0021

Implications for SNBTS of introduction of anti HCV testing

1 LABORATORY WORKLOAD (including comfirmatory testing)

2 DONOR MANAGEMENT

a Administration
b Informing donors

3 LOOKBACK

4 PUBLICITY

5 COSTS/STAFFING IMPLICATIONS

1 LABORATORY WORKLOAD

a Routine Testing

Assume daily workload equivalent to other EIA tests (HIV, Hepatitis B).

Calculate numbers of specimens to be repeated from SNBTS evaluation (report awaited).

Use existing procedures to notify Medical Officer responsible for donor care.

b Confirmatory Testing

No independent confirmatory test exists at present.

Samples from donations giving repeatably reactive results should be sent to a reference laboratory for independent confirmation of the results (see 2a below for numbers).

Reference lab should be asked for hepatitis B markers.

Serum sample should be sent to Clinical Chemistry for liver function tests (expecially ALT). Where this is impossible, SNBTS should consider carrying out ALT on reactive samples. Data recording systems will need to be developed for this procedure.

2 DONOR MANAGEMENT

a Administration

Initial results of SNBTS evaluation suggest a repeat reactive rate of approximately 0.5%. Anticipated number of 'positives' for each region:

	n/year	n/month	n/week	n/day
WBTS	750	64	16	3
SEBTS	400	33	8	1.5
EBTS	150	12	3	< 1
NEBTS	200	16	4	< 1
NBTS	100	8	2	< 1
SNBTS	1,600	133	33	> 5

ie WBTS will have the equivalent of 2 'new patient' clinics each week, SEBTS one and the other regions at least one clinic per month. Efficient systems are needed for:

1 Handling "pending" results after donor record has been married to results and "medical hold" status created.
2 Marrying confirmatory results to record 1
3 Recalling donors
4 Marrying results from new specimen with previous record
5 Informing GP
6 Arranging referral/follow up as necessary
7 Ensuring donor is permanently off service.

Lookback is considered in 3 below.

3

b Informing donors

It is SNBTS policy to inform donors of significant test results in person.

Where the significance of results is uncertain and the potential for harming donors is thought to outweigh the advantages of informing them, the principle is established that donors can remain on service but held in a "medical hold" category which ensures that donations cannot be used until the significance of the results is clarified.

WE NEED TO DECIDE URGENTLY WHETHER WE SHOULD DELAY INFORMING DONORS UNTIL MORE IS KNOWN ABOUT THE SIGNIFICANCE OF A POSITIVE ANTIBODY TEST.

The 2 most important questions to be answered are:

1 Is the donor infectious?
2 What is the likelihood of chronic liver disease?

The answers will come from lookback studies and large scale clinical studies respectively. Some results should be available within a year. Can we sit on the above numbers for that length of time? Would we be able to cope with the backlog if a decision was then made to inform all positive donors?

Advantages of not informing

1 Avoids need for counselling/ follow-up

2 Avoids risk of psychological morbidity in donors

Disadvantages of not informing

1 Difficulty in maintaining donor records

2 Backlog of donors who may eventually have to be told

3 Ever-expanding laboratory workload (isolation and destruction of packs etc)

4 RISK OF ERROR - "missing" a donation from a donor previously known to be positive

Advantages of Informing

1 Possibility of medical intervension to prevent progressive disease

2 Prevention of infecting donor's contacts

3 Availability of epidemiological data

Disadvantages of Informing

1 Donor psychological morbidity

2 Counselling/follow-up workload

ASSUME SNBTS POLICY IS TO INFORM

How? 1 Letter to donor with information, advice, and request for GP's name and address?

2 Letter to donor offering interview?

1) is not used by SNBTS and is intrinsically unsatisfactory.

2) is in line with current procedures, and is our inescapable duty. Donors should receive a standard letter within 2-3 weeks of donation requesting their attendance for a further sample to check test results. This initial interview should be conducted as a first counselling/medical assessment.

The MO should have:

a Full donor record
b Reference lab results, including hepatitis B markers
c ALT etc

A standard interview format should be developed in each centre. MO's will need specific training so that they

a provide appropriate advice and reassurance

b obtain enough information to allow a consultant decision on the need for referral and/or follow-up.

It is recommended that directors should discuss the implications of the numbers for referral with the relevant clinicians.

3 **LOOKBACK**

The need to trace, test (and inform?) recipients should not be in dispute. However, the large numbers involved place a major constraint on the feasibility of lookback procedures. The system used for HIV lookbacks, ie tracing recipients in reverse chronological order until a negative is found (up to 5 years before index donation), will be too unwieldy to be applicable.

I favour a system whereby a standard letter would be sent to the clinicians of all patients identified in the lookback.

The administration of this should be as automatic as possible:

ie donor identified
list of previous donation numbers -- QA officer
list of recipients/products to PFC -- donor MO
PFC informed
Donor office send standard letter (reference - [donation number], our reference [registration number]) to consultant in administrative charge of the ward or peripheral blood bank concerned, unless the identity of the relevant consultant is known. Letter requests copy of recipient's test results, or GP's name and address of patient no longer attending.
Complete record stored

4 PUBLICITY

Stories appeared in national newspapers when the test was announced. Controversy was avoided by the openness of official comments and the fact that we are evaluating the kits.

When the starting date is announced a co-ordinated press release/media package should be handled by the NDPM.

Information for donors - national leaflet required (NDPM)
Consent - new wording should suffice.

5 A. COSTS

Assuming £2 per test (generous, to allow for repeats, inflation etc), total cost to SNBTS will be approximately £640,000 per annum. Extra computer hardware/software for handling results may be necessary.

B. STAFFING IMPLICATIONS

1 Laboratory

WBTS and SEBTS are likely to require one additional MLSO. Other regions may need some additional MLSO time.

2 Donor Administration

WBTS and SEBTS will need a clerical officer to handle results/lookbacks/letters/appointments/records. Other regions likely to need at least a part time CO.

3 Donor Counselling/Follow-up

WBTS and SEBTS may need a full-time MO to undertake counselling/follow-up and supervision of lookbacks and records. Some additional MO time will be required in the other regions.

SUMMARY

Systems already in place for Virology testing and management of donors can be exploited to allow introduction of the new test with minimal alterations to existing procedures. Because of the large numbers of positive donors expected, and the implcations of "lookback" procedures, extra staff will be required in all regions proportionate to the numbers of donors attending. The NDPM should be given a clear remit to develop an appropriate publicity strategy.

JG/AB
9/89