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SNBTS HQ UNIT BRIEF REPORT

HEPATITIS AND THE TRANSFUSION SERVICE:

STATUS REPORT AND PROPOSALS

FOR DISCUSSION BY SNBTS DIRECTORS

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March, 1981

## INTRODUCTION

This brief Report considers two aspects only of the interface between the Blood Transfusion Services and hepatitis. They have been selected because of two current events: the imminent issue of the Jenkins Report, and a recent SNBTS Workshop on Hepatitis Immunoglobulin. The author is particularly grateful to Mr A Barr, Dr R Crawford, Dr R Hopkins, Dr D B L McClelland and Dr A Welch for the opportunity of extensive discussions.

## JENKINS REPORT

(a) It seems certain that more formal requirements will be made with regard to quality assurance programmes for HBs-Ag testing in RTCs.

### It is proposed that:-

- (1) One Centre be nominated as the SNBTS Q.A. (Hepatitis) Reference Centre, and that this Centre establishes and issues the necessary protocols and reagents for effective Q.A.
- (2) The West of Scotland Centre be nominated as the SNBTS Q.A. (Hepatitis) Reference Centre.
- (3) In discharging this service a small Advisory Group is formed which would include one member from 2 other Regional Centres, appointed by the Directors.
- (4) The Reference Centre pays particular attention, in the first instance, to the following:-
  - (i) The issue to all RTCs of a panel of difficult (low antigen content) sera 4 times a year.
  - (ii) The establishment of 'on-line' sensitivity monitoring systems in each RTC.
- (5) The Reference Centre would issue an Annual Report to the SNBTS Directors, via the HQ Unit.

(b) There is likely to be a recommendation that some form of formal training programme for staff involved in antigen tests is established.

### It is proposed that:-

- (i) For the time being training be continued and confined to local arrangements in each RTC.
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- (ii) The question of a national SNBTS training programme be left open for further review soon after the receipt of the first Annual Report of the Reference Centre.

#### ANTI-HEPATITIS A VIRUS (HAV) IMMUNOGLOBULIN

With the inevitable increase in access to assays which assess the immune status (antibody status) of contacts to HAV and the knowledge that many individuals are not immune, a demand for specific immunoglobulin to HAV will soon emerge. Fortunately, this will not prove to be an excessively difficult task, particularly in Scotland, because the incidence of donors with anti-HAV is considerably higher than those with anti-HBs.

#### It is proposed that:-

- (i) The SNBTS approach the MRC Blood Transfusion Committee and request they consider establishing a clinical trial on the efficacy of specific anti-HAV immunoglobulin in non-immune contacts.
- (ii) That the SNBTS offer to supply a batch of anti-HAV immunoglobulin for such a trial.
- (iii) In anticipation of this trial and future requirements for routine use in Scotland, steps be taken to invite the Edinburgh Centre to co-ordinate the collection of specific high titre hyperimmune plasma, as soon as possible.

#### ANTI-HEPATITIS B VIRUS (HBV) IMMUNOGLOBULIN

It is the view of the author that the demand for anti-HBs immunoglobulin is likely to escalate considerably in the next 5 years. There is sufficient evidence to show that a double dose regime will be required for routine prophylaxis after accidents, that the reporting (and appropriate action) of such accidents will increase, that neonatal use will increase and that in the event of a failure of interferon to be of value in acute (HBs-Ag) hepatitis, then trials of large (and sustained) doses of anti-HBs will be considered.

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It is not possible to quantitate the likely future demand at the present time in view of the severe shortage of suitable donors, but it seems reasonable for the SNBTS Directors to consider the following proposals:-

- (i) Every effort should be made to harvest the maximum amount of specific plasma possible and to encourage the development of clinical approaches which would permit the optimal use of a scarce material.
- (ii) To this end it is proposed that:-
  - (a) Full anti-HBs screening of all donors in each Region is completed as soon as practicable.
  - (b) Subsequent screening be confined to all new donors.
  - (c) The cut-off for the anti-HBs titre should be adjusted to give 3 bands: 1-5 i.u./ml., 6-10 i.u./ml. and > 10 i.u./ml.
- (iii) The SNBTS Q.A. (Hepatitis) Centre provide anti-HBs standards to cover the required ranges and liaise with each RTC with a view to introducing a standard SNBTS anti-HBs screening test.
- (iv) PFC should aim to produce a vial content (5 ml.) of anti-HBs of 500 i.u.. However, consideration should also be given to the introduction of a 250 i.u. vial for low risk cases.
- (v) Serious consideration be given to the introduction of immunising volunteers (? staff in Renal Units), followed by plasmapheresis, using an acceptable vaccine. To this end Dr Cash would invite Professor Ari Zuckerman to give his opinion on the safety of current vaccine preparations, and invite the SHRD to consider the legal cover of donors immunised with such a vaccine.
- (vi) SNBTS studies be established in which free anti-HBs levels are compared in low risk accident cases receiving 500 i.u. and 250 i.u., respectively. Once completed, consideration might be given to extension to known risk subjects (needle stick accidents).
- (vii) Drs Crawford and McClelland be invited to explore the position with regard to the use of specific immunoglobulin in infants born of mothers who are chronic HBs-Ag carriers.