Ministear airson Slàinte Phoblach, Slàinte Bhoireannaich agus Spòrs Jenni Minto BPA



Minister for Public Health, Women's Health and Sport Jenni Minto MSP

Clare Haughey MSP Convenor, Health, Social Care and Sport Committee The Scottish Parliament

By email: hscs.committee@parliament.scot

3 October 2023

Dear Clare,

## SaBTO recommendations on Hepatitis B testing and lookback and FAIR III for tissues and cells

I am writing to update the Committee on action taken to implement two recommendations by the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO), the UK-wide scientific body with expertise in this area.

First, additional Hepatitis B Virus (HBV) testing was introduced for blood donors in Scotland on 5 April 2022 in line with recommendations made by SaBTO in October 2021 Occult hepatitis B infection in UK blood donors - GOV.UK (www.gov.uk). The aim of these recommendations is to enhance blood safety by reducing the risk of HBV transmission from donors with 'occult' HBV infection, following a small number of cases in England where recipients are believed to have been infected with HBV by this route. Occult HBV infection is where a donor has HBV in their blood and/or liver which is capable of replicating but is at too low a level to be detected by routine tests, but where their HBV could still potentially be transmitted to the recipient(s) of their donated blood. The additional testing, which all other parts of the UK also began from May 2022, is designed to better detect such cases.

Following the completion of the testing, the Scottish National Blood Transfusion Service (SNBTS), NHS Scotland territorial health boards, and Public Health Scotland are now, also as recommended by SaBTO UK-wide, conducting a 'lookback' exercise. This involves contacting recipients of blood donations where they have had a transfusion from a donor subsequently found to have occult HBV, or where such a donor has potentially had occult HBV in the past, testing those recipients to determine if they have active HBV and, if so, directing them to appropriate care and treatment. The lookback has now commenced, with the first recipients being contacted from the end of July. Latest estimation is that around 350 recipients will need to be contacted in Scotland across the duration of the lookback. The

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lookback is supported by a national communications support package, ensuring that any recipients who are contacted will have clear information on how to access testing, detailed FAQs about what the need to test means, and access to a free telephone helpline. Based on modelling, initial estimates are that the numbers of HBV cases in recipients that will be detected as a result of the lookback will be in single figures. Furthermore, these recipients are very likely already to have cleared their infection, so it is probable that the lookback may not detect any active cases of HBV. So, the risk of infection is very low, but if any cases of active infection are detected then Boards will provide support and treatment.

Second, on 14 December 2020 all four UK administrations accepted the recommendations of SaBTO's FAIR (For the Assessment of Individualised Risk) report on blood donation. As a result, a new donor questionnaire for blood donors went live on 14 June 2021 in Scotland, Wales and England, and in August 2021 in Northern Ireland. This enabled a more individualised risk assessment approach to blood donor selection, whilst ensuring the safe supply of blood to patients, meaning men were no longer automatically barred from giving blood if they had had sex with another man in the last three months, and allowing more gay and bisexual men to donate blood, particularly if they are in exclusive relationships. It also allowed people whose partners have previously lived in sub-Saharan Africa to donate blood. The review of the first year of implementation of FAIR for blood donors found it had gone well and there was no evidence of any increased risk of transmission of infection as a result of the changes.

Following these changes, the FAIR III Steering Group was set up to look at whether FAIR could also be applied to tissue and cell donors using a similar evidence base. In May 2022, SaBTO members agreed to the recommendations in the FAIR III group's report. Members agreed that a risk-based approach, similar to the changes made to the blood donor selection criteria in June 2021, should be introduced for living and deceased tissue, cord blood and stem cell donors. The updates to the national donor selection guidelines to allow FAIR III recommendations to be implemented safely are expected in the near future.

SNBTS is responsible for the collection, testing, manufacture and supply of a range of products including living and deceased donor tissue, surgical bone and haematopoietic stem cells and will be responsible for implementing the FAIR III changes for tissues and cells in Scotland, working closely with NHS Blood and Transplant and with the Joint UK Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee. SNBTS expects to begin to operationalise the FAIR III changes over the coming months, once the national donor selection guidelines have been updated.

I hope this update is helpful.

Regards,

Jenni Minto MSP
Minister for Public Health and Women's Health

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