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13/3

M E M O R A N D U M

To: Roger Scofield
From: Angela Robinson
Date: March 10, 1995
Subject: National Register of Transfusion Acquired HCV Infection

I am enclosing a proposal that Mary Ramsey and Philip Mortimer gave to me to consider today in the hopes that the MSBT would seriously consider it on Tuesday March 14th.

Having spoken to Jeremy Metters, he suggested I send it to you for consideration and circulation to the internal MSBT team "only" prior to 14th March. Neither Jeremy or I are against this proposal in principle but Jeremy has already flagged up the need for informed consent.

Thanking you.

GRO-C

The National Blood Authority
Oak House, Reeds Crescent, Watford, Herts WD1 1QH
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National register of Transfusion Acquired HCV infection

Introduction

Since 1991, serum from all blood donors has been screened for antibody to hepatitis C virus (HCV). This process has identified a small number of donors who are able to transmit HCV infection via the transfusion of infected blood components, who have then been excluded from further donation. In early 1995, the Department of Health announced its decision to perform a "look-back" exercise to identify recipients of transfusions prior to 1991 who received blood components arising from donors who were subsequently found to be anti-HCV positive. It is likely that a high proportion of recipients of HCV infected blood will also be anti-HCV positive, but the majority will currently be asymptomatic.

It is proposed, therefore, that a national confidential register and serum archive from such individuals is established in England and Wales. This register will be administered jointly by the PHLS Communicable Disease Surveillance Centre and the National Blood Authority and serum will be held at the Virus Reference Division of the Central Public Health Laboratory.

Objectives

1. To establish a central, national register of cases of presumed transfusion acquired HCV infections.
2. To establish a central, national archive of sera from cases of presumed transfusion acquired HCV infections.

This will facilitate the retrieval of important clinical and laboratory data in case of medico-legal, clinical and research purposes. It will not preclude proposals to follow up and investigate this cohort from other agencies.

Choice of collaborators

The Public Health Laboratory Service is a suitable agency to perform this function. The service provides epidemiological and virological expertise, and is funded by the Department of Health for the protection of the public health. It also forms part of a network of high quality microbiology laboratories who provide virology services to a high proportion of the population and offer public health advice to individual practitioners. CDSC has a proven ability to coordinate the national collation of epidemiological data and has established links with the National Blood Authority and with individual health authorities.

10 March 1995

Dr Mary Ramsay

Consultant Epidemiologist, PHLS Communicable Disease Surveillance Centre.

Dr Philip Mortimer

Director, Virus Reference Division, Central Public Health Laboratory.

Appendix: Proposed information held on the register

Patient identifier:

DOB:

Sex:

Ethnic origin / country of birth:

Method of ascertainment:

Lookback BTS ref no
Random testing

Clinical features at registration:

Asymptomatic, no evidence of liver disease
Asymptomatic but abnormal liver function
Asymptomatic but abnormal liver histology
Symptomatic liver disease
Other

Presumed source of infection:

Transfusion of known infected blood component	Date(s)
Transfusion of blood component of unknown status	Date / period
Blood product recipient	Date / period

Presence of other risk factors:

Intra-venous drug use
Known contact with HCV positive individual
Occupational exposure
Sexual contact

Laboratory findings

Date of specimen	Laboratory	Specimen number	Test	Result

GP / clinician name and address: