APPENDIX D(ii)

Public Health Laboratory Service

PHLS

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Our ref JC/PH Your ref

OXFORD HEPATITIS B VACCINE TRIAL

This trial has been carried out in 23 patients who were given three doses of 20 micrograms of hepatitis B vaccine subcutabeously at 0, 1 and 6 months, and 10 normal subjects at the Haemophilia Centre who received the vaccine intramusuclarly with an identical injection schedule. All these subjects have been found to be negative for anti-HBs and anti-HBc prior to immunisation using haemagglutination tests. However, subsequent testing using AUSAB radioimmuno assay showed 9 subjects to be positive for HBs Ab before vaccination. All subjects were followed up clinically and serologically for at least 9 months.

Results: It has not proved possible to obtain sufficient numbers of staff to take part in the trial to reach statistical significance as a control group compared with the patients. The results show, however, that there is no significant difference between the immune response in those who received vaccine subcutaneously (patients) compared with those who received the same vaccine intramuscularly. The results have therefore been pooled.

The main finding is that the age of the recipient of the vaccine has a profound effect on the degree of immune response whether patient or a member of staff. The lower section of the accompanying table shows the relationship of the age of the recipient of the vaccine to the degree of immune response obtained. In subjects 40 years or over, 6 out of 11 (55%) produced an adequate response compared with 11 out of 13 (85%) who were less than 40 years of age. With the proviso that the numbers here are small and that further observations are needed, this means that 45% of persons 40 years or over who received vaccine failed to produce an antibody response which would indicate that they were immune to hepatitis B.

The main significance of this finding is that persons less than 40 years of age produce a good response in general to hepatitis B vaccine and that vaccine can be recommended for these patients and, therefore, one can be fairly confident that a degree of protection will be obtained. In persons over 40 it will be necessary to follow up anybody immunised at 6 and 9 months to ensure that the immune status after immunisation is known as this might effect the clinical management of the patient. Directors should therefore bear this in mind when considering the immunisation programmes they may be contemplating amongst their own patients.

I will be interested to know if similar results have been obtained in older patients or staff in other Haemophilia Centres.

GRO-C

J. Craske
Consultant Virologist

46/229

Public Health Laboratory

1810(e)

OXFORD HEPATITIS B VACCINE TRIAL

33 SUBJECTS COMPLETED 3 INJECTIONS WHO WERE FOLLOWED FOR 9 MONTHS

	PATIENTS 23	NORMAL SUBJECTS 10	
IMMUNE	9	0)	PRE-IMMUNISATION ANTIBODY SCREEN ANTI-HBc and ANTI HBs
NOT IMMUNE (negative both antibodies)	14	10)	
ANTI-HBs RESPONSE (>50 miu's/ml)	10	7	
NO RESPONSE	4	3	

RELATIONSHIP OF AGE TO IMMUNE RESPONSE

	<40 years	>40 years
NUMBERS	13	11
RESPONDERS	11	6
NON RESPONDERS	2	5

46/230