14 The Importance of Quality Patient Advocacy to Biobanks: A Lay Perspective from Independent Cancer Patients Voice (ICPV), Based in the United Kingdom

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Abstract

Biobanking in the twentieth century will become of increasing importance in health research. Regulation and governance of biobanks must be open and transparent to ensure public trust and confidence and increase donation. Effective Lay Involvement all levels in biobank organisations should be standard practice helping ensure patient benefit remains the central aim and assisting the Promotion of Biobanks and Recruitment of Donors. Properly selected, educated and supported, they become valued members of the Biobank Team. This chapter is based on the work of Independent Cancer Patients' Voice (ICPV) in the UK and recognises that the National Health Service provides a framework which is not universal and neither is the model of patient advocacy which has been developed particularly in cancer research. However, although it has not been easy to find potential members for ICPV, nor to attract funding, we have earned the respect of our professional colleagues by our commitment in giving time and developing the skills necessary to provide effective involvement. These colleagues have enthusiastically mentored and supported us and have provided venues and tutoring for Educational Events. We are sure that patient advocates in other countries would welcome the opportunity for similar involvement and hope our experiences will be of interest.

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14.1 Introduction

Independent Cancer Patients' Voice (ICPV) is a patient led group founded 6 years ago to provide education, mentoring and support for people who, having been treated for cancer, wanted to add a more informed patient perspective to cancer research. The founders were lay members of the Breast Clinical Study Group (BCSG) of the National Cancer Research Institute who initially recruited other interested breast cancer patients. Some had undertaken the very effective Project LEAD Advocacy training offered by the National Breast Cancer Coalition in the USA and wanted similar education for patient advocates in the UK. Although initiated by breast cancer patients, ICPV is now a generic cancer patient group which is reflected in ICPV training events.

ICPV members wish to be active partners in research rather than just passive recipients of care. They recognise that effective input requires education as well as experience and, knowing that they cannot claim to be representative, they prefer the title of 'Patient Advocate'. Study days are held at academic centres across the UK with the enthusiastic support of professional colleagues who host and tutor these events. This reduces costs whilst increasing both collaboration and ICPV's geographic spread. These events started with a 1 day course in Leeds at the invitation of Professors Andy Hanby and Val Speirs and have expanded to some being run over 2 and 5 days. In 2013, Professor Louise Jones and Professor John Marshall at Barts Cancer Institute helped ICPV achieve their original aim – a 5 day residential course in biology – "Science for Advocates". This course was repeated in 2014 and is now annual with EU delegates registered to attend at 2015.

ICPV works with many other charities, academic organisations and government bodies but is independent – thus able to provide an informed and unfiltered patient perspective to cancer research and development of new treatments. Members of ICPV sit on many Trial Development, Management and Steering Groups, Executives and Boards. ICPV has stakeholder membership with the All Party Parliamentary Group on Cancer (APPGC), the National Institute for Health and Care Excellence (NICE), The Human Tissue Authority (HTA) and the Health Research Authority (HRA). It has been invaluable to have the support and encouragement of our professional colleagues together with the easy access to factual information about ethics, regulation and governance from Dr Janet Wisely and team (HRA) and Dr Shaun Griffin (HTA).

ICPV involvement in tissue banking has developed from involvement in cancer research and increases the need for more specialised education and mentoring. This involvement is within the framework of the UK National Health Service but could be applicable in services in other countries. The major aim of patient advocates actively involved with biobanking is to ensure that patient benefit remains the prime objective of any research using donated tissue and that this research is carried out to high level quality and ethical standards. Most donors would wish for maximum possible use of both tissue and related data for the benefit of future patients and want all data, including negative results, to be shared in order to increase knowledge and prevent duplication. However, it should not be assumed that all donors have no further interest in what happens with their tissue and current press interest is raising concerns. Open inclusion of patient advocates at all levels would help biobanks demonstrate transparency and

proper governance together with respect for the donors and their tissue, thus helping to retain public trust and confidence. However, some current projects do not currently involve patients and public and the huge potential benefit of exciting and innovative biobanking initiatives could be hampered by loss of public confidence. At the same time proposed changes in European Data Protection Regulations threatens the proper collection of health data for research. The collection, storage and use of data held in European biobanks is governed by national laws based on the EU Data Protection Directive. A new data protection regulation has been proposed by the EU to update the law, which includes exemptions for medical research with certain safeguards. However, the existing research exemption from consent would be restricted if the European Parliament adopts amendments to Articles 81 and 83 of the Data Protection Regulation. ICPV is a signatory to the Wellcome Joint Statement on this issue [1] and works closely with the National Cancer Intelligence Network (NCIN) on the ethical collection and use of health related data in cancer research and welcomes projects which safely link data across organisations.

14.2 Different Models: Specific Examples

The following pages show specific examples of different models of involvement in cancer biobanking by individual members of ICPV and will illustrate both the value of effective lay involvement and the potential for greater collaboration and innovation:

14.2.1 "Science for Education": A Participant Experience

Margaret Grayson
Independent Cancer Patients' Voice (ICPV)
London, UK

As a patient advocate and member of ICPV I was a student on this course, the first of its kind to be run in the UK. The course was a mixture of lectures and practical lab sessions. Topics covered included basic cell biology – how cells behave, grow and die, the nucleus, DNA, RNA, proteins, specialisation, signalling, oncogenes and tumour suppressor genes. Biomarkers, (very relevant to use of tissue samples), what they are, how they are used – to predict future risk/diagnose disease/prognostic outcomes in predicting the effectiveness of treatment and side effect risks. All of this was combined with daily sessions in the lab with the scientists – not just watching but as a hands on experience (Fig. 14.1): extracting DNA, treating cancer cell samples with toxic agents and measuring the effects with a biochemical test. The most memorable session for me was in the pathology lab as breast tissue was processed for diagnosis and tissue banking, following the process through the various stages. I am a breast cancer patient and I have had a mastectomy, I was so impressed at the way the pathologist and all the staff handled the tissue with such care and respect. How reassuring for patients the care shown to a part of you that you have consented to be used in research.

So was this simply an enjoyable week? I believe that research is an intricate part of quality health care and central within the NHS. As an advocate I am involved in partnering with researchers to ensure that research is ethical and of benefit to both patients and the NHS. The use of human tissue is an essential part of that research to help expand knowledge in the areas of how disease works, how disease can be prevented, diagnosed and treated. The opportunity to be part of the VOICE course gave me a level of understanding of the science involved and this in turn further equipped for effective lay involvement. The knowledge gained has enabled me to be more effective in reviewing research proposals and trial design; and the use of tissue samples with issues around consent for a specific trial; generic consent for future research. It has highlighted the importance of information given to people in relation to the donation of tissue, urine, blood and saliva samples, their preparation, storage and use; including access to their health data. The importance of trust when a patient gives that permission. There is the dual role of the patient

Fig. 14.1 ICPV members learning lab techniques

advocate in partnering with the pathologists and Biobank scientists and also engaging with the public.

14.2.2 Breast Cancer Campaign Tissue Bank

Mairead MacKenzie
Independent Cancer Patients' Voice (ICPV)
London, UK

The Breast Cancer Campaign Tissue Bank (BCCTB) opened in 2010 after the 2008 Gap Analysis [2] showed that research was being limited due to lack of available good quality tissue. From the very start Breast Cancer Campaign saw the importance of patient input and two patient advocates were involved in the early discussions and site visits to potential biobanks. Today there are five advocates taking active roles in the tissue bank; two sit on the management board and three on the tissue access committee. This means that no research project is approved or tissue released without the agreement of lay members. The lay reviewers do not need to be scientists, but have to have an awareness and understanding of research. Our key role is that if we don't see the patient benefit in a piece of research then we say so. Tissue is a valuable resource and donors need to be assured that their tissue is being used wisely. Breast Cancer Campaign took the extra step in involving patients at the very early stages of this project and we believe that lay involvement can only improve the standing of the bank. As BCCTB Chair Professor Alastair Thompson said *"Patient Advocates have kept us grounded in reality, have been very helpful with ethics and information sheet issues and have made us all realise that the standard practice of just throwing tissue away is a terrible waste of resources. They have also been a real pleasure to work with, have made good comments and often respond to e-mails better than professionals"*.

The Bank's data return policy was also driven by the patient advocates who were keen that the tissues donated were used to their maximum benefit. This has resulted in the first publication from Tissue Bank [3].

I have now been involved with the Tissue Bank for nearly 3 years and for the past year have been on the Tissue Access Committee. It is so important to have a patient view at this early stage of

research and I really believe that patient advocates can play a part in ensuring that all research proposed has the patient at its centre and that our precious tissue is used to its best effect. Any questions that I have posted to researchers have all been answered well with no feeling that I am asking the 'silly' question – although sometimes this can be the most pertinent. Patient advocates give the "public face" to tissue donation and can help promote the bank and the research that it provides.

The tissue bank advocates were interviewed for BCC newsletter in 2013 to help promote its use in the wider cancer community [4]. Patient advocates have also promoted PPI within Tissue Banks by having poster presentations at both the NCRI Conference 2013 and the San Antonio Breast Cancer Symposium 2013 [5].

Many of the researchers using the Tissue Bank rarely have any interaction with patients and Val Speirs, Professor of Experimental Pathology & Oncology, Leeds Institute of Cancer & Biology has said *"The phrase 'translational research' is now firmly embedded in the scientist's vocabulary but few have the opportunity to truly engage with patient advocates in the way that the people charged with the responsibility of running the BCCTB can. Having their views can really shape the future of translational search and help drive this forward, benefiting future generations of breast cancer patients."*(Note: since writing, 'Breast Cancer Campaign' and 'Breakthrough Breast Cancer' have merged to become 'Breast Cancer Now').

14.2.3 Brain Tumour Tissue Bank: The Brainstrust Proposal

Helen Bulbeck
Independent Cancer Patients' Voice (ICPV)
London, UK

To build a UK wide network of brain tumour tissue banks that will support a diverse range of research so that the prevention, diagnosis, and treatment of brain cancer are improved.

The need Brain cancer is an area of unmet clinical need. It is one of the most lethal human diseases; only 32 % of the 7000+ people diagnosed with primary brain cancer will be alive at the end of the first year following diagnosis and drops to 14 % at 5 years [6].

Despite these statistics, neuro-oncological research has been, until recently woefully underfunded. This has meant that there has been no structured research base for neuro-oncology and so it has become fragmented and uncoordinated. This is due mainly to the bureaucracy surrounding the use of human tissue, where tissue has been gathered first and ethical consent for use has followed. This has led to tissue banks being set up which are a closed resource to researchers.

Patient voice Significant changes are happening within the health sector which mean that patients have been able to engage with this project. Our community knows the importance of:

- Clinical need – brain cancer is being left behind. As survival rates for cancer improve, survival rates for brain cancer remain unchanged with the outcome of patients with high grade gliomas remaining poor with the median survival below 18 months [7].
- Empowerment – 'no decision about me, without me' is fundamental to the current political healthcare agenda. Patient empowerment and closer engagement with their care lies at the heart of this initiative.
- Stratified medicine – we are now treating the biology of cancer, rather than cancer. But to do this accurately and effectively large numbers of samples are needed. A particular challenge for the coming decade will be the increasing stratification of treatments and their tailoring to much smaller subsets of patients [8].
- Data is a valuable commodity – an ongoing modernisation of cancer registries, combined with new datasets now either mandated for collection or in the process of being mandated, is making a step change in the data available. Patients know this and are able to access their data.
- Increased patient awareness and understanding around the collection of tissue; patient

voice can drive the agenda. Seeking authorisation for tissue collection from patients makes it meaningful and creates space to talk. Individuals who are informed about biobanking are much more likely to participate and give broad consent [9].

By unlocking the potential value of collections of brain tumour tissue samples this project will facilitate many research studies. Shared reciprocity will be at the core – between patients, clinicians and researchers.

Willie Stewart, Consultant Neuropathologist at Southern General Hospital, Glasgow, says, 'one problem researchers in this field continually meet is a lack of tumour tissue for high quality research, yet there are vast resources of material in diagnostic laboratories throughout the country. This project paves the way for this invaluable material to be accessed to support high quality research projects' [10].

14.2.4 Confederation of Cancer Biobanks

Maggie Wilcox
Independent Cancer Patients' Voice (ICPV)
London, UK

The Confederation of Cancer Biobanks (CCB) in the UK has produced quality management and data standards. It is of interest that there was no mention of PPI in the report from an ISO workshop on International Standards for Biotechnology. However, the CCB is committed to effective lay involvement and included an ICPV member in each of the four working groups of the Harmonisation Project. The working groups covered (1) Public Engagement, Ethics and Consent (2) Sample quality (3) Biobank governance/IT (4) Quality Assurance [11].

A lay person chairs the Exec of CCB which also includes a member of ICPV – Both have been treated for cancer, are full members of the team and consider that their views are respected and genuinely valued by their professional colleagues. However, as people who have been involved in biobanking organisations for several years, they are still surprised at the lack of genuine lay involvement in research tissue banks and large cohort studies in the UK. Patients and the public as tissue donors are key stakeholders for any organisation or project that is collecting human samples for research and, without their support and trust, there would be no samples. Some organisations rely on the fact that many research participants give their consent without actually being aware of what research may be undertaken or whether the sample will ever actually be used. PPI in the work of the biobank provides reassurance that research is for genuine patient benefit and that ethical considerations and high quality standards are maintained. Indeed, biobanks and large epidemiological studies could risk losing public trust by not engaging and involving lay advocates. CCB member biobanks who have involved patients can illustrate the benefits of embedding this activity throughout the organisation of the biobank; a position that the NCRI and Confederation of Biobanks are fully supportive of and recommend in their biobanking standard [11].

Wales Cancer Bank (WCB) and Breast Cancer Campaign Tissue Bank (BCCTB) are members of the CCB with established PPI at all levels. In the early days of planning, patients and lay people were involved in discussions about the scope and proposals for developing these tissue banks. In Wales patients were part of the Steering Group which developed the bid for funding and establishment of the tissue bank. They also provided key input into the participant information sheet and consent forms as well as advising on the Ethics committee application and when to approach patients regarding tissue donation. Dr Alison Parry-Jones, Manager of Wales Cancer Bank considers that the input on this latter aspect was vital. "We would have had much more complicated processes and caused ourselves issues if we hadn't involved our Lay Liaison Group. We had preconceived ideas of how sensitive patients might be at the time of being diagnosed with cancer and were told very firmly by our lay colleagues that we should just go ahead and approach them. If it's not a good time they'll tell us but they are people and they're not made of glass."

This challenging of pre-conceptions was also apparent during the establishment of the BCCTB

who included two patients on their Management Board when the applications to host the bank were being reviewed. Alastair Thompson, Chair of BCCTB highlights, "As researchers and clinicians we saw this as a competitive process but rather than looking for a single winner, our lay colleagues challenged us to rethink the process and said – 'there are several good bids – why can't they work together to create a virtual bank?' It's fair to say the altruism of patients donating tissues to the bank is enhanced by those patient advocates guiding the workings of the bank."

Dr Bridget Wilkins, Lead Pathologist at NCRI, is a member of the CCB Exec and facilitated ICPV collaboration with Trainee Pathologists to use questionnaire responses from public, patients and clinicians to inform the potential production of a "Lay Guide to Tissue Donation"

This project is continuing at present.

14.2.5 Local Cancer Partnership Research Group Event: October 2013

Robert Flavel
KSS Cancer Partnership Research Group
London, UK

The Surrey, West Sussex and Hampshire Cancer Partnership Research Group (SWSH CPRG)[1] comprises a group of patients, carers and healthcare professionals interested in cancer research. The group was founded in 2004 under the auspices of Macmillan and is based in Guildford. The group is now part of the Kent, Surrey and Sussex Clinical Research Network.

The main aim of the group is "to involve patients and carers in cancer research, ensuring that it is easily understood and accessible to all". The group feels so passionately about Tissue Banking that it devoted its Annual Educational Research Event to the subject.

The event was held at the Royal Surrey County Hospital (RSCH) in the Post-Graduate Education Centre. Dr Albert Edwards, Prostate Brachytherapy Research Fellow at RSCH and member of the CPRG, chaired the event, encouraging lively discussion and interaction between the audience and the speakers. The guest speakers were Dr. Agnieszka Michael, Clinical Lead for then SWSH CRN and Director of the Tissue Bank at the University of Surrey, Dr. Balwir Matharoo-Ball, Operations Manager for Nottingham Health Science Biobank and Dr. Bridget Wilkins, NCRI lead for Pathology and executive member of UKCCB.

The many topics covered by the presenters included: How to set up a tissue bank and the resultant data protection implications; Using lay people to obtain consent from patients for donations to the tissue bank; Using NHS stored biopsy and tumour samples as the basis for a tissue bank.

The event was attended by approximately 60 people including members of the public, healthcare professionals (GP's, oncology clinicians, specialist and general nurses, pharmacists, pathologists), research staff and research data managers.

Feedback from the audience was very positive with the following quotation being a typical example:

> I have not really paid too much attention to tissue banks before, but I found your event most interesting. With the steady move towards gene therapy, cell treatments and immunotherapy...the 'bank deposits' will have a great influence on research and hopefully treatment of cancer.

What is also very pleasing is that one of the pathologists who attended the event is leading the setting up of a Tissue Bank at RSCH. Perhaps a good example of PPI helping cancer research.

14.2.6 A New and Innovative Patient-Led Consent Pathway for the Nottingham Health Science Biobank (NHSB), Nottingham, UK

Hilary Stobart
Independent Cancer Patients' Voice (ICPV)
London, UK

Consent to donate tissue and data is an expression of partnership and goodwill between donors and a biobank. Research has shown that consent

[1] Since April 2014 the CPRG has been a part of the Kent, Surrey and Sussex Local Clinical Research Network (KSS CRN).

rates are typically high if patients are made aware of the opportunity to donate tissue and samples, and informative and accessible, but also sensitive and user-friendly consent pathways are key to this. In 2011 the team at Nottingham Health Science Biobank set out to improve its processes around patient consent to donate tissue and samples, and began working with their Patient and Public Involvement Advisory Group to develop improved methods.

The Nottingham Health Science Biobank is an NHS Trust led initiative which along with its related bioinformatics strategy creates a platform for translational and clinical research. Patients are invited to consider donating surplus tissue that arises from tests and treatment, along with blood and urine samples, to create a single, centralised, quality assured, biofluid and tissue resource to underpin translational studies and to add value to clinical trials.

I was privileged to be part of the initial PPI Group, when it was suggested that the consent process could be driven and delivered by patients and volunteers. NHSB went on to design a comprehensive consent training package, including presentation, role-plays, hand-holding, shadowing observation, competencies and final sign-offs. Five of us volunteered to be involved and received a full induction by the hospital Trust, and were offered honorary contracts. We were, of course, required to complete all required safeguarding checks and then undertook the consent training package. Since we started in 2011 we have taken on responsibility for taking consent in all of the out-patient clinics in a busy regional centre breast unit, and have spoken to several thousand new and follow-up patients between us.

Patients are sent copies of the information leaflets and consent forms for the biobank with their initial appointment letters, and are offered the opportunity to discuss further, ahead of their appointment with the healthcare team. The new pathway and role of the volunteers has had excellent feedback from both patients and volunteers taking consent and has led to increases in consent rates. I, personally, was initially surprised at how willing almost everyone is to have a conversation on the subject of donation, whether or not they go on to choose to donate themselves. In fact one of the values of the conversation with patients is an opportunity to increase awareness generally of the need for research and the role of donated tissue and data. Even those who choose to decline or wish to consider their options at a later date are usually appreciative of the chance to consider the issues.

An advantage of the new approach is that the volunteers and patients generally have more time to discuss the issues arising than would be possible for clinicians in the midst of health-care appointments. A further added benefit of the process is the separation of the consent process from the discussion with doctors. At Nottingham consent is both generic and enduring and this separation helps patients to consider this long-term use of their tissue and data away from the immediate pressure of current decisions about their health-care.

I am pleased to be involved in the next roll-out of the process at Nottingham where those who already take consent will be involved in training new patient advocates. It is good to know that there has been much interest in the model and requests are often received from other centres for the training and consent packages.

14.3 Lay Involvement in Action: What Is Possible?

ICPV has presented papers on the value of Lay Involvement in Tissue Banking at Patient Advocacy Conferences/Meetings in Cape Town, Milan and Bucharest, the European Cancer Organisation Conference in Amsterdam, the San Antonio Breast Cancer Symposium as well as here in the UK. When NCRI invited ICPV to host a parallel session on Tissue Banking at their annual conference in 2013, the remit was to include young researcher, European and lay perspectives. This was achieved by input from the European Organisation for Research and Treatment of Cancer (EORTC) and scientists from University College London & the University of Manchester together with 2 lay speakers under the Title of “The Issues about Tissues”. A Fringe

Fig. 14.2 ICPV Group after a meeting at House of Commons

meeting about the need for human tissue in cancer research was hosted by ICPV at the annual conference of the All Party Parliamentary Group on Cancer in 2013 (Fig. 14.2). Chaired by Baroness Diana Warwick from the Human Tissue Authority, panel members included Helen Bulbeck (Brainstrust), Victoria Chico (School of Law, Sheffield), Prof. Charles Swanton (UCL), and Mathew Cooke (ICPV).

Involvement of patient advocates is valuable in many aspects of biobanking and should be integral at all levels from management boards to tissue access committees to public engagement activities. However, to do this properly requires selection and training of both patient advocates and the professional staff and ICPV recommends that experienced patient advocates should be part of this process. Some biobanking organisations are still avoiding the inclusion of lay members other than as donors of tissue. This does not, currently, cause a barrier to recruitment as the British public still has great trust in the NHS so that anything badged as NHS is generally accepted as safe. However, with recent controversies regarding the use of health related data, supply of DNA data to Europe and the implementation of "any suitable provider", we consider that public trust and confidence is being put at risk. ICPV was invited to contribute to the Parliamentary Office of Science and Technology briefing document on biobanks which confirms this as a potential risk for biobanking [12].

Biobanks which can demonstrate active and effective lay involvement at all levels can earn and retain the trust and confidence of donors and their relatives and this could lead to increased participation. Patient advocates can work with biobanks to increase public awareness of the need for tissue and related data in health research and ICPV considers that donation of tissue should become as acceptable as blood donation. Researchers in London have shown that where there has been previous experience of biopsy or personal family experience of breast cancer, there is a much greater interest in donating tissue for research [13]. It is likely that wider publication of the work of biobanks will increase interest of the general public and ICPV would like to see greater public engagement as well as patient involvement in biobanks –e.g. giving donors of tissue the

choice of further involvement by receiving newsletters giving updates about research using donated tissue, fundraising, publicity, ethical oversight and governance. However, whilst interested donors should feel they are valued as partners/shareholders in "their" biobank, the views of those opting out of further contact should be respected. During a recent effective campaign in USA, the Susan G. Komen Foundation was able to recruit healthy women to donate normal breast tissue for use in breast cancer research – this may become possible in other countries but, for most, the aim should be that donation of tissue from tumours is accepted as standard clinical practice.

Current advances in knowledge of the biology of cancer cells, including metastatic cancer, needs access to samples from different areas of a tumour and then from metastases. This raises ethical, sensitivity and patient safety issues but, when effectively explained to potential donors, is usually acceptable in practice. Patient advocates can help scientists and clinicians explain the need for such tissue to patients after diagnosis of secondary disease. Many doctors and nurses are protective of patients in their care, especially at times of great stress such as hearing that metastases have been found, and will be reluctant to add further stress. However, this creates barriers to important research which may not help this patient but would enable this patient to help future patients – this altruistic donation can give some comfort by adding a positive aspect to a very negative experience. By not discussing the possibility of donation, the clinician is actually preventing patient choice when the attitude of most patients will be "Why Not?" Obviously, the site of some metastases makes collection difficult but ICPV suggests that these patients should be given the option of post-mortem donation. Careful explanation and much greater public awareness of the need for such tissue is needed to make the latter an acceptable practice for clinicians, patients and their families. At the same time there needs to be discussions with pathologists, GPs and palliative care providers to have policies and procedures in place to ensure safe, timely and effective collection can be available when needed. Effective communication with potential donors and their families will also prevent unrealistic expectations and possible distress if particular tissue is not required. The GIFT Bank, run by Aidan Hindley in Leeds, is an excellent example of a bespoke tissue service for researchers using efficient and empathetic organisation of donation of tissue to be collected post mortem (www.gift.leeds.ac.uk).

ICPV has very recently joined a working group chaired by Dr James Flanagan at Imperial College London regarding an innovative collection and use of human tissue. This group is collecting donated breast milk to harvest epithelial breast tissue cells which they will use to increase their understanding of the mechanisms driving epigenetic variation which will improve breast cancer risk prediction and enable better targeting of preventative treatments. This has great potential for patient benefit but, by giving healthy young women the opportunity to donate excess breast milk, this is also an excellent opportunity to raise public awareness of the need for tissue in cancer research.

14.4 Feedback of Findings to Donors of Tissue for Research

There is variation in practice regarding the feedback of both incidental and research findings. This does not reflect donor choice but is usually governed by individual biobank policy. However, with the increasing role of biobanks and genomics in health research, there is a growing debate on the subject of donors' rights to receive feedback and how this should be managed. Some tissue provided is non-identifiable but where related follow-up health data is needed the tissue has to have some identifier.

In 2012 ICPV invited views from members and other patient groups as to whether feedback should be offered. Comments received generally fitted with two quotes from Genetics in Medicine/ Special Article "Managing incidental findings & research results in genomic research involving biobanks and archived data sets" [14].

- Kohane et al. [15]
- Offering discoveries back to individual research participants allows them to be "partners in research rather than passive, disenfranchised purveyors of biomaterials and data"
- CIOMS 1990s [16]
- International Ethical Guidelines for biomedical research involving human subjects has provided that "individual subjects will be informed of any finding that relates to their particular health status"

Most who responded felt it was their right to be offered feedback and that it was ethically wrong to withhold this. Some expressed strong belief that this was not a decision which researchers should be taking on behalf of donors – which was seen as patronising or paternalistic.

However, the majority qualified their views by saying that some advice/counselling would be needed alongside receiving the findings – together with appropriate referral for further investigations and/or treatment. Some said they were not so sure that they would want to know that they were at high risk of developing certain conditions – e.g. dementia – whilst others said this would be important to them as it would enable them to make proper provision whilst they were able to do this effectively.

It appeared that some were not fully aware of the possible implications of receiving feedback, for themselves and/or for their families, nor of the cost implications for the NHS in providing the information and counselling which would be needed. The general public do not realise that clinicians do not know themselves what the vast majority of coding alterations in the human genome mean so feeding this information back to patients could be seen as irresponsible and could cause unnecessary distress. Caution therefore needs to be exercised together with collaborative efforts to increase public understanding of the implications of feedback.

The Wellcome Trust then published a report which showed overwhelming interest in feedback of health-related findings to research participants- particularly when serious and treatable [17].

In the US, a consensus statement from the National Institutes of Health (NIH) with specific regard to biobank research says: findings that are (i) analytically valid, (ii) belie an established and substantial risk and (iii) are clinically actionable should be returned to participants, where such consent has been given [14].

Feedback of findings is still being debated by professionals and interested lay people and provision of feedback is still very variable in practice. Much more open discussion between biobanks and potential donors is needed to establish guidelines which are acceptable to donors, researchers and biobanks.

14.5 Validations from Researchers

"Patient Advocates have kept us grounded in reality, have been very helpful with ethics and information sheet issues and have made us all realise that the standard practice of just throwing tissue away is a terrible waste of resources. They have also been a real pleasure to work with, have made good comments and often respond to e-mails better than professionals."

Professor Alastair Thompson, Professor of Surgery, MD Anderson Cancer Center, Houston Texas and FORMER Chair of NCRI Breast Clinical Studies Group

"Patients challenge the somewhat paternalistic attitudes of the medical profession which impacts on what we consider to be acceptable to patients. This has the very positive effect of promoting much more open discussion of how patients can be approached to discuss donation to the tissue bank – and, in particular, has guided (and been very thought provoking) on how we might address more sensitive issues such as collection of metastatic lesions. Of equal benefit has been the opportunity to discuss in detail the huge value of tissue banking to the research community through which patient advocates actually become powerful spokesmen for tissue donation which is invaluable."

Louise J Jones, Professor of Breast Pathology, Barts Cancer Institute – a Cancer Research UK Centre of Excellence

"It is vital that patients have a say in how the Breast Cancer Campaign Tissue Bank works. The patient advocates involved with the Breast Cancer Campaign Tissue Bank make sure the patient perspective is considered in all key decisions."

Dr Lisa Wilde, Former Director of Research, Breast Cancer Campaign

"ICPV have been an invaluable to provide patients' perspective to our translational research program to understand cancer evolution through longitudinal cohort studies such as TRACERx. From trial concept development, through to protocol writing and regulatory submission, ICPV have provided invaluable advice at every step of the process. Their network and attention to detail is unparalleled. Their ability to canvas opinion during protocol development has helped us adapt to the needs of patients rapidly, accelerating the approval process and hastening trial recruitment. I look forward to further collaborations with ICPV during the course of TRACERx and other studies we are planning [18]."

Professor Charles Swanton, UCL Cancer Institute, Cancer Research UK London Research Institute and The Francis Crick Institute, London

"The involvement of lay people in collections of tissue samples for research has been critical in many ways but particularly in allowing professionals to feel confident about what can be reasonably asked of patients in their research partnership with them. Lay advice has been and remains very important to us in our trials of pre-surgical treatments of primary breast cancer; without this it is highly unlikely that these trials could have been successful."

Professor Mitch Dowsett, Breakthrough Research Centre, Royal Marsden Hospital

"Current progress in research, such as the ICGC/TCGA cancer genome projects, are founded on donations of samples from interested, altruistic patients across the world. Novel approaches to molecular diagnosis of disease will require continued engagement of donors across disease sites if we are to see progress in stratified medicine. There remain tensions between research and patient care, between access to samples and privacy for patients, between the rights of the donor and the responsibility of the recipient – be they medical practitioners or researchers. No-one is more able to speak to these issues than the donors themselves, and no-ones' voice should be more prominent than theirs."

Professor John Bartlett, Provincial PI Ontario Tumour Bank, Member of CTRNet,

14.6 Conclusions

Lay involvement in Biobanks should not be a "tick the box exercise" to meet current NHS or other organisations' expectations but should be integral at all stages of development, at all levels and in all activities. This involvement should be honest, effective, and evident in any biobank literature, as this will increase public confidence. However, members of the public who take on this role should commit to giving time for self-development and education to empower them as informed, realistic and effective lay members of the Biobank. Mutual respect and effective collaboration between lay members and professionals is essential for biobanks to achieve their potential value in health research and thus for future patient benefit. This process of involvement is a learning opportunity for both the lay members and the professionals involved. The lay members are able to increase their understanding of cancer biology and biobanking processes. At the same time, professionals are able to improve their understanding of the concerns and needs of potential donors. Most cancer patients are unaware of the intricate work which is done by pathology departments and which is essential for them to receive optimal treatment for their particular tumour. Lay involvement can also provide the vital connection between the bank and the potential donors. The role of ambassador and advocate is one that many patients take on when they become involved in research and tissue banking is no different. Raising awareness of research using tissue samples is becoming even more important with the development of genomic

technologies and the need for samples to be collected at multiple timepoints to monitor the progression of diseases like cancer. The consent and willingness of patients and the public to participate in this research will be vital and their involvement will help ensure that the trust and transparency, which is needed, can be maintained.

From the patients' perspective this can be a very rewarding activity. It is fascinating and exciting to learn about the science being carried out with the samples and some donors really do want to know how they are helping progress in medical research. Many biobanks don't send a newsletter to their donors or have information on their website about the research being carried out. How will they continue to be sustainable if they don't capitalise on the additional resource that their donors can provide in becoming advocates for them?

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