**Event: Progress in Transplantation, Organ Donation and Research**

Tissue Access for Patient Benefit (TAPb) hosted an event aimed at raising awareness of human tissue donation, including how human tissue is used for biomedical research.

**Introduction**

Tissue Access for Patient Benefit (TAPb) is a group of individuals tasked with developing a model for UCL and its NHS partners that allows researchers to use surplus and often discarded human tissue for research. The surplus tissue comes from surgical procedures or during diagnosis. Patients will be asked for consent to use their tissue for research that has been approved by the UK Government National Ethical Review Service (NRES).

Tissue alone is not enough; accompanying anonymised clinical data is needed to link disease with development of new treatments and to provide evidence to improve patient care. The tissue samples and clinical data together are referred to as biospecimens. Currently in the UK there is a shortage of biospecimens to fulfil research needs, with many research companies importing up to 90% of their biospecimens (Ann Coorman, Tissue Solutions).

“...research companies importing up to 90% of their biospecimens”

TAPb is streamlining the process of providing biospecimens to researchers. However, input from all the stakeholders is extremely important, these include:

- The patient or donor family donating the tissue
- The clinical team treating the patients
- The pathology team who administer diagnostic testing
- Research technicians to collect and process tissue into useful biospecimens
- Biobank staff and infrastructure for biospecimen storage and traceability
- Research academics and companies who use the tissue
- Clinical trial and healthcare workers who are involved with experimental medicine delivery of new treatments

**Background**

TAPb is based in the UCL Academic Department of Surgery located in The Royal Free London Foundation Trust, which provides close links with Royal Free Transplant Services, the hub of the solid organ transplantation for North Central London. The link provides access to a highly-focused pool of clinical information at the cutting-edge of healthcare delivery.

**Events**

Initially, we assessed current working practices from members of regulatory bodies, clinical and research professionals. After which professional, patient and public engagement was encouraged through two events:

- 12th November 2011 - Improving Liver Transplant Outcomes, Your Views
- 23rd April 2012 - Progress in Transplantation, Organ Donation and Research

**Event 1: Improving Liver Transplant Outcomes, Your Views**

The aim of the first event was to gather and circulate information from the focus groups and obtain additional commentaries from other researchers, clinical professionals and patients. Key presentations were published on the TAPb website (www.ucl.ac.uk/tapb/videos).

**Event 2: Progress in Transplantation, Organ Donation and Research**

We introduced two-way engagement to gather opinions from the different stakeholders to balance the needs of researchers for a human tissue supply with the concerns expressed by patients, members of the public and clinical professionals. The event was predominantly advertised using email lists of professionals working within the life sciences at universities and hospitals across London. Macmillan Cancer Support was involved in recruiting patients and members of the public through their established mailing lists.

---

**Adrian Bailey MP speaking at the TAPb event on human tissue donation. The full video is available at YouTube/tapbatacl**
We used three interactive techniques to capture anonymous data from the different stakeholders:

1. The real-time interactive voting system
   - Anonymous real-time opinions
   - Recording demographic groups present in the audience
2. Question board
   - Enables attendees to expand on questions
   - Pose questions anonymously
3. The online survey served two functions:
   - Information on the overall event (e.g., food, length of day etc.)
   - Gather opinions from attendees who were unable to attend the interactive session
   - Reformulated questions captured potential changes in opinion over time

The questions asked on the comment boards are listed in Table 1, where appropriate comments were incorporated into data from the voting system and online survey.

<table>
<thead>
<tr>
<th>Question</th>
<th>Interactive data gathering</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Generic Consent</strong></td>
<td><strong>We used three interactive techniques to capture anonymous data from the different stakeholders:</strong></td>
</tr>
<tr>
<td>Science moves forward quickly. We sometimes need to store tissue for future research. Are you comfortable with giving your consent for researchers to use your tissue in future research, wherever that may be?</td>
<td>1. The real-time interactive voting system</td>
</tr>
<tr>
<td>Research ethics</td>
<td>o Anonymous real-time opinions</td>
</tr>
<tr>
<td>Are there any aspects of medical research you have concerns about?</td>
<td>o Recording demographic groups present in the audience</td>
</tr>
<tr>
<td>Research ethics</td>
<td>2. Question board</td>
</tr>
<tr>
<td>Would you NOT want your tissue to be used for? If so why?</td>
<td>o Enables attendees to expand on questions</td>
</tr>
<tr>
<td><strong>Tissue utilisation funding</strong></td>
<td>o Pose questions anonymously</td>
</tr>
<tr>
<td>Tissue collection services cost money to run. The future operation of biobanks cannot continue to be subsidised solely by the NHS or Universities. They need to receive funding from a number of other resources. Would you be happy for the cost of collecting and providing the tissue to research to be reimbursed at what is called the full cost recovery rate</td>
<td>3. The online survey served two functions:</td>
</tr>
<tr>
<td>Use of Clinical Data</td>
<td>o Information on the overall event (e.g., food, length of day etc.)</td>
</tr>
<tr>
<td>Anonymised clinical data is important, are you happy for information from your medical records to be given to researchers along with your samples?</td>
<td>o Gather opinions from attendees who were unable to attend the interactive session</td>
</tr>
<tr>
<td>Research ethics</td>
<td>o Reformulated questions captured potential changes in opinion over time</td>
</tr>
<tr>
<td>Does Human tissue and associated medical information have value?</td>
<td><strong>The questions asked on the comment boards are listed in Table 1, where appropriate</strong></td>
</tr>
<tr>
<td><strong>Tissue Utilisation</strong></td>
<td>comments were incorporated into data from the voting system and online survey.</td>
</tr>
<tr>
<td>Organ donation is the ultimate gift. In certain cases organs offered cannot be used for transplant. How do you think these organs can be used in research?</td>
<td><strong>Table 1: Questions asked to the audience through interactive methods during the day</strong></td>
</tr>
<tr>
<td>Research ethics</td>
<td><strong>Table 1: Questions asked to the audience through interactive methods during the day</strong></td>
</tr>
<tr>
<td>Why do you think it is important for researchers to be able to use human tissue and body fluids in research?</td>
<td><strong>Table 1: Questions asked to the audience through interactive methods during the day</strong></td>
</tr>
</tbody>
</table>

**Table 1: Questions asked to the audience through interactive methods during the day**

- Science moves forward quickly. We sometimes need to store tissue for future research. Are you comfortable with giving your consent for researchers to use your tissue in future research, wherever that may be?
- Research ethics: Are there any aspects of medical research you have concerns about?
- Tissue utilisation funding: Tissue collection services cost money to run. The future operation of biobanks cannot continue to be subsidised solely by the NHS or Universities. They need to receive funding from a number of other resources. Would you be happy for the cost of collecting and providing the tissue to research to be reimbursed at what is called the full cost recovery rate?
- Use of Clinical Data: Anonymised clinical data is important, are you happy for information from your medical records to be given to researchers along with your samples?
- Research ethics: Does Human tissue and associated medical information have value?
- Tissue Utilisation: Organ donation is the ultimate gift. In certain cases organs offered cannot be used for transplant. How do you think these organs can be used in research?
- Research ethics: Why do you think it is important for researchers to be able to use human tissue and body fluids in research?
Figure 1: Demographic of the attendees: How would you describe yourself?

- General Public: 16%
- Patient: 6%
- Carer: 3%
- Hospital Doctor: 5%
- Hospital Manager: 5%
- Other healthcare worker: 17%
- Healthcare researcher (not directly involved with patients): 34%
- Health related industry: 11%
- Active lay member: 3%

Figure 2: Science moves forward quickly. We sometimes need to store tissue for future research. Are you comfortable with giving your consent for researchers to use your tissue in future research, wherever that may be?

- Yes: 84%
- No: 16%
No problem (with consent and ethics) 86%

Donor family not being consulted 4%

Pharmaceutical companies and clinical trials 5%

Information accessed by private companies e.g. insurance 5%

No problem (with consent and ethics) 86%

No, should be centrally funded (e.g. NHS, UCL) 20%

No, tissue procurement should solely work through private sector providers 2%

No Responses 5%

Yes 73%

Figure 3: Are there any aspects of medical research you have concerns about?

Figure 4: Tissue collection services cost money to run.

The future operation of biobanks cannot continue to be subsidised solely by the NHS or Universities. They need to receive funding from a number of other resources.

Would you be happy for the cost of collecting and providing the tissue to research to be reimbursed at what is called the full cost recovery rate?
Conclusions

A high proportion of attendees were in favour of allowing better access to human tissue for research, attracting support from 84% (Figure 2). The concerns raised on the comment board included research into defence (Warfare), cloning, release of information to third parties (e.g. insurance companies) and direct commercial use for profit.

Many of these concerns will be allayed through NRES and TAPb review board criteria for use of biospecimens. This process is coupled with obtaining generic and enduring consent to use the tissue for future approved research, including commercial and international companies and academics. Regardless of final TAPb system, it will function under not-for-profit principles.

However, providing high quality biospecimens incurs a running cost, which could be paid for in the following ways:

1. Through private investment only (e.g. Tissue Solutions, Bioptra) i.e. no public support, with tissue recovery to pay for entire cost, including new infrastructure
2. Centrally funded by NHS and/or academia with tissue supplied to researchers free of charge
3. Cost recovery where NHS and academia support through existing infrastructure, charging staff and estate costs to the researcher i.e. “cost recovery” (Oxford Biobank)

The most popular and potentially efficient way of providing biospecimens in the short term is through number 3, with 73% of attendees in favour.

Informed consent is taken for therapeutic procedures during hospital consultation; leading to the conclusion that gaining consent for research should happen simultaneously. Consequently, a member of the clinical team, treating the patient wishing to donate cancer tissue for future cancer research, would be well placed to discuss any questions raised with information provided by TAPb. Furthermore, the UK governments Health and Social Care Bill 2012 supports this position, with an emphasis placed on supporting research activities by helping the release of NHS held clinical data and requirement of clinical staff to be involved with research. On a local level this translates to using current infrastructure to support patient consent during general hospital consultation.

Consequently, existing NHS infrastructure can be optimised to support research obligations and development of new treatments in the UK.

With only 4% of attendees previously being unaware of the researchers using human tissue (data not shown) and 25% being members of the public, patients or active lay persons, there was evidence of self-selection amongst attendees. Our next challenge is to attract greater numbers of attendees not involved or previously aware of this issue (Figure 1).

Future events

The data so far provides a platform for future events to gather representative opinions across all the stakeholders involved with providing and/or using biospecimens.

Our next event will focus on:

- Increase number of patients and public
- Improving question session participation
- Provide more interactive sessions with greater incentives to attract different demographics
- Expand on specific questions relating to consent, ethics and patient information

The focus of the coming TAPb public engagement will concentrate on specific demographic groups and to disseminate information in a more accessible way. We will increase the proportion of patients and members of the public, whilst maintaining a small contingent of professionals, by choosing a neutral location and inviting patients and community leaders (religious groups, local societies e.g. law society) to speak at the event.

The majority of the event will focus on interactive techniques:

- Voting at the very beginning, then at timed intervals throughout the event
- Start with short focused talks on human tissue research
- Allow attendees to mingle around stalls showcasing aspects of human tissue research
- Provide comment boards with asking specific questions
- Incentivise attendance by providing food

A different approach will be used to gather opinions from greater numbers of professionals. The videos from this event will be collated and edited to create an interactive online questionnaire, with a financial incentive to participate.

We will use the information from the different methods of engagement to influence the implementation of the TAPb system and to provide material for NHS and UCL management to allow provision of biospecimens to research. Above all, we need to assert the role of TAPb as an organisation supporting cutting-edge research in academia in partnership with the private sector using not-for-profit principles.

With thanks to all the speakers and organisers and funders (Amir Gander, Barry Fuller, Brian Davidson, Linda Selves, the Royal Free London Trust, and UCL Enterprises)

Please go to www.ucl.ac.uk/tapb for more information