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From : K M Paley
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Date : 1 May 1996

cc : Dr Bourdillon
Ms Sidonio
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Ms Pearce
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HEPATITIS C : EB PAPER AND BEYOND

1. I am attaching a SO/RL version of your draft, which subsumes advice I have received from colleagues in FPA FHS and follows further in-house discussion about PES handling.

2. As I indicated when we met the other day, I fear Karen Marsden's earlier prompting - together, perhaps, with the bruising you suffered from the renal review - may have coloured too strongly your very proper instinct to avoid precipitate action in case that should prejudice PES. I explained that there is a world of difference between the centre recognising, and exhorting a considered response to, a new/growing public health risk; and requiring/endorsing prescriptive action or specific funding on the part of the NHS. Whilst even after the meeting I was left uncertain about what was the authoritative clinical view of the most approporiate response to the HCV phenomenon, I am sure that, depending on the EB's view, it is quite possible to describe options which both respond to reasonable expectations of the Department and enable us to factor the pressure into PES. I hope the relevant redrafting makes clear how that is so. Please let me know urgently if anything remains unclear.

3. Having said that, it would still, of course, be possible to blow our chances of having HCV (assuming in the event it warrants it) pulling its weight in PES. The trick, as ever, will be in how we express ourselves in guidance or other public utterances on the subject, and on how we handle the Treasury.

4. The implications for you and I after the EB business has passed are that we still need to pursue the supporting detail (paras 6&7, and Annex A), even if we end up, as I think you indicated was quite possible, with a significant level of uncertainty as to prevalence. That work, and with overall NHS priorities in mind, will inform Ministers' judgement, when the settlement is finally reached, whether the cost of a given level of response can be deemed affordable within its terms.

5 Finally then, we had better get our foot in the Treasury door as soon as maybe, and I shall have to look your way for a draft to broach the subject. I feel sure that the relevant sentiments will fall out of various of the correspondence exchanged over the renal review. Good to think that that exercise may have had some useful outcomes after all !

K M PALEY
1/N/22
QH GRO-C

PAPER TO NHS EXECUTIVE BOARD - CONFIDENTIAL

HEPATITIS C: ISSUES FOR THE NHS

The problem.

1. The NHS is faced with dealing with an unknown but potentially significant number of patients who are infected with Hepatitis C, a blood borne virus which frequently causes chronic infection and can result in severe liver damage in some patients after a number of years. Establishing ~~precise~~ prevalence is difficult although the experience of other developed countries suggests that a considerable number of people are likely to be infected with this virus. The purpose of this paper is to seek the Board's views on:

(DN : see my covering note. The public health issue has to come first. I think that implies inverting the indents, as well as some drafting changes)

- what action is needed to further inform and better prepare the NHS to deal with the growing number of patients starting to come forward for testing and treatment (see paragraph~~s~~ ~~11~~ 9 - 11).

- the pace and priority of implementation of any action, recognising that action instigated by the centre will have to be begun within existing resources and without guarantee of additional funding commensurate with need (see paragraph ~~8 - 11~~ 12 - 13);

Background

2. There are similarities between hepatitis C and HIV. Both are blood borne, with one of the main sources of infection being needle sharing amongst Intra Venous Drug Users (IVDUs). Although estimates vary, prevalence is estimated to be between 0.1 and 1% of the population. By way of comparison, in the US, there are an estimated 3.5m with chronic hepatitis C which is roughly 1.2% of the population. Further information on prevalence is set out at Annex A.

3. The licensing of Alpha Interferon for the treatment of hepatitis C in January 1995 has drawn attention to the disease and was one of the reasons why the "Lookback" was set up (see paragraph 4 below). This raises many of the same issues that the more recent licensing of Beta Interferon raised as to possible resource implications and the need to satisfy public demand; the handling of the introduction of new and expensive drugs is the subject of a current submission to Ministers. **(DQ : I thought Dr B questioned this analogy - I note his proposed revise avoids making it. Colleagues in FPA FHS here support keeping in the reference to the submission on new and expensive drugs. I believe PC-Prescribing have suggested annexing that to this paper. We'd go along with that).**

Work in hand.

4. The Department/NHS Executive have the following programme of work in hand to deal with the virus:

- The "Lookback" of blood transfusion recipients infected with hepatitis C prior to the introduction of screening for Hepatitis C in September 1991. There are thought to be approximately 3000 recipients of infected blood who are still alive and they are currently being traced; Ministers have given assurances that these patients will be tested and treated.

- Support for the voluntary sector who are working with patients who are already infected or at risk of infection. Section 64 grants are awarded to the British Liver Trust, Mainliners and the Haemophilia Society specifically for work related to hepatitis C.

- The MRC and NHS are taking forward research on the basic science and treatment effectiveness issues. The MRC is considering a proposal to address the effectiveness and cost-effectiveness of Alpha Interferon. Funding of £1m has been identified by the Department for research into prevalence, transmission routes and the natural history of the disease.

Pressures

5. There are increasing pressures on the Department/NHS to address this disease:

- The Advisory Council on the Misuse of Drugs are pressing the Department to issue further advice to drug clinics and drug users warning of the dangers of HCV to reduce the spread (cf HIV). (Guidance was issued to health authorities last year on drug misuse services which referred to the high prevalence of hepatitis C amongst injecting drug users and former injectors. This asked health authorities to review prevention programmes.)

- The voluntary organisations are lobbying the Department for additional resources for this group of patients and for publicising how it can be prevented. There is pressure for compensation from the Haemophilia Society for those infected with hepatitis C through the use of blood products prior to 1985. Approximately 3000 haemophiliacs are thought to be infected who are not covered by the HIV compensation scheme.

- Some clinicians are pressing for ring-fenced resources for the cost of Alpha Interferon. There have already been some disputes over funding since the cost of treating each patient is high - some £2-5000 **[DQ : per year/course/lifetime supply - which ?]** depending on the patient's compliance and response and how and when it is administered.

~~Resources~~**Costs**.

6. The main potential costs to the NHS of handling Hepatitis C comprise:

- research

- manpower, both medical and non-medical
- linked to the above, the cost of providing counselling
- Alpha Interferon and other drugs including Ribavarin.

Alpha Interferon is not indicated for prescription by GPs because of unpleasant side-effects and because higher compliance is reported to be achieved when care is managed in the acute sector. This is therefore where any costs should fall. However, there is anecdotal evidence that some GPs are being drawn into 'shared care' arrangements in order to shift the cost to the FHS Drugs bill. This needs to be vigorously resisted (see para [new] 11 below).

7. Wessex Institute of Public Health have prepared some expenditure projections for alpha interferon as part of their work on assessing the cost implications of new technology. They have identified this as one of the major potential new pressures on the NHS in 1997/8. If prevalence is in the upper range of our estimates, this is likely to increase over the next decade or more.

Alpha interferon for hepatitis C: Expenditure increases in 1997-98 on 1996-7 to meet incident/prevalent need England NHS 1994-95 prices		
Low estimate	Middle estimate	High estimate
£9m	£30m	£51m

The range reflects uncertain prevalence, take up and duration of therapy. The middle estimate reflects the average of 0.05% and 0.2% prevalence, 50% initial response to therapy and 10% take up.

Main issues for decision:

(i) Need for public health information:

8. There is a need for clear and comprehensive public health information similar to publicity on HIV/AIDS. The objective is to stop needle-sharing and other high risk behaviour and raise awareness of the possible consequences of infection. This ~~will inevitably encourage~~ is likely to lead to more people ~~to~~ coming forward for testing and, where appropriate, treatment which will add to existing pressures on specialist services which are already thought to be fully stretched. Although it will be some time before we can estimate the scale of the problem, there is evidence of [**DQ : should we not cite or try to quantify - or is it mainly just anecdote ?**] patients ~~are~~ starting to come through in sufficient numbers to put pressure on the service. Some specialist hepatologists have told us that hepatitis C now represents 2/3 of their workload. Even though they know that Alpha Interferon will not be effective in all the patients treated, the feeling amongst [**DQ : 'all'; 'some' ?**] hepatologists is that there is sufficient evidence of clinical effectiveness to justify prescribing it to all *patients who may benefit* [**DQ : does this concept need explaining - perhaps a X reference to Dr B's new para 3**].

~~10~~ 9. One approach would be to recognise that this is just one of many pressures on the acute services and that giving priority to this rather than other specialties is not sound policy. Simply in terms of value for money, there may be better candidates for additional resources. *However, there is a public perception as well as a Ministerial commitment that those infected through NHS treatment should be treated. Distinguishing between people infected in this way as opposed to other transmission routes such as drug misuse would be highly contentious* **(DN : though I see where this argument leads I found the logic a bit strained. I would recommend simplifying to something along the lines of 'on the other hand, the NHS can't be seen to be backsliding on its PH obligations.)** Similarly, appearing to be ~~W~~withholding treatment on cost grounds is politically unacceptable, particularly given the wide range of people who may be at risk (eg: health care workers, renal patients, haemophiliacs and people who injected drugs some 20 years ago, perhaps on a one off basis, who are only now manifesting signs of liver damage). ~~**Officials recommend that giving up what is thought to amount to a strong claim for extra resources is a sufficiently important issue for Ministers to be asked for their views. The Board is asked for views as to whether this is the best way forward.**~~

(ii) Need for ~~purchasing and clinical~~ guidelines.

1~~1~~0. ~~One~~ Another option would be for the Department to issue advice on how to address the problems of testing, counselling and treating patients who may be infected. The Home Office have already issued guidance to the **[prison medical service - DN is that the right name?]** calling for prisoners to be tested and treated if they are infected and emphasising the need for prevention. The Task Force on Drug Misuse is about to publish a report which will recommend that action is needed to raise the profile of this disease **[DN Mr Dunlevy to confirm/elucidate].** Issuing guidance would have the advantage of satisfying the public, the profession, the Advisory Council on the Misuse of Drugs and the voluntary sector that we are raising awareness of this disease and encouraging purchasers to tackle it locally. Good practice guidance of this kind, suitably worded, would avoid any presumption that purchasers or providers should reprioritise or increase actual or relative spending on the tackling of hepatitis C infection.

1~~2~~1. **The Board is also asked whether the Department/Executive should produce purchasing guidelines and (with the profession) up-to-date clinical guidelines on treatment.** This is consistent with the recommendations to Ministers in the submission on clinical guidelines for major new drugs [dated - latest draft 22.4.96] and would help to prevent attempts at cost shifting to the FHS Drugs bill. (although Alpha Interferon is not new in that sense, the extension of its licence to treat hepatitis C has increased pressure for departmental action) and makes it difficult to justify a do-nothing approach, raising the possibility of litigation in the future by patients who could claim that their condition could have been prevented by early treatment. Issuing clinical and purchasing guidelines, however, implies a new signal about the relative priority to be attached to treatment, and in the current climate of serious strain on

acute services generally that at worst, and ultimately, the consequence might impact on the quality of other services.

Resource implications

~~9~~12. Although public health priorities must clearly be the first consideration, any new pressure on the NHS of the potential scale forecast by WIPH would obviously be a prime candidate to cite in the PES round. However, if we ~~intend to raise this as a pressure in this or future Survey discussions, it is essential that we do not say anything publicly which indicates that we are looking for an exceptional response to the problem by the NHS or considering a policy change.~~ are to do so we risk falling over the PES convention that requiring the NHS to respond to new pressures or to extend the range of treatments offered before resources have been secured is deemed to be acceptance that this is affordable within the existing settlement, and thus off limits as a future PES issue. There is therefore a potential conflict between the Department's overriding responsibility for public health, compounded by growing lobby pressure for a more pro-active approach, and ~~the pressure on acute services generally in the NHS which suggest that we should flag this up as a new pressure.~~ conventional PES tactics. ~~We are reluctant to jeopardise what could be a strong negotiating position but are under pressure to take a more proactive stance from a public health point of view.~~

13. But [we believe]this is [clearly] not an issue which the NHS or the Executive can any longer duck or defer. To do so would merely be to invite further criticism for holding back up-to-date public health advice. It is also at least arguable that in the long run that would also make treatment more costly since prevention is cheaper as well as better than cure. **(DN : I take it you would subscribe to this ? But in a sense it's part of the exam question for EB - hence the [ ])** At the same time, PES is becoming increasingly a process in which spending departments are being dissuaded by Treasury from adopting a bottom up, item by item, costing approach. It is therefore in principle becoming more possible than perhaps in the past to marry a cautious but positive response to new pressures with a PES strategy which, while recognising that there can be no guarantee as to PES outcomes, nonetheless allows Ministers to cite issues as part of the range of pressures on the service which can properly be taken into account in survey discussions, whilst at the same time to be dealing with them actively and responsibly.

Conclusion.

~~13~~4. Our current line in response to pressure from pressure groups, such as Mainliners and the British Liver Trust, is that money is not allocated to support specific treatments or for specific segments of the population and that it is for health authorities to assess the health needs of their local residents and decide which services to purchase and where to place contracts. Hepatitis C is just one of a large number of growing pressures that can be identified on the acute services. This may, however, be a difficult argument to sustain given that there is a growing awareness of the virus, a growing public expectation about treatment which is likely to increase and the availability

of new drug therapy (stimulated to some extent by the "look back" exercise). The way in which the government tackled HIV infection is cited as a precedent since there are strong similarities and comparable arguments in favour of similar action. Purchasers generally are unlikely as yet to have identified Hepatitis C as a priority although there are some examples of good practice.

145. The Board is asked for its views on the issues raised in paragraphs 10 and 12 above:

- should we put a submission to Ministers asking whether they are willing to jeopardise our negotiating position for more resources with Treasury in order to fulfil our responsibility to publicise the dangers of hepatitis C infection more actively?

- should we draw up purchasing guidelines and clinical guidelines on treatment bearing in mind that if we do publicise the danger of infection as above, more patients are going to come forward for treatment, adding to the existing pressures on the NHS?

(DN : As at para 1 I think these indents should be transposed and made to reflect the changes indicated there. The first also needs to allude to the GPG approach, ie. the 'do something, cost nothing' option; the second to reflect the changes suggested above, but including the 'refer on to Ministers' bit.)

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