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All Party Parliamentary Hepatology Group

Inquiry into progress in improving outcomes in liver disease

Call for written evidence, Tuesday 16th July 2013

Background to the inquiry: Annual deaths from liver disease have almost doubled since 1993 and liver disease is predicted to become England's biggest killer within a generation.

The All Party Parliamentary Hepatology Group (APPHG) is extremely concerned about the rise in rates of liver disease in England. The APPHG is committed to supporting NHS services to improve liver disease outcomes, and reversing England's poor record in tackling the disease.

Liver disease is mainly caused by alcohol, obesity and viral hepatitis; all of which are preventable. Despite this, it has been consistently under-prioritised and is the only major killer lacking a national strategy. There have been successive governmental commitments to publish a national liver strategy since 2009 but the promised strategy still has not been published.

The implementation of the Health and Social Care Act 2012 is a turning point for the NHS. With the correct action, it can also be a turning point for liver disease. The APPHG has therefore decided to launch an inquiry into how we can best ensure a strategic approach to tackling liver disease in England within the new health structures.

We would like to hear from people who have responsibility for commissioning or providing liver or related services to make sure that we have a comprehensive picture of the challenges and opportunities that exist, and how we can secure the required improvements in outcomes for liver patients.

Questions for written evidence:

1. What is your assessment of progress in tackling liver disease since 2010?

Whilst there have been some positive developments in stemming the rise in liver disease, progress remains modest at best. Recent data from Public Health England show that both admissions and deaths from HCV-related end stage liver disease (ESLD) and hepatocellular carcinoma (HCC) are continuing to rise in the UK, with hospital admissions having risen from 612 in 1998 to 2268 in 2011, and deaths having increased from 98 in 1996 to 381 in 2011. This failure to diagnose and treat adequately has furthermore contributed to a rise in liver transplants due to post-hepatitis C cirrhosis, having risen from 45 in 1996 to 124 in 2012. NHS care services therefore seem to be spiralling in a downward trajectory. The Department of Health committed in 2009 to oversee the development of a liver strategy, but thus far no strategic approach has been forthcoming and the commitment has not been upheld. If this trajectory is to be reversed, the Government, NHS England and Public Health England need to hold true to this commitment and prioritise liver disease, not only to bring about an increase in testing and diagnosis, but also to ensure that those who are diagnosed receive immediate treatment to prevent further spread of HCV. Additionally NHS England must use its contractual relationship with providers to ensure that they are offering care according to best practice as described by NICE.
2. Looking at the reforms to health and social care, what are

   a. the biggest opportunities for tackling liver disease?

The NHS reform programme presents an opportunity to renew the focus on liver disease, due to its inclusion in Domain 1 of the NHS Outcomes Framework and Domain 4 of the Public Health Outcomes Framework, alongside other major killers such as cancer and cardiovascular disease. The real test of whether these frameworks have any traction will be the extent to which they influence provider contracts for service provision and change local protocols on diagnosis and treatment. Since the commissioning of hepatitis C services will now sit jointly with Clinical Commissioning Groups, local authorities (for the public health elements) and NHS England (for specialised types of hepatitis C treatment), there is an opportunity to re-invigorate the quality of services provided, scrutinise areas of the country where improvements can be made and ensure that the new structures work cohesively to improve outcomes.

   b. the biggest threats to tackling liver disease?

Given the scale of organisational change within the NHS since the enactment of the Health and Social Care Bill, there is still a degree of uncertainty about which bodies will be responsible for the commissioning of testing and treatment, and how quality will be scrutinised. For example, a recent audit by the Hepatitis C Trust of local authorities showed that only a fifth of councils who responded currently had a lead in place for hepatitis C, and even fewer had a strategy in place for tackling it. It also showed that many NHS commissioners had not been effectively monitoring the uptake of hepatitis C treatment, with only just over half holding data on numbers of patients initiated on treatment, and only a third knowing how many people have cleared the virus as a result. As the recent report from Public Health England notes, NICE recommended antiviral treatments that will successfully clear hepatitis C virus in most patients should be available, and that results from statistical models suggest that numbers of HCV-related ESLD/HCC cases can be substantially reduced each year by increasing treatment, with an estimated total of 5880 additional cases averted over the next 30 years if the numbers treated are doubled over the next 10 years. The achievement of this target will be contingent upon adherence to NICE guidance as a matter of urgency, using the Innovation, Health and Wealth scorecards, produced on a quarterly basis by the Health and Social Care Information Centre, as the basis for monitoring uptake.

3. What support do different organisations need in improving liver disease outcomes?

In order to guarantee that services for liver disease, blood borne viruses or hepatitis C are working effectively so that each part of the patient pathway is operating in an integrated fashion, local authorities and CCGs will need assist each other in the appointment of an appropriate individual to performace manage the quality of services. An essential part of this role will involve the gathering and scrutiny of information about the uptake of testing in community and acute settings. Local authorities and CCGs will therefore need to ensure that they also collaborate with providers regularly in assessing the number of patients on treatment and, within that group, the numbers achieving a sustained virological response. As the first healthcare professional with whom patients usually come into contact, GPs are also an underused resource in terms of increasing testing in appropriate patients. Wider roll-out of e-learning modules, such as the RCGP Certificate in the Detection, Diagnosis and Treatment of Hepatitis C (and B) in primary care, should be explored more thoroughly as a solution to raising national awareness of the crucial role that GPs can play in this regard.
4. What opportunities do you see for early diagnosis and/or prevention of liver disease?

To improve early diagnosis of liver disease, awareness-raising activity should also be targeted towards “at-risk” groups, such as those in prisons, to ensure that greater numbers of people within this demographic are tested and levels of undiagnosed infection are consequently reduced. As mentioned in the previous section, early diagnosis will also be enhanced if clinician awareness of hepatitis in primary care is raised through e-learning modules, such as the RCGP Certificate in the Detection, Diagnosis and Treatment of Hepatitis C (and B) in primary care. Numbers of newly infected patients are also likely to fall as the proportion of newly diagnosed patients receiving treatment increases. Reliable data on the number of patients treated for hepatitis C, including the use of recently recommended drugs, should therefore be collected by providers and be made available to commissioners for performance management purposes. These can be tracked on a quarterly basis through the aforementioned Innovation, Health and Wealth scorecards, published by the Health and Social Care Information Centre. As the recent report from Public Health England notes, proposals for more up-to-date prevalence studies, both overall and in migrants, should also be considered to improve national prevalence estimates and identify whether additional targeted awareness-raising campaigns are required.

5. How can we avoid unwarranted variation in liver disease outcomes across England?

It is likely that unwarranted variation in the diagnosis and treatment of liver disease will continue, given the fact that there is no national specification for services related to liver disease and the mixed commissioner landscape for hepatology services. In its absence, the best strategy for avoiding further extremes in the quality of care is to ensure that services are designed around patients’ needs, are based upon the principles of the NHS Constitution and adhere rigorously to NICE guidance and the quality standards developed for services related to liver disease. Additionally, as the NHS Atlas of Variation in Healthcare for People with liver Disease notes, the data available which can be used to make an assessment of variation tend to be disproportionately skewed towards the severe and late end of the spectrum of liver disease, with “upstream” data lacking on the number of people at risk or identified with early disease. More specifically, such areas of deficit within data collection include the number of people with established and/or different stages of cirrhosis; the number of people experiencing complications that require expensive resource or intervention; the numbers of people receiving various levels of interventions for alcohol-related problems and the associated outcomes; the numbers of people tested and treated, or not treated, for hepatitis B or hepatitis C, and the outcomes of treatment; the outcomes of interventions for people with fatty liver disease; and, activity data for treatment of patients in primary care and ambulatory care settings (e.g. outpatient clinics). In the absence of such data, it may be difficult to plan services and in the absence of any coherent national structure for data analysis of provider performance, understanding the outcomes of care will be a particular challenge. The Department of Health, NHS England and Public Health England should therefore seek to redress the imbalance in data collection within these areas if unwarranted variation is to be tackled in future.

6. Can you give examples of where a part of the pathway is working well in an area, or where it is not?

The HALO report, endorsed by Hepatitis C Trust, British Liver Trust and ELPA, provides an outline to the current practical barriers that exist around treatment and their relative importance in hepatitis care so that providers and commissioners are able to improve the quality and efficiency of their hepatitis pathway. The report focuses on sharing best practice across the UK and aims to capture real life case studies where innovative approaches have been used to deliver quality in the hepatitis C pathway using a step by step implementation approach. Each of the case studies are linked to NHS key drivers to enable change more rapidly and ensure
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buy in to change is achieved with all customer groups. The following case studies are included within HALO, and further details of three of them are included in Appendix A:

- Hard to reach patient groups: The blood Borne Virus Champions Programe
- Collaboration with third party organisations: Managing hepatitis in a community based setting
- Delivering effective care for prisoners: Establishing a prison-based hepatitis clinic
- Accessing new treatment strategies: Rapid uptake of triple therapy
- Increasing patient adherence to therapy: Placing the patient at the heart of decision-making
- Redesigning hepatitis services to improve efficiency: Tracking patient outcomes and patient-held records

For further information, or to request a copy of the HALO report, please contact Adrian Ward, Public Affairs Manager, Roche Products Ltd, +441707 366494, adrian.ward@roche.com
Appendix A – best practice examples: HALO case studies

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

Summary
Treating inmates outside of a prison setting severely restricted the service the hepatitis C team was able to provide in the Regional Infectious Disease Unit at the Western General Hospital, Edinburgh. The team was keen to increase the number of prisoners tested, assessed and treated for hepatitis C and therefore chose to establish a hepatitis C treatment clinic inside a local prison.

The service was subsequently extended to a second prison in the local area. The dedicated hepatitis clinic inside the prison has allowed the service significantly to improve the quality of patient care provided, increasing the number of inmates on treatment for hepatitis C and allowing the team to streamline their services and assess more prisoners. The programme has also resulted in an improvement in patient experience and patient safety as inmates are seen in an environment that is familiar to them and without the stress associated with the additional security arrangements necessary when leaving the prison complex.

Motivation to change
The primary motivation for change was to overcome the severe restrictions associated with managing prisoners at the RIDU clinic. Patients transported from the prison to the hepatitis clinic needed to remain chained at all times and be accompanied by two guards, allowing only one prisoner to be included in each clinic list and compromising patient-healthcare professional confidentiality, even following a concession to help maintain their privacy. Additionally, the attendance of prisoners at the RIDU clinic was unsettling for both the prisoners themselves and the other clinic patients. The objectives for the Western General Hospital team were therefore to:

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

Outcome
The team at the Western General Hospital established a relationship with a nurse at one of the local prisons who historically would conduct hepatitis C testing and initial patient assessment, before referring prisoners to the hepatitis clinic at the RIDU for treatment. Following a proposition to the local MCN to develop and improve the hepatitis C service, the team felt that a prison-based blood-borne virus clinical nurse specialist (BBV CNS) liaison would provide a beneficial “in-reach” hepatitis C service for inmates. The creation of a new post allowed this nurse to be employed to establish a dedicated, prison-based clinic.

The patient experience and patient safety have also seen a significant improvement as inmates are seen in an environment that is familiar to them without the additional security arrangements necessary when leaving the prison complex. Establishing a dedicated BBV CNS 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 NHS Lothian Hepatitis C MCN has also set a target for 10% of all patients treated for hepatitis C to be prisoners. The Western General Hospital team has exceeded this target for the past two years and have exceeded it again in 2012/2013.
2. **Accessing new treatment strategies: Rapid uptake of triple therapy**

**Summary**
Prior to June 2012, a large number of genotype 1 hepatitis C patients at the Bristol Royal Infirmary were reluctant to commence treatment prior to NICE approval of protease inhibitors. Around one third of these patients had progressed to liver cirrhosis and had previously failed to clear the virus with standard of care therapy, so would be a priority for treatment with triple therapy once protease inhibitors were approved. During this period the team encouraged any treatment-naive genotype 1 patients to undergo standard of care therapy, as well as genotype 2, 3 and 4 patients.

The service was keen to ensure rapid access to triple therapy once protease inhibitors were approved to ensure that the team was effectively resourced during this period and to build a business case for additional resource in the future. The team was able to substantially increase the number of patients on treatment, with a research nurse stepping into a clinical role to provide support. The data generated from the increase in the number of patients on treatment has also allowed the team to build a business case for additional nursing resource, and it was recently awarded resource for an additional specialist nurse for 18 months.

**Motivation to change**
The primary motivation for change was to improve patient outcomes by providing a treatment option for hepatitis C genotype 1 patients who had either opted to receive triple therapy as first line or for whom previous treatment attempts had failed. The team was keen to begin treating as many genotype 1 patients as quickly as possible with protease inhibitors 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. The objectives for the Bristol Royal Infirmary team were therefore to:
- ensure rapid access to, and uptake of triple therapy following NICE approval of protease inhibitors
- effectively and efficiently treat the genotype 1 hepatitis C patients 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

**Outcome**
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 the increase in the number of patients on treatment also allowed the team to build a business case for additional nursing resource and it was recently awarded resource for an additional specialist nurse for 18 months.

Due to well-established relationships and forward planning with service commissioners and the NICE Implementation Lead well before NICE approval, the service quickly adopted protease inhibitors as part of triple therapy for genotype 1 patients. Due to budgetary concerns, the hospital pharmacy team wanted to delay access to the new treatment for three months – the maximum timeframe for uptake of NICE approved medicines. The hepatitis team liaised effectively with the pharmacy team to overcome this obstacle, highlighting that the number of patients who required treatment would not decrease over this period and they were likely to progress further, possibly resulting in some patients requiring high-cost interventions such as liver transplantation. As the number of patients on treatment for hepatitis C has increased significantly, this initiative also supports both the 2012/2013 NHS outcomes framework reducing the mortality of under-75s from liver disease and the related public health outcomes framework target to reduce preventable mortality from liver disease between 2013 and 2016.
3. **Redesigning hepatitis services to improve efficiency: tracking patient outcomes and patient-held records**

**Summary**
In 2010, the hepatitis service at the Royal London Hospital had a considerable number of patients waiting for treatment. A drive to increase treatment rates resulted in a disorganised service where patient records were not well maintained, impacting on the ability of the service to track their activities and generate income from the local primary care trust.

The team was therefore tasked with reorganising the service to enable the department to work more efficiently and maximise the resources available. As a first step, a number of patient databases were established to track nursing activity and record patient outcomes. Following a successful pilot study, patient-held records were also introduced into the service, thereby allowing the then primary care trust to charge for some of the team’s activities.

The first step in the redesign of the hepatitis service was to introduce the hospital-wide Clinical Record Service (CRS) to the nursing team, so that all nurse-led clinical activity could be recorded and patient care documented at every visit. An additional patient database was set up to keep a record of patient outcomes on treatment as well as a separate database of all patients with hepatitis C maintained by an administrator and populated with information obtained from hepatology clinic letters.

**Motivation to change**
The use of these databases allowed the team to easily track a patient’s disease and treatment regimen, and has substantially improved the experience for patients as waiting times have been reduced and side effects can now be dealt with rapidly. By tracking patient outcomes, the team is also able to learn from previous experience and is more comfortable in handling the side effects of novel agents, such as protease inhibitors.

Following a successful pilot study, patient-held records booklets were also introduced into the service. These reduced the administration burden of follow-up correspondence with GPs. The use of patient-held records also avoided a delay in patient care, as patients no longer had to wait for follow-up letters. The record booklets also included supportive information on potential side effects and management of treatment. They were particularly useful when protease inhibitors were first introduced as the associated side effects were not familiar to all GPs. In addition, the service has established joint clinics with other departments within the Royal London Hospital such as the renal, haemophilia and haematology teams. The joint clinics have allowed patients with these comorbidities to access hepatitis C treatment more easily.

**Outcome**
As well as helping the service to run more smoothly, the introduction of the CRS and other databases allowed the primary care trust to charge for some of the team’s activities. It has also provided a documented record of the work conducted by the department that may aid them in future fund applications. The introduction of clinical trials into the service has generated a substantial financial income that has enabled the team to employ a full-time nurse. Establishing joint specialty clinics has improved productivity for staff by improving access to treatment for patients with comorbidities. The initiatives implemented by the hepatitis service at the Royal London Hospital also support the 18 weeks Public Service Agreement target (PSA 19), which states that patients should wait no more than 18 weeks from GP referral to the start of hospital treatment or other appropriate outcome.
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2 Department of Health, Department of Health to develop National Liver Strategy, October 2009

3 There are already national strategies for cancer and cardiovascular disease

4 Department of Health, Department of Health to develop National Liver Strategy, October 2009, Department of Health, Extent and causes of international variations in drug usage, July 2010