Second meeting of National HCV Register Steering Group
8th April 1998 at 2.30pm
PHLS, CDSC Library

Present:	**Observers:**
Dr Graeme Alexander (GA) - *Chair*	Dr Helen Harris (HH) - *Register Co-ordinator*
Dr Mary Ramsay (MR)	Ms Shirley Boland (Minutes)
Dr Virge James (VJ)	
Dr Hugh Nicholas (HN)	

1. Apologies

Ms Kate Soldan (KS)
Dr Julia Heptonstall (JH)
Dr Brian Gunson (BG)
Dr Angela Robinson (AR)
Dr Bernard Portman (BP)

1. Minutes of the last meeting

The minutes of the last meeting were approved.

1. Matters arising

a) BMJ/GUT/CDR editorials

AR has received a reply from the BMJ stating that they are interested in the possibility of an editorial, however, they would prefer just a small mention of the register and a more general editorial on the issue of blood transfusion and hepatitis C (with an international perspective). The original will need re-drafting. It was generally felt that this editorial should appear as soon as possible so that registration forms can be issued immediately after its publication in June 1998.

The article for GUT was more straightforward and all members agreed on its format. GA felt this should be submitted as soon as possible to ensure it appears around the same time as the BMJ editorial.

A shorter version of the GUT article will be submitted for publication in the CDR around the same time.

ACTION
AR, HH, KS (re-draft and re-submit BMJ Editorial)
GA (submit GUT article)
HH (arrange submission of CDR article)

b) Additional membership of the steering group

Brian Gunson was nominated by the Patient's Association as a suitable candidate to represent the views of the patients. BG has accepted the invitation but was unable to attend this meeting as he is on annual leave.

Dr Bernard Portman has also agreed to become a member of the steering group. GA mentioned that BP was happy to act in an advisory capacity, but was unlikely to be in a position to undertake histolopathological examination of specimens due to constraints of time.

c) Progress with the MREC

The register was submitted to the Multi-Centre Research Ethics Committee on the 2 February 1998, after incorporating the anonymisation procedures, amended registration forms and accompanying letters. The application was heard at their meeting on 25 February 1998 and unconditional approval was granted. GA felt the paperwork concerning anonymisation procedures should be passed to BG.

ACTION
HH to forward paperwork on anonymisation procedures to BG

d) Replies to applicants who have requested access to registry data

Letters were issued to both Di Gibb and Mark Thursz to notify them of the steering group's decision that applications could not be considered until the register is more fully established and its existence has been published.

HH subsequently met with Mark Thursz and David Stobbs to discuss the over-lap between the HCV register and their natural history study. The St Mary's group offered to register all of the London and SE cases (the overlap) and to forward these data to CDSC. They will also collect the additional data that the register requires that they were not originally collating. It was agreed that we should pass the lookback information to Mark Thursz that he needs as he already has an agreement with AR for this lookback data.

Di Gibb at the Institute of Child Health is happy to wait for the call for proposals when the register is more fully established.

e) Collaboration with Wales, N. Ireland and Scotland

Wales: HH reported that good progress had been made with the Welsh Blood Service. HH has visited the Welsh Blood Service on two occasions and had also met with the consultant responsible for the care of the majority of Welsh lookback patients. We have already managed to register 50% of the Welsh cases and are well on the way to registering the remainder.

N. Ireland: HH has met with Chittra Bharaucha at the N. Ireland Blood Transfusion Service and is in the process of drafting letters that are more appropriate for registering the Irish cases. This is well under way and HH anticipates that they will be in a position to begin registering the N. Irish lookback patients over the next few weeks.

Scotland: Following AR's letter to Ian Franklin at the Scottish Blood Service, HH has written to both the SBTS and SCIEH to arrange meetings to discuss how the national register might best collaborate with the Scottish register, which is a more general register that will cover all known Scottish HCV infections. HH has pointed out that the overlap between the two registers is likely to be small (110 lookback cases, plus "documented seroconversions"). HH has also sent them a copy of our MREC protocol and the proposed registration and follow-up forms. Helen has met with David Goldberg (Deputy Director of SCIEH) and spoken to Jack Gillon, both of whom feel that they have no principal objections to registering the SNBS cases in the national register. Collaboration with SCIEH regarding non-transfusion acquired infections will need to be revisited once the definition of "documented seroconversions" has been finalised and they have a better idea of the number of cases involved. Following this meeting HH or AR will write to Ian Franklin again to see if the inclusion of Scottish lookback cases in the register can be discussed at the next meeting of the Medical and Scientific Committee which determines policy for the SNBS.

ACTION

HH/AR to write to Ian Franklin.

1. Current "clinical evidence of liver disease": a reliable and valid definition

HH and others experienced difficulty in classifying patients according to their current clinical evidence of liver disease. It was agreed that this question may be ambiguous so HH put forward a revised question, which was agreed by the group.

ACTION

HH to substitute new question on current clinical evidence of liver disease

5. Extension of the register to include documented seroconversions: definition, recruitment and follow-up:

MR felt that the second definition (and another) was unnecessarily complex. It was agreed that the first definition should be used, after insertion of the word "reliable", to read:-

Seroconverters "Individuals with virologically confirmed HCV infection for whom a reliable negative result of a test of the same type for HCV infection has been recorded at any point in the preceding 4 years".

HN questioned whether the window period of 4 years was too long, however, HH explained that this window period had been chosen for two reasons. First, those who are frequently tested for HCV may be unrepresentative of the majority of HCV infected individuals, and selection of a narrower window would therefore restrict registration to a selected, and possibly unrepresentative, group. Second, analyses may be performed using a definition based on less than four years, by excluding those with a wider window, and the possible effect of the width of the window on the rate of disease progression can be studied.

It was agreed that the register would limit documented seroconversions to those detected by routine surveillance in England and Wales. E.g. occupational exposures, lab reports of acute HCV infections, and seroconversions in donors and their recipients.

6. Archiving of samples at a central laboratory/genotyping

MR has spoken to Philip Mortimer regarding archiving of HCV samples, and Philip is happy to undertake this and does not anticipate any problems resourcing it.

It was unanimously agreed that samples should be gathered, and that baseline samples would ideally be best. It was agreed that we should ask clinicians to either send a specimen for archiving or ask them for the location of any specimen that already exists. We could then request further specimens if required at follow-up. It was generally felt that the archiving of specimens would make the register more attractive to outsiders.

ACTION

HH & MR to arrange a meeting with Philip Mortimer regarding archiving of HCV register specimens.

7. Procedure for annual follow-up of registered cases

The group agreed that the best way to proceed with annual follow-up would be to send out follow-up forms in a batch at the same time each year. This would make modification of the follow-up forms in response to research proposals easier to manage.

8. Profile of HCV lookback recipients eligible for inclusion in the register: preliminary descriptive data

HH presented charts on the following:

- Initial test results following patient's first HCV lookback counselling session
- Transfusion details
- Sociodemographic profile
- Current clinical status
- Liver function tests
- Known confounders for liver disease
- Previous risk factors for HCV infection

It was generally felt that the progress of those patients whose test results were indeterminant at the time of counselling would be extremely interesting.

9. Appropriate conferences/forums for presenting/introducing the national HCV register

BASL/British Liver Meeting or the BBTS Meeting could be possible forums for introducing the national HCV register. We could use either of these forums to display descriptive data for patients eligible for inclusion in the register and use these meetings to prompt/remind hepatologists to return their registration forms (which will hopefully have been issued around June time). AR, HH and KS should probably be authors as lookback (not registry) data will be used.

ACTION

GA to speak to Kevin Moore (MRC Royal Free) regarding possible submission of a poster for the BASL/British Liver Meeting.
HH to confirm with AR whether it is possible to use lookback data for this purpose.
HH to prepare poster.

10. A call for proposals : When and how?

We will use Gut and the BMJ editorial to call for proposals. Hopefully these can appear in June and the registration forms can be issued later that month. Proposals will be asked for by mid/end October 1998.

ACTION

GA and AR to arrange for immediate submission of the BMJ editorial and the article for GUT, so that the issue of registration forms is not delayed.

11. Any Other Business

A proof of the registration form was presented and approved by the group.

12. Date of next meeting

To be arranged for sometime in late November 1998 at the same venue.

Close

The meeting closed at 4.00pm