage complications of hepatitis C exceeded those that would be better employed to nip the virus in the bud. For clinicians and commissioners alike, eradicating the virus early on in patients is a realistic, achievable and critical goal. And for the benefit of patient outcomes, it must be a priority – are we willing to sit by and watch patients suffer rather than treat early?

While hepatitis C action plans have been developed across the UK, they have been implemented with varied success. Scotland has led the way by setting targets to reduce the number of newly acquired infections and the gap in health inequalities to ensure those living with hepatitis C lead longer and healthier lives. However, even in Scotland we are still a distance from the full realisation of public health policy and treatment targets. Wales’ blood borne viral hepatitis action plan is a good start and we are beginning to see improvements but further progress is imperative. England’s plan, published almost a decade ago, has had little, if any impact due to its complete lack of timetables, targets and funding.

This report has been developed to help us all stop and look at where we are with hepatitis C in the UK and better understand how to move forward. With best practice examples identified and provided in this report, it is clear that innovative programmes, where best practice principles are implemented, can lead to impressive outcomes. At the core of current health reforms is the resolve to reduce health inequality and “improve the health of the poorest, fastest”. When it comes to this objective, there could be no disease more relevant or which more often affects the lowest socio-economic groups than hepatitis C.

Charles Gore
Chief Executive, The Hepatitis C Trust

References
Hepatitis C: the state of the nation

More than 200,000 people in the UK are infected with a virus capable of causing serious liver damage and death. Effective treatments exist, but less than one in 30 of those infected is treated every year. Many remain unaware of their condition until serious symptoms emerge, even though tests exist that can detect the infection sooner and treatment is more likely to succeed the earlier it begins.

An infection that is well understood, that can be detected and in most cases successfully treated, and that has been the subject of repeated initiatives, plans, and well-argued reports, causes each year as many deaths as are believed to have occurred at Stafford Hospital – without provoking a fraction of the hand-wringing about poor care. Hepatitis C – the cause of this silent slaughter – is a virus that seems able to slip all too easily below the threshold of awareness.

The hepatitis C virus has probably infected humans for hundreds or thousands of years, but its transmission was slow. It languished in obscurity until blood transfusion offered it a fast track to global prominence, starting at the beginning of the 20th century. In a few people who had received blood from an infected donor, it caused rare, acute complications, the cause of which was not positively identified until the virus was isolated in 1989. By then it had infected many people without triggering any obvious symptoms in most of them, and diversified into a family of closely-related but distinct genetic variants. Thanks to testing, blood supplies in the UK have been clean since 1992. The most common route of new infections today is through contaminated needles shared by intravenous drug users, but there are many other potential sources including medical treatment in high prevalence countries, mother-to-child transmission, and needlestick injury among healthcare workers. Globally, unsafe healthcare remains by far the most important cause, responsible for 140 million of the 150 million cases worldwide.

Because hepatitis C is an invisible infection without symptoms in most patients, estimating how many people are infected is not easy. Two categories of infection need to be distinguished. A minority of people can clear the virus without treatment, but still carry antibodies, which means that they test positive. But it is the other three quarters in whom infection becomes chronic, who face the risk of serious long-term consequences, and they are the best candidates for early treatment. The Health Protection Agency (HPA) estimates that there are around 216,000 chronically infected people in the UK – though others, such as The Hepatitis C Trust, believe the number may be greater.

There are regional variations. In England, the prevalence of chronic infection for the adult population is 40 per 10,000 people, but in Scotland it is estimated to be twice as high- 80 per 10,000. Within England, London and the North West have higher levels than the rest of the country. There are also variations between ethnicities – people of South Asian (and especially Pakistani) origin are much more likely to be infected. Very high infection rates have also been found in immigrants from Eastern Europe but this may simply be because they have been targeted for testing.

Untreated chronic infection with hepatitis C may cause no perceptible damage. In a significant minority of people, however, damage occurs in the form of cirrhosis of the liver or, in the worst cases, liver cancer. The numbers of UK hospital admissions and deaths from hepatitis C-related end-stage liver disease and liver cancer have been increasing steadily. Admissions rose from 612 in 1998 to 1,979 in 2010, deaths from 98 in 1996 to 323 in 2010. Liver disease is the fifth biggest killer in the UK.
If left untreated, the Health Protection Agency (HPA) estimates that 15,840 people in England will be suffering from cirrhosis or liver cancer caused by hepatitis C by 2020,\textsuperscript{1} a huge burden of illness and a major cause of death, as well as a heavy cost to the healthcare system and a significant loss to the economy (as an example, the annual cost of care for a person with cirrhosis is £12,432, and for liver cancer £11,078).\textsuperscript{6}

Testing has focused on the groups most likely to carry the infection. Among intravenous drug users in England, 45 per cent tested positive in 2011, with slightly lower rates in Wales and Northern Ireland, and higher in Scotland.\textsuperscript{1} Between 2008 and 2011, a quarter of women in UK prisons who were tested were found to be infected, and about an eighth of male prisoners. In the general population, 2.8 per cent of South Asians who were tested for hepatitis C in 2011 were positive, and 6.0 per cent of East Europeans. The number of positive tests among blood donors has fallen sharply since 1991, with only 38 per 100,000 of first-time donors testing positive in 2011, most of those from South Asia or Eastern Europe.

Figure 1a: Deaths from, and hospital admissions for, HCV-related end stage liver disease (ESLD)\textsuperscript{1}

Figure 1b: Deaths from, ESLD or HCC in those with HCV mentioned on their death certificate in England: 1996–2011\textsuperscript{1}
The current management of hepatitis C

While all four UK nations have plans in place for treating people infected with hepatitis C, treatment rates remain low. The aim is to clear the virus from the blood to prevent progression to liver disease, which will otherwise affect about 20 per cent of those with chronic infection. Two drugs used in combination – pegylated interferon and ribavirin – form the basis for treatment and can achieve success in about 55 per cent of cases. Pegylated interferon (so-called because the interferon is bound to polyethylene glycol, or PEG, to prolong its action) is given weekly by an injection delivered under the skin. It helps the body’s immune system fight the virus. Ribavirin, taken twice a day in the form of tablets, helps stop the virus from multiplying. A full course of treatment with these two drugs (dual therapy) can last 48 weeks, with the aim of achieving a sustained viral response (SVR) which in practice means that the virus can no longer be detected in the blood six months after the end of treatment. Those who respond well may not need such a lengthy treatment, and those who do not respond at all may be removed early from treatment that is not succeeding. The success rate depends on which genetic variant has caused the infection, with genotype 1 (the most common in the UK, responsible for 40–50 per cent of cases) responding less well than genotypes 2 and 3.

Nearly a decade after England’s Action Plan for hepatitis C was launched, there are still large variations in policies and outcomes as well as a significant lack of reliable data.

The All-Party Parliamentary Hepatology Group, in a 2010 report, presented data from 69 of 107 hospitals and of these only 39 provided data on the number of people treated, and the number cured. It is worrying, the report said, that many hospitals do not record cure rates, a failure that needs to be urgently addressed by imposing national data reporting. Such data unearthed large discrepancies between hospitals in cure rates (defined as an SVR), which for genotype 1 infection ranged from as low as 10 per cent to as high as 78 per cent and for genotype 2 and 3 between 15 per cent and 100 per cent. Such huge variations may suggest defects in data gathering rather than real differences in treatment quality, but it is impossible to be sure.

Little has changed since this report was published and in 2013 The Hepatitis C Trust found that almost a quarter of health commissioners in the NHS had yet to make any estimate of the numbers diagnosed with hepatitis C. Two thirds had no estimate of the numbers cured by treatment – a “worrying” lack of data, the Trust concluded. Collection of such data by commissioners should be routine, to assess how well services are performing, the Trust said.

Two new drugs, called protease inhibitors, can improve the success rate in genotype 1 infection. Boceprevir and telaprevir, taken as tablets three times a day in combination with pegylated interferon and ribavirin, have both been approved for use in the NHS by the National Institute for Health and Clinical Excellence (NICE), which says they offer a major improvement in cure rates and may encourage more patients to accept treatment. “In the past, patients have declined treatment because the perceived chance of SVR with peginterferon alfa plus ribavirin was too low for them to accept the associated side effects”, said Professor Carole Longson, Director of the NICE Health Technology Evaluation Centre.

However, treatment is long, complex and expensive and can include unpleasant side effects such as flu-like symptoms, fatigue, and depression. Many patients from high-risk groups such as injecting drug users are not always well suited to such lengthy and demanding regimes. The addition of the protease inhibitors has made treatment more complex, imposing extra demands on clinics and medical staff that can lead to fewer patients being treated. Serious adverse effects including two deaths and 112 serious skin reactions have been reported by the US Food and Drug Administration among patients given telaprevir, which has carried a ‘black box’ warning, the highest cautionary level, since December 2012.
Calls for action have been ignored

The Hepatitis C Action Plan for England, published in 2004, set out actions to be taken by Primary Care Trusts (PCTs) and hospital trusts but evidence gathered by the All-Party Group found that by 2008 its adoption had been inconsistent. Only a third of PCTs were implementing the plan fully, only half were partially implementing the plan, and 15 per cent had done little or nothing (figure 2a). Hospitals reported delays in starting treatment. By 2008 Scotland had drafted its own plan, promised the resources needed to support it and a governance structure to ensure targets were met, but Wales had yet to publish its plan.

Figure 2a: Four years after the launch of the Hepatitis C Action Plan for England

Figure 2b: Variations in hepatitis C treatment practice
A report by The Hepatitis C Trust a year later found that 70 per cent of Strategic Health Authorities (SHAs) were failing to ensure the plan in England was implemented, in spite of the fact that they had been given responsibility for overseeing. Inaction and complacency at every level of the NHS were preventing the full use of treatments approved by NICE, the Trust said. Gaining control of hepatitis C was a national public health problem that would require central direction and leadership – “something which this report reveals is singularly lacking”.

Similar criticisms were made in the 2010 report by the All-Party Group which found “huge variations” in hospital treatments of hepatitis C (figures 2a and 2b). Of 69 hospitals offering services, 10 refused NICE approved medications to all injecting drug users; 12 did not offer re-treatment to any patients; and two refused re-treatment to any patients continuing to drink alcohol (figure 2b). It found that a third of hepatitis C patients referred to hospitals were not offered treatment and that less than a third of hospitals measured patient satisfaction. There was a “worrying shortage of basic monitoring” by hospitals which was hampering local and national service planning. The report’s conclusion was stark: “it is unacceptable that the number of deaths from liver disease and liver cancer is rising sharply in the UK, while it is falling in the rest of Europe.”

A report by Rand Europe, published in January 2013, outlines what will happen if present patterns of testing and treatment continue (figure 3). It projects that by 2035 the number of

Figure 3: An increasing hepatitis C patient population

![Graph showing increasing hepatitis C patient population](image-url)
people living with hepatitis C in the UK will have increased to 370,000. To prevent this rise would require a quadrupling of treatment rates, at a cost of £43.8 million a year, but the gains in productivity would far exceed that, at £73.3 million a year. These gains would come from reducing the number of people progressing to advanced disease from the 17,000 expected under present trends to 12,000. The impact would be long-term, the report acknowledges, and the extra costs short-term, but continuing as we are will have little impact on the future burden associated with hepatitis C.

The changing commissioning environment

Given the delays involved in establishing the Hepatitis C Action Plan for England, the last thing clinicians wanted was another excuse for inaction. Unhappily, the wholesale changes in the way specialised services are commissioned in England could provide just that. Under the 2012 Health and Social Care Act, on 1 April 2013 commissioning of most services passed from PCTs to Clinical Commissioning Groups (CCGs), (GP-led local organisations that are expected to take some time to find their feet). PCTs and SHAs have been abolished and specialised commissioning has passed to NHS England (the new name for the NHS Commissioning Board) which, like the CCGs, is an entirely new organisation. Responsibility for public health has moved to local authorities, backed by another new body, Public Health England.

The All-Party Group, while clear that the existing system has failed, fears that the changes could disrupt and destabilise services, damaging patient outcomes rather than improving them. All three parts of the new NHS structure need to be involved; public health for awareness programmes, hepatitis C testing and needle exchange schemes, while CCGs and NHS England will both have to be involved in planning and funding hepatitis C treatment. Actions in one part of the system could easily have consequences for the others. For example, if a local authority launched a public awareness campaign it could identify more patients needing treatment and swamp the available services, leading to patients waiting too long for treatment. One possible way of avoiding failures of coordination, the group suggested, was to create a clinical network for liver disease, (based on the model already established for cancer and cardiovascular disease). But in its announcement in July 2012 of the new networks it planned, NHS England omitted any mention of liver disease. This decision is disappointing, says The Hepatitis C Trust, which has called for NHS England to support the piloting of such networks with a view to later implementation nationwide.

The Hepatitis C Trust asked a series of questions of commissioning bodies and local authorities to test how ready they were for the new environment. In its report published in March 2013, it found local authorities to be unprepared for their new responsibilities, with only a fifth having a clinical lead for hepatitis C in place, and even fewer a strategy. Only a quarter of those who replied had assessed the current and future burden of hepatitis C in their community. PCTs were in a slightly better position, but it remains unclear how reliable the systems they have in place transferred to the CCGs. The Hepatitis C Trust concludes that the new arrangements are an opportunity to set right the mistakes of the past, but “serious work has to be done now to make this happen.”

Comments from a specialist, provided through new market research, highlighted similar concerns:

“I think the pressure from commissioners is only going to increase.

Although NICE has approved treatments, I’m not sure commissioners will continue to see it as good value for their money.”
Another had concerns about the financial pressures facing local authorities.

“We have actually had a reduction in referrals from the local Drug and Alcohol Teams as the local authority is restructuring and cutting back” he said. “I’m not sure how this is going to work out.”16

Clinicians more widely are also anxious and disappointed that more than three years after it was announced, a new National Liver Strategy for England has yet to appear, despite repeated promises.

Figure 4: Hepatitis C treatment rates in the UK and Europe14

**Practical barriers to optimal treatment with dual and triple therapy**

**What is standing in the way of improving the treatment of hepatitis C infection in the UK?** The evidence is that despite many efforts to improve care, results have been poor. The Health Protection Agency claims in a 2012 report that the UK is one of the worst nations in Europe,17 with just over half not yet diagnosed and only three per cent of those diagnosed have received treatment with NICE approved drugs.1 In France, The Hepatitis C Trust has found that an estimated 6–12 times as many people diagnosed with hepatitis C are likely to received treatment, than in the UK.17

The evidence is quite clear that treatments are cost-effective. For genotypes 2 and 3, dual therapy achieves a cure in up to 95 per cent of cases, at a cost of £6,246, HCVAction reported in October 2012.6 The NICE recommended triple therapy for genotype 1 infection costs £34,890, but evidence suggests that the additional expense increases the success rate (as defined by SVR) in genotype 1 cases by 30 per cent. For comparison, the annual cost of care for a person with cirrhosis is £12,432 and for liver cancer £11,078.
Despite these positive figures, the number treated in England fell by six per cent between 2010 and 2011, a fall attributed by the HPA to a number of possible factors. These include clinicians and patients waiting for the new drugs, reaching the limits of existing treatment capacity, or achieving saturation in easy-to-access patients such as prisoners and injecting drug users, leaving many more elusive patients untreated. The data from Scotland, where targets have been set, is more encouraging, with rises each year from 2007–08 onwards. The number of patients treated in Scotland in 2011–12 was 1,002, against fewer than 5,000 in England, the population of which is ten times bigger.

The failure to arrest the rising number of infections means that a growing proportion of those who need a liver transplant is attributable to hepatitis C – up from 10 per cent in England in 1996 to 18 per cent in 2011, and from 9 to 12 per cent in Scotland over the same period. A liver transplant – should a donor be available – costs more than £50,000, and the HPA estimates that if treatment rates for hepatitis C do not increase, 4,200 transplants will be needed by 2020.

Treatment for hepatitis C is not unique in failing to implement NICE recommendations, a study by IMS Health published in November 2012 found, but it is an extreme case. Comparing treatments for a range of conditions (including asthma, hepatitis C, osteoporosis, rheumatoid arthritis, non-small cell lung cancer and multiple myeloma) IMS Health identified factors that inhibited uptake of NICE approved therapies, a failure to diagnose, varying access to specialists, insufficient capacity, deficient commissioning and postcode variations. “Gaps appear throughout the treatment pathway, the gaps varying in terms of impact by disease”, IMS Health concluded. “The cumulative effect of these gaps is most notable in the treatment of hepatitis C.”

Similar conclusions were reached by Professor Sir Mike Richards in his 2010 report for the Department of Health on international variations in drug use. He found that that UK lay 13th out of 14 countries in its use of hepatitis C drugs (outlined in the table below), blaming challenges in “organisation, planning and capacity” for the shortfall. Even when differences in prevalence rates were taken into account, he concluded, the UK was still a relatively low user. He said that the department was responding through the development of the liver strategy, but nearly three years later this has still not appeared.

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Specialists in treating the disease identify a series of important issues that need to be addressed:

- A lack of funding for additional screening, because of fears that identifying many more cases would put excessive pressure on treatment

- A lack of engagement among some GPs in managing hepatitis C, possibly caused by a lack of incentives. GPs can earn ‘points’ for good care under the quality and outcomes framework, which translate into increased earnings, but hepatitis is not included. Alternative means need to be found to incentivise GPs to do more. Some success has been achieved by specialists working with local GPs in areas where there is a large Asian population, to increase awareness and encourage people to come forward for testing and treatment. “This has made a difference to finding patients” one specialist said

- GPs also lack confidence in counselling patients about hepatitis and in interpreting liver function tests

- Referrals from primary care are falling. Recent cuts to drug and alcohol services are also seen by some specialists as a cause of a drop in referrals

- Treatment centres are not pushing hard to treat more patients, some because there are funding restrictions or a cap on local budgets, others because of uncertainty over the introduction of triple therapy and how difficult it will be to manage. Consultation time is much longer with triple therapy than with dual therapy, because of the need to explain the possible side effects and the need to see the patient weekly. This adds significantly to the clinical burden and results in fewer patients being seen. “Capacity to treat patients is always an issue, even more so now with triple therapy” one specialist said. “Our nurses cannot cope with more patients at any one time”

- A lack of drive or sense of urgency from the Department of Health and the Government, epitomised by the delay in publishing the liver strategy. If this was remedied more patients could be identified and treated

- Some specialists believe that funding is unequal. “Some units do seem much better resourced than ours” was one comment made. “I don’t know why.” It is impossible to tell if this perception is true, because no breakdown of spending by unit exists.

**Overcoming challenges with the hepatitis C patient population**

Treating patients infected with hepatitis C presents special challenges. Research by Health Protection Scotland showed that three quarters of hepatitis C patients were from the two lowest social-economic quintiles, raising issues such as travel costs, low levels of literacy and low levels of engagement with services. Those who are easier to treat, if they could be found, are elusive because although the total number of infected people is large, prevalence in the general populations is low – much lower than in France or the US, for example.
Interviews with clinicians and nurses who specialise in hepatitis C reveal a range of views. Some are cautious about taking on patients who may not stay the course, but there is also evidence that supporting patients and taking chances can achieve some gratifying results.

“Some of these people have made bad life choices in the past”, said one interviewee. “They don’t feel they deserve good treatment. We need to encourage them to see they can have this, they can stick with it.” Another said: “I feel we have to have a good reason not to treat someone. If they make it to clinic, that for me is a good sign in itself.”

Those who are more cautious suggest that the high treatment burden legitimises waiting if patients are not yet “in the right place”. As one said: “we have to weigh up the clinical issues, how urgently we feel we need to intervene, with all the other things going on in their lives.” Another commented: “over the years you become more realistic. But I’ve also had situations where we’ve had success when you wouldn’t imagine it was possible.”

Treatment is also a serious undertaking, very different from a short course of antibiotics to cure a bacterial infection. It can take six months of weekly injections and daily pills to clear the virus if it is genotype 2 or 3, possibly twice as long if it is genotype 1. “The ideal is to treat the patient early” as one specialist said, “because you don’t know what the trajectory of the disease will be.” NICE guidance has also changed practice: “ten years ago we would not treat anyone with mild disease, but new NICE guidance has changed this. Patients with mild disease respond better, our efforts are more successful more often” was another comment made.

The first course of therapy offers the best chance of a cure – if patients withdraw they have to start again at the beginning, with their resolve already undermined. So there is a difficult choice to be made over whether a particular patient should be treated at all, if there is no evidence of liver scarring and the virus does not seem to be doing enough damage to warrant the treatment. But the obverse is that the earlier treatment starts, the greater its chance of success. And waiting imposes the need to continue to monitor patients’ liver health, which is not easy. As one specialist said: “it’s tricky, because there is a long window of opportunity, so you can afford to wait until the time is right. But once it is too late, it is difficult, expensive and nasty.” Patients remain on the caseload and are monitored every three or six months, patient circumstances permitting.

Pre-treatment assessment and support are of key importance. At St Mary’s Hospital in London, for example, a full hour is allocated for the first consultation to ensure that the patient understands the treatment and is sufficiently motivated to undertake it. Each patient is allocated a clinical nurse specialist for the duration of treatment, improving adherence and reducing costs because it means that many patients require only a single course. Specialists agree that such support is vital.
“We’ve done quite a lot of work organising our clinics in order to make them accessible and available for patients” one said. “You have to be a bit flexible with some of these patients; they don’t always attend in exactly the way you’d like” Another said: “we’ve reorganised our clinics to be able to provide a more support-based service to patients, particularly the complicated ones, the chaotic ones, the ones who find it really hard to stick it out. We’ve definitely been able to get more people to comply with treatment, which I think is really good.”

Looking to the future

The 2004 Hepatitis C Action Plan for England called for the establishment of clinical networks for the assessment and treatment of patients, recognising that care needs to be linked across primary, secondary and tertiary care and with other services such as virology, social care, prison, and mental health services. Hepatitis C is the absolute antithesis of a ‘prescribe and forget’ condition. But the All-Party Group’s 2010 report found that less than half the hospitals that responded to their survey were part of a managed care network. Only 29 of the 64 hospitals that responded said they employed one or more full-time, dedicated hepatitis C care nurses, for a condition in which regular contact with a nurse is a key requirement. Less than a third of responding hospitals said they measured patient satisfaction, while 43 responded they did not do so and had no plans to do so – an extraordinary omission for a condition where successful treatment depends critically on patient engagement.

The approval by NICE of the two protease inhibitors has added another complexity to the mix. Consultation times are longer and patients need to be seen weekly to monitor potentially serious side effects. And, paradoxically, the development of new medicines has caused some patients to pause, in the hope that better ones are in the pipeline, with greater effectiveness and fewer side effects. Some doctors believe that ‘warehousing’ patients with mild disease is reasonable while awaiting better treatments, but others argue that for many patients likely to respond well to existing treatment, waiting doesn’t make sense and could be doing patients a disservice. Drug development is uncertain, so nobody can be sure that better treatments will actually emerge and be licensed – last year a promising treatment was discontinued by Bristol-Myers Squibb after serious safety issues emerged. If clinicians’ opinions differ about the right approach, it is even harder for patients to make the decision.

Among the risks of waiting are that patients seeking treatment will surge after new drugs get NICE approval, and swamp the clinics. The team at the Bristol Royal Infirmary anticipated just such a surge and deliberately geared up for the approval of protease inhibitors by incorporating a research nurse with experience of triple therapy into the team, using the increase in patient numbers to make a successful case for an additional nurse as well as engaging a psychiatrist, through existing relationships with the BRI psychiatry team, to attend clinics to identify issues and assist patients. Through effective forward planning, the team was able to increase patient numbers from 50 to 110 between June and September 2012.
Where treatment is offered is another dilemma. Units treating hepatitis C with triple therapy should treat at least 20 patients a year to be deemed an experienced centre, but accessing such centres may involve lengthy travel for some patients. Treatment of prisoners raises special issues, as Western General Hospital in Edinburgh has found. Prisoners from two local prisons who were being treated had to travel regularly to clinics, while remaining chained at all times. This was costly, inconvenient, and compromised patient confidentiality. The solution in this case was to establish clinics inside the prisons, supported by the prison service staff. The initiative has proved very successful, with more patients treated at a lower cost in circumstances that preserve their confidentiality. But such initiatives are patchy: “Up until now some units have been very proactive in going out to treat prisoners” one specialist said. “And others have not even looked at it. I’m just wondering if the Government is going to give us the funding to cover it.”

Looking five to ten years ahead, specialists consulted fear that costs will increase and come under great scrutiny from commissioners. “The support given to individual patients will be increasingly difficult to justify”, one said.

While the issues are complex, they cannot justify a situation where access to treatment remains so uneven and services so variable. If the action plan drafted a decade ago was at last to be fully implemented, it would be a start. The National Liver Strategy is long overdue. In March 2013, The Lancet reported that over the last 20 years the UK has declined from 6th to 11th in a league table of 18 comparable countries for years of life lost to cirrhosis. While alcohol consumption has played a part in this change, so has hepatitis C. Action is needed, and for those patients who could end up suffering or putting more pressure on the health service it cannot come soon enough.
Best practice case study appendix

Hard to reach patient groups: blood-bourne virus testing champions

Adherence to therapy

Delivering effective care for prisoners: establishing a prison-based hepatitis clinic

Accessing new treatment strategies: rapid uptake of triple therapy
Hard to reach patient groups: blood-bourne virus testing champions

Situation and challenge
The significant South Asian population of Reading, in which hepatitis C is prevalent compared with the wider population, and the extensive transport network in the region, has been associated with an observed increase in the transmission and diagnosis of the disease. This has been attributed to the high number of injections administered when South Asian people receive medical treatment abroad, often as a result of falling ill when visiting family.

Treatment services have found it a challenge to reach this patient population as they are often unaware of these groups, or the patients themselves are suspicious of health services or unaware they exist. In addition, there are significant cultural sensitivities and even stigmatism surrounding blood-borne virus (BBV) infections, particularly among women, preventing access to hepatitis C testing and treatment.

Furthermore, the diagnostic tool for hepatitis C has itself become a barrier to effective management. The existing service found that by the time a sample was sent to the laboratory and the results returned, patients were no longer accessible. The team was keen to move to an alternative and novel technique using an oral swab to determine if a patient is reactive or non-reactive to the hepatitis C virus. This test provides a result within 30 minutes and has a similar specificity and sensitivity to the standard blood-based test.

Implementing change
To address this unmet need, the objectives for the Royal Berkshire Hospital were:

- To gain access to test and treat hepatitis C among these specific high risk groups – particularly women in the South Asian population
- To increase the number of people screened for hepatitis C among high risk groups
- To establish a network of ‘BBV champions’ to work closely with niche patient populations to implement and drive forward the service over the long-term.

Following previous experience of working with culturally sensitive ethnic populations overseas, the clinical nurse specialist (CNS) felt that engaging with these patient groups outside of the traditional healthcare system could be effective in testing and treating hepatitis C. As a result, a team of dedicated BBV champions was created and trained extensively on the disease area and associated tests. A key feature of the new service was the substitution of traditional hepatitis C blood-based testing for a 30 minute oral swab. This innovation – yet to be widely adopted in the UK – offered a convenient and fast diagnostic tool helping to overcome the problems associated with delivering blood tests.

The CNS-led team undertook a pilot in substance misuse clinics. The programme was centrally managed, with six BBV champions working across different service providers. During the first year of the initiative clinical quality was vastly improved, as demonstrated through the significant 150% increase in the number of diagnostic tests undertaken. During this period the service detected two cases of acute hepatitis C infections (an infrequent event) and 32 patients were reactive to the hepatitis C virus (suggesting a potential hepatitis C diagnosis), 27 of whom are now either engaged with services, on treatment, or have completed their treatment course.

Following the successful pilot, the service was extended to reach the South Asian population. A former patient and two further women from the South Asian community were recruited as a new female-led, core BBV champions’ team, to form a wider community group. The CNS led a comprehensive training programme to empower and up-skill the team on the disease area, how to test using the oral swab and to communicate the test results in an effective and appropriate way. The service now has four dedicated BBV champions working with this population, regularly conducting testing from an outreach clinic set up in the community.

Due to the convenience of the hepatitis C oral swab test and its relative safety compared with standard blood-based testing, both patient safety and patient experience were significantly improved. Greater confidence in testing was observed in both groups as a result of the accessibility and convenience of the oral swab tests combined with the cultural dynamic of the team itself. This was also reproduced by the team testing the injecting drug user population since members of the team had close links to this patient population, having worked with them on similar outreach programmes in recent years.

The routine use of the oral swab technique to test for hepatitis C has allowed the team at the Royal Berkshire Hospital to revolutionise the service they provide to patients, particularly in those groups who do not routinely engage with health services and are difficult to reach, providing better care and effective management.

Key lessons
- The innovative service has addressed a clear unmet need in specific patient populations through overcoming challenges to reach these groups
- To ensure the success of this initiative, it was essential to have good working relationships with staff and managers in the substance misuse community, contacts in the South Asian community and service commissioners
- The change in diagnostic tool has not just delivered a faster and more efficient way of testing these groups but has also provided a saving in cost for the service as a whole
- A wider audience was reached through adapting information into local languages
- The creation of the BBV champion teams was critical to provide a key access route to these groups and ensure that the service is targeted and accessible for patients
- The success of the BBV champions has also provided a platform to educate patients on hepatitis C itself, as well as the risks of transmission, through creating experts within the group itself, particularly among the South Asian community
- As the service grew it was necessary to work with public health officials to ensure continuity long-term, as well as defining key roles and responsibilities to ensure effective project management.
Adherence to therapy

The situation and challenge

In 2006, the hepatitis service at St Mary's Hospital in London was staffed by a single clinical nurse specialist (CNS), following the departure of another member of nursing staff. As a result, this nurse was responsible for managing the entire 130 patients and therefore treatment initiation had to be responsibly phased to match the available support and assistance. When this situation was addressed, staff reviewed the service design and the need to expand the service team. The primary motivation for change was to increase the number of patients accessing treatment, while maintaining the high quality of care provided by the unit, showcased by the impressive levels of patient adherence and, by extension, the rate of patients achieving a sustained virological response (SVR).

During the review it was established that the first course of therapy offers patients the best chance of achieving SVR. If patients withdraw, it is necessary to restart the full course of treatment in spite of the negative first experience dramatically affecting the patient’s attitude to future courses. The review also established that if SVR is achieved on first course of treatment there will substantial financial savings by reducing the number of patients re-initiating treatment.

Implementing change

The objectives for the St Mary’s Hospital team were:

- To increase access for patients to high quality care and treatment for hepatitis C
- To continue to improve the number of hepatitis C patients achieving a SVR
- To create and deliver a strong clinical trials programme in hepatitis C.

Following the service redesign, the team has increased in size to comprise of four, supported by a senior nurse and a further three junior nurses in training, to ensure effective succession planning. This has allowed the team to significantly increase the number of hepatitis C patients on treatment.

The team feels that pre-treatment support is the most important part of the care pathway and therefore new patients are allocated a full hour for their first consultation. In this consultation, the CNS is honest and open in their discussions of treatment strategies and challenges, exploring all aspects of a patient’s background that may impact on adherence or their ability to tolerate or continue treatment.

It is critical to treatment success that the patient is engaged in starting treatment and understands the needs and benefits of early treatment and achieving SVR. On commencing treatment, the patient is allocated a CNS for the duration of treatment course and any dose reduction is resisted.

Treatment will not commence until the patient feels they are ready to begin therapy and are designated a CNS for the duration of treatment. The team resist any dose reduction as patients who understand the consequences of non-adherence are more willing to tolerate treatment side effects.

The patient-centred approach to hepatitis C management and related improvement in patient outcomes has established St Mary’s Hospital as a leading centre for hepatitis C treatment. The team has built up a large clinical trial programme and this experience allows close integration of trial protocol into their standard clinical practice. The growth in clinical trials participation means that St Mary’s Hospital is now the largest hepatitis C research centre in the UK.

Key lessons

- A focus on pre-treatment support ensures patients understand the need to treat and take responsibility for their course of treatment
- A tailored and personal approach to hepatitis C management increases quality of care and as a result, patients’ adherence rate improved. This success has seen 98% of patients adhere to their first course of treatment with approximately 65% of genotype 1 patients achieving SVR, rising to 79% for those who completed their full treatment course
- The expansion of this patient-centred approach has proved highly effective. In a recent review of 419 patient response cards, 99% of patients rated their care as excellent or good
- A larger team enables defined roles and responsibilities, ensuring an efficient and effective service
- Significant cost savings have been seen through high levels of adherence, with many patients requiring only one course of treatment
- The healthcare burden is reduced as a result of patients being well informed and empowered to take responsibility for their own care, encouraging high attendance at clinic and effective hepatitis C management
- Through this effective service expansion St Mary’s has attracted partnerships, building up a large clinical trial centre and attracting additional funding for its expansion to the largest hepatitis C research centre in the UK.
Confronting the silent epidemic: a critical review of hepatitis C management in the UK

The situation and challenge

Previously, the hepatitis C service at the Western General Hospital in Edinburgh, based at the Regional Infectious Diseases Unit (RIDU), organised one regular clinic per month in two local prisons, initially to test and assess prisoners. Prisoners were required to travel to RIDU to receive treatment for their hepatitis C. As a result of the transport and security arrangements involved with bringing prisoners to the clinic, the level of service the team was able to offer patients was significantly restricted and to a limited number of patients.

One of the key challenges was that patients needed to remain chained at all times, as well as being accompanied by two guards leading to a cost and personnel burden to the prison service and resulting in only one prisoner being able to attend each clinic. In addition, patient confidentiality was compromised – even following a concession to allow prisoners longer chains to the guards in an attempt to maintain privacy – and attendance at clinic was unsettling for both the prisoners themselves and the other clinic patients.

Implementing change

To improve the existing service, the objectives for the Western General Hospital team were:

- To increase the number of prisoners being tested and treated for hepatitis C, in line with NHS Lothian Hepatitis C Managed Clinical Network (MCN) targets
- To establish a hepatitis C service inside local prisons to help meet these targets.

The team at the Western General Hospital held an established relationship with a nurse at the local prison who historically would conduct hepatitis C testing, and later patient assessment, before referring prisoners to the hepatitis clinic at the RIDU for treatment. Following a proposal to the local MCN to improve and develop the hepatitis C service, two dedicated BBV liaison posts were established. Once these posts were filled, the team were able to provide in-reach clinics within the prisons, in order to provide fair and effective service to these patients.

Establishing a dedicated hepatitis clinic inside the prison has streamlined services, allowing the team to assess and treat more inmates with hepatitis C while they are incarcerated. It has also provided the service with a link to external hepatitis C services to ensure inmates are followed up and continue treatment once they are released from prison.

The patient experience has also vastly improved, as inmates are seen in an environment that is familiar to them without the additional security arrangements necessary when leaving the prison complex. This has restored their comfort and reassurance when discussing their hepatitis C status and management, provided them with the opportunity to be treated effectively and ensured their confidentiality.

Through delivering this bespoke service, there has been an observed increase in productivity for the hepatitis service within the prison population. It has also allowed financial savings for the prison itself due to the staff time and resources previously required to transport patients between the prison and the RIDU clinic.

Delivering effective care for prisoners: establishing a prison-based hepatitis clinic

Key lessons

- This innovative service provided the right care for patients, meeting a clear need for those who were otherwise receiving restricted treatment and lacking basic equalities in service for hepatitis C patients who are in the community
- Strong relationships with key stakeholders, in this case healthcare managers, prison staff and a local voluntary service is essential to the success of a clinic inside this environment to support the implementation and management of the services
- Previously, patient transfer or release from prison could interrupt treatment through lack of communication confirming transfer, resulting in patients being transferred without medication. This has been addressed and resulted in improved communication between HMP liaison nurses and improved knowledge of all involved in the service
- In addition to responsibility of those involved in the service, it is essential that the prisoners understand the need for effective treatment and take responsibility for ensuring this continues if their environment changes. A patient’s treatment and prison status are therefore both carefully considered when assessing patients for treatment
- Although initial outgoings may increase to set-up the service, there should be key savings on the logistical burden of an external clinic and the health economics per patient is certainly improved.
Accessing new treatment strategies: rapid uptake of triple therapy

Situation and challenge

Within hepatitis C management there are six types of hepatitis C virus which are managed. These are referred to as genotypes, with types one to three being the most common. Prior to June 2012, the hepatitis service at Bristol Royal Infirmary (BRI) was awaiting NICE approval of protease inhibitors to treat a large number of genotype 1 hepatitis C patients. A third of these patients (approximately 50) had progressed to liver cirrhosis and were the priority for triple therapy treatment, having failed standard of care at the time. In addition, a number of patients with no indication of liver fibrosis decided independently to wait until new treatments were approved. These groups of patients were therefore stalled (‘warehoused’) in their treatment pathway while the treatment awaited approval.

The BRI team was anticipating a surge in patient numbers upon NICE approval because of the high number of genotype 1 patients whose treatment was currently on hold. After approval, the team’s focus would be to manage the patients with advanced disease (eg liver cirrhosis) and those prone to complications.

To ensure that the service could adequately cater for the increased patient burden and maintain the quality of service, the team identified the need to improve the existing service design. The priority for service design was to ensure that genotype 1 patients who qualified for triple therapy (either as first line or following previous failed treatment attempts) could initiate treatment following NICE approval of this treatment course.

The primary motivation for change was to improve patient outcomes by providing a treatment option for genotype 1 virus of hepatitis C. The team was keen to begin quickly treating as many genotype 1 patients with protease inhibitors as possible following NICE approval, in particular those who had developed liver cirrhosis, but was also aware these patients would be most challenging to manage – underlining the need to be familiar with, and confident using, triple therapy in this complex cohort of patients.

In addition, due to the maternity leave of one of the clinical nurse specialists (CNS), the service required effective contingency planning to ensure that levels of patient care were maintained in this busy period. The service was also looking to build evidence for a business case for additional nursing resource in the future.

Implementing change

The objectives for the BRI team were to:

- Ensure rapid access to, and uptake of triple therapy following NICE approval of protease inhibitors
- Treat the genotype 1 hepatitis C patients effectively and efficiently for whom treatment had been delayed
- Ensure the team was effectively resourced during this busy period
- Build a strong business case to ensure adequate resourcing for the future.

Following NICE approval, the BRI team observed a rapid uptake of triple therapy for the genotype 1 patient population and therefore a swift increase in the quality of patient care, with patient numbers increased from 50 to 110 in September 2012.

As the service treated the most challenging cohort of patients first, it was essential that nursing staff were familiar with triple therapy. To this end, a research nurse with experience of using triple therapy was able to step into a clinical role to support the existing team. The data generated from this treatment course.

To ensure patients were receiving support on all aspects of their treatment, through existing relationships with the BRI psychiatry team a psychiatric nurse was able to attend the multidisciplinary meetings as a ‘link nurse’ to manage onward referrals to the community mental health team. These were particularly important to support patients on triple therapy, ensuring optimal treatment success through early identification of any issues.

Due to well-established relationships and forward planning with service commissioners and a NICE implementation lead prior to NICE approval, the service quickly adopted protease inhibitors as part of triple therapy for genotype 1 patients.

Key lessons

- Relationships with the wider healthcare team were critical to the success of the service redesign. Through strong partnerships the team was able to agree the urgent need for additional budget by the hospital pharmacy team therefore ensuring no delay for patient access to treatment following NICE approval
- Teamwork among the core service team was also pivotal to the success of this service redesign while under resourced, prior to the approval of funding for an additional CNS
- When operating in a fund-limited environment, the preparation of a business case and stakeholder engagement for access to treatment must begin well before NICE approval
- Effective allocation of clinical time is essential when preparing for the implementation/prescribing of new treatments. Ensuring as many genotype 2 and 3 patients were treated prior to NICE approval enabled staff to prioritise genotype 1 patients, facilitating rapid access to therapy.
This illuminating report on hepatitis C in the UK and the public health response to prevent both infection and related disease paints a mixed picture. In the context of the availability of ever-improving cost-effective therapies, with more in the pipeline, it is disappointing that only a minority of chronically infected people have been diagnosed and only a minority of those diagnosed have been treated. It would be delusional to deny that, from a case-finding and therapeutic perspective, much more should have been achieved, particularly in the last decade.

It would also be wrong to not acknowledge the considerable challenges that hepatitis C infection poses. One of its principal properties – stealth – means that it can smoulder away for decades doing serious but invisible damage. And arguably hepatitis C, because of the dominance of its association with injecting drug use, has a stronger relationship with deprivation than almost any other condition observed in the UK. Identifying, and then supporting through the clinical pathway, infected people whose lifestyles are often chaotic because of drug and alcohol addictions – and the economic disadvantage and poor health associated with these – is by no means straightforward.

The struggle for infected people to complete their journey along the path means that patient demand for therapy is dwarfed by unmet patient need for it. And so the delivery of hepatitis C clinical services to this population has to be viewed through the prism of such deprivation and inequality, and acknowledging the potent combination of insidious agent and vulnerable, hard to reach, target is critical if progress is to be made.

It is precisely because of the intensity of this challenge, clouded in the socio-economic atmosphere of inequality that we should be doing so much more. Now is a great time to raise our game! For the majority of those infected, irreversible damage has not yet been done. Our understanding of the extent and characteristics of the problem is better than ever. The trajectory of HCV therapeutic advancement is stunning. Evidence, indicating that the health of treated people who clear their virus improves immediately and dramatically, is incontrovertible. Islands of outstanding clinical and public health practice in the UK demonstrate that, with adequate resources, imaginative thinking, robust leadership and major input from the third sector (such as the UK Hepatitis C Trust), the seemingly tortuous patient journey for those with lifestyle issues can be completed very successfully. Further, ground-breaking statistical modelling work suggests that treatment is likely to have a population, as well as an individual, effect if given to infected individuals who inject drugs and thus have the potential to transmit infection to others.

So in recent years, the seemingly insurmountable challenge has evolved into a terrific opportunity – one which, if grasped, will transform the hepatitis C landscape. Maintaining the current level of response is not an option if we are to interrupt the UK’s relentless escalation in serious disease and death caused by hepatitis C. Action Plans without muscle have suboptimal impact. There is no time to lose.

Professor David Goldberg of Hepatitis Scotland
References:


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