Histopathology Information Leaflet

Reasons for Histopathology:

An unexpected and undiagnosed lesion/s in a donor organ/s.

These lesions are often asymptomatic and as such they may not have ever been investigated.

As part of safe donor characterisation and safe transplantation, it is of paramount importance to evaluate any abnormality with a biopsy for urgent processing and examination by a histopathologist.

Depending on the nature of the specimen, the sample may be "fixed" or sent as a frozen section. The sample is then prepared by a BMS for examination under the microscope for urgent reporting by a histopathologist who will then make available their findings to the NORS Team and transplant centres.

Facilitating Histopathology Samples can be supported by:

SOP5352 Findings During Retrieval Requiring Histopathology Assessment

FRM5867 National Histopathology Request Form

SOP5735 New Findings Made at a Transplant Centre Requiring Histopathology

FRM6390 National Histopathology Request Form - For Use a Transplant Centres

Urgent biopsies can also be carried out to assess organ quality. When organs are retrieved from certain categories of donors, such as elderly patients, obese patients or patients with complex medical histories (e.g. diabetes, hypertension, alcohol abuse), it may be necessary to evaluate the quality of the specific organ.

Understanding the Impact:

For SNODS - Many of you report feeling under pressure by spending a lot of time making calls to establish where biopsied lesions can be sent for examination. This often exacerbates delays in retrieval timings which can impact transport including flights and additional costs accrued (if the airport was to be kept open) and concern if the donor subsequently becomes unstable. This can have a detrimental result on the donating hospital emergency and elective theatre patient lists.

For NORS Retrieval Surgeons - There is also an impact on members of the NORS team, in particular the lead retrieval surgeon. As the lead surgeon is responsible for the safe retrieval of organs, the inability to obtain histopathology and the subsequent impact on organs for transplantation can also lead to issues with morale. Likewise, disease transmission with loss of life is a devastating blow for retrieval staff.

For Patients - There is a risk to patients of not receiving an organ – if there is concern and no histopathology available, organs will be turned down. This affects all organs from that particular donor, not just the one/s in which lesions were identified.

The Stats

Between 1 January 2018 and 4 August 2021, there were 13 reported incidents related to delays in obtaining histopathology, 11 incidents related to a lack of service, and 20 incidents where there were issues due to a lack of clarity with the process.

In this period, there were four SAEARs which were reported to the HTA – however, none of these related to disease transmission because of no access to histopathology services.

It would appear from the incidents, therefore, that there is 24/7 access to histopathology on many occasions, but the service is fraught with delays and confusion about the overall process (including who is responsible for arranging biopsies, and how/where these are reported).

Over a recent six-month period, there were 93 cases where one or more lesions were identified which required histopathology. It is estimated, therefore, that approximately 200 biopsies would be required per annum (approx. 10% of all donors) when screening focal lesions

Service Provision

The Service is currently commissioned by NHSE&I through local pathology budgets, but as users, NHSBT systems, people and processes are impacted by the lack of 24/7 coverage in all centres across the UK. This has been a concern for NHSBT and clinicians for a while now.

A working group was set up to examine a range of options to find a solution and their preferred option is presented below, which was presented to OTDT in September 2021 and subsequently NHSE&I.

Potential Solution

As you are all aware, the PITHIA trial (now completed) was successful because the workforce and technology had been funded. The proposed solution is therefore, based on the principles of PITHIA, using the same technology, with separate funding for workforce.

Lesion/s would be sent from the donor hospital to one of the seven NORS Centres (spokes) with a slide scanner (Birmingham, Cambridge, Leeds, Edinburgh, Royal Free, Newcastle, Kings), processed by a Biomedical Scientist (BMS) using Slide Scanner technology and uploaded for remote review by a histopathologist.

NHSBT would work with a National Histopathology Assessment Centre (hub), comprised of six rotas of histopathologists providing advice across each of the six main sub-specialties. It is anticipated the rotas will be delivered on a 1:10 basis.

Donor Histopathology assessment would be the responsibility of a single National Histopathology Assessment Centre. Expressions of interest would be sought from potential providers, and the successful candidate would be required to set up and manage the histopathologists' rotas to provide 24/7 specialist advice. The successful candidate would be encouraged to work with histopathologists from a range of specialities to ensure there is 24/7 cover.

There is an existing process in place for management and communication of results post-biopsy however, with this service, retrieval surgeons can contact a specialist on-call histopathologist for advice as to whether biopsy is required.

This proposal has been accepted by both NHSBT and NHSE&I and we are currently working through the business case to make this happen. As with all new processes things are always more complicated especially working through the legal, regulatory and contractual requirements. Unfortunately, this is estimated to take 15 months before it will go live. I know this is disappointing, but we are working on an interim solution to bridge the gap and hopefully we will get an agreement soon.