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"Fw: Hep C: 1. Access to medical records of deceased patients; & 2. what constitiutes reasonable evidence of treatment-acquired hep C in those who died before a test was available?"

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Ailsa Wight/PH6/DOH/GB
31/01/2011 16:20

To Ben Cole/HP-SL/DOH/GB@GRO-C
cc Rowena Jecock/PH6/DOH/GB@GRO-C, Debby Webb/HP-SL/DOH/GB@GRO-C, Gerry Robb/PH6/DOH/GB@GRO-C
bcc
Subject Fw: Hep C: 1. Access to medical records of deceased patients; & 2. what constitiutes reasonable evidence of treatment-acquired hep C in those who died before a test was available?

Will you add this evidence/eligibility review point, plus comms round-up (separate note to Gerry last week refers), to an updated version of the internal contam. blood action plan, please, to discuss at Thursday's stocktake?
Thanks

Dr Ailsa Wight
Deputy Director and Head of Programme
Infectious Diseases and Blood Policy
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London SE1 8UG

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----- Forwarded by Ailsa Wight/PH6/DOH/GB on 31/01/2011 16:17 -----

Ailsa Wight/PH6/DOH/GB

28/01/2011 17:25

To "Kent Graham LEGAL GROUP DH LEGAL SERVICES" <GRAHAM.KENT@ GRO-C >, Jonathan Stopes-Roe/HP-SL/DOH/GB@ GRO-C , gerry.robb@ GRO-C

cc Ben Cole/HP-SL/DOH/GB@ GRO-C , Debby Webb/HP-SL/DOH/GB@ GRO-C , Edward Goff/HP-SL/DOH/GB@ GRO-C , Nannerl Herriott/DHSC/DOH/GB@ GRO-C , Rowena Jecock/PH6/DOH/GB@ GRO-C , maggie.tomlinson@ GRO-C , ailsa.wight@ GRO-C

Subject Re: Hep C: 1. Access to medical records of deceased patients; & 2. what constitiutes reasonable evidence of treatment-acquired hep C in those who died before a test was available?

Thanks Graham.

Gerry,
In the meantime, so we have something to slot into Graham's draft, do you think we can progress getting an expert view on the evidence requirements for pre-2003 via the 'October' group?
If you need support from say, Charlie, let me know (I had a general word with Maggie today and I think she'd be willing to help).
Thank you, and happy to discuss

Ailsa

Message sent from a Blackberry handheld device.

----- Original Message -----
From: "Kent Graham LEGAL GROUP DH LEGAL SERVICES" [GRAHAM.KENT@ GRO-C
Sent: 28/01/2011 14:53 GMT
To: Ailsa Wight; Jonathan Stopes-Roe
Cc: Ben Cole; Colin Staniland; Debby Webb; Edward Goff; Gerry Robb; Kay Ellis; Matthew Birkenshaw; Nannerl Herriott; Rowena Jecock
Subject: RE: Hep C: 1. Access to medical records of deceased patients; & 2. what constitiutes reasonable evidence of treatment-acquired hep C in those who died before a test was available?

Ailsa,

Given that we are going to have to enter into a new Agreement with Skipton to implement this new England-only arrangements which were recently announced I don't think you have to worry about the existing provisions.

The important thing is to get it right now, because there are clearly going to be some very real evidential problems in relation to people who died a minimum of more than seven years ago and in some cases many more than that. Indeed, I am just turning to drafting such a new Agreement

now, using the existing agreement as a model (it is rather longer and more complex than I would wish and certainly much more so than the arrangements we entered into with MFET Ltd, but it seems to me we have to have broadly compatible arrangements with Skipton under both agreements).

I will circulate the draft when I have completed it, but it will be a lengthy job, and I am clearly going to have to be breaking off from it at regular intervals to deal with other, more urgent, matters, so I imagine will be at least a week before I'm in a position to circulate anything,

Graham

Graham Kent
NHS Organisation, Secondary Care & Information
DH Legal Services (part of Legal Group)
GRO-C
graham.kent@ GRO-C

-----Original Message-----
From: Ailsa.Wight@ GRO-C [mailto:Ailsa.Wight@ GRO-C
Sent: 28 January 2011 14:34
To: Stopes-Roe Jonathan DOH GSI
Cc: Cole Ben DOH GSI; Staniland Colin DOH GSI; Webb Debby DOH GSI; Goff Edward DOH GSI; Robb Gerry DOH GSI; Kent Graham LEGAL GROUP DH LEGAL SERVICES; Ellis Kay DOH GSI; Birkenshaw Matthew DOH GSI; Nannerl.Herriott@ GRO-C Jecock Rowena DOH GSI
Subject: Re: Hep C: 1. Access to medical records of deceased patients; & 2. what constitiutes reasonable evidence of treatment-acquired hep C in those who died before a test was available?

Yes, Ro and I have just discussed and we think we may need an expert review before we just accept any change to eligibility evidence, although we recognise that pre 1991 there wasn't a test and that is now more relevant in view of pre-2003 deaths,.

Given what happened with SKF is a while ago, if we don't know or can't re-engage exactly the same people what about seeking views of experts who provided evidence base for our review report, which considered (admittedly
current) diagnostic criteria, and who should be well placed to consider the past position? Charlie was on that group and we could do by email. The last part of his email captures the key points:

- exclusion of alcohol as a cause of live disease
- abnormal LFTs [probably need to clarify which especially relevant, at that time]
- preceeding evidence of treatment with a high-risk product [again, probably need to identify such products]

I take it any such tweaks to evidence would not pose a problem in terms of Fund deeds or anything?

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Jonathan

Stopes-Roe/HP-S

L/DOH/GB

To

Rowena Jecock/PH6/DOH/GB@GRO-C

28/01/2011

cc

13:55

Ailsa Wight/PH6/DOH/GB@GRO-C Ben

Cole/HP-SL/DOH/GB@GRO-C Colin

Staniland/OIS/DOH@GRO-C Debby

Webb/HP-SL/DOH/GB@GRO-C Edward

Goff/HP-SL/DOH/GB@GRO-C Gerry

Robb/PH6/DOH/GB@GRO-C

Graham.Kent@ GRO-C Kay

Ellis/SHASM/DOH/GB@GRO-C Matthew

Birkenshaw/HSCD-PP-PPRT/DOH/GB@GRO-C

Nannerl Herriott/DHSC/DOH/GB@GRO-C

Subject

Re: Hep C: 1. Access to medical records of deceased patients; & 2. what constitiutes reasonable evidence of treatment-acquired hep C in those who died before a test was available?

(Document link: Ailsa Wight)

Rowena

Nannerl is off sick today, although she hopes to be back on Monday. But in any case, I think she would not mind me saying that she cannot answer your question about acceptable historical evidence for HepC infection (and nor can I). I am aware that, back at the beginning, Hugh Nicholas spent a lot of time on such questions, from a medical point of view. However I do endorse Graham's point that the criteria must reflect a prudent use of public money - there must be reasonable evidence.

Jonathan Stopes-Roe
Deputy Director, Legislation & Environmental Hazards
Health Protection Division
Department of Health
Wellington House
GRO-C

Rowena

Jecock/PH6/DOH/

GB

To

Gerry Robb/PH6/DOH/GB@GRO-C Nannerl

28/01/2011 Herriott/DHSC/DOH/GB@GRO-C

13:22

cc

Jonathan Stopes-Roe/HP-SL/DOH/GB@GRO-C
Edward Goff/HP-SL/DOH/GB@GRO-C Colin

Staniland/OIS/DOH@GRO-C Ailsa

Wight/PH6/DOH/GB@GRO-C Debby

Webb/HP-SL/DOH/GB@GRO-C Ben

Cole/HP-SL/DOH/GB@GRO-C Kay

Ellis/SHASM/DOH/GB@GRO-C Matthew

Birkenshaw/HSCD-PP-PPRT/DOH/GB@GRO-C

Graham.Kent@ GRO-C

Subject

Hep C: 1. Access to medical records of deceased patients; & 2. what constitiutes reasonable evidence of treatment-acquired hep C in those who died before a test was available?

Dear All,

You will see from the email below that Charlie Hay (UKHCDO Chair) is in direct contact with the SKF. The UKHCDO is working hard to be as helpful as possible in trying to identify individuals with bleeding disorders from the pre-2003 cohort, who may have had hepatitis C, and provide records to families who request them.

The Haemophilia Centres are prepared to invest effort in doing this in respect of former patients, for which I have thanked them. It is possible though, that some of their employing Trusts may not be prepared to sanction this without payment. Having spoken to Matthew Birkenshaw (DH Lead for Data Protection and Data Confidentiality) I understand that Trusts are entitled to charge for cost recovery under the Access to Health Records Act 1990, although individual Trust policies vary.

It is also possible that we may be asked by individuals who may want want to claim in respect of someone who has died, whether DH will reimburse charges incurred to obtain medical records. Just to be clear - it is not our policy to do so.

As it is likely that many pre-2003 records will have been destroyed, Matthew advises that we may also receive complaints about that. Please make him aware of any correspondence that you receive on these or related points.

In case you receive correspondence asking how health records can be

accessed, Matthew has kindly provided the link to the guidance on the DH website:
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_112916

Secondly, please note Charlie's and Nick's exchange on what might constitute reasonable evidence of treatment-acquired hep C infection in the pre-testing era, ie before 1991. Charlie said: "In the pre-testing era, NANB hepatitis was defined by exclusion of alcohol, hepatitis A and hepatitis B in patients with abnormal liver function tests for >6 mths. For some of the patients who died a long time ago, that, plus a history of treatment with a high-risk product may be the only evidence of chronic hepatitis C there is. That would persuade me. Would it be adequate for Skipton? What is your minimum dataset?"

Nick Fish is seeking DH's view on whether that would be acceptable. Grateful for advice - particularly from Gerry and/or Nannerl - on whether this is already likely to be adequately covered in the instructions DH has previously given to the SKF, ie would we expect them to seek advice from their clinical expert(s) on this point? If not, what would be the best mechanism to ensure fair criteria are established? (Do you recommend seeking advice from AGH, or going back to the clinical expert group for
instance?)

Many thanks,
Rowena

----- Forwarded by Rowena Jecock/PH6/DOH/GB on 28/01/2011 10:32 -----

"Hay Charles
(RW3) CMFT
Manchester"
To
<Charles.Hay@GRO-C "Nick Fish" <nick@GRO-C
GRO-C
cc
<gerry.dolan@GRO-C
28/01/2011 "Chris James"
10:09 <chris@GRO-C, Rowena
Jecock/PH6/DOH/GB@GRO-C 'Mike
Makris"
<m.makris@GRO-C,
"Dewhurst
Lynne (CENTRAL MANCHESTER
UNIVERSITY
HOSPITALS NHS FOUNDATION TRUST)"
<lynne.dewhurst@GRO-C "Peter
Stevens" <peter@GRO-C,
"Martin
Harvey" <Martin@GRO-C,

"Michael Makris"

GRO-C

Subject

RE: Skipton Fund payments

Dear Nick,

That's all very helpful. Thank you. It also gives me one or two more ideas.

The problem is that the records issue will be far greater than before because for most of the patients I am worried about they will have died more than 8 years ago and there will have been no legal obligation to retain their records that long. In many but not all cases the hospital records may have been retained. Only the activists will have their own copy records. The GP records go back to the Local Family Practitioner's Committee and are retained for only six years, as far as I am aware.

For those who have liver disease mentioned on their certificate, particularly as a cause of death, it should be easy, and we are drawing up a list with data, which we will share with you asap. The problems I anticipate will be with the much larger group of patients who died from some other cause, prior to 1993, but who had some degree of chronic hepatitis C and whose estate may therefore be eligible for a part 1 payment at least. I had an enquiry yesterday which illustrates this problem well: -

The widow of a Manchester patient, (DOB 1967) who died of AIDS in GRO-C 1992, before I took up post here, phoned to ask if her husband had had liver disease. He had moderate severity haemophilia and the treatment history in the NHD indicated that he had almost certainly been exposed to HCV. HCV is not mentioned on his death certificate of which NHD have a copy. His date of death coincided with the introduction of the second generation HCV antibody test and antedated the introduction of the PCR. In all likelihood he had not been tested with either, though I am checking. His adult notes were destroyed as a result of a burst steam pipe under the floor of the storage room in 2006, consumed with fungus. The GP notes will also have been destroyed, I think. His wife has no copies. I have requested his children's notes and all the computer printout of all our virology records for all of our patients as far back as it goes. I am about to advise all centres to ask their virology labs do the same (it will save them work with this and the HCV lookback).

Best wishes,
Charles Hay

From: Nick Fish [mailto GRO-C
Sent: 27 January 2011 16:43
To: Hay Charles (RW3) CMFT Manchester
Cc: gerry.dolan@ GRO-C ; 'Chris James';
Rowena.Jecock@ GRO-C 'Mike Makris'; 'Dewhurst Lynne (CENTRAL MANCHESTER UNIVERSITY HOSPITALS NHS FOUNDATION TRUST)'; 'Peter Stevens'; Martin Harvey
Subject: RE: Skipton Fund payments

Dear Dr Hay

Thank you for your email, I will address the points in order.

With regards to leaflets and posters, this has been brought to the attention of the Department of Health today and I understand that they are (and already had been) considering designing something which could possibly be distributed as early as next month. I agree this would be useful in increasing awareness of the scheme.

I share your concerns on some people not being able to furnish sufficient evidence for the purposes of the application. However we hope that with a combination of i) information printed on the death certificate (I have spoken to the Trustees of people whose death certificate specifically mentioned hepatitis C, which I assume would only have been done if the infection was chronic, rather than them being AB positive?) ii) records held at Haemophilia Centres iii) records retained by the estate and iv) records which still exist at the hospital and/or GP surgery, most people will be able to receive a payment where it is due. For applications which are declined there is always the appeals system whereby the medical knowledge and experience of the panel members may be sufficient to overturn certain unsuccessful applications.

You wrote:
"In the pre-testing era, NANB hepatitis was defined by exclusion of alcohol, hepatitis A and hepatitis B in patients with abnormal liver function tests for >6 mths. For some of the patients who died a long time ago, that, plus a history of treatment with a high-risk product may be the only evidence of chronic hepatitis C there is. That would persuade me. Would it be adequate for Skipton? What is your minimum dataset?" We would need guidance from the Department of Health on this matter.

On the registration form we request a copy of the death certificate but in cases where the estate is unable to provide a copy we could approach you for one; this would be useful, thank you.

You wrote:
"The National Haemophilia Database does not currently hold HCV testing data though we are beginning to collect it. We do have treatment history data and mortality data however and I wonder if this could be helpful to patients. For DPA reasons we could provide this to patients themselves and already do so but could provide you with data only from patients who have sadly died"

For any living applicants who are struggling to obtain records of their treatment with blood products I will refer them to you (although for people with haemophilia this is very rarely a problem as opposed to one-off transfusion recipients). For people who were registered with the Macfarlane Trust the source of the HCV infection has always been assumed to be the same as that of the HIV infection so the only records the estate must supply is with regards to the HCV. For those people with haemophilia who have died and did not have HIV then a copy of their treatment history data on your headed paper would be very useful.

Kind regards

Nick Fish
Scheme Administrator
Direct Line: GRO-C
Email: nick@ GRO-C

From: Hay Charles (RW3) CMFT Manchester [mailto:Charles.Hay@ GRO-C]
Sent: 25 January 2011 15:17
To: nick@ GRO-C
Cc: gerry.dolan@ GRO-C ; Chris James;
Rowena.Jecock@ GRO-C ; Mike Makris; Dewhurst Lynne (CENTRAL MANCHESTER UNIVERSITY HOSPITALS NHS FOUNDATION TRUST)
Subject: FW: Skipton Fund payments
Importance: High

Dear Nick,

Thank you for the information earlier.

I attach my letter to DH. I have had no response to this yet but will probably follow up with a phone call because further questions have arisen since I wrote it. I also wish to specifically ask again about the deadline of 31/3/11.

I think we are all concerned that patients may fall through the net because they don't know about it or because of the deadline. We are trying to get haemophilia centres to bring it to their patient's attention and will be providing patients with lists of patients that they may or may not be able to contact. Have you thought of printing a public information poster which we could display in haemophilia centres and clinics?

We are also concerned that some applications may fail because of a lack of supporting documentation. This will be unavoidable to some degree, for the following reasons: -

1. The notes may have been destroyed or lost (though some relatives have
   copies of notes, which may be very helpful).
2. The patient may have died before the advent of HCV antibody testing
   in 1992 or HCV PCR testing several years later.

In the pre-testing era, NANB hepatitis was defined by exclusion of alcohol, hepatitis A and hepatitis B in patients with abnormal liver function tests for >6 mths. For some of the patients who died a long time ago, that, plus a history of treatment with a high-risk product may be the only evidence of chronic hepatitis C there is. That would

persuade me. Would it be adequate for Skipton? What is your minimum dataset?

In some cases there is documented evidence of severe liver disease on the death certificate. We have death certification data from ONS that we can provide you with. Data Protection Legislation does not apply to the dead, by the way.

The National Haemophilia Database does not currently hold HCV testing data though we are beginning to collect it. We do have treatment history data and mortality data however and I wonder if this could be helpful to patients. For DPA reasons we could provide this to patients themselves and already do so but could provide you with data only from patients who have sadly died

With best wishes,
Charles Hay
Chairman UKHCDO.