

-M Thornton ✓

EDINBURGH AND SOUTH EAST SCOTLAND BLOOD TRANSFUSION SERVICE

PREPARATION FOR INTRODUCTION OF HTLV-III AB SCREENING MEETING

19TH AUGUST 1985.

PRESENT: Dr D B L McClland ✓
 Mr R Wilson ✓
 Mrs M Thornton ✓
 Dr J Gillon ✓
 Dr R Barclay

Copy to Participants and to
 Dr P L Yap
 Dr F Boulton
 Sister J McDonald

[ITEMS IN BRACKETS ADDED AFTER MEETING - DECISIONS FROM DIRECTORS' CO-ORDINATING GROUP 20TH AUGUST 1985]

	<u>ACTION</u>
1. <u>KIT SELECTION FOR SEBTS</u>	
<u>AGREED</u>	
i. We will complete evaluation on 1000-2000 tests of Organon and Wellcome before decision .	RW
ii. NBTS trial false positive information will be reviewed.	RB
iii. Initial evaluation will be in a 100 - sample panel provided by GRB from plasmapheresis donors with pos controls.	RB
iv. BMcC will advise JDC that SNBTS should not opt for supplies from a single source .	BMcC
v. RW to contact Dr Taylor, PHLS Colindale + Dr Peutherer about supply of pos controls. BTS Law already have pos controls.	RW
vi. Required kits for evaluation to be ordered on Donor Testing Cost Centre.	RW

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- ACTION
- [vi. FUNDING IS NOW AVAILABLE FOR KITS FOR FULL TESTING FROM MID SEPT TO END OF F.Y. SO ORDERS MAY BE PLACED IMMEDIATELY AFTER DECISION ON SELECTION. NOTIFY JOHN FRANCIS WHEN ORDER IS TO BE PLACED.] RW
2. PHASING OF IMPLEMENTATION
- AGREED
- i. After the evaluation above we move directly to testing of incoming donation samples.
- ii. Target date for starting routine testing 23rd September, 1985. [OFFICIAL "D DAY" WILL BE DURING OCTOBER]
- Not Discussed - NB For Next Meeting
- Testing of existing inventory - Red units, platelets FFP, Cryo.
3. SPACE, STAFFING
- An options report to be provided for decision by BMC as soon as possible. [FUNDS MAY BE AVAILABLE FOR ALTERING ACCOMMODATION. ESTIMATES TO MISS CORRIE AS SOON AS POSSIBLE.] RW
4. EQUIPMENT
- AGREED
- i. Major hardware may be obtained from kit suppliers as a package deal or [PURCHASED OUTRIGHT - FUNDS AVAILABLE. A PRICED LIST HEADED "HTLV-III TESTING EQUIPMENT LIST - SEBTS" MUST BE WITH MISS CORRIE BY 30/8/85 IF OUTRIGHT PURCHASE IS REQUIRED]. RE/BM
- ii. Minor items - obtain as soon as possible. List from GRB to RW. GRB
- iii. Special disposables - sample storage etc. Obtain as soon as possible.

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ACTION5. QA ARRANGEMENTSAGREED

i. Regular QA must be built-in from the start.

ii. BM to consult W. Scotland and make outline proposal to virus lab directors at 27th August meeting.

BM

iii. AGREED

i. Initially we require a coded panel from a central source, with the results supplied to a named senior person for immediate assessment of performance, plus central reporting and analysis.

BM propose
on 27/8/85

ii. ASAP, a daily blind QA system as for HBsAg testing.

iii. Scheme run, if possible, by an independent Non-BTS Lab.

6. CONFIDENTIALITY OF RESULTS IN THE LABAGREED

i. All staff to be informed of extreme importance of confidentiality issue.

RW/BM
Co-ordinate

ii. Laboratory procedures to ensure that the link between test results and donor i.d. is made exclusively by nominated service staff in the Testing Lab.

RW

7. PROCEDURES (SOP) FOR REPORTING POSITIVES AND ENSURING NECESSARY ACTIONS ARE COMPLETED.AGREED

i. Should be based as far as possible on existing Hepatitis B reporting/action procedures.

ii. Written SOP must be prepared and approved by JG before routine testing starts.

RW JG

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ACTION8. NATIONAL SURVEILLANCE OF TEST RESULTS

Dr Gunson's form was accepted.
BMcC to write to HG.

BMcC

9. PRE DONATION INFORMATION TO DONORS

- i. Draft by MT + JG appended. Differs from JDC proposals in its reference to informing "own doctor".*

*[THIS IS NOT ACCEPTABLE TO RTD'S. FINAL DRAFT OF A NATIONAL LEAFLET NOW BEING PREPARED.]

- ii. Consent. MT + JG advise direct consent to testing is not necessary or desirable. Recommend signature that leaflet has been read and intensive efforts to get full coverage of donors.
[AGREED BY RTD'S]

iii. Distribution of new leaflet:

- all call up letters.
- with publicity to all work place session organisers.
- hand out + available at all sessions.
- blow up on display at all sessions.
- NOT another total mail shot at present.
[AGREED BY RTD'S]

10. ACTION - CHART FOR MANAGEMENT OF RESULTS

The following alterations were agreed to be desirable.

- i. In cases where initial screen test is reactive but repeat screen test is negative on pack + tube:

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ACTION

ACTION: If possible repeat test on initial pack + sample using an independent test.

- if negative, don't mark card.
- retain record in testing lab of all such initial screen positives.
- check all positives against this record.
- once computer data base is operative, all ISP donors can if necessary be flagged.

[AGREED BY RTD'S]

RATIONALE: - These donors need to be clearly labelled as NEGATIVE.

- Flagged record cards, in our system, would be a confidentiality problem since we don't, at present have any suitable "laboratory file" category.
 - No additional action can be taken by the testing lab on receiving a sample from a donor known to be previously ISP: the approved protocol merely requires a standard screening test.
 - The new proposals still permit detection of the "biological false positive" problem.
- ii. In cases where the screening test is all screens positive but confirmatory tests are negative

ACTION

- Suspend donor
- Counsel
- Test new sample.

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ACTION

RATIONALE

- These donors should not continue to donate and it is appropriate to counsel them on the "false positive" test as early as possible.
- The numbers will be very small.

11. Next Meeting, Friday 30th September at 10.00 a.m. - Seminar Room.

Done