Confederation of Cancer Biobanks

CCB Update

Issue 7, March 2013

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Note from the Editor

Caroline Magee, CCB Secretariat

Welcome to this issue of CCB Update – the newsletter from the National Cancer Research Institute's Confederation of Cancer Biobanks (CCB).

We are excited to report on the great progress that is being made with the Biobank Harmonisation and Accreditation Project - a wonderful example of the biobanking community working together for the benefit of all.

CCB Members have also been busy and we are pleased to be able to showcase activities at two banks in this issue. Northern Ireland Biobank report on their recent launch and the integration with Molecular Pathology and we talked to Nottingham Health Science Biobank about their ground-breaking initiative involving patient advocates in the consent process.

The format of our member-hosted meetings is proving successful and three more events are planned this year.

To provide feedback on the newsletter, please contact ccb@ncri.org.uk

CCB Events in partnership with members

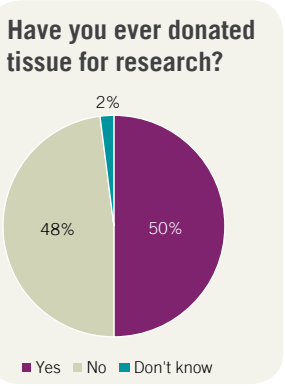
Workshop on Access and Consent in Biobanking

This event in October, held in association with Newcastle Biomedicine Biobank, continued the success of this format of member-hosted meetings. The topics of access and consent proved popular with over 60 delegates attending. Seven presenters covered aspects of access and consent from both the public and researcher's perspectives and also tackled the challenging area of post-mortem tissue donation. An interactive voting system was used to promote discussions and provided some interesting results.

Feedback on the event was extremely positive with 100% of delegates rating the event as excellent or very good and highlighting the impact of lay involvement in biobanking.

The speakers' presentations and results of the voting can be viewed on the CCB website.

http://www.ncri.org.uk/ccb/previousevents.html



2013 Events

Data Standardisation and Management will be the focus of the next event to be held in the early summer in Scotland in association with Tayside Tissue Bank and Glasgow & Greater Clyde Biorepository.

Other topics to be covered in future events are pathology imaging and patient/public engagement. Further details will be posted on the CCB website as they are confirmed.

http://www.ncri.org.uk/ccb/upcomingevents.html

Development of biobank quality mark gains momentum with community support

Anne Carter, Portfolio lead provides an update on the progress of this exciting biobanking project.

The last time I wrote about the CCB's harmonisation project in this newsletter was in July 2010 when the project had barely begun. There have been many developments since then and the project has moved on considerably.

The National Cancer Research Institute (NCRI) Board gave their go-ahead for the development of a biobanking standard and accreditation scheme at their meeting in March 2011, with the stipulation that the project should be delivered with the full involvement of the biobanking community.

The project kicked-off in September 2011 with a meeting of stakeholders attended by representatives of CCB members, researchers, research funders and pharmaceutical companies. Representatives of non-cancer biobanks were also included as any scheme needs to be applicable to all biobanks, whatever their focus. The meeting explored the need for harmonisation, standardisation and accreditation of biobanks, and has been key in setting the tone for the work that has followed.

Delegates at the launch meeting felt that, in the first instance, an accreditation scheme should be based on those areas of practice where simple standards can be defined, and should be pragmatic and realistic in a clinical setting. Ensuring that there is complementarity with, and no duplication of, existing systems that audit elements of biobanks (Clinical Pathology Accreditation, the Human Tissue Authority or the Medicines and Healthcare Regulatory Authority, for example) was seen as essential.

A peer review system was seen to be the most cost-effective and would be acceptable if it was used as a mutual help system, with the reviewer learning from the bank being reviewed and vice versa. It was proposed that the accreditation process should start with self assessment, to highlight areas of non-compliance to internal staff, and be followed by a peer review stage, that would lead to sharing of best practice and improvements in quality. Self assessment alone was felt to be insufficient; however if used correctly by banks it can provide a baseline for improvement and act as a motivational tool, giving direction to quality initiatives.

Following the stakeholder meeting, fifteen volunteers formed a Steering Group (SG), chaired by Professor Andy Hall, and four areas of work were defined in the following Working Groups (WG):

WG 1 Consent, ethics and public engagement
(Chair: Dr Bridget Wilkins, 10 members)

WG 2 Sample quality
(Chair: Dr Stephen McQuaid, 12 members)

WG 3 Biobank governance and IT
(Joint Chairs: Dr Ian Forgie and Mr Phil Quinlan, 12 members)

WG 4 Quality Assurance
(Chair: Dr Nigel Westwood, 11 members).

These groups have identified a total of 159 areas where standards can be defined and have drafted standards and best practice guidelines for each of these. The compiled draft standard has been reviewed by the SG and WG members and a second draft is being prepared for wider circulation within the biobanking community.

In parallel with this work, an accreditation scheme, based on compliance with the requirements of the standard, has been devised and trialled in one volunteer biobanks. A self-assessment questionnaire, based on the clauses of the draft standard, proved to be useful to the biobank in judging how well it meets the standard and to the audit team in preparing for the audit.

Next steps

It is anticipated that the second draft of the standard will be ready for review by the SG and WGs in March and will be circulated more widely for comment towards the end of April.

A second mock audit will be undertaken to test the suitability of the standard and help develop the assessment scheme, followed by audit visits outside of the current project participants. The outcomes of the mock audits will be reviewed by the SG and WGs with input from the assessors and the assessed biobanks and the information used to make improvements. This iterative process will continue until the SG is confident that the system is robust, after which the standards will be published and the

accreditation scheme launched formally. One option being explored is to have the scheme "adopted" by an independent accreditation body which will give greater independence and hence greater authority to the accreditation scheme.

Team Effort for the Benefit of All

The rapid progress made in development of the standard and accreditation scheme has been due to the hard work and professional approach of all of the volunteer SG and WG members, who should be commended for their efforts. The next stage looks very exciting and will allow the work to be much more visible to the biobanking community. The goal is for samples from different banks to be of consistent quality and to be "interoperable" as far as the researcher is concerned, so that samples from different biobanks can be used in the same hypothesis-driven study.

Biological samples and data have become a critical resource for translational research. Achievement of accreditation for a biobank will provide assurance to donors that their samples are valued and treated appropriately, to biobank funders, managers and staff that the biobank is operating to widely accepted quality standards and to researchers that the material they obtain from biobanks is of known quality. All of these will help to achieve a situation in which the availability of biosamples of appropriate specification and quality is no longer a significant limiting factor for research in the UK.

For more information on the project contact Anne at **anne.carter@ncri.org.uk**

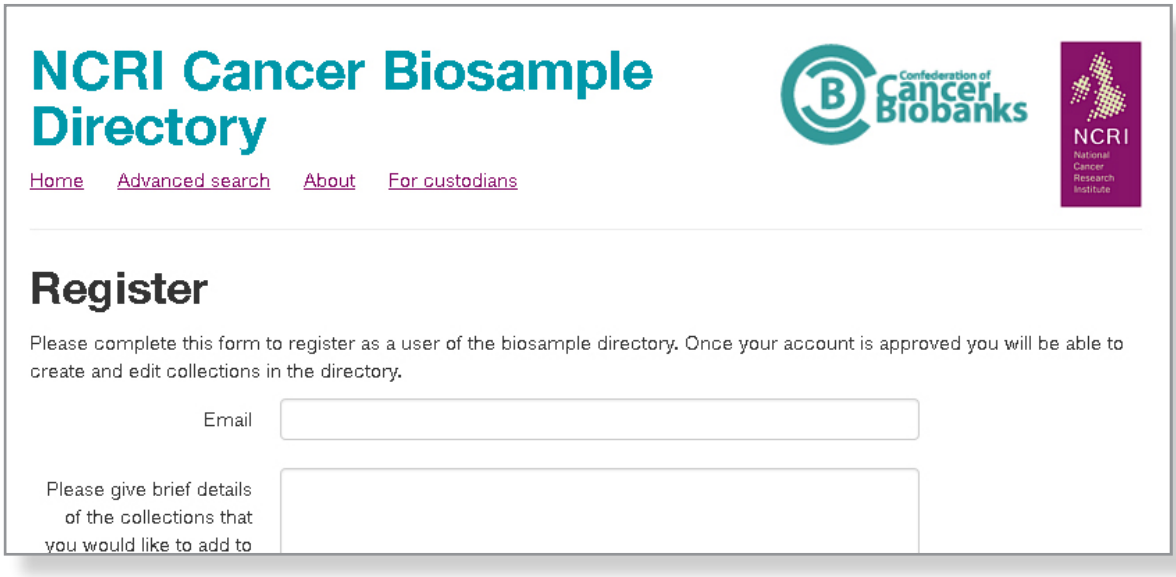
In memory of Neil Formstone

We were sad to hear of the death of Neil Formstone in December. Neil was a vocal and passionate supporter of patient involvement in research and many lay people and researchers have benefited from training sessions he has led in this area. He was not afraid of challenging systems or breaking down barriers to encourage more patients to be offered the opportunity to participate in research. He was also a strong advocate of tissue banking, being actively involved with Wales Cancer Bank from its earliest days and providing support for CCB and several member banks over the years. Neil's style did not suit everyone but his drive and commitment to the cause was unshakeable and he opened the door for many others to take an active part in delivery of research. We celebrate the contribution he made during life and the additional legacy of donating his body for research.

Redeveloped NCRI Biosample Directory goes live

Users can now manage their collections directly on the NCRI Biosample Directory to keep the details up to date.

Details of how to register with the Directory can be found at **http://biosampledirectory.ncri.org.uk**



Official Launch of Northern Ireland Biobank

The Northern Ireland Biobank (NIB) and the Northern Ireland Molecular Pathology Laboratory were officially opened by the Northern Ireland Health Minister, Mr Edwin Poots, on Wednesday 9th January 2013.

The new hybrid facility, which is a partnership between Queen's University Belfast and the Belfast Health and Social Care Trust, underpins a comprehensive molecular pathology programme based at Queen's Centre for Cancer Research and Cell Biology. The seamless integration of biobanking with a molecular diagnostics operation together with molecular and digital pathology research is the first of its kind in the UK and Ireland and is set to enhance cancer research and diagnostics for patients across Northern Ireland and further afield.

The NIB is comprised of three main components to support cancer research. There is a prospective collection of clinical samples, acquired with full patient consent, which focuses specifically on colorectal, breast, head and neck, gynaecological, prostate and lung cancers. Tissue samples are acquired from the two pathology laboratories within the Belfast Trust. The NIB also consents patients for matching donations of blood, urine and saliva as appropriate. In addition to the prospective collections the NIB has ethics and governance approvals in place to access the formalin fixed, paraffin embedded samples held in the Belfast Trust's pathology archives. Using the archival materials the NIB has created unique TMA resources and extensive DNA libraries of large cohorts of anonymised cancer samples all linked with robust clinical and pathological data. The NIB resources are available to researchers with or without baseline data for known biomarkers specific to that cancer type. The third component of the NIB which has been developed recently focuses on the collection of haematological malignancies.

The launch event was attended by the Chief Executive of the Belfast Health and Social Care Trust, The Vice Chancellor of Queen's University, the Director of Health and Social Care Research and Development (HSC R&D), Cancer Research UK's Chief Scientist and Northern Ireland's Chief Medical Officer, among others. Not surprisingly, the launch generated a lot of local media interest with coverage on both TV and radio. There were a series of talks in the afternoon by the President of the Royal College of Pathologists, Professor Archie Prentice, Professor Stephen Finn, Pathology and Cancer Molecular Diagnostics, St. James's Hospital and Trinity College Dublin, Dr. David González de Castro Head of the Molecular Diagnostics department at The Royal Marsden Hospital and The Institute of Cancer Research and Mr Derek Stewart OBE, cancer survivor and founder Chair of the Consumer Liaison Group. For more information visit **http://nibiobank.org/**

Peter Hamilton, Jackie James and Manuel Salto-Tellez of NIB

Patient-led approach to consent piloted at Nottingham Health Science Biobank

We spoke to members of the biobank on their innovative approach to consent.

The team at the Nottingham Health Science Biobank (NHSB) has set out to take an innovative approach to both people and process when establishing their biobank. A key innovation involving people is helping to build lasting relationships with an important stakeholder that biobanks often neglect – the patient donors of the tissue samples.

Consent to donate is an expression of partnership and goodwill between the Biobank and potential donors and the process of taking this consent should be sensitive, user friendly and inclusive of both patients and donors. This is particularly important as consent given for the purpose of Biobanking is often generic and enduring. The team therefore approached the Patient and Public Involvement (PPI) Advisory Group, comprising volunteer patients, carers and the public, to ask for volunteers to engage in the design of a new information and consent pathway.

"The involvement of the PPI group has been pivotal to the success of the new pathway", said Dr Balwir Matharoo-Ball, Operations Manager of the NHSB.

From these initial consultations, the Biobank and the Advisory Group evolved the idea that the consent process should be driven and delivered exclusively by the patients themselves. Members of the PPI Advisory Group who wished to take part received a full induction by the hospital Trust including the required governance issues and were issued with honorary Trust contracts. In addition, the NHSB provided a comprehensive consent training package, including presentation, role plays, hand holding, shadowing, observation, competencies and final sign offs. This training package is available to other parties if they are interested. As part of the on-going training the advocates were also able to tour the histology laboratories to see what happens to the samples. "This was really interesting" said Hilary Walker, a volunteer in the breast cancer follow-up clinic, "It made me so much more convinced that the tissue is really needed for research."

Several of the volunteers have had breast cancer and they commented that they wanted to contribute to research without just fundraising. This has its own challenges; "It was difficult initially being back in the Breast Unit," said Beverly Liddle "but the feeling that I'm giving something back and helping people in the same situation is so positive".

The new consent approach has been piloted in the Breast Institute and five PPI Advocates have been recruited to date, with responsibility for taking consent in all of the out-patient breast clinics. Information on

the tissue bank is sent to patients with their appointment details and when they arrive at the clinic they have the opportunity to speak to the volunteers ahead of their appointment with the healthcare team. The separation of the consent process from the discussion with the doctor is seen as an added benefit of the new arrangement. "There is a real value in us having this role", said volunteer Hilary Stobart, "I was surprised initially how happy most people are to have this discussion as they are often anxious waiting for their appointment, but many seem to appreciate the opportunity to ask questions about the tissue consent process. It is good to help people gain a greater awareness of research."

The new pathway and role of the volunteers have had excellent feedback from both patients and the advocates and has led to increases in the rates of consent. "I feel part of the biobank team" commented Andrew Buckland, who volunteers at the male breast cancer clinic, "It was challenging at first, having the confidence to introduce the subject to the patients, but you develop your own style and there's such a sense of satisfaction at the end of the clinic when you've signed up a good number of patients." Andrew's wife Barbara also volunteers and she added "It's lovely to know we're doing some good".

The aim is to now recruit further PPI advocates to lead in other specialties, with urology clinics the next area to be piloted as well other Oncology clinics. The innovation moving forward is that for the next roll-out the NHSB PPI advocates already taking consent will themselves become the trainers for the new PPI advocates. This consent initiative is the first we are aware of in the UK and it would be wonderful to see it become established in other trusts.

For more information contact **NHSB@nuh.nhs.uk**