18 March 2016

Dear Duncan,

I am writing with regard to issues raised at the Penrose Inquiry evidence session on 9 February 2016 concerning financial support for those affected by infected NHS blood and consent for the use of stored human tissue for research. I am also responding to your subsequent letter of 17 February that welcomed the findings of the Scottish Financial Review Group report and commended them to me.

In response to the Review Group’s recommendations, the Scottish Government is announcing a package of improved financial support arrangements that will be available in the future for those affected by HIV and hepatitis C via infected NHS blood and blood products in Scotland. I can confirm that we have accepted the key financial recommendations of the Review Group.

For those infected in Scotland, this means that the Scottish Government will commit to:

- Increasing annual payments to £27,000 for those with advanced Hepatitis C (at Stage 2) or HIV and increasing them to £37,000 for those co-infected with both Hepatitis C and HIV.
- Providing annual payments to widows and widowers of those who have died as a result of their advanced (Stage 2) Hepatitis C or HIV infection. These payments will be 75% of the amount the infected person would be entitled to under the new arrangements if they were alive.
- Providing an additional lump sum of £30,000 to all those who are infected with chronic Hepatitis C at Stage 1. This will bring the total lump sum all those infected in Scotland have received to at least £50,000, given that those with chronic infection have already received £20,000. Given the additional impact of co-infection with Hepatitis C and HIV, the co-infected people currently at Stage 1 will automatically move to Stage 2 and receive a £50,000 lump sum payment.
• Increasing Scottish Government funding for a Support and Assistance grants scheme for those infected and their families to £1 million per year.

We will also consider each of the Group’s proposals for further work that should be undertaken in the future. For example, we will carry out a review to consider the current assessment criteria for determining if someone with hepatitis C should receive higher, regular payments. This review will be based on the latest clinical and scientific evidence from international research, with input from experts on the health impacts of the disease.

We will also take account of the Group’s recommendations for the delivery of the funding. In particular, we accept the recommendation that the new support should in future be delivered through a single Scottish agency – such an agency could be more responsive to the needs of those infected in Scotland and would provide a single point of contact for beneficiaries, rather than several different bodies handling different categories of funding. The Group highlighted simplicity, accessibility and accountability as crucial factors in future service delivery and we will seek to apply those principles when considering delivery by a new Scottish agency. We hope to be able to deliver interim arrangements via the existing UK-schemes in order to make increased payments as soon as possible in 2016. We are making progress in our discussions with the existing schemes and the Department of Health, who have been willing to assist us with our interim arrangements, although the UK Government proposals regarding the future operation of the UK schemes could impact on the feasibility and timing of our planned transitional measures. A further update regarding implementation timescales will be given after the Scottish Parliament elections in May, by which time we should have a clearer indication of the timing of implementing transitional arrangements. I will inform the Committee of that statement when it is made.

In relation to the query raised by Rhoda Grant MSP about use of tissue samples for research, I can assure you that the Scottish Government fully recognises the need to respect and uphold the rights and dignity of donors of tissue and has set high standards for the consent, storage and use of human tissue for NHS-supported research. Robust governance arrangements are in place to ensure those standards are met while supporting the use of tissue in approved research. These standards are based on the provisions of the Human Tissue (Scotland) Act 2006 for donations from the deceased and through adoption of the principles of the Human Tissue Authority Codes of Practice on Consent. Under the Human Tissue (Scotland) Act 2006 appropriate consent is required to remove, store and use tissue from the deceased for research purposes. Since the requirements of the Act are not retrospective, existing holdings (i.e. material held before the Act came into force 1 September 2006) collected post mortem may be used for research without consent as long as the research has gained ethical approval from a NHS Research Ethics Committee.

Under the provisions of the Human Tissue Authority Codes of Practice on Consent, consent from the living is needed for the storage and use of tissue for research. Only under circumstances where the researchers are not in possession of information that identifies the donors, and not likely to come into possession of such information, and the research in which the tissue will be used has ethical approval from an NHS Research Ethics Committee can tissue be used without consent.

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1 https://www.hta.gov.uk/guidance-professionals/codes-practice/code-practice-1-consent
In order to ensure that these standards are met, an external expert accreditation process has been introduced to provide assurance that the appropriate governance arrangements are in place at each NHS Scotland Health Board. Healthcare Improvement Scotland (HIS) is the organisation responsible for assessing the NHS Boards against the standards and for accreditation.

In order to be accredited, NHS Boards must adequately address three key aspects when using human tissue for research: consent, governance, and premises.

In terms of consent, the standard for accreditation is the following:

- There is a formal procedure for obtaining consent to donate tissues which meets the principles of the Human Tissue Authority Codes of Practice on Consent from living donors, and the provisions of the Human Tissue (Scotland) Act 2006 for donations from the deceased.
- Consent procedures have received NHS Research Ethics Committee approval.
- Consent is taken in line with statute, common law requirements and Scottish Government guidance with respect to the collection, storage and use of tissue and associated data.
- Patient information on tissue donation is available in a variety of formats, and with provision for those with hearing or visual impairments.
- There is a clear policy for the management of withdrawal of consent/authorisation.

Additionally, NHS Boards wishing to retain tissue for research must bring tissue collections under the governance of the NHS Board's biorepository.

The four main human tissue biorepositories based in NHS Tayside, NHS Greater Glasgow and Clyde, NHS Grampian and NHS Lothian have all been awarded accreditation. A report on this accreditation was published by HIS in 2014\(^2\). The accreditation process of other Health Boards is anticipated to conclude during summer 2016.

The introduction of this accreditation scheme demonstrates our continued commitment to the highest possible professional governance standards for human tissue used in research to both protect the rights and dignity of tissue donors and to facilitate research that can lead to important medical advances.

Finally, I can confirm that I will ensure that the Committee receives a copy of the Health Protection Scotland short life working group report on implementing the single Penrose Inquiry report recommendation when it is available.

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\(^2\)http://www.healthcareimprovementscotland.org/our_work/governance_and_assurance/human_tissue_banks.aspx