National Cancer Research Institute (NCRI) Confederation of Cancer Biobanks (CCB) Annual General Meeting

17 June 2015, University of Nottingham

The meeting was attended by professionals from academia, research, health care professionals, and significant attendance from ICPV and other patient groups. There were a few trade stands which were well attended and covered areas such as informatics and sample collection and storage. Biobanks exist to facilitate research which is important for the progression of stratified medicine. Biobank work is supported by a number of organisations, including the British Heart Foundation.

The morning provided a talk which gave an update on the UK Cancer Research Centre (UKCRC) Tissue Directory and the Co-ordination Centre, followed by round table discussions with feedback and lunch before an afternoon of lectures. The day was enjoyable and informative and provided an opportunity to network and gauge initial level of desire for participation in the development of National Data Standards for Diagnostics.

The first talk of the day gave a historical overview of the origins and development of the Biobank and Tissue Directory. This included funding (or rather lack of it), obtaining of consent, and historical regulation of sample collection. In 2011 the Strategic Tissue Repository Alliance through Unified Methods (STRATUM), engaged patients and members of the public and developed. It produced a standards required for biological research, identified sample characteristic, data sets and regulation requirements. The output of some of their work was the production of standards for Biobank Quality and Data Standards. The Biobanking and Biomolecular Research Infrastructure (BBMRI) work stream helped develop a pan European directory for sharing information. More information on the BBMRI can be found on the following link https://www.biobankinguk.org

This harmonisation built on existing work to identify gaps in standards and promote co-ordination and alignment. Biobanking work also takes into account the following international and European standards:

(ISO TC 276 Biotechnology WG5 which covers data processing, annotation, analysis, comparability and integration of information systems.

CEN TC 140 is a standard in development for Invitro medical devices.

The BBMRI European Research Infrastructure Consortium (ERIC) provides a hub and spoke model of pan European Biobanks, with aims and objectives aligned to the CCB. In addition, it has capacity building.

The Partners Charter fosters scientific excellence and provides guidance on interoperability.

The next annual meeting of the BBMRI is 29 September 2015 in Olympia.

The round table session explored the future of the CCB in the context that there is no further funding available. The process employed for this was DeBono's six thinking caps. The concluding outcome from this session was that there has been significant work of high value that is too important to lose. As the CCB is incorporated into an overarching organisation of biobanks and tissue directories, the experience gained from the unique development of Cancer Biobanks must be employed to provide benefits in the form of knowledge and lessons, and to aid the further development and expansion of Biobanks for other disease sites.

The afternoon's talks focussed on sustainability, consent and data. The Biobanks in Wales shared their experience of funding restrictions. They highlighted the very difficult decision that was made to refocus the service provided in Wales, with the outcome of reducing the number of Biobanks - thus removing a pan-Wales service and limiting the number of tissue and tumour types catered for. However, they would still able to provide a service that could accommodate ad-hoc requests for tissue collection such as those required for research into rare diseases. The Welsh experience also allowed for cost savings by the introduction of innovative approaches such consenting, which is now obtained electronically rather than paper based and utilises volunteer consenters for the majority. This being made possible due to consent being obtained in a specialised unit where patients are already aware of the reasons why they are attending, i.e. they have already receive their cancer diagnosis. They are also looking toward initiatives that will allow income generation. These include digital imaging within

laboratory services and progressive sample collection through a patients cancer journey.

The East Midlands Biobank is situated within the pathology department and are connected to the e-health records as a Biobank resource and has interoperability with the hospitals patient administration system. They highlighted the importance of the existence of Biobanks with sharing of 60,000 tissue samples in the past 4 years. They also shared a costing and charging model.

A talk by Steve Gardner highlighted the issues encountered when tissue, not data, is the focus, with the result of a rewrite of the definition of a Biobank. He outlined the data fields required by researchers, which can be broken down to different subsets such as:

- **Patient:** patient demographics, family history, patient phenotypes
- **Clinical History** – co-morbidities, adherence to drug regimes, outcomes, follow-up
- **Samples:** molecular subtypes, proteomics, epigenetics
- **Data Regulation and Audit** which includes Information Governance - highlighting that it can be electronically simple to identify a patient even when data is anonymised or pseudonymised; digital consent; sample audit trails; USA Healthcare Insurance Portability and Accountability Act (HIPAA) (which interestingly does have an impact on the UK).

He also highlighted that the large amount of data storage required for genome sequencing that will require its own data warehouse storage system. Due to the amount of data, a relational database will not suffice. This is partly due to the need to compare methodologies employed in genetic analysis, which can have an impact on data quality.

A talk on requirements for patient consent covered legislation and obtaining consent. Regulation of health data requires that before information can be shared there must be either:

- a statutory basis
- consent
- serve clear public interest

For consent to be legally valid it must be given voluntarily without coercion and the individual must have the capacity to provide that consent. There are two types of consent:

- Real consent and informed consent. Real consent is the tort of battery where there is a need to be aware of procedures. As an example litigation may result from a patient going for an eye operation and receiving an unconsented procedure on their leg

- Informed consent is the tort of Negligence

There is a lack of legal authority when it comes to informed consent, due to the fact that there has to date been no claim made under common law. Informed consent involves the 'Information disclosure standards'. As it is difficult to base legal information on the disclosure standards, it is based on the characteristics of the information itself. The information disclosure standard is based on the giving and receiving of what is considered reasonable. There has been a couple of test cases in medical treatment that have had significant impact on the 'informed' consent model:

1984 Sidaway v Bethlem: the claim for damages was rejected because the judge stated that the Bolam test should not apply to the issue of informed consent. The Bolam test states that if a doctor reaches the standard of a responsible body of medical opinion they are not negligent. This means that there must be professional support for a course of action to be legitimate. This is seen as guidance for reasonable professional disclosure.

2015, Montgomery v Lanarkshire highlighted that a patient is entitled to be told of risks where it is necessary for them to make an informed decision whether to incur them. What this means is an adult that is of sound mind is entitled to decide which treatment, if any, to undergo. Also, their consent must be obtained beforehand. This case is seen as reasonable guidance for the patient. The test case turned the legal standing around, resulting in an alignment with that employed in the rest of Europe.

When it comes to health data it is important to consider the standard employed in consent to disclosure. Studies have shown that 41% of patients concerns are not restricted to their privacy – they do care about the use of their data.

The presentation given by the Scottish Biobank highlighted the need to obtain patient approval for use of surplus tissue and the obtaining and use of additional tissue taken at the time of diagnostic procedures. This is recorded in the electronic health system. It is worth considering if the patient's wishes change over time and, hence, would need to be captured electronically. Other consents that also need to be captured include:

- post mortem consent in advance of the patient death
- advance notification of tissue required for research

On the whole, the meeting was both interesting and stimulating and highlighted that there is a need to capture significant amounts of data that will be used in varying amounts by different professionals in order to improve patient care and treatment outcomes. The desire for standards is extremely high and is likely to stimulate significant interest and desire to participate in reviewing and testing.

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