Biobanking Roundtable – 29 June 2012 - Summary of Discussion

Facilitator: Dr Nik Zeps (Chair NHMRC Biobanking Working Group)

Attendees:

Attendees came from the following organisations:
Cancer Australia
Department of Health and Ageing
Department of Industry, Innovation, Science, Research & Tertiary Education
Leukaemia Foundation
National Breast Cancer Foundation
National Heart Foundation
National eResearch Collaboration Tools and Resources (NeCTAR
Ovarian Cancer Australia
Royal College of Pathologists
Victorian Cancer Agency Consultative Council

Introduction

The following document summarises the issues raised at NHMRC Biobanking Roundtable.

Mission Statement of biobanks

The purpose of a biobank is to supply human biospecimens that are of suitable quality and with appropriate annotation (clinical information and follow up) that enables researchers to create new knowledge leading to the prevention of or improved treatment of human disease.

Summary of discussion

Attendees were unanimously in favour of developing a national strategy but emphasised that it should be:

- focused on function (one size could not fit all)
- light in its touch (not an additional tier of expensive bureaucracy).
A national policy and strategy encompasses developing national approaches to:

- governance;
- QA and accreditation/certification;
- Ethics;
- cost effectiveness;
- IT planning and integration;
- promoting national collaboration;
- international liaison and collaboration; and
- expert advice to government and funders.

**Measures of success**

The number of samples accrued and distributed per year was identified as an activity based metric (an output measure rather than an outcome measure) and even then a poor indicator of the value of biobanking and should not be used.

The primary outcome was improved healthcare/survival/wellbeing of the community, but this was difficult to measure in a time frame that biobanks could report on.

The utilisation of the biobank by researchers for quality research was generally agreed to be a clear output measure. There is a need to identify the output and outcomes measures of biobanks now so that they could be compared to what they are after the development of any national strategy would be essential. These may include qualitative measures rather than purely quantitative measures. Without baseline measures evaluation of effectiveness of a national strategy would be very difficult.

**Issues warranting consideration**

1. **Co-ordination or centralisation?**

Biobanking is a decentralised and largely ‘cottage’ industry, that derives its vigour from the enthusiasm and commitment of those who found the biobank. This remains the case notwithstanding the formation of some centralised activities like the Victorian Cancer Biobank (where 228 biobanks were involved in the initial consultation on establishment).

Any national strategy needs to take this biobanking community structure into account, to ensure local engagement and participation.

Funding for biobanking comes from a variety of sources (government, universities, medical research organisations and philanthropy). None of these sources can be expected to fund significant initiatives independently. The issue is really one of co-ordination and co-operation.

A number of hard issues need to be addressed:

- Is the current concept of biobanking still valid?
• Is there a shortage of specimens or is the issue one of knowing what is stored and being able to access it?
• Is all biobanking needed? That is, does a biobanking proposal meet a real medical need or is it simply a form of research that appeals to the proponent?

There is clearly a need for better communication and better utilisation of existing resources. This includes the need to have better methods of collecting and linking clinical data to specimens.

There is some existing support for this, one example being the National eResearch Collaboration Tools and Resources (NeCTAR) initiative. This is an Australian Government project to build new infrastructure specifically for the needs of Australian researchers. NeCTAR is using existing and new information and communications technologies to create new digital efficiencies specifically for the needs of Australian researchers. NeCTAR does not fund operational costs: indeed to access its funds users have to be able to demonstrate on-going operational support once an infrastructure project is completed.

If governments are to continue to provide, let alone increase access to, such infrastructure funding, the biobanking community needs to demonstrate that it has a coherent strategy for the future and can present a strong case for on-going support.

2. Governance issues

Governance was identified as a key issue. There is no point in collecting biospecimens unless there is confidence on the part of researchers about the quality of what they are getting. That is, there needs to be clear and verifiable standards of collection, annotation, storage and access. For example, the high standards expected of pathology services were not always met by small biobanks and in some instances collection practices rendered sample not fit for purpose and destined for destruction.

Pathology services complied with National Association of Testing Authorities (NATA) accreditation standards (following National Pathology Accreditation Advisory Council (NPAAC) guidelines). This is a good mechanism to look at for accreditation/certification of biobanks.

Some steps were being taken to define the standards for data collection. For example, Cancer Australia has recently developed minimum data sets for biobanking for cancer. It was important that such data frameworks were promoted nationally.

Compatibility with international collections standards was also important. International collaboration was increasing and this was one way of accessing biospecimens cost-effectively, especially in the case of rare samples.
Consideration of the ethics of collection and the way consent is done is needed. Questions were also raised around the need for cryopreserved samples – if not needed this will lead to significant reductions on some of the labour intensive elements of biobanks. Such gains however have to be balanced with the need to place greater emphasis on governance and quality assurance.

Another area where operational economies could be made is the way in which data is handled. Consistent data was not always collected and clinical data systems were not always able to communicate with each other. The technology existed to resolve such issues but the impediments were often institutional or political.

There is a case for some form of registration of biobanks, akin to accreditation, to ensure researchers are able to access samples they can trust. It is also important to meet patients’ expectations about how the samples they consent to are handled and used. The issues here relate to how this can best be done and the cost.

3. **Sustainability**

One of the issues facing biobanks is sustainability. Biobanks can often obtain seed funding to be established, but few such funders, including government and philanthropic organisations, are able to maintain support indefinitely.

There were a couple of ways in which this issue had been addressed. For the Victorian Cancer Biobank, area health services had signed agreements to take over various components within their jurisdiction should state funding cease. There were OECD guidelines which explicitly cover the necessity for newly established biobanks to have a wind up plan (an approach adopted by the WA government).