

Cancer biosample banking in the UK

Despite the prominence given to cancer in the media and society, and the large cancer research effort in this country and others, cancer still represents a significant and growing problem in Western societies and in developing countries. There is no single panacea for this problem of uncoupled effort and success. However, there is a growing movement towards addressing this problem through the use of more 'human-based' research, variably described under the headings of applied research, translational research or experimental medicine. In some respects, this is also resulting in a convergence of public sector research and that done by pharmaceutical and biotechnology companies, where the commercial imperative to translate research from the laboratory to the patient is strong.

Intrinsic to fruitful human-based research is the need to harness the powerful battery of existing and future technologies for studying human biology in the laboratory as well as in the clinic. The substrates for such laboratory studies are, very naturally, samples from humans *ex vivo*. This is probably not news to pathologists, but what may be news to some is that there has never been a better time in recent years for pathologists to contribute to the development of new interventions against cancer – prevention, diagnostics or therapeutics. This bold statement is made at a time when academic pathology in the UK is ailing, research output from pathologists in UK institutions is falling, the demands of NHS service are increasing at the expense of research and human tissue for research has been a virtual no-go area for some time.

So why is this a timely opportunity for human cancer biosample-based research?

First, there are strong indicators that cancer patients are in support of research using donated samples and patient advocacy groups are in support of efforts within the UK to bolster cancer biobanking.

Second, the research ethics community is considering new ways of assessing human biosample-based studies for approval and these are expected to facilitate the process rather than impede it.

Third, pathologists and cancer patients are well represented on the new Human Tissue Authority and the staff of the authority (and their counterparts in the Department of Health) are currently engaging in productive dialogue with members of the cancer biobanking community. Furthermore, the Scottish Bill intended to be the counterpart of the Human Tissue Act in that jurisdiction will apparently have no coverage over samples donated during life.

Fourth, information technology within the NHS, the research community and the biobanking field is maturing rapidly, through initiatives such as Connecting for Health, the National Cancer Research Network's (NCRN) Electronic Remote Data Capture project and the National Cancer Research Institute's (NCRI) Informatics initiatives. Information about the donors of samples, their disease, their treatment and their outcome is vital for samples to realise maximum research utility and, in the final analysis, the samples themselves are latent data, awaiting deciphering through research.

Fifth, the Department of Health in England and the health departments of the devolved UK administrations recognise the importance of sample biobanking and the critical role the NHS plays in contributing to the mechanisms for doing so. For example, the Welsh Assembly has funded the establishment of the Wales Cancer Bank.

Lastly, other funders of cancer research in the UK, most notably Cancer Research UK and the Medical Research Council, in partnership with the Department of Health, have also funded the establishment of onCore UK and this is widely supported by other funders of cancer research within the NCRI partners. In other words, opportunities are arising as a consequence of changes in patient attitudes, policy, application of ethics, regulation, funding and establishment of new infrastructure. Pathologists are pivotal custodians of biosamples on the journey from donor to researcher, and many are interested in conducting research on such samples – the contribution of pathologists to the success of human tissue-based research is paramount.

onCore UK is a new organisation that has been created to serve as the national biospecimen and information resource for research towards new interventions against cancer. It was formed as a new charitable company in 2005, through a joint venture funding agreement between the Department of Health, Medical Research Council and Cancer Research UK. It is an organisation that recognises that partnership and collaboration underpin its activities and that values ethics, quality, safety and service. onCore UK is not a research active organisation – it is a service organisation to serve by facilitating the passage of donated samples from donors to researchers. It will achieve this by acting as an independent not-for-profit broker and custodian of donated samples.

onCore UK's strategic goals are to increase sample availability and, perhaps more importantly accessibility, to researchers. It will do so by focusing on a small number of integrated work-streams. It will function as a biobank itself, by collecting samples of tumour and peripheral blood from patients participating in clinical trials within the NCRN clinical trials networks. This is a high-numbers, long-term approach that will produce a sample and information resource unparalleled elsewhere in the world. It will build on the existence of the NHS and the growing strength of the cancer clinical trials infrastructure and portfolio in the UK. onCore UK will also recognise that there are many other cancer biobanks in the UK that accrue samples on a population-based approach in specific centres. It aims to invite such banks to agree to common principles and practices and to form a confederation of cancer biobanks that can serve the varied needs of the cancer research community from the collective sample portfolio of the allied resources. This will be strengthened by the creation of a new purpose-built information management system, which will act as a web-based portal for researchers seeking samples from the allied biobanks.

How can pathologists contribute?

By playing their part in the smooth running of the sample journey whenever required. In the first instance, this will probably mean working with colleagues in their Trust management and in the local NCRN to become designated as a sample acquisition centre for onCore UK. Thereafter, when it is clear that a patient wishes to donate a sample, the pathologist could serve that patient by assisting in the passage of the sample via their laboratory to onCore UK whenever possible. This might involve the pathologist allowing the creation of an additional paraffin-embedded block of tumour from the surplus tissue of a diagnostic specimen. It might involve the pathologist allowing the creation of extra unstained sections of a tumour from a diagnostic block, or the removal of a core of tissue from such block when no opportunity exists for an additional block to be produced. It might involve the pathologist releasing a copy of the pathology report or other laboratory results, with patient consent, as part of the donation of information about the patient.

What is in it for pathologists?

- The opportunity to contribute as recognised and valued experts in biological sample handling and characterisation to the multidisciplinary effort of translational cancer research.
- The opportunity to contribute to the development of a new part of the R&D portfolio of their local Trust and NCRN structure.
- The opportunity to gain reimbursement for the costs incurred in research sample handling.
- The opportunity to use a national framework to address local concerns over research ethics and human tissue regulation.
- The opportunity to reinstate pathologists as the professionals in the NHS best able to manage the tensions that arise between the needs of diagnostic practice and the needs of researchers.
- For those who wish to use samples in research, a means to access a broader range and larger number of samples from a large-scale, national organisation without the need to collect for personal use.
- Perhaps most of all, the opportunity to serve the patients who are willing to donate samples from their body and sensitive information about themselves whilst expecting no personal benefit in return. Fulfilling the donation for the donor is surely reason enough for a healthcare professional.

onCore UK expects to commence tendering for biosample acquisition networks early in 2006 and to commence operations by the middle of 2006.

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