Final

Lord's unstarred question: 1 November 2000:

The Earl Howe to ask Her Majesty's Government what plans they have to improve the care and treatment of patients with hepatitis C.

Key Facts / Bullet Points

- Hepatitis C is virus that can infect and damage the liver. The virus is found in the blood of people who have this disease. Hepatitis C is spread primarily by blood to blood contact with an infected person. Currently the main route of transmission in the UK by the sharing of blood contaminated equipment by injecting drug misusers. Other less important routes of transmission are from infected mother to baby at birth and by sexual intercourse with an infected person.

- Current information suggests that the prevalence (current level) of chronic carriage of hepatitis C may be around 0.5 per cent of the general population (i.e. about 300,000 people in the United Kingdom or about 250,000 people in England).

- The prevalence in injecting drug users is higher. Data from the Unlinked Anonymous Surveys of injecting drug users in contact with specialist drugs agencies in 1999 showed a prevalence of 35%. Other smaller studies have shown local prevalence rates of 50-80%.

- The incidence (new infection) of hepatitis C is not known, as the virus is usually acquired without symptoms. There is likely to be an increase in the diagnosis of hepatitis C in the next 10 years as individuals who have carried the virus for some time are identified through wider testing of groups who have been at risk.

- Routine surveillance by the PHLS includes publication of antibody positive hepatitis C laboratory reports. The cumulative total by the end of 1999 was around 15,000 with over 5,000 reports in 1999, with more than 80% in injecting drug users. Although there is likely to be some under-reporting by laboratories. These figures suggest that only a relatively small proportion of those with infection will have been tested so far. The PHLS also run a register of people with hepatitis C infections with known dates of acquisition. This provides a facility for studying the natural history of infection/disease and enhancement of the register is under consideration. The DH managed unlinked anonymous surveys have recently started collecting data on a regular basis in the injecting drug user survey.

- To raise awareness, the Government has produced guidance for the NHS on the purchasing of services for and clinical management of injecting drug misusers, which includes advice about hepatitis C. We have also issued advice for health care workers on protection against occupationally acquired infection with blood-borne viruses. Advice on minimising the risk of hepatitis C infection is also included in Department of Health leaflets for the public e.g. on sexually transmitted diseases and travelling abroad. The former Health Education Authority has produced a specific leaflet for the public on hepatitis C.

- Current measures to minimise the spread of hepatitis C amongst drug misusers include:

    - Needle exchange facilities – now provided by all regional health authorities

and nearly all the 120 health authorities.

- Prescription of liquid substitute medication (methadone and buprenorphine) reduces opportunity for injecting.

- General health promotion messages – including literature for drug misusers on the dangers of injecting drugs, and of sharing needles and other paraphernalia.

- Guidance on the management of drug misusers carrying hepatitis C is included in the Department's *Drug Misuse and Dependence – Guidelines on Clinical Management.* The Department is also developing integrated models of treatment that will be published later this year.

- Recent DH funded research (soon to be published) indicates that the prevalence of hepatitis C amongst drug misusers who have been injecting for less than 3 years is less than expected (10% compared to a prevalence rate of 40% for injectors as a whole). The study concludes that this is evidence of the effectiveness of harm minimisation measures such as needle exchanges.

- NICE published its recommendations on the use of combination therapy (alpha interferon with ribavirin) yesterday (ie 31 October). These will spread the most effective use of the therapy quickly through the NHS, and reduce variation from one area to another.

- Evidence-based clinical guidelines for the treatment of patients with hepatitis C have been drawn up by the British Society for Gastroenterology, the British Association for the Study of the Liver, and the Royal College of Physicians. They are in the final stages prior to publication. These will ensure that patients receive high-quality treatment.

- The British Association for the Study of the Liver (BASL) is drawing up recommendations for a review of the status of hepatology as a clinical sub-speciality. This would have implications for the appropriate training of clinicians, and for the structure of clinical services.

- Information on Hepatitis C was made available to all prison medical officers in a Dear Doctor Letter" (DDL96.3) by the Prison's Service's former Directorate of Health. This letter was prepared in consultation with the Department of Health and the Public Health Laboratory Service and endorsed by them. It provided prison doctors with information on the natural history, epidemiology, prevention, treatment and guidance in those areas.

- Treatment guidelines for prisoners with Hepatitis C will be revised once the national treatment guidelines commissioned by the Department of Health become available.

- Officials are included in the initial discussions with healthcare commissioners about the possibility of bringing hepatology within the arrangements for commissioning specialised services, through the Regional Specialised

Commissioning Groups.

- In 1996/7 £1million was allocated for research projects into the natural history, prevalence, transmission and treatment of hepatitis C, with a further £0.5 million in 1998/9 for research into HCV and injecting drug users.

- DH have commissioned £0.5m of research into hepatitis C and other blood-borne viruses. Areas covered include:

    - prevalence and incidence of, and risk factors for, hepatitis C virus infection among new injecting drug users

    - Comparison of sensitivity and specificity of Epitope Orasure and Sarstedt Salivette oral fluid, and dried blood spot, laboratory tests to detect antibodies to hepatitis C virus among injecting drug users

    - Addition of anti-HCV testing to unlinked anonymous survey of injecting drug users in 2001

    - The efficacy of enhanced counselling in the primary prevention of hepatitis C among injecting drug users: a randomised controlled trial.

    - A study of the impact of HCV screening on injecting risk behaviour reported by injecting drug users.

- A multi-centre research study is under way, commissioned by DH at a cost of more than £1 million, into the potential health benefits of treating hepatitis C in its early, mild stage. Currently patients with mild disease are usually monitored, not treated, because the known benefit is outweighed by the potentially serious risks of currently available therapies. The result is expected in 2003.

- DH provides financial support, through Section 64 grants, for several voluntary organisations working in the field, the British Liver Trust, Mainliners and the Haemophilia Society. Grants have been awarded for information leaflets; a telephone helpline; advice and support projects; an educational programme for patients with chronic disease; and targeted work with risk groups, including a hepatitis C resource centre.

- The Advisory Group on Hepatitis currently does not recommend routine antenatal screening for HCV as there is no well-proven means of preventing transmission of infection from mother to baby, and there are currently no drug therapies licensed for treating children. This is in line with international guidance. The prevalence rate (0.8%) reported by a recent research study at St Mary's Hospital, London, is not believed to be typical of rates nationally, and studies of pregnant women outside inner cities show smaller numbers infected.

Lines to take / supplementary paragraphs

National HCV Strategy

Why there is no national strategy for Hepatitis C like the HIV Strategy?

Our approach to hepatitis C is to develop a strategic programme which involves co-ordination in areas such as public health work on epidemiology, prevention and surveillance; tackling drug misuse; prison healthcare; research; commissioning healthcare services; and implementing the recommendations of the National Institute of Clinical Excellence.

Possible epidemic

The figures for HCV infection clearly show that we are likely to be facing an epidemic in years to come. What is the Government doing about this?

The Government is aware of the significance of hepatitis C as a public health issue, although estimates suggest that we are a relatively low prevalence country. We have commissioned studies to increase knowledge about the natural history, prevalence, transmission and treatment of hepatitis C. This will allow us to ensure that prevention activities and treatment and care services are based on the best scientific and medical evidence base available.

Dear Citizen letter.

I understand that the US Department of Health is planning to send every American household a 'Dear Citizen' letter detailing the dangers of HCV. Shouldn't the British Government be doing the same?

It is not yet confirmed if the US Department of Health and Human Services has undertaken to send a 'Dear Citizen' letter. The cost of doing this will be very high [~$30m] and there is uncertainty as to the cost effectiveness of raising awareness through this method.

We are aware however, of a similar letter that has been sent by the US Surgeon General to all members of Congress and that this letter will be cascaded down to interested parties. A copy of the letter is also available on the US Surgeon Generals' website.

The UK Department of Health has no plans to send a similar letter. Instead, we are concentrating our efforts on identifying and targeting at risk groups and individuals. To do this successfully, we are working with voluntary organisations such as the British Liver Trust and Mainliners who are in an excellent position to readily apply information and awareness projects.

In addition, we have also funded the British Liver Trust to help them produce comprehensive patient and public literature on all types of liver disease. These publications are widely available in hospitals, GP surgeries and advice centres.

Action on Hepatitis C's presentation to the Advisory Group on Hepatitis

What has happened as a result of *Action on Hepatitis C's* presentation to the Advisory Group on Hepatitis on 11 October 2000?

I am aware of *Action on Hepatitis C's* presentation on prevention initiatives for hepatitis C in injecting drug misusers. I understand that the Advisory Group on Hepatitis is considering the information provided.

Awareness

What are you doing specifically to raise awareness about hepatitis C in the general population?

We are funding work with the voluntary organisations, specifically the British Liver Trust, Mainliners, and the Haemophilia Society, to provide information and advice for the general population and for those at higher risk of acquiring hepatitis C infection, injecting drug users in particular.

Prevalence & incidence of HCV

What is the estimated prevalence and incidence of hepatitis C in the UK?

Current information suggests that the prevalence (current level) of chronic carriage of hepatitis C may be around 0.5 per cent of the general population (i.e. about 300,000 people in the United Kingdom and about 250,000 in England). The incidence (new infection) of hepatitis C is not known, as the virus is usually acquired without symptoms. There is likely to be an increase in the diagnosis of hepatitis C in the next 10 years as individuals who have carried the virus for some time are identified through wider testing of groups who have been at risk.

The prevalence in injecting drug users is higher. Data from the Unlinked Anonymous Surveys in 1998 showed a prevalence of 35%.

Data published in the medical journal *Gut* on 18 July reported a hepatitis C prevalence of 0.8% in a population of inner London pregnant women. However, estimates of hepatitis C infections based on studies carried out in inner cities, where there may be clusters of people at higher risk due to injecting drug use, will not be representative of the country as a whole. Surveys of pregnant women have reported prevalences as low as 0.2% in other parts of the country. Current information suggests that the prevalence of chronic hepatitis C infection may be around 0.5 per cent of the general population.

Notifiable disease

Would it not be wise to make HCV a notifiable disease, so that proper monitoring of incidence and prevalence can be achieved?

We recognise that the surveillance and studying of epidemiological data is an intrinsic part of any health care strategy. Viral hepatisit is a notifiable disease but designating a disease as such may not be making full use of the available resources. Notification is not primarily a tool for surveillance of general trends in incidence and prevalence. The main reason for making a disease Notifiable is to ensure that where there is an outbreak local agencies get the details they need to inform urgent control measures to stop the disease spreading. Surveillance of many diseases is carried out without making them Notifiable.

The Public Health Laboratory Service provides routine surveillance for HCV, including the publication of antibody positive hepatitis C laboratory reports. The PHLS also holds a National Registry of HCV infections. Indeed, the Department of Health has recently agreed a further 3 years funding, totalling £210,000 for the register. This will help to provide information about the long-term rate of progression of HCV in cases where there is a known date of infection.

[In addition, the Department's unlinked anonymous surveys programme has recently started collecting data on hepatitis C prevalence in injecting drug users on a regular basis. These surveys have already been used to look at the prevalence of hepatitis C in pregnant women and genitourinary clinic attenders.]

Hepatitis C screening

At risk groups – mainly current and past injecting drug users

Those who have been at risk of exposure to hepatitis C and who seek testing are offered well-informed advice and made aware of the implications of a positive test. Those who test positive are referred to a specialist for confirmatory testing, further assessment and treatment if appropriate. They are also advised about minimising the risk of transmitting infection to others and on the need to limit alcohol intake to reduce disease progression. Those who test negative are advised about ways of avoiding further exposure, as there is no vaccine against hepatitis C.

Antenatal screening

The Government's Advisory Group on Hepatitis is currently not recommending routine antenatal screening for hepatitis C as, unlike HIV or hepatitis B, there are no well-proven means of reducing the risk of transmission of hepatitis C from mother to baby, and there are currently no drug therapies licensed for treating children. This is in line with US guidelines, those of the World Health Organisation, and a consensus statement produced by the European Association for the Study of the Liver.

Screening health care workers

Current advice from the Advisory Group on Hepatitis is that hepatitis C infected health care workers should be restricted from carrying out exposure prone procedures only if they have been associated with transmission of hepatitis to a patient.

In the light of a number of recent transmissions of hepatitis C to patients the Advisory Group has reviewed its previous recommendations and will shortly be submitting revised advice to the Chief Medical Officers of England Wales Scotland and Northern Ireland.

(exposure prone procedures are those which carry a risk of injury which could cause bleeding, usually in surgery, obstetrics and dentistry)

Counselling services

Counselling services are a vital component of HVC management. What is the Government doing to improve them?

HCV patients often rely as much on their counsellor and advisors as on their medication. The support that counsellors provide is invaluable. Counsellors may come from a variety of different backgrounds. Some may be specialist in drugs misuse, others may have a background in other diseases such as haemophilia, which have close ties with HCV. But all have an important part to play. This is why we are considering the NICE recommendations that counselling and advice services be reviewed. We hope we can introduce a co-ordinated approach.

NICE Funding

How are NICE recommendations funded?

In this year's budget the Government has made a step change in the resources available to the NHS. These new spending plans mean that the service will receive the largest level of sustained real terms growth over any 4 year period in NHS history. One of the key areas that Health Authorities will be expected to use this money on is implementing NICE guidance.

For future years funding to implement the NICE recommendations will be included in the general allocation for HAs. [However, there will not be a specific amount earmarked for the implementation of the recommendations referring to Ribavarin, in common with this year.]

What is DH doing about the recommendations made by NICE about the need for further research?

NICE's recommendations were only published yesterday, 31st October. DH has noted the recommendations for further research, and will be considering how they can best be followed up in DH's research programme.

NICE – Drug misusers

What is the DH response to NICE recommendations that omit current injecting drug misusers?

Very much welcome the recommendation and the clarification that those who misuse drugs (but are not current injecting drug misusers) need not be excluded from therapy. It is sensible to exclude those who are currently injecting and at risk of re-infection but this presents an excellent opportunity for professionals working in with this group to offer increased help and encouragement to stop injecting and sharing.

Are people who misuse drugs excluded from having combination therapy?

NICE recommends that in general current injecting drug misusers should be excluded from this treatment. However if a prescribing clinician is reliably assured that re-infection, compliance and drug interactions pose no problems, a person in this group might be considered to combination therapy. Former IDUs and those on oral substitute treatment need not be excluded from therapy.

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HCV-HIV co-infection

What is the treatment of HCV-HIV co-infected patients?

Because HCV and HIV share some risk factors and transmission routes, a number of patients become infected with both viruses. Chronic HCV appears to progress to serious disease more rapidly in such co-infected patients, and now that the prognosis for HIV has improved with the use of highly active retroviral therapies, the liver disease is an increasingly serious problem. Treatment of HCV-HIV co-infection, and possible drug interactions, are currently the subject of much clinical debate.

Liver transplantation

Are there enough donor organs for liver transplantation?

When the liver becomes very badly damaged, a transplant may be appropriate. More than 600 liver transplants are now carried out annually in England. The increasing practice of dividing livers into two parts (liver splitting) is helping maintain the size of the liver transplant programme in spite of a fall in organ donors.

What efforts are being made to increase the number of patients receiving liver transplants from live donors?

Liver transplantation in England is a national service provided by 6 specialised centres designated by the National Specialist Commissioning Advisory Group (NSCAG). Live related adult to child transplants are provided by this service currently but the number of children who cannot be treated satisfactorily by a cadaveric transplant is very small.

Live liver transplantation carries a significant risk to the donor, more so in the case of adult to adult operations. Adult to adult live transplants currently represents the cutting edge of liver transplantation medicine and so the technique is not yet routinely available on the NHS. At present the waiting list in England for liver transplants is not very long so there is very limited need live transplant operations.

The UK Transplant figures for 1999 indicate that 13 living lobe donor transplants took place that year. The Department of Health and NSCAG will keep the service under review and expand the provision of live transplants if the benefits outweigh the undoubted risks to the donor.

Needle sharing by drug misusers

What is your estimate of needle sharing by injecting drug users and what are you doing about it?

Data from the Unlinked Anonymous Prevalence HIV Seroprevalence monitoring programme indicate that the level of current sharing of needles and syringes did not change greatly between 1991 and 1997 in England and Wales remaining at around 20%. However this proportion increased in 1998 to 32% and in 1999 to 33%. This underlines the importance of needle exchanges schemes and work to persuade people to stop injecting.

Is the Government currently phasing out needle exchange schemes?

Within England and Wales, we are working to improve availability through shared care schemes and by working closely with health authorities. We continue to expect health authorities to provide full needle exchange programmes as part of their drug misuse activities.

HCV transmission in prisons

What is being done to prevent hepatitis C transmission in prisons?

The Prison Service has a strategy for preventing the spread of communicable diseases in prisons covering training, education, prevention, and risk reduction and harm minimisation. This is complemented by the Prison Service's Drug Strategy. Key points in these strategies include:

the successful reintroduction of disinfecting tablets through pilot projects in 11 establishments since 1998: extension to all establishments is under consideration.

treatment of substance misusers which includes the management of symptoms of withdrawal in line with Department of Health guidelines; rehabilitation programmes and therapeutic communities;

health promotion and harm minimisation information

the provision of drug workers in all prisons who provide counselling, assessment, referral, advice and facilitate throughcare for substance misusers.

Regulation of body piercing businesses

When will additional legislation be introduced?

The Government has decided to introduce legislation to give local authorities outside London powers to regulate cosmetic body piercing businesses when Parliamentary time allows. It is not possible to say precisely when this might be because of our other heavy legislative programme and priorities.

Why are body piercing businesses outside London unregulated?

It is untrue to say that body piercing businesses outside London are unregulated. Local authorities are able to use enforcement powers under health and safety at work legislation which is not just designed to protect employees from risks to health and safety but also customers of these businesses. We aware that some local authorities have used these powers.

Many and perhaps most cosmetic body piercing businesses also carry out tattooing or ear piercing, which local authorities outside London do have powers to regulate. Local authorities, therefore, have the opportunity to work with businesses also offering cosmetic body piercing to promote safe and hygienic practices.

Will the Government introduce a minimum age of consent for body piercing?

The Government has no current plans to introduce a minimum age of consent as this might only lead to young people going to disreputable businesses or attempting to pierce themselves.

Public Inquiry into infected blood products

There should be a Public Inquiry into the hepatitis C scandal (ie re infected blood products)

There have been some calls for a public debate about events leading up to the introduction of the heat treatment of blood products in the mid 1980s. However, information on research into hepatitis C and the inactivation of the virus in blood is already in the public domain. I therefore do not believe that a public inquiry would add to what is already well established.

The important thing now is to look to the future and ensure that haemophiliacs with Hepatitis C receive the best treatments we can provide. The recommendations of NICE provide guidance here, and the clinical guidelines will be published shortly.

NBA Litigation

Why is the NBA contesting the hepatitis C litigation in court at the moment?

The National Blood Authority is defending this case on the basis of legal advice. However, they have offered an out-of-court settlement to claimants infected with hepatitis C through blood transfusion after 1 April 1991 by which time a state of the art screening test was available. I understand that this offer has now been accepted.

I cannot comment on events leading up to the introduction of a screening test for hepatitis C in blood, as this is a matter currently before the courts.

Research into BSE versus HCV

Why has the Government spent £50m this year on research into BSE and only £0.5m on research on HCV and injecting drug misuse?

Despite being a relatively new disease, quite a lot is known about hepatitis C in terms of the groups at risk, the modes of transmission, prevention, diagnosis and treatment. Measures have already been taken to improve prevention, detection and treatment. By contrast, the research spend on BSE reflects the fact that many things are not known about BSE and CJD, and that it is still uncertain how many people will be affected by CJD.

Background Notes

Hepatitis C – the disease

1. Hepatitis C is virus that can infect and damage the liver. The virus is found in the blood of people who have this disease. Hepatitis C is spread primarily by blood to blood contact with an infected person. Currently the main route of transmission in the UK is by the sharing of contaminated equipment by injecting drug misusers. Other much less important routes of transmission are from infected mother to baby at birth, by sexual intercourse with an infected person.

2. The majority of patients who acquire hepatitis C will live out their normal lifespan. Hepatitis C infection is cleared in about 20% of those infected, but persists in about 80% to become chronic infection. Most of those with chronic infection will have only mild liver damage, many with no obvious symptoms. About 20% of patients with chronic infection develop cirrhosis after 20-30 years. Studies carried out in a number of countries so far have generally indicated that about 1-5% of patients with chronic infection may develop liver cancer.

3. Current information suggests that the prevalence of chronic carriers of hepatitis C infection in the population may be around 0.5% (about 200,000 chronic carriers in England). The incidence of new hepatitis C infection is not known as the virus is usually acquired without symptoms. There is likely to be an increase in the diagnosis of hepatitis C in the next 10 years, as individuals who have carried the virus for some time are identified through wider testing of groups who have been at risk.

Public health measures

4. There are measures in place to prevent the transmission of hepatitis C such as the screening of blood donations, the heat treatment of blood products and the provision of needle exchange schemes. Advice on the management of drug misusers and hepatitis C is included in the Department's *Drug Misuse and Dependence - Guidelines on Clinical Managment*. Guidance for professionals, expanding on the information in the clinical guidelines, will be published later this year.

Risk factors associated with hepatitis C infection

5. The PHLS analysed risk information (where available) on laboratory reports of hepatitis C infection in England and Wales between 1992 and 1996 and found the following risk factors cited;

- 80% injecting drug use
- 7% blood product recipients

- 4% transfusion recipients
- 3% sexual exposure
- 2% renal failure
- 1% vertical transmission/household ie mother to baby
- 1% unspecified drug use
- <3% other known (including, being in prison, tattooing, invasive surgical treatment and occupational exposure)

(percentages rounded)

Surveillance

6. Routine surveillance by the PHLS includes publication of antibody positive hepatitis C laboratory reports. The cumulative total by the end of 1999 was around 15,000 with over 5,000 reports in 1999, more than 80% in injecting drug users. Although there is likely to be some under-reporting by laboratories, these figures suggest that only a relatively small proportion of those with infection will have been tested so far. The PHLS also run a register of people with hepatitis C infections with known dates of acquisition. This provides a facility for studying the natural history of infection/disease and enhancement of the register is under consideration.

7. The DH managed unlinked anonymous surveys have recently started collecting data on a regular basis in the injecting drug user survey; results for 1998 showed a hepatitis C prevalence of 35% overall with prevalence higher in London than elsewhere. 'One off' data from these surveys have shown prevalences of 0.2% in pregnant women outside London and 0.4% inside London and 0.7% in genito-urinary clinic attenders. A survey of hepatitis C in prison inmates in 1997 showed prevalences of 9% for men, 11% for women and 0.6% for young offenders. Some 82% of infected individuals gave a history of injecting drug use.

A Vaccine against hepatitis C

8. There is currently no vaccine to protect against hepatitis C infection, and one is unlikely in the near future. The virus is known to mutate (leading to a change in molecular structure) at a particularly rapid rate, which makes the development of an effective vaccine difficult.

9. A number of centres around the world are involved in research into a vaccine against hepatitis C; we are not aware of research in this country, and the Department is not supporting such research.

[NB: There are a number of difficulties for researchers working in this field, not least being that the only species that can be infected by hepatitis C are humans and chimpanzees.]

Hepatitis C infected health care workers

10. There have been 3 patient notification exercises since October 1999 following the transmission of HCV from 3 different health care workers to patients during surgical procedures. These exercises took place in Boston and other parts of England and Wales (in two phases), London and Birmingham. About 7,000 patients were notified and offered testing. So far it appears that the infected health care workers may have infected around 12 patients. Patients with HCV virus infection have been referred for specialist clinical assessment. Those found to be negative have been informed and reassured.

11. These three incidents followed the first reported incident in the UK in 1994 in which a hepatitis C infected HCW transmitted infection to a single patient. We are only aware of one other published report world-wide relating to an infected surgeon in Spain.

12. Existing AGH advice recommends that hepatitis C infected healthcare workers should be restricted from carrying out exposure prone procedures only if they have been associated with transmission of infection to patients. (Exposure prone procedures are those which carry a risk of injury which could cause bleeding, usually in surgery, obstetrics, dentistry etc) In the light of this evidence that the risk to patients may be greater than previously thought, the AGH has reviewed its previous recommendations and will shortly be submitting revised advice to the Chief Medical Officers of England, Wales, Scotland and Northern Ireland.

NICE

13. NICE published its Final Appraisal Document on 31 October, giving its recommendations for the use of combination therapy – alpha interferon with ribavirin – to treat HCV.

14. Briefly, combination therapy is recommended as the treatment of first choice for moderate to severe HCV in the following:
    a) previously untreated patients
    b) patients treated with interferon monotherapy, who responded but have relapsed.

15. Treatment should be for 6 months, except for those with genotype 1 virus who, if they show a response, should have 12 months.

16. Treatment is not recommended for:
    a) continuing intravenous drug users – though they may be treated if the prescribing clinician can be sure that re-infection, compliance and drug interactions pose no problems. (Former drug users can be treated.)

b) current heavy drinkers, because of the increased risk of liver damage
c) non-responders to monotherapy (further research is needed on clinical and cost effectiveness of treatment for this group)
d) use for decompensated cirrhosis is contra-indicated

17. There is insufficient evidence for recommendations on use in under-18s, or after transplantation; also for mild disease, though unpublished evidence suggests this may need to be reviewed.

18. Monotherapy should be considered only if ribavirin is contra-indicated, or cannot be tolerated.

19. Figures given for prevalence and costs are broadly in line with DH estimates. Drug costs are estimated at £18 million per year for three years and at least £5 million annually thereafter. Costs of testing, monitoring and counselling will be in addition.

20. Recommendations for further research are made on:
a) the prognostic value of monitoring viral load to reduce length of therapy
b) audit of biopsy rates
c) treatment of current intravenous drug users (usually omitted from trials)
d) clinical and cost effectiveness of treating mild disease (NB: DH-commissioned trial under way)
e) treatment for non-responders to monotherapy.

21. Two recommendations are made for implementation: that viral genotyping facilities will need to be upgraded, and that counselling facilities will need to be reviewed.

22. DH has noted and accepted the need to upgrade genotyping facilities, and review counselling facilities. We will consider how best to carry out this work, but have not yet had time to formulate detailed plans.

23. The allocation of £660m in the budget is intended among other things to enable NHS bodies to fund positive recommendations from NICE. NHS bodies fund treatment on clinical recommendations and in line with the guidance from NICE. Sufficient resources have been allocated for the current tax year to allow this to be done. This would apply in the case of Ribavarin for Hep C. For 2001-02, funding to implement the NICE recommendations will be included in the general allocation for HAs from April 2001. However, there will not be a specific amount earmarked for the implementation of the recommendations referring to Ribavarin, in common with this year.

Those without treatment

24. There is a significant number of patients for whom treatment will not usually be available:
a) Continuing injecting drug users, and heavy drinkers
b) Those with decompensated cirrhosis
c) Those who did not respond to monotherapy (as opposed to relapsing after it)

d) Those with conditions for which the drugs are contra-indicated, or who have to discontinue treatment because they do not tolerate the drugs:
   - Interferon: psychosis or severe depression; symptomatic heart disease; seizures; organ transplant (except liver); uncontrolled diabetes; autoimmune disorders, especially thyroiditis.
   - Ribavirin: renal failure; anaemia; pregnancy; haemoglobinopathy; severe heart disease.

e) Children

f) Those with mild disease.

25. For these patients, some treatment of their symptoms may be possible, but further research is needed. Many will need counselling and support.

26. NICE recommends non-responders to monotherapy be included in trials for newly-developed therapies. This group will include some infected through blood products before it was possible to make supplies safe.

Clinical Guidelines on the use of alpha interferon and ribavirin in the treatment of hepatitis C

27. These have been drawn-up by a group from the British Society of Gastroenterology (BSG), the British Association for the Study of the Liver (BASL) and the Royal College of Physicians (RCP), with funding from DH.

28. They have been a long time coming: they were delayed again to include combination therapy. It was originally intended DH should endorse them once they had gone through the St George's approval system. However this has been replaced by the NICE process, so now we expect them to be issued as BSG guidelines. They are in the BSG peer review process and are expected to be published by GUT, the journal in whose supplements many BSG guidelines are published. We are awaiting clarification of the timescale, but currently expect publication in early 2001.

29. The guidelines are wider and more detailed than the NICE recommendations, including testing for diagnosis; risk behaviour; different needs according to different infection routes.

Counselling & Testing

30. NICE says that the importance of ready access to adequate counselling, particularly about the side effects of treatment, is recognised, and confidential HCV testing and counselling should be made available whether or not treatment is initiated. Regarding implementation, NICE recommends counselling facilities be reviewed. The clinical guidelines make clear the importance of counselling and support, and what might be needed for various groups of patients. Counselling has also been a subject high on the agenda of pressure groups, who have emphasised the importance of confidentiality.

31. DH's own guidance, in *Drug Misuse and Dependence – Guidelines on Clinical Management*, is that patients should receive well-informed advice and should be made aware of the implications of a positive test. Those who test negative should receive advice on ways of minimising the risk of transmitting infection to others.

32. C Change, a lobby group formed by the British Liver Trust with professionals and patients, has drawn up recommendations for pre and post test consultation procedures. DH cannot endorse them, because they:
    - include a maximum 4 months from request for a test to diagnosis with full treatment plan
    - Suggest referral routes which would require special arrangements (eg direct from testing unit to hepatologist or gastroenterologist, to mental health/social service/spiritual aid agencies, for whose competence the referrer is responsible)
    - are aspirational and include unrealistic time/numbers of visits
    - assume the kind of social stigma and need for secrecy which HIV once had, but is moving away from (eg. HIV pre-test discussion now takes place with an informed health professional rather than a specialist counsellor).

    However, they do identify the issues which need to be covered, and will matter to patients.

33. Most IDUs are tested in specialist drug misuse treatment services, while primary care, general drug services and other specialist drug misuse treatment services will refer patients for testing.

34. Informed advice is needed pre-test because of the implications of a positive result (insurance, etc). Patients must make an informed choice for testing. Post-test advice and counselling will vary according to the result, but some will be needed (risk behaviour, about HCV) before those testing positive are referred to a specialist.

35. Further counselling and advice will be needed according to the results of detailed diagnostic tests and assessment, and according to what treatment is offered, if any.

36. Thus both primary and secondary care include counselling and advice services. Currently many drugs and HIV clinics have expanded to serve HCV patients. Reports indicate they provide a good service: that provided by GPs is variable.

37. The clinical guidelines make clear that patient groups with different routes of infection are likely to have different counselling, advice and support needs. These must be met, but without categorising patients.

38. DH is anxious to avoid HCV being regarded as a cause of the same fear and social stigma that HIV had in the early days. Confidentiality for the patient is as important for HCV as for many other conditions, but must be complemented by good information, widely disseminated to groups with whom HCV patients will come in contact (dentists, insurance etc.)

39. Officials recognise the need to review counselling and advice facilities, as recommended by NICE.

Genotyping facilities

40. NICE recommends that those with genotype 1, who show a response after 6 months' combination therapy, should receive a further 6 months.

41. Genotyping and viral load testing are not routinely available. They have been used mainly in research, rather than routine care, and DH accepts that capacity will need to be increased to deal with rising numbers, and to provide the data to determine the appropriate duration of treatment.

Hepatology services: review by BASL, and Regional specialised commissioning

42. It has been recognised for some time that hepatology services could come under the arrangements for commissioning specialised services.

43. The British Association for the Study of the Liver (BASL), on behalf of the profession, have set up a small working group to draw up proposals. DH is contributing to this. (*Not to be made public: proposals include the recognition of hepatitis as a sub-speciality of gastroenterology, which would have implications for training, and the establishment of Regional Liver Centres.)*

44. DH is also in the early stages of discussions with healthcare commissioners about the possibility of bringing hepatology within the arrangements for Regional commissioning of specialised services.

45. Factors leading to this include:
    a) increasing burden of liver disease, especially cirrhosis and HCV
    b) increasing complexity of managing complicated liver problems
    c) need for further training in transplantation and managing complex problems
    d) economic implications of treatment regimes
    e) need for clinically-driven hepatological research.

Roche economic model

46. DH is in discussion with Hoffman LaRoche about a health economic model they are developing. This could be a useful tool for healthcare commissioners, enabling them to model long-term service needs and financial implications, according to the data for their own local population.

47. We also understand that PHLS are considering expanding their work on projections to include HCV.

Pegylated Interferon

48. Pegylated interferon is a modified form, requiring one weekly injection not three, and released more slowly and steadily.

49. Schering Plough has a licence from EMEA for monotherapy with ViraferonPeg, and a licence is pending to Hoffman LaRoche for monotherapy with Pegasys.

50. Trials indicate peg interferon in combination therapy is well tolerated and more effective than ordinary alpha interferon.

Action in the Drugs Misuse area

Needle exchanges

51. Needle exchange facilities are now provided in all regions and by nearly all health authorities. Needle and syringe exchange service coverage stood at 93% service coverage in 1999. The number of needles and syringes distributed may be higher in the UK than in the US and many other European countries. Studies suggest that well over half the need for clean syringes was met by 1997 distribution levels and should be even higher today.

52. It is agreed that the introduction of syringe exchanges, along with other harm reduction activities have been instrumental in averting an HIV epidemic amongst injecting drug users in the UK. HIV prevalence amongst injecting drug users, at around 3% in London and 1% elsewhere, is low and stable. In the rest of the EU, prevalence ranges from 1% in the UK to 32% in Spain.

53. Furthermore, there is increasing evidence that the prevalence of hepatitis C amongst injecting drug misusers is less than expected (40%). This suggests that syringe exchanges and other harm reduction measures are also playing a key role in reducing the spread of hepatitis C.

54. Compared to the rest of the EU (with the exception of Luxembourg), the latest EMCDDA figures show that the UK has the lowest rate of hepatitis C prevalence (figures range from 20% to 90% in the EU). However, this does not mean that the Government will cease to take this problem seriously. The Department of Health is committed to preventing the spread of hepatitis C and other blood-borne viruses and will continue to work towards reducing levels of injecting and sharing of needles and other harm reduction activities.

Reducing injecting and sharing

55. Another key component of a programme to reduce the transmission of hepatitis C is to develop skills of those who work with drug misusers so that they can effectively advise and encourage drug misusers to stop injecting and sharing and to avoid initiating people to the injecting and sharing habit. There is also a need to increase general awareness of the impact of hepatitis C among those who work in the drug treatment field.

56. Additional funding for drug misuse services has just been made available for this financial year and PS(H) has agreed that up to £1 million of this can be used to develop detailed guidance to all who work in the drug misuse field on Hepatitis C, its consequences and strategies to reduce transmission.

57. The funding will also be used to run a series of workshops in all regions, based upon research from the University of Kent which demonstrated that professionals can make a difference to initiation into injecting and sharing.

58. Health Authorities will also be given funding to obtain sufficient health promotion materials to circulate to all drug misusers in contact with treatment and where possible to those not in contact.

59. The aim of this concentrated work is to ensure that all who work with drug misusers give regular, consistent and effective messages about the dangers of injecting and sharing in particular in relation to hepatitis C, although not excluding the other blood borne diseases.

60. The funding for this programme comes from an additional £25 million which SoS agreed this week could go to drug misuse services. We are currently planning a series of announcements for PS(H) to cover this programme but she has agreed that you can announce this part of the programme in general terms in your speech.

ACMD report on reducing drug related deaths

61. The Advisory Council on the Misuse of Drugs recently published a report on reducing drug-related deaths. The report covers a wide range of areas including methadone, data collection, prisons and primary care and also makes a large number of recommendations on chronic and acute illnesses.

62. The Department of Health is currently leading the government response to this report and will be co-ordinating the production of an action plan to reduce drug related deaths. A major component of this is likely to be action to improve the monitoring, prevention, testing and counselling for hepatitis C infection among drug misusers.

Care and treatment of prisoners with Hepatitis C

Cases Reported

63. Prisoners are not routinely screened for Hepatitis C. Figures on the number of cases of hepatitis C in each prison in England and Wales, based on information volunteered by prisoners themselves, have been collected only since 1995.

New cases identified in year:

95/96	96/97	97/98	98/99

Chronic HCV:	543	760	916	1089

Source: Statistical Returns from Prison Service Establishments

Prevalence of Hepatitis C in Prisons

64. A study the prevalence of HIV, Hepatitis B and hepatitis C in eight prisons in England and Wales conducted by Public Health Laboratory Service (PHLS) in 1997/8 showed, for Hepatitis C, that amongst:

- the **total** prison population sampled the rate was 7%
- those who had ever injected the rate was 30%

(The total prison population rate for Hepatitis B was 8%, with 0.4% for HIV. The rate for Hepatitis B amongst those who had ever injected was 20%.)

65. The 1997 ONS survey of psychiatric morbidity amongst prisoners in England and Wales reported that 28% of men on remand, 40% of women on remand, 23% of sentenced men and 23% of sentenced women said that they had ever injected drugs. The numbers of those who said that they inject regularly, or had done so in the month prior to reception into prison custody, were lower. The prevalence of injecting in the last month is as follows: Male remands 17%, Female remands 28%, Male sentenced 13%, Female sentenced 14%.

Screening

66. Prisoners are not routinely screened for Hepatitis C in Prison Service establishments. However, testing is available for those who wish on request. Such testing will be undertaken in line with professional guidelines. It involves pre and post testing and counselling. The results are confidential to the patient. Testing methods involve invasive action (the use of a needle to obtain blood) which could only be undertaking on a voluntary basis. The Department of Health has not suggested population screening.

Treatment

67. If clinically indicated prisoners who test positive for Hepatitis C will be referred to an NHS specialist for advice on further management.

Harm minimisation issues

68. The Prison Service's harm minimisation policy includes:

- disinfecting tablets for the purpose of cleaning illicitly held drug taking equipment have been piloted in 11 establishments since 1998: all these establishments have

been expected to continue making disinfecting tablets available pending a decision to roll out the programme across the estate. *The Home Secretary has approved the roll out programme and the announcement will be managed through PQs in both Houses, the texts or which will need to be agreed by all the Ministers concerned.*

- Disinfecting tablets are not available in the three special hospitals. This is because the level of supervision does not allow injecting equipment to exist.

- prison doctors have authority to prescribe condoms, if, in their clinical judgement, there is a known risk of HIV infection: the Prison Service is exploring ways of making condom provision policy clearer and more uniformly applied, though revised guidance and instructions.

- the Prison Service has no present plans to introduce needle exchange schemes but continues to monitor developments at home and abroad.

The new partnership to improve prison health

69. The Government accepted the recommendations of the joint Prison Service / NHS Executive working group (Report March 1999*) for a substantial programme of change within prison health care, with a formal partnership between them taking the programme forward. The aim is to provide prisoners with health care on a par with that received from the NHS by the general population. Such closer working should lead to the better management of services for prisoners diagnosed with communicable diseases, whilst they are in prison, and following their release.

Background

70. The background to the care and treatment of prisoners is set out in the Dear Doctor Letter DDL(96)3.

71. The new joint working arrangements between the NHS and Prison Service are led and managed through the Prison Health Policy Unit and the Prison Health Task Force at Headquarters level and involve close co-operation between individual prisons and their local health authorities at the local level. These arrangements came about following the recommendations, which Ministers accepted, in the Joint NHS Executive /Prison Service Working Group report: " The Future Organisation of Prison Health Care."

Interest in Hepatitis C amongst prisoners

72. We are not aware of Earl Howe expressing any interest in Hepatitis C amongst prisoners. The only interest we have received from members of the House of Lords has been from Lord Haddington. In March 1999 he asked about numbers of cases of HIV, Aid and Hepatitis B and Hepatitis C in the last 10 years.

73. On 2 June 2000 the Public Health Service Laboratory published an article on the results of their "Survey of Prevalence of HIV, Hepatitis B and Hepatitis C Amongst Prisoners in England and Wales" in the Journal "Communicable Disease and Public Health". The journal also contained an editorial which highlighted the survey findings and commented on Prison Health Policy on needle exchange and the provision of condoms.

Antenatal screening

74. The medical journal *GUT* has recently published a paper about the prevalence of HCV infection in patients attending a London antenatal clinic. The authors do not appear to be advocating routine antenatal screening in an attempt to reduce mother to baby transmission (they admit appropriate interventions are not available). Rather they are suggesting that routine screening of antenatal clinic attenders in high prevalence areas may provide an opportunity to detect women who are infected so that they can be offered early treatment. It notes that deliveries from infected mothers might be managed differently to try to avoid transmission and also that their babies can be followed up.

75. Pregnant women with chronic blood-borne virus infections may transmit these infections to their babies at or around the time of birth. Mother to baby transmission of HCV is about 5-6% (less than HIV and hepatitis B) but is about 14-17% where the mother is co-infected with HIV. There is no vaccine or post-exposure prophylaxis to prevent transmission of HCV infection. There is no approved anti-viral therapy for use in pregnancy (indeed ribavirin is contra-indicated in pregnancy). At present published literature is unclear as to any benefits that might accrue from delivering babies born to HCV infected mothers by elective Caesarian section, and breast feeding is <u>not</u> thought to play a significant part in mother to baby transmission of HCV.

76. Babies are not usually tested for HCV under a year old, as antibodies from the mother may affect test results until then. There are no licensed treatments for children.

77. Line to take: The Government's Advisory Group on Hepatitis is currently not recommending routine antenatal screening for hepatitis C as there is no well-proven means of reducing the likelihood of transmission of infection from mother to baby. This is in line with US guidelines, those of the World Health Organisation, and a consensus statement produced by the European Association for the Study of the Liver.

78. Estimates of hepatitis C infections based on studies carried out in inner cities, where there may be clusters of people at higher risk due to injecting drug use, will not be representative of the country as a whole. Studies of pregnant women outside inner cities show smaller numbers infected.

Guidance on Blood Borne Viruses in Renal Units

79. The Public Health Laboratory Service (PHLS) has drawn up guidance on the management of blood borne viruses (BBVs), including HCV, in renal units.

80. The working group have recently met to finalise their report and a summary of the document will be prepared which will be easy for renal units to use and implement.

Section 64

81. Section 64 grants have been awarded to support the provision of advice, counselling and support by Voluntary Organisations:

- The British Liver Trust has received grants for the production and dissemination of information leaflets; a telephone helpline; an educational programme to help patients with chronic disease to play a fuller part in their own management; and a major new initiative to work with groups at high risk of hepatitis, especially HCV.

- The Haemophilia Society has an HCV worker, and has received funds for its HCV Youth Information and Support project, which has produced guides on HCV for young people of different ages, and for parents, carers and teachers.

- Mainliners has received funding for its HCV worker, and an HCV resource centre. They also have a support group.

CMO's Expert Patient Programme

82. British Liver Trust run a chronic disease self-management programme, for patients with all sorts of chronic disease, including HCV. DH supports it with a S64 grant. Small groups (8 – 18) are taught by a trained leader (lay and also with a chronic disease) in a tightly scripted programme, for 6 weekly sessions of 2.5 hours, cost £2 per person per week. The programme aims to provide patients with the skills to manage their condition better day to day, and become confident and informed so they can take an active part in their health management ('expert patients'). Subjects covered include goal setting/action planning and problem solving, fatigue and symptom management techniques, dealing with emotions, communication, medication and community resources. The programme, devised at Stanford University, California (the Kate Lorig model), has been tested: research showed measurable decreases in hospital admissions and use of healthcare services, as well as patient perceptions of feeling better overall.

Research into HCV

83. There is much we still do not know about HCV. In 1996/7 the Department of Health made £1 million available for research into the prevalence, transmission and natural history of HCV. Last year (1999/2000) the Medical Research Council spent approximately £800,000 on research into HCV. In addition to this, DH funding for research has been targeted at treatment (.£1 million) and studies of intravenous drugs misuse (£0.5 million).

84. The Health Technology Assessment Programme has commissioned a £1 million project to investigate the health benefits from anti-viral therapy for mild chronic HCV. This guidance will help to provide evidence to determine whether patients whose hepatitis is still mild will benefit from treatment with combination therapy. The NICE guidelines do not currently recommend combination therapy for this patient group because the overall outcome may not be beneficial. This research, due to be published in 2003, will go a long way towards establishing if patients with mild disease would significantly gain from this treatment.

85. Further funding of over £0.5 million has been used to commission five studies on hepatitis C and intravenous drug misuse. These all begin between April 2000 and January 2001. A list of these is below. Two of the largest studies will provide estimates of prevalence and/or incidence of HCV infection, in one case amongst community-recruited recent initiates to injecting in London, and in the other amongst injectors recruited through specialist community and hospital drug services in SW London and in Surrey. The five studies also span a range of approaches to understanding risk behaviours and ways to reduce these. Collectively these studies should help inform policy development by increasing the evidence base.

- Comparison of sensitivity and specificity of Epitope Orasure and Sarstedt Salivette oral fluid, and dried blood spot, laboratory tests to detect antibodies to hepatitis C virus among injecting drug users. (Ms A Judd, Imperial College School of Medicine).

- Addition of anti-HCV testing to unlinked anonymous survey of injecting drug users in 2001. (Dr V Hope, Communicable Disease Surveillance Centre).

- The efficacy of enhanced counselling in the primary prevention of hepatitis C among injecting drug users: a randomised controlled trial. (Dr M Abou-Saleh, St George's Hospital Medical School).

- A study of the impact of HCV screening on injecting risk behaviour reported by injecting drug users. (Dr M Walker, PHLS Bangor).

- A cohort study to assess prevalence and incidence of, and risk factors for, hepatitis C virus infection among new injecting drug users (Professor G Stimson, Imperial College School of Medicine)

Compensation for haemophiliacs with HCV

86. When we came to office, we met the Haemophilia Society and listened to their arguments for a special payments scheme for people with haemophilia and hepatitis C similar to that in place for HIV. After long and careful consideration, we came to the conclusion that a special payments scheme should not be established. Succeeding Ministers, including myself, have reviewed this decision and reached the same conclusion. Speaking from personal experience, it was a very difficult decision to make.

87. Government policy remains that compensation or other financial help to patients is only paid when the NHS or individuals working in it are at fault. The underlying principles are clear cut and independently established under common law. They apply to personal injury cases in general – not just those arising from health care.
The same conclusion was reached by the previous Government.

Comparisons with HIV

88. Comparisons are inevitably made between the decision not to offer special payments to haemophiliacs with hepatitis C and the special payments established in the late 1980s for haemophiliacs with HIV. However, there are significant and real differences between the two situations.

89. If we think back to the 1980s, HIV had a vast and dramatic impact. It was a source of fear and stigma for all those who became infected with the virus. There was widescale public reaction. Here was a new sexually transmitted infection which was rapidly fatal. There was no treatment and, at that time, death from AIDS related diseases was considered inevitable.

90. It was in this context that special payments were introduced and the Macfarlane Trust was established. We see this as a reflection of those truly exceptional circumstances, the very poor prognosis at that time for people with haemophilia who became infected with HIV.

Media coverage and previous parliamentary business & correspondence

Media Coverage

Article in *Gut* (18 July 2000) -antenatal screening for hepatitis C

1. Data published in the medical journal *Gut* on 18 July reported a hepatitis C prevalence of 0.8% in a population of inner London pregnant women, and suggests routine screening. This lead to headlines in the national press e.g. *"Nearly 500,000 in Britain carrying hepatitis C virus...will lead to significant numbers with serious liver disease ....will kill more people than AIDS" (national press on 18 July).*

2. Other surveys of pregnant women have reported prevalences as low as 0.2% in other parts of the country. Our best estimate is that around 0.5% of the general population may have been infected with hepatitis C (i.e. about 250,000 people in England or 300,000 in Britain). The authors do not appear to be advocating routine antenatal screening in an attempt to reduce mother to baby transmission (they admit appropriate interventions are not available). Rather they are suggesting that routine screening of antenatal clinic attenders in high prevalence areas may provide an opportunity to detect women who are infected so that they can be offered early treatment.

Article in *The Lancet* (9 September 2000) - mother to child transmission of hepatitis C: evidence for preventable peripartum transmission

3. This article reports a study of infants born to hepatitis C infected mothers (441) attending a number of hospitals in the UK and Ireland between 1994 and 1999. The overall transmission rate of hepatitis C from mother to child is reported as 6.7%, and this was found to be increased to 18.6% when the mother was co-infected with HIV. These rates are higher than previous studies which reported average transmission rates of 5% in women with hepatitis C infection alone and 15% in women co-infected with HIV.

4. No effect of breast-feeding on transmission was observed in the study, although only 59 women breast-fed. However, elective caesarean section compared to emergency section or vaginal delivery showed a lower transmission risk. The authors suggest that this indicates most hepatitis C transmission occurs around delivery and if their findings are confirmed in other studies, the case for antenatal hepatitis C testing should be reconsidered.

PQs

PQ 2284: 6 April 2000: Mr Brian White: To ask SofS, if he will list the health authorities which currently fund the use of Interferon and Ribavirin for the treatment of HCV; and what is the estimated cost of offering this nationally and

PQ 2285: 6 April 2000: Mr Brian White: To ask SofS, what plans he has to create a national standard of care that will be available to all sufferers of HCV.

PQ 3123: 7 June 2000; Dr Ian Gibson: To ask SofS, what plans he has to tackle the problems of the HCV infection in Norwich amongst intravenous drug users; and if he will include HCV infection in a general programme on blood borne viruses.

Reply:

Norfolk health authority funds specific initiatives to prevent and control blood-borne viruses, including hepatitis C, among injecting drug misusers. These initiatives include needle exchange schemes; outreach services; an immunisation programme against hepatitis B; information and advice on preventing blood-borne virus transmission; testing for hepatitis B, hepatitis C and HIV; and training and guidance for health professionals.

We recognise that blood-borne viruses, in particular hepatitis C, are a public health issue in relation to injecting drug misusers. We are therefore commissioning research specifically about hepatitis C and injecting drug misusers, who currently form the largest source of new cases.

We have also asked the National Institute of Clinical Excellence (NICE) to consider the use of combination drug therapy (interferon alpha plus ribavirin) for the treatment of hepatitis C. NICE is also looking at evidence-based clinical guidelines for the management of patients with hepatitis C. NICE's recommendations, which are due this autumn, and the clinical guidelines will provide authoritative guidance to health care commissioners and clinicians.

PQ4093: 24 July 2000: Dr Ian Gibson: To ask SofS, if he has plans to carry out routine screening for HCV.

Suggested reply:

There are currently no plans to carry out routine screening for hepatitis C.

PQ 4071: 24 July 2000: Dr Ian Gibson: To ask SofS, what assessment he has made of HCV infection levels of Government cancer strategy in relation to liver cancer (sic).

Suggested reply:

Studies carried out in a number of countries have shown that a percentage (generally about 1-5%) of individuals with chronic hepatitis C infection may progress to primary

hepatocellular cancer. The Public Health Laboratory Service, in association with the British Association for the Study of the Liver, is setting up a surveillance system to monitor end stage liver disease attributed to hepatitis C.

As part of our modernisation programme for the NHS, we are taking action on a number of fronts to ensure prompt access to cancer diagnosis and treatment across the country. This will include improving liver cancer services.

PQ 4280: 2 October 2000: The Lord Rea - To ask Her Majesty's Government, in view of estimates that 200,000 or more people in the United Kingdom may be infected with hepatitis C, whether they are developing a national startegy for this condition; what is their estimate of the current level of the hepatitis C epidemic in the United Kingdom; and what projections exist for its future course and PQ 4282: 2 October 2000: The Lord Rea - To ask Her Majesty's Government what is the current effectiveness and availability of treatment for hepatitis C through the National Health Service.

Suggested reply:

The Government's health strategy for England is an action plan to improve health and is set out in the White Paper *Saving Lives: Our Healthier Nation.* As part of this, hepatitis C initiatives may be taken forward under the umbrella of wider action on public health.

Studies suggest that the prevalence (current level) of chronic carriage of hepatitis C may be around 0.5 per cent of the general population in the United Kingdom. The incidence (new infection) of hepatitis C is not known as the virus is usually acquired without symptoms. There is likely to be an increase in the diagnosis of hepatitis C in the next 10 years as individuals who have carried the virus for some time are identified through wider testing of groups who have been at risk.

Two drug treatments for hepatitis C are currently licensed; monotherapy with alpha interferon and combination therapy with alpha interferon plus ribavirin. The National Institute for Clinical Excellence (NICE) is considering the use of combination therapy to treat hepatitis C, and will issue recommendations on its clinical and cost effectiveness shortly.

Evidence-based clinical guidelines on the management of people infected with hepatitis C are being developed by a group from the British Society of Gastroenterology, the British Institute for the Study of the Liver and the Royal College of Physicians. The authoritative guidance provided by NICE and by the guidelines will ensure that combination therapy is provided consistently throughout the NHS, and that the most effective treatment is delivered.

In addition, the NHS Health Technology Assessment Programme is funding a £1.1 million multi-centre, clinical trial into the potential health benefits of treating mild disease.

PQ 4283: 2 October 2000: The Lord Rea - To ask Her Majesty's Government, with particular reference to the high costs of antiviral drugs for treating hepatitis

C and HIV, whether they intend to review price mechanisms and monopolies among pharmaceutical companies.

Suggested reply:

The prices of branded medicines are controlled indirectly by the Pharmaceutical Price Regulation Scheme (PPRS) which limits the profits which companies can make from the sale of these products to the National Health Service. Within this ceiling on overall profits companies have freedom of pricing with a high price on one product being balanced by a lower price on others. A new scheme was introduced in October 1999 under which the prices of medicines covered by the PPRS were reduced by 4.5% overall representing savings to the NHS of around £200 million per year. The new Scheme incorporates an inquiry into the extent of competition in the supply of branded medicines to the NHS, which will inform the mid-term review of the PPRS, which will be undertaken after April 2002.

Pharmaceutical companies often concentrate their research in particular therapeutic areas in which there may well be few suppliers. New products benefit from intellectual property protection which rewards and encourages research. In this particular area there has been a tendency for products to be launched at a common European price. Although their relative prices in different countries may be affected by currency fluctuations and controls of the kind exercised by the PPRS, they are at a similar level in other European countries.

Outstanding PQs

PQ4525 ordinary written from The Baroness Jeger –
To ask Her Majesty's Government what help is given by the National Health Service to haemophilia sufferers. Draft due by Mon 30 Oct for response on Tuesday 31 Oct or Wednesday 1 November.

PQ4535 ordinary written from Dr Brian Iddon (Bolton SE):
To ask the Secretary of State for Health, what action is being taken to combat hepatitis C within the Prison Population. Draft due noon Wednesday for response on Thursday 2 Nov or Monday 6 Nov.

PQ4533 ordinary written from Dr Brian Iddon (Bolton South East):
To ask the Secretary of State for Health, what assessment he has made of whether there are sufficient practising hepatologists to cope with the increasing number of patients with hepatitis C. Draft due noon Wednesday for response on Thursday 2 Nov or Monday 6 Nov.

POs:

In July there was a London-based correspondence campaign, in which two new lobbying groups, Re-act and Butterfly C West London, wrote to MPs and Health Authorities in London. Although they mentioned specific areas each time, the issues raised were national ones.

Manlio Fahrni, of Re-act, has since written to request further clarification of some aspects of the reply.

In recent months, there have been a few Private Office cases expressing concern about the recent hepatitis C infected health care worker patient notification exercises.

We currently have a letter from Dr Graham Foster of a hepatitis C lobbying organisation *C Change*.

Lobbying groups:

Apart from the 2 new London groups, 'Action for Hepatitis' lobbies on behalf of drug-misusing people infected with HCV, and has pressed hard for a national strategy.

C Change, an umbrella group of the British Liver Trust, the professions and patients, is still active. They drew up recommendations for pre and post testing procedures.

The Haemophilia Society is active in pursuing compensation for those infected through NHS treatment.

In July a group of 5 Labour MPs led by Hazel Blears met PS(L) to discuss several aspects of HCV services. They were accompanied by Dr Graham Foster of St Mary's Hospital, London, who is also a member of C Change and Action for Hepatitis. He has since written to ask for further clarification of some issues.