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Strasbourg, 16 January 1987

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Agenda 12.3

COMMITTEE OF EXPERTS

on

BLOOD TRANSFUSION AND IMMUNOHAEMATOLOGY

10th meeting

Rome, 19-22 May 1987

SYNTHESIS OF REPLIES TO THE QUESTIONNAIRE

ON NON-A NON-B HEPATITIS

Secretariat Memorandum

prepared by
the Directorate of Social and Economic Affairs

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NOTE

The Secretariat has collated on the attached tables the replies received from members of the SP-HM to the questionnaire on Non-A Non-B hepatitis.

Although some replies are still missing, it can be seen from the tables that the issue is in general being given careful consideration by most blood transfusion services; study groups have been appointed and research projects are underway to assess the value of "surrogate" testing. The general impression is that the NANB hepatitis incidence is considered rather low, notwithstanding its variance from region to region: this casts doubts on the cost/effectiveness of the introduction of such tests. Some countries, however, indicate that these tests will eventually be introduced.

As to an examination of the issue by the SP-HM, the unanimous positive reply by respondent members will lead to this item being added to the 1987 agenda. The Secretariat will ask the Bureau to prepare the ground for a fruitful discussion leading hopefully to the adoption of an opinion or a recommendation.

SP-HM Synthesis of replies to questionnaire NANB - Hepatitis

COUNTRY	i. Are blood donations routinely screened for: - ALT - Anti-HBc?	ii. What is the yearly incidence of post-transfusion NANB hepatitis?	iii. What is the estimated yearly percentage of prevented NANB hepatitis?	iv. Do you consider that increased safety justifies the introduction of additional tests?
AUSTRIA (Federal Ministry of Health)	ALT = No Anti-HBc = Yes	Data not available	-	-
BELGIUM	- blood donations ALT = No Anti-HBc = No - plasmapheresis ALT = Yes Anti-HBc = Yes	1 - 2% 50% after multiple transfusions	-	Yes
CYPRUS	ALT = No Anti-HBc = No	0.2%	-	No
DENMARK	ALT = No Anti-HBc = No	Number of reported transfusion-associated NANB - cases in '83: 2; '84: 1; '85: 6. Total number of donations /year: ~ 400,000	-	No, not justified, due to the low frequency of NANB hepatitis in Denmark and to the estimated poor cost-effectiveness.
FRANCE	ALT = No Anti-HBc = No	No large scale data available. Only local or regional studies in Toulouse and Lyon (data available on request).	-	Yes
FEDERAL REPUBLIC OF GERMANY	ALT = Yes Anti-HBc = No	Approx. 3.6% in view of Anti-HBc (Ref. U sugg Tübingen prospective study on NANB - PTH non matched control groups available)	ALT being compulsory since 1968, there are no "historical control Groups".	Yes, but only after controlled studies of the effect of Anti-HB negative vs. - positive units.
GREECE	ALT = No Anti-HBc = No	? %. Incidence of NANB hepatitis: 18.6% of the total number of cases with icteric hepatitis.	-	-
IRELAND	ALT = No Anti-HBc = No	-	-	-
IRELAND	ALT = No Anti-HBc = No	Extremely low. 2 reported cases in last 2 years. No cases last year in National Cardiac Surgery Unit.	-	No
ITALY	ALT = mandatory Anti-HBc = No	10 - 18% (?)	?	Yes

v. What action is taking place to determine whether these tests should be performed?	vi. Do you consider that the tests will be introduced and on what time scale?	vii. Would you favour the examination of this question by the Council of Europe (ag Recommendation)?	viii. Would you favour an urgent procedure through the SP-IM Bureau?	ix. Other comments
This question is being discussed with the Association of Blood Banks	No	Yes	Yes	-
-	Within months	Yes	No	A prospective study (1986- and 1987) is being carried out to determine the yearly incidence of post-transfusion hepatitis after ALT and anti-HBc testing. The results should help decide on routine testing.
The project is under study.	Yes in the near future.	Yes	Yes	-
No specific action at present.	Not likely unless the number of registered cases of transfusion-associated hepatitis (NAB) increases significantly	Yes	No	Replies to questions iv, vi, vii and viii are personal opinions.
The French Society for BT has appointed a study group in 1985 i.e. to examine hepatitis. A report containing information collected and results of partial trials on Anti-HBc and ALAT testing should be available end of 1986.	Yes, probably at the beginning of 1988.	Yes. A recommendation should however take account of differences between countries.	Yes	-
Several scientific societies (eg German Soc. of Transfusion medicine and Immunohaematology, Federal Board of Health etc) are evaluating the situation.	Yes, but presumably not before 1988 so as to solve the economic problems and the need to discard > 5% of blood units	Yes	A draft should be prepared for the Rome meeting.	A prospective study (1980-1982) in the Southern part of Germany in open-heart surgery patients demonstrated a 3.8% incidence of hepatitis NAB. This is much less than in USA (ALT - screening? A different epidemiological environment?)
Some pilot studies.	-	Yes	Yes	-
-	-	-	-	-
Pilot study of tests presently being carried out on limited number of donors	Will await Council of Europe recommendation.	Yes	Yes	The reported figure of post transfusion hepatitis is extremely low in Ireland. While this may in part result from non reporting, it is confirmed that the major Cardiac Surgery Centre in the Mater Hospital has not seen post transfusion hepatitis in the past 12 months. The incidence of post transfusion hepatitis would require to be of significant proportions to justify the implementation of what at the present time is a test(s) of unproven benefit.
?	?	Yes	No	-

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LUXEMBOURG	ALT = Yes Anti-HBc = No	Unknown	Unknown	-
MALTA				
NETHERLANDS	ALT = No Anti-HBc = No	Unknown but presumably low. A prospective study is underway.	-	No decision will be taken until the results of the study under (iii) are known (probably early 1987)
NORWAY	ALT = No Anti-HBc = No	The exact incidence is unknown but must be very low. Not a single verified case has been reported since 1980 when some cases were reported in haemophiliacs. They had received commercial factor VIII preparation produced in a foreign country during a short period of time when selfsufficiency was not ensured.	-	The incidence being very low there is little value in introducing these tests. The introduction seems therefore not justified at present.
PORTUGAL				
SPAIN				
SWEDEN				
SWITZERLAND	ALT = No Anti-HBc = No	Unknown	-	For the time being there is still a discussion about pros and cons of such screenings (personal preference for receiving blood with normal ALT values and negative for Anti-HBc)
TURKEY				
UNITED KINGDOM	ALT = No Anti-HBc = No	3% (estimation)	Not applicable	There are serious doubts on this matter since the step was taken in the USA on an analysis of data between 1974 and 1979

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ALT-testing, AST-testing and J-OT testing performed since October 1 1986 Anti-HBc: no studies undertaken	Yes, anti-HBc in the beginning of 1987 or mid 1987	Yes	Yes	-
No action	The first impression is that the incidence is low and that the introduction of additional tests would be of little value.	Yes	No	As the incidence of NANB hepatitis may differ from region to region and country to country, each country should consider the need for introducing additional tests.
In December 1986 the matter will be discussed at a meeting of regional blood bank directors.	At present it does not seem likely that they will be introduced.	Yes. Since the epidemiological situation concerning NANB hepatitis may differ considerably from one part of Europe to another, it may be difficult to unite around a joint policy.	No	
No special action except for the discussions in the various bodies of the Blood Transfusion Service SRC as mentioned above.	The test will probably be introduced; the time-scale is unknown	Yes	No	-
A UK Working Party on Transfusion Associated Hepatitis met in November 1986, to consider the matter and advise the DHSS.	There are no pressures at the present time to introduce these tests, but the situation could change quickly. If the general consensus throughout Europe were to introduce these tests then this could influence the situation in the UK.	Yes	Yes	1. There is a danger that political considerations may outweigh scientific findings in this matter and it is thought important to have up-to-date scientific data on both ALT and anti-HBc screening. Hopefully the Federal Republic of Germany could provide the former. 2. It is estimated that the Council of Europe could make a major contribution to Blood Transfusion by providing a reasoned argument either for or against the introduction of these screening tests.

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<u>OBSERVERS</u>				
FINLAND	ALT = No Anti-HBc = No	Unknown (see other comments)	-	Under consideration
AUSTRALIA	ALT = No Anti-HBc = No	2.1% 13.75 cases/1000 units transfused. Data from Cossart et al, Lancet, 1, 1982, 208)	-	Possibly
CANADA Canadian Red Cross Society Blood Services - CRCSSB	ALT = No Anti-HBc = No	Not known.	-	CRCSSB is not convinced that the introduction of additional tests is justifiable on the basis of current uncertainty concerning the incidence of post transfusion NANB hepatitis in Canada.
USA	ALT = Yes Anti-HBc = No (Phase-in period for anti-HBc)	5.7%	35%	-

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A study is planned determine incidence of post-transfusion NANB. Earlier studies not valid due to self-exclusion of AIDS risk groups.	Not known yet. Depends on v.	Yes	Yes	A prospective study conducted on 65 patients after open-heart surgery showed a 4.6% frequency of NANB hepatitis.
Matter is on the agenda of the National Blood Transfusion Committee's February 1987 meeting.	Possibly. Not before 1 July 1987	Yes	Yes	-
Experts from both Canada and the US have been consulted. For the present CRCBS will maintain a watching brief on the data being generated in the US by the implementation of the two surrogate tests. A Canadian study on the incidence of NANB hepatitis in transfused and non transfused patients is under consideration.	If the data sources outlined above indicate the introduction of surrogate testing is justifiable, it would be introduced nationwide. However, the data analysis and follow-up required could not be expected to allow this to occur before 1988 at the earliest.	Canada has observer status only.	Canada has observer status only.	-
Prospective studies are underway in several institutions	By spring 1987 blood donations will be tested nationally for both ALT and Anti-HBc.	Yes	Yes	-