(114)

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DRAFT SUBMISSION ON HEPATITIS B VACCINE

I attach a copy of the revised draft of this submission which takes into account the comments made on both earlier drafts. The only substantial change has been the incorporation of material from Finance Division so that more explicit reference is made to the serious practical difficulties in financing purchase of the vaccine centrally.

GRO-C

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DRAFT SUBMISSION TO MINISTERS

AVAILABILITY OF VACCINE AGAINST HEPATITIS B

SUMMARY

Ministers may like to know that a vaccine against hepatitis B infection will be available commercially soon in the United Kingdom. This vaccine will be very expensive, in short supply for at least a few years and subject to competing claims from groups of individuals considering that they should have priority in its use. Decisions as to its purchase and distribution are therefore likely to create serious problems.

BACKGROUND

Hepatitis B infection is one of the major types of infectious jaundice. Infection with the hepatitis B virus may not give rise to any significant illness, and in those cases where illness does occur it is usually fairly mild, with complete recovery. However, a small number of patients may die during an attack, and a few others are left with chronic liver disease which may ultimately prove fatal. A certain proportion of patients become chronic carriers of the disease; they may be perfectly well but they have the virus in their blood stream and are able to infect others. The disease is unusual in that it is not spread by the more common routes of inhalation or ingestion but by direct contact with the blood or blood products of a sufferer or chronic carrier. It is also a sexually transmitted disease. In the general population, approximately one person in a 1,000 is a chronic carrier though the proportion is much higher in certain groups. The majority of these chronic carriers are perfectly fit and have never had any evidence of the disease.

Hepatitis B is fairly common, with about 1,000 cases a year being reported in England and Wales. Certain groups of people have an increased risk of contracting the disease, especially:

(a) Health care personnel and other workers (mainly in the public sector) who are exposed to the risk of contamination with blood from a carrier.

(b) Patients who are receiving regular treatment with blood or blood products.

(c) The sexually promiscuous, particularly homosexual men.

A vaccine has been produced commercially in the United States and an application for a licence in this country has been made and will probably be granted soon. The manufacturers have asked Supplies Division if the UK would like to put in a bid for a supply of the relatively small amount of vaccine likely to be available. If the offer is not taken up the manufacturers might decide not to market the vaccine in this country while supplies are scarce.

PRIORITY GROUPS

There is agreement that this vaccine should only be given to certain categories of people, but views as to these categories are certain to vary considerably. A number of articles by experts in this field have been appearing in medical journals recently, each suggesting somewhat different but often rather large categories for priority immunisation. A Joint Working Group of the Advisory Group on Hepatitis and the Joint Committee on Vaccination and Immunisation (JCVI) has been considering priority groups, and their recommendations will shortly be considered by the JCVI. A summary of these recommendations is attached as an appendix to the submission; in general various groups have been allocated to two levels of priority - category A (higher priority) and category B (lower priority). Supplies of vaccine which are likely to be available in the next one to two years will only cover category A at best and may even fall short of this.

THE VACCINE

The vaccine which is about to be licensed for use in the UK is manufactured in the USA, and has been shown to be safe and very effective in extensive clinical trials. It has however not been used on a large scale in any country and further experience is needed before a final assessment can be made of its safety and effectiveness. The manufacturers are now completing the production of a large batch of vaccine which will have to cover the entire world-wide demand. After this they will commence production of a second batch but this will not be ready for distribution for 15 months, or even longer if technical problems occur. If the United Kingdom does not obtain supplies from the first batch of vaccine, then there will be no opportunity to obtain more supplies for 15 months or more.

VACCINE RESEARCH

Pharmaceutical firms and research workers in this country and elsewhere are working on methods of producing the vaccine, either on lines similar to those used by the firm in the USA or using different techniques. It is too early to say whether this research will succeed in producing a much cheaper vaccine, but there is some possibility of success within the next few years. The Department has given considerable financial support to research in hepatitis B vaccines, and has recently given some money towards developmental work on a new British vaccine; it will be carried out at the Public Health Laboratory Service Centre at Porton Down.

NUMBERS

Some estimates of the number of individuals in the two priority categories proposed by the Joint Working Group have been made. For both categories there would be a certain number of people to be vaccinated initially, and thereafter a smaller number to be vaccinated each year to cover new entrants to these categories. The sub-totals for various groups within each category are shown in the appendix, but the grand totals for England and Wales are as follows:

CATEGORY A: 55,000 initially and 9,000 a year thereafter

CATEGORY B: 350,000 initially and 36,000 a year thereafter.

COSTS

The manufacturers state that the cost of a full course of three doses of vaccine is likely to be about £60, though if all supplies were purchased centrally there might be a saving of £5-10 per course. On the basis of £60 per course the costs of vaccine, for England and Wales only, are as follows:

CATEGORY A: £3.3 million initially and £540,000 a year thereafter

CATEGORY B: £21 million initially and £2.2 million a year thereafter.

These figures only cover the cost of vaccine; in the case of vaccinations performed by general practitioners a fee, which will have to be negotiated

but could be about £7.50 per course, might have to be paid. However, only a small proportion of vaccinations are likely to be carried out by general practitioners in the foreseeable future.

DECISIONS NEEDED

Decisions are needed on national policy for the use of this vaccine. Some of these decisions will be needed fairly soon as the manufacturers will need to know the likely UK demand within the next two months and also the JCVI will be sending advice about the use of the vaccine to Ministers after their meeting in April. There are a number of policy options open.

1. Ministers could decide not to purchase any vaccine, nor to support its use in this country, because of its high cost. This decision could be coupled with a commitment to continue to support the development of a cheaper British vaccine, and to review the decision if cheaper vaccines were to become available. It is undoubtedly possible to make a case for this line of action since the incidence of hepatitis B infection, even in the high risk groups, is comparatively low in this country (for example, an average of 57 cases a year in all health service staff). As the vaccine is so expensive, the cost of prevention is very high; possibly £25,000 to prevent each case of hepatitis, £500,000 to prevent each case of chronic liver disease and £3 million to prevent each death. But there would undoubtedly be serious criticism of such a decision by health service unions, professional bodies and doctors; also it would mean going against the advice of the JCVI.

2. Ministers could publish the JCVI advice but leave it up to individual health authorities and general practitioners to obtain supplies of vaccine and give it to the appropriate groups. This course of action would undoubtedly lead to protests from health authorities who would have to cover the costs of the vaccine from within their existing allocations, which are already fully stretched. It would also mean that there would be no way of ensuring that the vaccine only went to high priority groups and there would be criticism of this inappropriate distribution.

A further difficulty arises with both options 1 and 2. The vaccine manufacturers may decide not to market the vaccine in the UK if they do not receive a large initial order from central Government, so that the vaccine would be unobtainable. This would lead to all sorts of complaints and instances of individuals obtaining the vaccine at great expense and with great publicity from other countries.

3. The Department could purchase sufficient vaccine to vaccinate all the individuals in category A, or as much as the manufacturer is willing to supply if this were less. This is the course of action likely to be recommended by the JCVI, but it would cost up to £3.3 million and it would require the setting up of an organisation framework within the Department or PHLS to make sure the supplies were allocated to the right groups. There would be financial implications in the staffing of such an organisation and some doctors would be critical of the limitations on their freedom to prescribe. But the majority would probably support this system as being the best way to ensure rational distribution of a scare resource.

It has to be realised that there are no unallocated resources to meet this requirement in the 1982/83 estimate and the money could only be found from savings within the existing centrally financed services.

4. The decision to purchase the vaccine could be postponed until the next batch of vaccine came onto the world market in about 15 months time. This could be defended on the grounds that there was inadequate vaccine to cover even the highest priority groups this year, and it would also allow time for consultation within the various groups involved and to allow the setting up of a vaccine distribution framework. It would then be possible to make a bid under the 1983/84 PESC for the funds to purchase the vaccine, though the proposal would have to compete with other programmes in the 1983/84 PESC and as Ministers are aware centrally financed services are already over committed in regard to existing priorities.

The disadvantage of this course of action is that the vaccine would be unavailable in the United Kingdom at a time when other countries were already using it. If technical problems occurred with the manufacture of the next batch of vaccines, it might be substantially longer than 15 months before further supplies could be obtained.

APPENDIX

DRAFT SUMMARY OF INTERIM RECOMMENDATIONS ON THE USE OF HEPATITIS B VACCINE

CATEGORY A - VACCINATION STRONGLY RECOMMENDED

Health Care Personnel

1. Personnel involved in direct contact with patients in residential institutions for the mentally subnormal.

   28,000 initially, then 5,000 a year.

2. Personnel directly involved in patient care working in units giving treatment to known carriers of hepatitis B infection.

   1,000 initially, then 250 a year.

3. Personnel directly involved in patient care working in centres regularly performing maintenance treatment of patients with blood or blood products.

   1,000 initially then 250 a year.

4. Laboratory workers in Hepatitis Reference Laboratories.

   100 initially then 20 a year.

5. Laboratory and production workers in blood product laboratories.

   100 initially then 20 a year.

6. NHS and academic personnel on temporary secondment to work in areas of the world there there is a high prevalence of Hepatitis B infection, if they are to be directly imvolved in patient care.

   500 initially then 500 a year.

7. All staff working in reception centres for refugees from S.E. Asia who are involved in direct personal care of the refugees.

   100 initially then 25 a year.

Patients

1. In-patients in residential institutions for the mentally subnormal.

   46,000 initially, none thereafter.

2. Patients undergoing renal dialysis.

   5,000 initially then 1,000 a year.

Family contacts

1. Close family contacts of patients in mental subnormality institutions.

   138,000 initially then 4,500 a year.

Other groups

1. Members of the ambulance service and rescue services.
2. Prison officers.
3. Prisoners.

   } 100,000 initially then 20,000 a year.

4. Male homosexuals.
5. Drug addicts.

   } 50,000 initially then 10,000 a year.

Patients

1. Patients on first entry into residential institutions for the mentally subnormal.

   16,000 initially then 1,500 a year.

2. Patients receiving regular therapy with blood products or other products capable of transmitting hepatitis B infection.

   6,500 initially then 500 a year.

Family contacts

1. The spouses or other sexual contacts of carriers of hepatitis B in the following circumstances-

   (a) If the carrier is not HBe antibody positive.

   (b) If the potential vaccinee is neither a carrier of hepatitis B nor HB antibody positive.

   (Note: Close family contacts of individuals suffering from acute hepatitis B should be treated by passive immunisation with specific immunoglobulin.)

   1,000 initially then 1,000 a year.

CATEGORY B - INDIVIDUALS WHO SHOULD BE OFFERED VACCINATIONWWHEN SUPPLIES BECOME FREELY AVAILABLE

Health care personnel

1. Personnel working in units where the patient population has a high prevalence of hepatitis B infection. This recommendation applies to all staff in direct contact either with patients or samples from these patients.

   2,000 initially then 500 a year.

2. Personnel directly involved with patients attending dialysis centres.

   2,000 initially then 500 a year.