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Dr J Craske
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J/S240/78/7

27 July 1978

Dear Dr Craske

STUDIES OF THE EPIDEMIOLOGY AND CHRONIC SEQUELAE OF FACTOR VII AND IX ASSOCIATED TRANSFUSION HEPATITIS IN THE UNITED KINGDOM

At the meeting of the Small Grants Committee on 20 July 1978, conditional approval was granted to the above application and for your request for an additional £2,000 to cover the cost of a limited survey, as set out in your letter of 30 June 1978.

The Committee asked me to pass to you certain specific comments of which, they considered, you should take account and I was asked also to let you have a number of more detailed comments contained in the report from one of the referees consulted.

Epidemiological surveys of post-transfusion hepatitis are difficult because of the many possible complicating factors, some of which might be avoided if these comments were noted. It would certainly be right to get the Haemophilia Centres Directors to notify cases as they occur and to adhere strictly to any procedures specified by those conducting the survey. Immediate investigation of queries could provide for the retrieval of missing information or explain misunderstandings in a way which would be possible in retrospect. Personal visits to the patient and GP might well be necessary, despite the amount of time this could take. If this is to be done at the Centres, uniformity of procedure would be very important.

Patients are likely to have received concentrates from different batches and it it recommended that participating Centres undertake to use a given make of concentrate, or at the most two makes, that each patient will be given material from one make and that of this make only bottles from one batch will be used. This would simplify analysis and presentation of results but, more important, would increase the chances of detecting icterogenic material with a greater degree of certainty and permit the withdrawal of icterogenic bottles. There are obvious limits to the application of these proposals but it would be well worthwhile applying them as far as possible. Their adoption would necessitate the co-ordinated purchase and distribution of commercial material and also the use of rules of procedure in Haemophilia Centres which should in any case strictly follow uniform procedures.

Is the sub-zero storage of specimens adequate? Has a uniform and permanent method of labelling and a convenient form of storage been devised so that specimens can be retrieved and identified unequivocally?

In the follow-up of chronic sequelae, would informed consent be obtained from the patients and from the two groups of controls? This seems to be necessary as they would be undergoing examinations and giving specimens and as members of their families might be involved.

In this context, is it adequate to rely on laboratory investigation and clinical follow-up by someone who is not very experienced clinically in the field of liver disease? The assessment of clinical liver damage may well be difficult and laboratory investigations do not always give clear-cut results.

It is stated that patients in groups B and C found to have elevated transaminases will undergo repeat tests six months later. Is this interval too long? If there is any possibility that some laboratory tests have to be carried out in places other than Oxford, assurance of uniformity to technique and quality control would be important.

In view of the proposed starting date set down on your application, it would be helpful if you could let me have, in the near future, your comments on the points raised by the Committee and how, if incorporated, they would effect the research design.

Yours sincerely

GRO-C

R A KINGHAM
Small Grants Secretariat