THE HEPATITIS C SCANDAL

A REPORT FROM THE ALL-PARTY PARLIAMENTARY GROUP ON HEPATOLOGY

"We are going to have to face the consequences of this disease and it is better to do it sooner rather than later. There are hundreds of thousands of people out there with Hepatitis C who at the moment are undiagnosed and are a risk to themselves because they are not getting treatment, and a risk to others because they could infect them. There is also a wider problem of the huge burden this is going to put on the NHS" ***Charles Gore, Director, Hepatitis C Trust*** *('Ms London', 16/2/04)*

"There is no doubt that a large number of those infected are dying through ignorance...Compare the profile and publicity given to HIV with that given to hepatitis C. There are ten times as many people at risk from Hepatitis C and, in most cases, the disease could be aborted by an effective health campaign. How many patients will have to die before we get some kind of action?" ***Dr. Graham Foster, Hepatitis C Specialist, St. Mary's Hospital,*** *"The Times", 25 June 2002*

"Whilst the costs of not treating are low initially, as the disease progresses many more people move to decompensated cirrhosis where the treatment costs, which may include liver transplantation, increase enormously". ***The Chief Medical Officer*** *2002*

"It is therefore essential that we intensify our efforts to prevent new cases and to diagnose and treat those who are already infected." ***The National Hepatitis C Strategy*** *2002*

"…the harsh reality is that HCV infection is a serious public health problem that the UK is not equipped to address. US projections suggest that by 2008...the number of patients requiring liver transplants because of HCV will increase by 528 per cent.…The costs of liver transplants alone would be £123 million in the UK based on these projections. So unless the Government begins planning for this increase now…our existing services will be overwhelmed and many more people will progress to end stage liver disease and die." ***The British Liver Trust*** *2002*

"Five years ago I worked as the senior medical officer to a prison in the North of England…I would have estimated that 70% of the prison population proved positive for Hepatitis C...The crisis is no longer in waiting. It is here now, fermented in prisons and released in a continuous stream into the general population". ***Dr S. Hopkins,*** *"Daily Telegraph", 24th August 2004*

"Hepatitis C infection in the injecting drug using population is one of a number of public health concerns that demands a substantial harm reduction programme. Prisons need to consider routine screening for Hepatitis B and C". ***All Party Drugs Misuse Committee*** *1998*

"We need £750,000-worth of drugs a year but the PCT have only advanced us £198,000 - less than a third of what we need. So we will not be able to follow national Government guidelines because of a lack of money. The funding doesn't address staffing requirements - we have to pay for a specialist nurse out of charity funds and we need an additional consultant, but the money just isn't there. This under-funding is short-sighted as we are storing up trouble for the future." ***Dr. Adrian Hamlyn, Senior Consultant, Russells Hall Hospital.*** *April 2004*

RECOMMENDATIONS

- An over-riding requirement is for Government to demonstrate **greater urgency** in dealing with this coming "tidal wave" of disease: a thin and inadequate Action Plan without targets and over two years late gives no grounds for confidence, nor does a low-key awareness campaign.
- A **proactive screening programme** is needed especially amongst at risk groups; targets should be set for this screening, as in France. If targets are not set none are achieved. Target groups should include women who have had a C-section at birth and people who have received blood transfusions.
- The disjuncture between NICE guidance and its implementation and funding should be closely scrutinised; **lack of funds should never be an excuse** to deny or delay treatment for Hepatitis C.
- **Compare and contrast studies** should be undertaken of national strategies and their implementation in Canada, the US, France and Australia; achievement in the UK should be benchmarked against them.
- The English **database on Hepatitis C should be improved** to at least the level pertaining in Scotland so that we are better able accurately to measure the size of the disease burden and project it forward for the future.
- Those patients with **mild disease should be more carefully monitored and tracked:** cost-effective treatment may become available for them; and, treatment should be applied speedily as soon as their disease is detected as progressing.
- **All prisoners should be screened on entry to and exit from prison** on a mandatory basis; the application of treatment programmes should be standard throughout the prison service.
- Greater emphasis should be placed in official policy on **harm minimisation through maintenance therapy** rather than by encouraging the use of cleaner needles in prison.
- We strongly recommend that policy-makers include France **in a comparative study of outcomes of maintenance treatment** within and without prisons with particular attention to the buprenorphine policy adopted there.
- **Hepatology should be given a higher priority in the NHS,** given not only its current challenges but also the coming "tidal wave": more relevant specialist consultants and nurses are required: waiting lists for liver treatment should be shortened and monitored closely.
- **DGHs should develop local expertise** to enable them to provide a local service for uncomplicated Hepatitis C cases: this would create more time within the specialist centres to treat the complex clinical cases.
- Repeatedly, the evidence emphasises the need for **timely investment now** rather than turning half a blind eye to the problem; however, in practice Government action has been slow, low-key and under-resourced. We hope that short-term Treasury considerations are not preventing medium to longer-term NHS savings and a quality of public health that we all have the right to expect in the 21st Century.
- **The awareness campaign directed at the general public and target groups is far too low-key.** People should understand the benefits of knowing their Hepatitis C status: for themselves, they need to know that early modification of lifestyle, and monitoring with a view to timely treatment could help the course of the disease; and, they need to take precautions to protect others if they are Hepatitis C+. In the case of this disease, and especially when no symptoms are experienced, ignorance is quite the reverse of being blessed.

THE GROUP

The All-Party Parliamentary Group on Hepatology was launched at the House of Commons in July 2003. The Goup works with medical professionals, voluntary organisations, Government Departments, and suppliers of products used in the treatment of liver problems. It campaigns for action to reduce the mortality and morbidity caused by liver diseases. This report deals with a specific liver disease which in 1998 former US Surgeon General C. Everett Koop described as threatening a "tidal wave". The Officers of the Group are: Chair, David Amess; Vice-Chair, Jane Griffiths; Vice-Chair, Bob Laxton; Secretary, Bob Spink; Treasurer, Anthony Steen.

Acknowledgements:

The Group would like to thank Dr. Matthew Cramp and Charles Gore, who acted as unpaid advisers to the Group for the purposes of this Report. Also, all of the many Parliamentarians who have acted to press Government for a better response to this challenge. The Group would also like to thank all of those who kindly gave evidence, and Schering-Plough UK and Roche Pharmaceuticals who provided administrative support. The Group also receives support from Gilead Sciences.

This Report

This Report describes first the actions and planning undertaken by Government and the NHS to fight this disease; second, we consider evidence from published sources and our own researches which demonstrate the deficiencies in the current official approach; third, we record some of the Parliamentary coverage of the challenge presented by the disease, finally, we distil a number of recommendations which should assist a more effective and comprehensive response to this coming "tidal wave" of disease in the UK. The recommendations are printed at the front of this Report.

Witnesses

The Group would like to express their thanks to all the witnesses who gave up their time and, in particular, the patients who came to speak with us.

The witnesses made the same points over and over again: the Action Plan has no teeth because it has no targets or timetable; a national campaign of sustained publicity is urgently needed; GPs need to be educated; more hepatologists and more specialist nurses must be provided; adequate funds should be clearly allocated; the ethnic minority communities need to be brought in; counselling for patients is essential; the stigma attached to the disease should be lifted.

It is clear that there is a massive difference of opinion between the Department of Health and the specialists over the size of the epidemic. The Department says 200,000; the specialists all say up to 500,000. **If there is so much under-funding and lack of activity at the Department's estimate of 200,000, and if the specialists are right and the Department wrong, the prospects are bleak indeed.**

Statement of Future Intent

It became clear during the course of our investigation that the levels of service available were inadequate to cope well with even the current level of treatment offered to those 10-20% of sufferers who have been diagnosed. How the service could cope with the expected increased demand of either the near and medium-term future is not clear. **Government should review as a matter of urgency both current service provision and plan for the inevitable increased burdens.**

It is the intention of the Group to undertake a supplementary Inquiry into service provision. In the meantime, provisional recommendations supported by evidence given by expert clinicians and others follow:

1. **Further education of GPs is required as a matter of urgency.** In East London 30% of diabetics have abnormal liver tests, but only 1% are being referred. The witness wrote to the GPs in the region and found that only 20% of them had some knowledge of hepatitis C. And most of those were misinterpreting the results.
2. Without a timetable in the Action Plan, there is no pressure on the Primary Care Trusts to deliver. **Targets should be set for maximum waits and levels of diagnosis and treatment.** Also, one clinician told us he was sure his Chief Executive will simply sit on the Government's Strategy and Action Plan. **He can easily tick all the boxes on page 13 of the Action Plan and still actually do nothing. Unless the Action Plan has clear targets it won't happen.**
3. Ethnic minorities are extremely under-represented in terms of specialist attention. There is no mention in the Action Plan of Pakistanis, Bangladeshis etc. The prevalence of cirrhosis in Bangladeshi men over the age of 60 is 80%. It is possible that there are 70,000 Asians infected in England. **"It is *imperative* that a study be carried out to discover how many Asians in the UK are infected with hepatitis C."**

4. Every Primary Care Trust should have a **designated individual responsible** for liver treatment.
5. The Department should **take note** that clinicians who gave evidence took the view that this issue is "not a high priority" for DoH. The Action Plan is "a stalling document, in my opinion". Consultants have stopped "jumping up and down", are "becoming disenchanted" and "fed up with being ignored".
6. The lack of a **Centre of Excellence in the South-West** needs addressing.
7. Part of the problem is the way money is allocated. A liver transplant with complications could cost £200–300K. But because transplants are funded centrally, the cost does not come out of the PCT budget. **This financial disincentive on PCTs to treat should be addressed urgently.**
8. The Action Plan accepts, at least before 2002, that the **control of infectious diseases was seen as a "Cinderella service".** Hepatology itself is a sub-division of gastro-enterology. The Department should consider how that has affected service provision to date and how might that need to change with the inevitable growth in demand, either from proactive measures designed to save lives and money in the long run or from the inevitable expensive end-term treatments.

Background

Hepatitis C is a blood-borne disease, formally identified by doctors only in 1989. Its victims in the UK number **between 200,000 and 500,000 people** depending on which estimate you believe. 80-90% of those infected are undiagnosed and consequently unaware of the serious condition that is affecting them. Hepatitis C can be contracted through intravenous drug use, blood transfusions made with unscreened blood (in this country before 1991), tattoo needles, acupuncture, electrolysis, and body piercing. There are cases of people being infected through sharing shaving blades, or even a toothbrush.

People infected with Hepatitis C often have no initial symptoms - **only 25-35% show symptoms in the early stages.** The majority remain undetected. From 60-85% of infected people fail to clear the virus and progress to developing chronic disease. Symptoms may not appear for up to 30 years after infection. Warning signs are nausea, fatigue and jaundice. **Severe liver disease will affect 20-50% of people infected.** Without a liver transplant many of them will die. A further 8-40% will develop liver cancer.

There is currently no vaccine against Hepatitis C, so prevention of new infections is particularly important. Treatment is by the drugs interferon and ribavirin used in a combination therapy. **About 60% of people with the disease can be cured, as long as an early diagnosis is made.**

The Health Protection Agency's report "Shooting up - Infections among injecting drug users in the U.K. 2002: An update: December 2003" showed the strong link between drug misuse and Hepatitis C: "Overall more than two in five injectors have been infected with Hepatitis C, and in Glasgow the estimated incidence of Hepatitis C infection among recent initiates to injecting is approximately 30% per year. In England and Wales data indicate that Hepatitis C transmission among injectors has increased recently, and in 2002 one in seven of those who had started to inject since the beginning of 2000 had been infected."

"Hepatitis C infection will continue to place a growing demand on the NHS. By the end of 2002 there had been around 50,000 reported laboratory diagnoses of Hepatitis C in the United Kingdom, with the majority of these reports associated with injecting drug use. However, of those injectors with Hepatitis C almost three-fifths still remain unaware of their infection."

The National Institute for Clinical Excellence (NICE) position

In October 2000, NICE produced guidance on the use of Ribavirin and Interferon Alpha for Hepatitis C, recommending combination therapy of interferon alpha by injection and ribavirin in capsule form for the treatment of moderate to severe Hepatitis C. HMG claims to have "provided additional funds to the NHS to meet the costs…"

NICE judged the combination treatment **both clinically effective and cost-effective,** comparing 6 month of combination therapy with 12 months of monotherapy showing a cost per discounted QALY of £2,500 overall. Six months of combination therapy costs about £4800.

Para. 5.1 of the Guidance states, "If the prevalence of chronic hepatitis is 0.4%, if a quarter of these are diagnosed, if half of those diagnosed are under specialist care, if half of these have had a biopsy, and if half of those biopsied are treated, then there will be about 7000 patients in England and Wales treated in the first instance." The cost of drugs for this group would be about £18m per year. The annual continuing cost of drugs…would be about £5m. Para 5.1 concludes, "However, it is most likely that rates of diagnosis, referral to specialists, biopsy and acceptance of the therapy will all increase, so this estimate of annual costs after three years is likely to be an underestimate".

Comment: *The Group regards these aspirations as dangerously conservative resting as they do on diagnosing only 25% of those with chronic disease, and explicitly assuming that diagnosis and costs will rise in the longer term. As Everett Koop, pointed out six years ago: "We can treat the disease during this quiescent period and we can eliminate the infection for a large portion of the infected preventing progression to serious disease" (Evidence to Congress, March 1998). The British Liver Trust and the Royal College of Physicians stress the need for identification and treatment now rather than deferral of the problem.* ***The Chief Medical Officer (CMO) later wrote in "Getting Ahead of the Curve" (2002): "Whilst the costs of not treating are low initially, as the disease progresses many more people move to decompensated cirrhosis where the treatment costs, which may include liver transplantation, increase enormously".***

In January 2002, Government placed a legal obligation on the NHS to provide funding for treatments and drugs recommended by NICE. In January 2004, NICE issued further guidance on the use of combination therapy of the longer-acting pegylated interferon alpha and ribavirin for the treatment of chronic Hepatitis C: **"Combination therapy…should be used to treat people aged 18 years or older who have moderate to severe chronic Hepatitis C**…"

NICE found that with an estimated incremental cost per QALY of £4,000-£11,000 over ordinary alpha interferon combination therapy, pegylated interferon was both clinically- and cost-effective even after explicitly ignoring **"the additional potential treatment offsets down the line"**. NICE implicitly admits that numbers in treatment are disappointingly low: **"Currently, only about 2,000 people in England and Wales are being treated for HCV infection with some form of interferon or peginterferon".**

Comment: Concern remains that funds for the whole process of treating Hepatitis C, both drugs and care, were still not readily available. Pressed within Parliament on Hepatitis C (and cancer and rheumatoid arthritis) treatment, Government was stung into action on the effective implementation of NICE's recommendations generally.

In June 2004, Health Secretary John Reid set out plans to ensure patients across the country have equal access to treatments recommended by NICE and promised to work with the Healthcare Commission to examine how they can address this issue when assessing each hospital trust. A letter from Health Minister, Lord Warner, to key stakeholders set out the Department's plans to ensure better implementation of NICE recommendations across the NHS including steps to improve data concerning prescribing patterns and an obligation upon NICE to provide advice on all the major costs of its guidance and on the best ways of ensuring full implementation.

The National Hepatitis C Strategy

August 2002: The Foreword to Department of Health's "National Hepatitis C Strategy" (HCSE) reads: "Hepatitis C has emerged over recent years as a world-wide public health problem…Although there is a relatively low prevalence of infection in this country, Hepatitis C **represents a major challenge in absolute numbers of people infected,** the majority of whom are undiagnosed… current injecting drug users remain at greatest risk of infection in this country and intensified health promotion activities are necessary...With increasingly effective antiviral drug therapy available, professional and public awareness of Hepatitis C needs to be improved. This will enable those who may have been at risk of infection to come forward for testing, so that if they are found to be infected they can be referred for specialist assessment…
"This strategy…sets out proposals to improve the effectiveness of prevention, diagnosis and treatment services for Hepatitis C…"

"The main proposals in the strategy are that:

- **public awareness** of Hepatitis C will be raised by general and targeted health promotion campaigns about avoiding Hepatitis C infection and seeking testing, where appropriate
- **professional awareness** of Hepatitis C will be developed by further conferences, information and guidance
- **efforts to prevent new cases** of Hepatitis C infection will be intensified, particularly in relation to injecting drug users, with the continuation and improvement of harm reduction services, including needle exchange
- **diagnosis** of people at current or past risk of infection should be increased by raising awareness of Hepatitis C and promoting testing for those at risk of infection in a range of clinical settings
- **managed clinical networks** should be developed to provide accessible specialist assessment and treatment, where necessary, to people who have hepatitis C infection
- the evidence base will be improved through epidemiological surveillance and research so that, for example, trends in Hepatitis C infection in the population and the effectiveness of prevention measures can be monitored more closely and the future disease burden estimated."

"It is therefore essential that we intensify our efforts to prevent new cases and to diagnose and treat those who are already infected." The document continues: "[as proposed in the CMO's infectious diseases strategy "Getting Ahead of the Curve}…**This action plan will be drawn up by the end of 2002, following the consultation exercise."**

Comment: The Action Plan was not published until June 2004.

The Hepatitis C Action Plan for England

On 29th June 04 the long delayed Hepatitis C Action Plan for England (The Action Plan) was published. The Action Plan paints a gloomy picure: before 2002 the control of infectious diseases was often seen as a **"Cinderella service"**. Para. 1.10 admits that despite all actions taken to date, **"There is still a need for intensified action to prevent new infections".** Para. 2.8: "A recent study suggests that the rate of new Hepatitis C infections among injecting drug users in London and the South East is increasing" In Chapter 4, entitled "The Future", the **eight line content** confines itself to predicting that: **"In the short term (five to ten years) illness and death due to Hepatitis C are likely to increase".**

Chapter 3 is entitled "International Outlook: How do we Compare?": it quotes Canada which has a similar size of problem quantitatively (240,000 people currently infected) to low-end UK estimates as making forward projections of cases of serious liver disease. The Action Plan does not make similar projections for the UK. This chapter, running to less than a page, **does not make comparisons with treatment rates abroad** e.g. in France which are far higher than the UK, nor with any other country. It mentions that the US, Australia and France have developed national strategies to prevent new infections and control disease progression but makes **no attempt to contrast and compare.**

Some of the "new" actions merely repeat the aspirations of two years before, for example:

1. **The Action Plan 2004:** New Actions p11 "Modelling techniques will be developed to assist in projecting the future numbers of patients needing specialist treatment and care for Hepatitis C to inform planning of health services".

HCSE 2002, Chapter 2 – para. 19 "Estimation of the numbers of new infections and burden of Hepatitis C disease can be facilitated by the use of mathematical modelling. Using existing data sources on Hepatitis C transmission, patterns of injecting drug use and rates of progression to liver disease, it may be possible to make preliminary estimates of the current and future disease burden"

2. **The Action Plan 2004,** p14 "The Department…will develop health promotion information explaining the risks of injecting drugs and how to avoid Hepatitis C and other blood-borne viruses to give to all young people entering juvenile and young offenders' establishments and to other offenders".

HCSE 2002 Chapter 3: para. 36 "The integrated counselling, assessment, referral, advice and throughcare service (CARATs) is available in all establishments. This service provides information about the risks of drug use, especially injecting, and the risk of infection with blood-borne viruses including Hepatitis C. CARATs also provides advice on harm minimisation and advice if drug use will continue on return to the community.

Comment: So two years later we are still being promised the development of modelling techniques and are also promised information for prisoners said to be available in 2002 through the counselling service

Chapter 5 entitled, "The Actions", does not represent much advance over the position as outlined in HCSE: there is still no proactive outreach proposed, and no national screening programme nor even targets set to cover target groups. Such publicity as there is to be will be low key and targeted at specific narrow groups – "The Department of Health will work with other stakeholders…to launch a sustained public-awareness campaign on Hepatitis C that is non-alarmist and non-stigmatising, specifically targeting affected groups".

The Action Plan states that for prisoners: "A window of opportunity exists while they are in prison to take preventive action and to improve their access to health care services" (para. 2.15). In "Action 4 Prevention" (p14) the main thrust of the NTA, Drug Action Teams and the Prison Service appears to be harm reduction programmes concentrating on facilitating cleaner needle usage – provision of needles and syringes, safe disposal of same, provision of disinfecting tablets throughout the prison estate. The potential for harm minimisation through maintenance treatment for injecting drug users is not examined (see "Prisons and Hepatitis C" below).

The Action Plan emphasises the high cost of treatment rather than the "very cost effective" verdict of NICE on the pegylated version of combination treatment: "The consequences of hepatitis C infection are extremely serious. The impact on society is also significant. High costs of drug treatments (up to about £12,000 per patient), other medical interventions and liver transplants represent a substantial burden on the NHS." (para 2.13).

Comment: The Group hopes that this is not indicative of a short-term approach to economy with expenditure. The Group believes that the UK is behind the wave; we are reaching at best 5% of the target group that would benefit. In 2002, the UK treated around 2,000 patients per year. France, Germany and Italy treat between 10,000 and 23,000 HCV positive patients each, per year.

June 2004: The CMO sent out a "Hepatitis C: Health Care Professional Information Pack" as part of the launch of the Department's Hepatitis C Action Plan for England: "The pack marks the first step (our emphasis) in our Hepatitis C professional awareness campaign."

December 2004: The CMO announced the launch of a public Hepatitis C awareness campaign with a budget of £2m spread over 2 years. This amount is a reduction of almost 10% from the provisional figures supplied by Miss Johnson in a response to a Written Question to Mr. Simon Burns on 14 October 2004.

Comment: It is arguable that the Hepatitis C "timebomb" represents more of a health hazard than TB in the UK. Despite this, the actions proposed to tackle TB in "Stopping Tuberculosis in England" (DoH, Oct 2004) are more specific, the language more determined, adequate resources promised and active outreach and screening (including the use of mobile vans) is proposed, especially to high risk groups. With Hepatitis C, four fifths of those infected remain undetected and untreated, no screening is proposed of high risk groups, and discussion of resources is virtually absent.

2. Voluntary Agencies and other organisations

Voluntary agencies including The Hepatitis C Trust, the UK Assembly on Hepatitis C, the Haemophilia Society, the British Liver Trust, the Eddystone Trust, and the UK Hepatitis C Resource Centre collaborate

to raise awareness of Hepatitis C. UK Hepatitis C Awareness Day was held on 1st July 2004 at the House of Commons, under the auspices of the Group.

The British Liver Trust estimated in 2002 that Hepatitis C could kill more than 60,000 people and that approximately 400,000 people in the U.K are infected (note the significantly higher figure it uses compared with Government). The Trust called for urgent action to identify those infected.

Nigel Hughes, then Chief Executive of the Trust, said that **Britain was, "Woefully unprepared for an epidemic of liver viruses.** I don't feel that this is being taken seriously by the present Government". He pointed out that while 15,000 Germans, 22,000 Italians and 18,000 French received treatment for the disease in 2001, in this country only 1300 people were treated that year.

The Trust produced a report, "Hepatitis C the Public Stealth Disease" (2002). Extracts from the Executive Summary follow: **"Sixty thousand people in the UK will progress towards serious liver disease this year, approximately 460 will have a liver transplant and at least 1600 will die from liver cirrhosis as a consequence of Hepatitis C** (HCV) infection, an infection that we have the ability to identify and treat. However, much of the infection remains hidden, either undiagnosed or in disenfranchised social groups, with up to 400,000 people with HCV infection remaining undiagnosed. This will remain the case with tragic consequences unless urgent action is taken by the Government to remedy deficiencies in the ability of the NHS to respond to the HCV epidemic…".

"This may sound alarmist but the harsh reality is that HCV infection is a serious public health problem that the UK is not equipped to address. US projections suggest that by 2008, for example, the number of **patients requiring liver transplants because of HCV will increase by 528%.** The number of cases of hepatocellular carcinoma and cirrhosis will also increase and it is unlikely that the UK will be far behind. The costs of liver transplants alone would be £123 million in the UK based on these projections. So unless the Government begins planning for this increase now by commissioning services and increasing funding, our existing services will be overwhelmed and many more people will progress to end stage liver disease and die.

The Hepatitis C Trust: Charles Gore, Director of the Trust, said: "We are going to have to face the consequences of this disease and it is better to do it sooner rather than later. There are hundreds of thousands of people out there with Hepatitis C who at the moment are undiagnosed and are a risk to themselves because they are not getting treatment, and a risk to others because they could infect them. There is also a wider problem of the huge burden this is going to put on the NHS" ('Ms London', 16 Feb. 2004).

The Royal College of Physicians of Edinburgh produced a Statement following a Consensus Conference on Hepatitis C (April 2004). We quote their key messages with their permission:

- The Hepatitis C epidemic is a public health crisis.
- Services are already struggling to cope with the burden of infection and liver disease.
- Significant resources must urgently be directed at improving prevention and delivery of care.
- High priority for case finding should be given to former injecting drug users.
- Community-based and specialist nurse-led services should be provided.
- The requirement for liver biopsy to determine selection of patients for therapy is no longer essential for all patients.
- Access for treatment should be broadened to all those who might benefit.

Prisons and Hepatitis C

"Five years ago I worked as the senior medical officer to a prison in the North of England. This was at the time of the introduction of mandatory drugs testing...Drugs were readily available within the prison, but needles were not. This led to a sharing of dirty equipment with concomitant risk of infection. I would have estimated that 70% of the prison population proved positive for Hepatitis C...The crisis is no longer in waiting. It is here now, fermented in prisons and released in a continuous stream, into the general population".
Dr S. Hopkins, "Daily Telegraph", 24th August 2004

The Group did not take evidence within prisons but is extremely concerned by the argument advanced by Dr Hopkins, amongst others. The drug problem within prisons is serious. 90% of those entering UK prisons have a mental health or substance misuse problem (DoH website), and 48% of sentenced males and 34% of sentenced females used drugs during their prison sentences. 1 in 5 male prisoners using drugs did so for the first time when in prison. Heroin was most frequently mentioned as having first been used in prison, with 25% of users sampled stating they had first used it in prison.

The UK prison population is a significant, largely untreated reservoir of infection of the disease. Currently, most prisoners remain unscreened for the disease, and quite a large number of those infected will go on to develop an unpleasant, often fatal, disease which is largely avoidable. As this group ages, more and more will develop florid disease and will be a heavy – but potentially avoidable burden - on the NHS.

The **All Party Drugs Misuse Committee** reported: "The very high level of Hepatitis C infection in the injecting drug using population is one of a number of public health concerns that demands a substantial harm reduction programme. Prisons need to consider routine screening for Hepatitis B and C". That was six years ago (1998). HCSE 2002 recommends that prisoners should "have access" to clinical investigation and NHS care for Hepatitis C, and that information on Hepatitis C and harm minimisation should be given especially to young people entering juvenile and young offenders' establishments. **It does not propose compulsory screening of prisoners for Hepatitis C.**

HCSE accepted that "Evidence for the effectiveness of oral methadone (and more recently buprenorphine) treatment and maintenance programmes in reducing the risk of Hepatitis C infection is well documented and is based on the success of such treatments in reducing injecting and sharing behaviour." The CMO found an unsatisfactory position in prisons: "Clinical management of opiate misusers aims to provide effective evidence-based management. The provision of oral methadone therapy is proven to reduce the amount of injecting and risk behaviour. However, there is currently a lack of uniformity in its provision in prisons and this may lead to increased illicit drug use"

If intravenous drug abuse can be tackled more effectively in prisons by maintenance therapy, then the risk of re-infection with Hepatitis C is consequently reduced. This means that investment in treatment of the disease in prison can proceed with less fear of re-infection undermining that investment.

Schering-Plough Ltd, manufacturers of Subutex (buprenorphine), told us of developments in maintenance therapy in France where methadone is to a large extent replaced by buprenorphine, often prescribed by GPs. The evidence is of improved social outcomes and reductions in risk related behaviour, such as injecting and needle/syringe sharing. The NAO has reported on the rather disappointing comparative outcomes for maintenance treatment with methadone in countries under study ("Review of criminal justice outcomes for drug users in other countries - December 2002"). Unfortunately, the NAO did not include France in their study, where we believe the outcomes may prove better.

Comment: We strongly recommend that policy-makers do include France in any future comparative study of outcomes of maintenance treatment.

Comparison with Scotland

The debate in the Scottish Parliament on 30th June 2004 underlined the relatively advanced thinking and practice on Hepatitis C in Scotland as compared with England:

Diagnosis: In the debate, 18,109 Hepatitis C+ patients were said to have been identified in Scotland, out of an estimated 45,000 infected in all. On the basis of these figures **Scotland has identified 40% of the total.** The Action Plan for England (July 2004) quotes figures of 38,000 diagnosed in England out of an estimated 200,000 chronically infected (19%). Even if these sets of figures are not strictly comparable Scotland appears twice as successful as England in identifying its Hepatitis C disease burden.

Recognition of Need to Invest: The Royal College of Physicians Consensus Statement in Edinburgh 2004

read: **"What is certain is that, if we do not invest adequately now, we will not be able to afford the consequences of failing to tackle this epidemic."** The Action Plan for England had no discussion about making resources available for Hepatitis C but complained about the "High costs of drug treatments" (p8) without any countervailing reference to the "very cost-effective" finding by NICE (see above).

Recognition of Need for Active Screening: Malcolm Chisholm, Minister for Health and Community Care spoke in the debate: "We entirely agree that former drug users must be a targeted group and a focus for screening and wider attention....**The issue of screening will be dealt with and the plan should be ready later in the year."** The Action Plan for England has no mention of screening other than for blood products: there is an apparent lack of commitment to screening groups of people, let alone high risk groups.

Scottish Data Collection Ahead of England? Malcolm Chisholm: "On the treatment side, we are funding the establishment of a national clinical database of patients who have been diagnosed with Hepatitis C, with the aim of identifying treatments that patients have received and evaluating how effective those have been against the disease as it affects them...." The Action Plan for England does not seem to plan anything equivalent.

Malcolm Chisholm: "In addition, SCIEH [Scottish Centre for Infection and Environmental Health] is undertaking work to estimate the future burden, including cost, of Hepatitis C during the next two decades. Preliminary results from that work should be available shortly". The Action Plan for England: far from results being available shortly, the Plan promises a "new action" in the future tense: "Modelling techniques will be developed to assist in projecting the future numbers of patients needing specialist treatment and care for hepatitis C to inform planning of health services".

SCIEH's detailed weekly report of diagnoses of Hepatitis C in Scotland showing intravenous drug use, region, sex, age group is impressive. We are not aware of comparative figures for England. On these counts, there would seem to be considerable scope for England to improve its data collection and projection.

France and Treatment of Hepatitis C

Professor Marcellin of Paris claims that in the period 1999 to 2002 France spent 227m Euros (about £150m) treating Hepatitis C, with the result that by the end of 2002, 300,000 people with Hepatitis C had been identified (out of a estimated total of 600,000). France runs a large publicity campaign; they have 31 walk-in diagnosis centres where anyone can come to be screened. These centres are not directly linked to other local health providers e.g. GPs, so that those attending have some anonymity. 85% of the French at risk group population was the target for coverage by 2003 (UKHRA, 11th October 2000). **The Action Plan for England sets no such target.** The chapter in the Action Plan entitled "International Outlook" and running to less than a page makes only the briefest references to France. "Other countries", it says, "including the United States, Australia and France, have developed national strategies to this end" [preventing new infections and controlling disease progression] but **it avoids the opportunity to evaluate those plans and compare with the British situation.**

Evidence Taken or Collated by the APG

Visit to St. Mary's Hospital, Paddington, and the Institute of Hepatology (December 2003)
"There is no doubt that a large number of those infected are dying through ignorance. People including members of our health service are not aware of the risks...Compare the profile and publicity given to HIV with that given to hepatitis C. There are ten times as many people at risk from Hepatitis C and, in most cases, the disease could be aborted by an effective health campaign. How many patients will have to die before we get some kind of action?"
Dr. Graham Foster, Hepatitis C Specialist at St. Mary's Hospital, Paddington, "The Times", 25 June 2002

The APG met Professor Howard Thomas at the St Mary's Hospital Liver Centre. They also received a briefing from Professor Roger Williams, Director of the Institute of Hepatology. Professor Williams told

the APG: **"Hepatitis C is affecting about half a million people in the UK and alcoholic liver disease is increasing, especially among young people. But the good news is that results of treatment are increasingly effective".** He expressed concern that the underfunding for Hepatology was being aggravated by allowing asylum seekers to enter Britain without any medical screening. The NHS could save millions of pounds if there was an adequate multiple screening programme to identify a range of conditions which asylum seekers failed to disclose.

Visit by the APG to Manchester Royal Infirmary (MRI) (April 2004)

The APG met Professor Tom Warnes, former Consultant Physician at MRI, with a special interest in Hepatology. He has developed a liver service, including specialised out-patient clinics, with referrals from throughout the North West. The Liver Unit is recognised as a major national referral unit for the treatment of Hepatitis C.

He welcomed the second NICE report and recognised the extra funding being made available. There should be "no excuses" for further lack of action. They are now seeing reversal of cirrhosis with antiviral drugs. He was confident that the new resources would deliver substantial improvement, but he pointed out that **staff time was not additionally funded.**

He discussed the pros and cons of Major Treatment Centres as opposed to more localised services (such as District General Hospitals - DGHs). **When asked if Managed Clinical Networks are now practical, or whether they were simply more work for the GP he replied that the biggest single NHS problem was the lack of GPs.**

A Hepatology nurse described recent funding problems. They are required to apply for funding on a monthly basis but consents are often delayed: for example a patient waiting 9 months can be given the go-ahead at the same time as a patient waiting 3 months. **The main blockage in the system lay in the hospital trust.** Now, the limiting factor on delivery of treatment was not cash to buy the drugs, but the availability of clinic time, specialist nurse support, etc. These could not simply be provided "at will" so that all patients could be seen.

Visit by the APG to Russells Hall Hospital, Dudley (April 2004)

Dr. Adrian Hamlyn, Senior Consultant, needed £750,000-worth of drugs a year: "But, the PCT have only advanced us £198,000 - less than a third of what we need. **So we will not be able to follow national Government guidelines because of a lack of money.** The funding doesn't address staffing requirements - **we have to pay for a specialist nurse out of charity funds** and we need an additional consultant, but the money just isn't there. This under-funding is short-sighted as we are storing up trouble for the future. Failure to identify and treat those with Hepatitis C will result in thousands requiring expensive treatment for serious liver disease in the future". Chronic persistent Hepatitis leading to mild liver disease was not covered by NICE: this ignores progression and **sufferers are not monitored"**

Comment: Note the contrast with the NHS webpage on the Hepatitis C awareness campaign: "Given that many patients with chronic hepatitis C remain well and that treatment can have considerable side effects and will not always be effective, it has been usual for patients with mild liver disease not to be offered treatment. Such patients are kept under ongoing observation to monitor disease progression and initiate treatment, if required".

Dr. Hamlyn said the restricted **funds meant that he had to treat some patients with older interferon** (which in its turn has led to increased costs as failures need re-treating), and defer others to the next financial year. Sometimes he has had to lie or apologise to patients because modern treatments were not available. Only recently has he started to use pegylated interferon.

Management recently tried to set up a "NICE implementation committee", which would have required the submission of further information before treatment began. Several consultants revolted against this, and oncologists were especially angry. The feeling was that this might be a management control tactic designed to delay and limit expenditure, together with making further inroads into consultants' freedom to treat.

On the question of expert centres v. DGHs, Dr. Hamlyn pointed out that his patients would have to travel to Birmingham, a difficult journey not easily taken by public transport.

Visit by the APG to Derriford Hospital, Plymouth (June 2004)

The South-West has no specialist liver units despite the fact that more than 1,000 people died from liver-related problems in 2001 and 2002. Hepatitis C is a major problem here. Up to 10,000 people in Devon and Cornwall are infected with Hepatitis C, but the numbers that can be treated are limited by funding and a lack of trained nursing staff.

Dr. Matthew Cramp, Consultant Hepatologist at the hospital commented: "We want to raise awareness of the issues around liver disease in the South West, particularly with regard to transplantation and liver surgery, and to raise awareness of the scale of the Hepatitis C problem. 10 years ago only about 10% of patients with Hepatitis C were treatable, today the figure is 55%. He "does not have the capacity to see all who need to be seen". There are no major liver units in Wales and the South-West; both therefore have very low liver transplant rates. The nearest major liver units are in London and Birmingham.

An awareness campaign is needed. **However, a campaign which does not provide for increased testing and other diagnostic elements, together with counselling and treatment, will not help.**

Dr. Cramp sees everyone within 16 weeks to meet targets, but they are often not followed up soon enough. He has 800 patients awaiting follow up. A second Hepatologist is being employed in September 2004 which will be very helpful, but it is not enough.

"The career structure is unclear; until recently there has been no specialist training, and there are not enough specialist nurses" (Derriford Hospital now has one).

Evidence Session at the House of Commons 21 July 2004

Summary

The witnesses made the same points over and over again: the Action Plan has no teeth because it has no targets or timetable; a national campaign of sustained publicity is urgently needed; GPs need to be educated; more hepatologists and more specialist nurses must be provided; adequate funds should be clearly allocated; the ethnic minority communities need to be brought in; counselling for patients is essential; the stigma attached to the disease should be lifted.

Finally, it is clear that there is a massive difference of opinion between the Department of Health and the specialists over the size of the epidemic. The Department says 200,000; the specialists all say up to 500,000. If there is so much under-funding and lack of activity at the Department's level of 200,000, if the specialists are right and the Department wrong the prospects are bleak indeed.

3. Parliamentary Interest

We would like to thank the many Parliamentarians who have continued to press on this issue. Space does not allow a full review of all Parliamentary references in this Report.

Written Answers 20 May 2004

Mrs. Helen Clark: To ask the Secretary of State for Health what estimate he has made of the relative costs of a health policy of (a) applying treatment to Hepatitis C positive cohorts as they present to health services and (b) applying treatment to the Hepatitis C positive population actively identified by mass screening.

Ms Blears: We have not made such an assessment. Our consultation paper, 'Hepatitis C Strategy for England', recognises the need to improve diagnosis of Hepatitis C in those at risk of infection so that they are referred for specialist assessment and treatment in accordance with guidance from the National Institute

for Clinical Excellence. Mass population screening for Hepatitis C is not justified because of the relatively low prevalence of infection in this country, which is concentrated in groups at increased risk of infection, such as injecting drug users. Targeted screening of individuals at increased risk of infection is in line with international consensus statements from the World Health Organisation and the European Association for the Study of the Liver. We will be publishing an action plan to underpin implementation of the strategy in the next few months.

Comment: We are surprised that no assessment has been made of the cost-effectiveness of the two approaches. We suspect that (b) would be more expensive in the short run, but that (a) would be more expensive in the long run. Assessing the relative costs of the two approaches should not be too difficult.

Oral Answers 8th June 2004

Peter Luff: If she will make a statement on her policy on the treatment of Hepatitis C.

Miss Melanie Johnson: In recent years, increasingly effective treatments for chronic hepatitis C have become available. In January 2004, NICE recommended a combination of pegylated interferon and ribavirin for the treatment of patients with moderate to severe chronic Hepatitis C, which successfully clears the infection in around 55% of patients.

Mr. Luff: My own father died of Hepatitis C when I was eight years old-he probably contracted the disease in Palestine during the first world war-so the Minister will understand my personal grudge against the disease, and my concern for the 250,000 people in England alone who have the disease and do not know it. Why are the Government not showing more urgency in dealing with the looming Hepatitis C crisis? Why, for example, does the advisory group on Hepatitis website state this morning that the agenda and minutes of meetings "will be available starting with the meeting due to be held on the 8th October 2003"? More importantly, **why is the action plan, the publication of which was promised by the end of 2002, still not available?**

Miss Johnson: I understand why the hon. Gentleman is particularly passionate about the subject. I shall correct one figure that he gave: we estimate that about 200,000 people in England, 0.4% of the population, are infected with Hepatitis C-in some cases, the infection clears spontaneously. On current action, we have, as I said, improved the drug treatments. I assure the hon. Gentleman that the Department of Health will publish a Hepatitis C action plan, which will highlight the need for prevention and for increased identification and treatment of infected patients.

Mr. Simon Burns (West Chelmsford): Where? When?

Miss Johnson: I am just coming on to that subject. The plan will be forthcoming over the summer and into the autumn, and it will lead to more diagnoses of Hepatitis C, which will allow more people to be considered for treatment.

Comment: In the event, perhaps embarrassed by the excessive delay, a wholly inadequate Action Plan was rushed out at the end of June 2004

Parliamentary Debate Extract 21st June 2004

Andrew Lansley: "...On Hepatitis C…the Government estimate that there are 200,000 people with Hepatitis C, but there may be significantly more. The majority are undiagnosed. Effective treatments are available. "Getting ahead of the Curve", the report produced by the chief medical officer, stated that "good surveillance is the cornerstone of a system to control infectious diseases". However, **we do not have surveillance; we have got an awareness campaign,** which does not appear to be working. In a report in December 2003, the HPA found that transmission among those who inject had increased. The action plan-a familiar refrain, Madam Deputy Speaker-was first promised in 2002, and by May 2003, it was promised "in the next few months".

The Under-Secretary of State for Health, the hon. Member for Welwyn Hatfield (Miss Johnson) now says: "The plan will be forthcoming over the summer and into the autumn".-[Official Report, 8 June 2004; Vol. 422, c. 142.] Delay may be costly.

In 2002, the CMO said: **"Whilst costs of not treating are low initially, as the disease progresses, many more people move to decompensated cirrhosis where the treatment costs, which may include liver transplantation, increase dramatically".**

The disease is undiagnosed in 90% of cases, and up to 85% of people with it will develop chronic disease if it remains untreated-many such people would suffer the severe consequences arising from advanced liver disease. Surveillance now will forestall those costs later....(col. 1112)...

Dr Andrew Murrison: ...We would also like to know, please, when the action plan on Hepatitis C will see the light of day. We have rightly heard a great deal about the disease; in many ways, it is a covert disease, and a condition that many of us know very little about. We need an action plan to address this problem as well...(col. 1142)

Comment on PQs and Debate: Hepatology is not identified as a national priority in the NHS despite the highly significant disease burden within the general population. It was only after repeated parliamentary pressure that HMG eventually published its long-delayed HCAPE.

Written Answer 11th September 2004

Mrs Helen Clark (La. Peterborough):

1. To ask the Secretary of State for Health, what his latest estimate is of the incidence of Hepatitis C amongst the prison population,
2. To ask the Secretary of State for Health, what his latest estimate is of the proportion of prisoners with chronic Hepatitis C who are receiving treatment in accordance with NICE guidelines.
3. To ask the Secretary of State for Health, what his latest estimate is of the incidence of Hepatitis C amongst prisoners (a) on reception and (b) on discharge.
4. To ask the Secretary of State for Health, what steps he has taken to estimate the incidence of Hepatitis C amongst the prison population.

Dr Ladyman: Prisoners are not routinely screened for Hepatitis C. Individual prisoners often ask to be tested for evidence of chronic Hepatitis C infection and this is done, after pre-test counselling. The Public Health Laboratory Service undertook an unlinked, anonymised survey of the prevalence of blood-borne viruses amongst prisoners in England in 1997-98. This indicated that 9% of adult men, 11% of all women and 0.6% of young men had evidence of previous exposure to Hepatitis C. No research has been undertaken on the prevalence of Hepatitis C on reception and discharge. Prisoners newly diagnosed with Hepatitis C are referred to national health service specialists for further assessment and treatment, as clinically appropriate. People received into prison with Hepatitis C will have any treatment begun in the community continued while they remain in prison. **Information about the number of prisoners receiving treatment for Hepatitis C and what form that treatment takes is not collated centrally.**