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Co-Director of Population Health and Co-Chair, Infected Blood Oversight and Assurance Group, Scotland

16 October 2024

Dear Professor Sir Stephen Powis, Professor Sir Michael McBride, Professor Pushpinder Mangat and Christine McLaughlin,

Inquiry Recommendation 6: Monitoring Liver Damage

This letter provides clarification on Inquiry Recommendation 6: Monitoring liver damage for people who were infected with Hepatitis C, namely that the objective of Inquiry Recommendation 6 is that there should be both surveillance for hepatocellular cancer and monitoring for the progression of fibrosis and cirrhosis in the groups identified.

In Volume 1 of the Report of the Infected Blood Inquiry of 20 May 2024, at page 162, this was said about the importance of ongoing monitoring for liver damage:

"*Evidence provided to the Inquiry demonstrates that a lack of ongoing monitoring is an area of concern for people who were infected with Hepatitis C and have cleared*

the virus. The Expert Group on Hepatitis advised the Inquiry that successful treatment for Hepatitis C can considerably reduce (by approximately 70%) but not eliminate the risk of cancer. The major factor determining the long-term impact of Hepatitis C is the degree of liver fibrosis at the time when the Hepatitis C PCR test became negative. People with significant fibrosis or cirrhosis are likely to require lifelong surveillance for the risk of hepatocellular carcinoma, with six monthly testing usually involving an ultrasound of the liver and an alpha fetoprotein ("AFP") blood test. The expert group advised that people who did not have such liver scarring may be discharged from specialist care.

Professor Michael Makris recommends that patients with an inherited bleeding disorder who have cleared Hepatitis C should be seen by a consultant hepatologist and have blood tests, an ultrasound scan and a fibroscan. Where patients have no signs of advanced fibrosis/ cirrhosis but have abnormal liver enzymes, these should be assessed and they should be given advice on lifestyle factors to minimise the risk of liver failure. He recommends that patients with advanced fibrosis or cirrhosis are entered into a hepatocellular screening program, with six-monthly ultrasound scans and regular hepatology follow-up to detect early signs of liver failure."

I added on page 256:

"*He recommends that those who are infected, including those who have successfully cleared the virus, should be reviewed by a liver specialist at least once. He explains that many of the patients with bleeding disorders treated over the last 35 years, especially prior to the last decade, will have been treated through haemophilia centres rather than by an hepatologist. Studies have shown that successful Hepatitis C treatment does not eliminate the risk of liver-related complications in persons with infected bleeding disorders. Due to higher baseline risk, incidence was higher after direct-acting antivirals than interferon-based SVR – since people were being treated later.*"

The reference to six-monthly surveillance for hepatocellular carcinoma by ultrasound was clearly set out in this text, as was the use of a fibroscan, which assesses liver fibrosis and cirrhosis.

Reflective of this evidence, the Report then adopted wording advanced in submissions to capture the essence of the recommendations made by Professor Makris.

"**6 Monitoring liver damage for people who were infected with Hepatitis C**

(a) All patients who have contracted hepatitis via a blood transfusion or blood products should receive the following care:

(i) those who have been diagnosed with cirrhosis at any point should receive lifetime monitoring by way of six-monthly fibroscans and annual clinical review, either nurse-led, consultant-led or, where appropriate, by a GP with a specialist interest in hepatitis

(ii) those who have fibrosis should receive the same care

(iii) where there is any uncertainty about whether a patient has fibrosis they should receive the same care

(iv) fibroscan technology should be used for liver imaging, rather than alternatives

(v) those who have had Hepatitis C which is attributable to infected blood or blood products should be seen by a consultant hepatologist, rather than a more junior member of staff, wherever practicable

(vi) those bodies responsible for commissioning hepatology services in each of the home nations should publish the steps they have taken to satisfy themselves that the services they are commissioning meet the particular needs of the group of people harmed by NHS treatment"

Since the publication of the Report it has been pointed out that the recommendation could benefit from greater clarity: Professor Peter Hayes (Professor of Hepatology, University of Edinburgh), Professor Tom Bird (Professor of Hepatobiliary Cancer, University of Edinburgh), and Dr Tim Cross (President of British Association for the Study of the Liver) have written a joint letter to the Inquiry team, which broadly supports long term liver cancer surveillance for those who were infected with Hepatitis C. However, they note that fibroscans, and similar scanning technologies, are designed to assess stiffness of the liver as a marker of fibrosis/cirrhosis and are not cancer surveillance tests, and that an ultrasound (rather than fibroscan) for liver cancer (HCC) surveillance every six months (plus minus serum AFP every six

months) would be typical and recommended practice in the UK currently for early liver cancer detection.[1]

They add that "*In specific populations there is rationale for alternative imaging modalities (e.g contrast enhanced CT/MRI). There are UK guidelines on delivery and reporting of these ultrasounds which are being agreed currently and could be included in the recommendation, however as these are planned for implementation currently they should also apply to this population.*"[2]

Professor Graham Cooke, an Inquiry expert, summarises the point in this way: "*The reason to do six monthly scans in those with cirrhosis is to pick up cancers (for which patients are at increased risk). These are not detected by Fibroscan, but they can be (imperfectly) picked up by ultrasound. So using Fibroscans as recommended, would risk missing cancers. Elastography (usually via Fibroscan) is an important tool for assessing the degree of fibrosis in an individual patient.*"

NICE guidance in respect of surveillance for hepatocellular carcinoma is that ultrasound (with or without measurement of serum alpha-fetoprotein) should be offered every six months to people with cirrhosis who do not have Hepatitis B virus infection.[3]

NHS England has also sought clarification on some details related to this recommendation, following their discussions with national clinical experts.[4]

The purpose of this letter is to provide that clarity.

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[1] Email from Professor Tom Bird, Dr Tim Cross and Professor Peter Hayes Volume 1 Recommendations on Monitoring liver damage for people who were infected with Hepatitis C 29 May 2024 RLIT0002463

[2] Email from Professor Tom Bird, Dr Tim Cross and Professor Peter Hayes Volume 1 Recommendations on Monitoring liver damage for people who were infected with Hepatitis C 29 May 2024 RLIT0002463

[3] NICE *Cirrhosis in over 16s: assessment and management NG50* 8 September 2023 para 1.2.4 RLIT0002460. For those who have chronic Hepatitis B, NICE recommend that that there should be six-monthly surveillance, by hepatic ultrasound and alpha-fetoprotein testing in people "*with significant fibrosis (METAVIR stage greater than or equal to F2 or Ishak stage greater than or equal to 3) or cirrhosis*", and in addition such surveillance should be considered for those who do not meet this standard but are aged 40 or older and have "*a family history of HCC and HBV DNA greater than or equal to 20,000 IU/ml.*" NICE *Hepatitis B (chronic): diagnosis and management CG165* 20 October 2017 paras 1.7.1-1.7.3 RLIT0002461

[4] The correspondence between NHS England and the Inquiry is set out in full on the Inquiry website. Letter from NHS England Infected Blood Inquiry: clarifications for Recommendation 6 11 September 2024 RLIT0002462

The objective of the Inquiry Recommendation 6 is that there should be both surveillance for hepatocellular cancer and monitoring for the progression of fibrosis and cirrhosis in the particular groups identified in Recommendation 6.

A lack of clarity may have arisen from the recommendation that fibroscan technology should be used for liver imaging rather than alternatives. This arose from adoption of wording advanced in final submissions. This was not intended to, nor should it be read as, excluding the use of ultrasound for screening for liver cancer. Indeed, the Inquiry adopted the evidence of Professor Makris which clearly referred to ultrasound for that purpose. Nonetheless, given the correspondence, it is plain that greater clarity is needed.

For people reading this correspondence, based on all the material before the Inquiry at the time of the Report and since, monitoring for the presence of fibrosis, and of cirrhosis, and their progression, is best performed by a Fibroscan or a similar elastographic test. However, monitoring for the development of liver cancer is best performed by the use of ultrasound, with (or, as appropriate, without) the use of an AFP test.

I am copying this letter to the Paymaster General as sponsor minister.

Yours sincerely,

Sir Brian Langstaff
Chair, Infected Blood Inquiry