Reviewer's report

Title: Biobanking from the patient perspective

Version: 2 Date: 27 January 2015

Reviewer: Janet Wale

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File attached

1. This article addresses an important topic and is very timely.

2. It is also an important explanation of the broad range of roles that patient groups can play in biobanks, and factors that may determine that role. Factors include the biobank, the opportunities, and the types of patient organisations. To be read and understood by a broad audience, it would be very helpful to have additional 'explanations' included in the text (and/or the Definitions section). This would also provide a better understanding of the excellent examples (to highlight the points) and case studies.

3. Biobanks in themselves are very different to much medical research and indeed provide an important resource/tool for researchers. This article has important things to say that are specific to biobanks - the Figure adds value for only the 'more conventional, controlled roles'.

4. Because of the high quality of the content and its presentation, I consider that revision is needed.

The title of this article is “Biobanking – from the patient perspective”. Reading the paper I needed clarity on what a biobank is; and how patients/patient groups can contribute to their management and use for research/technology development:

It would be really helpful to have a description of biobanks, and the scope that they can cover. This is really important, particularly when talking about both patient led/controlled (and affiliations required eg with hospitals/clinicians for collection) and researcher/clinician controlled biobanks.

For example, do they differ in collection; access to the samples/derivative information etc? Any differences need to be acknowledged. It is important to discuss how specimens are collected; the 'ownership' of the specimens and the information obtained from them; the size of the specimens, and so how much can be done with them and guidance on further testing.

One controversy of large databases, of in particular genetic material, is the question of ownership of samples.

Another important consideration is how the different biobanks are funded and if they are 'commercial' in any way (eg in development of new drugs, diagnostics).
Biobanks in a range of countries are referred to – do they all follow similar standards (also patient led and clinician led)? Questions on governance, privacy, research ethics and medical ethics

In my following comments on the text I am again seeking clarity, from a patient/patient group and public perspective, and how this fits with the 'medical model'.

5. Specific comments:

Abstract

Biobanks and biobanking research plays an increasingly important role in healthcare research and delivery as health systems become more patient-centered and medicine becomes more personalised. There is also growing acceptance and appreciation of the value that patients, patient advocacy organisations and the public can bring as stakeholders in biobanking, and more generally in research. Therefore the importance of active, early, and sustained engagement and involvement of patient and public representatives in biobanks will become increasingly relevant.

Point: WHAT SPECIFICALLY DO THEY/ PATIENTS, PATIENT ADVOCACY ORGANISATIONS AND THE PUBLIC OFFER, IS IT TRANSPARENCY AND ACCOUNTABILITY (ESPECIALLY WITH REGARD TO GOVERNANCE AND ETHICS OR IS THIS A TWO-WAY RELATIONSHIP WHERE INDIVIDUALS CAN HAVE MORE CONTROL OVER HOW THEIR TISSUES (AND THE INFORMATION FROM THEM) ARE UTILISED AND HOW THIS MAY BENEFIT THEM?)?

Organising and facilitating patient and public involvement in biobanking takes considerable time and effort for all stakeholders involved. Therefore, for any biobank operator considering involving patients and the public in their biobanking activities, consideration of best practices, current guidance, ethical issues, and evaluation of involvement will be important.

Point: IS THIS MORE ABOUT EVALUATION OF THE PROCESSES FOR INVOLVEMENT (AS FIRST STEP)?

In this article we demonstrate that patients are much more than donors to biobanks - they are collaborators at the heart of biobanking with an important voice and a unique perspective, which can be an extremely valuable resource for all biobanks to utilise.

NEED TO ALSO EMPHASISE THE ETHICAL ASPECTS AND THE ROLE OF PATIENTS, PATIENT GROUPS AND THE PUBLIC IN THAT

The case studies herein provide examples of good practice of patient and public involvement in biobanking as well as outcomes from these practices, and lessons learned. Our aim is to provide useful insights from these efforts and potential future strategies for the multiple stakeholders that work with patients and the
public involved in biobank-based research.

– I SEE THE IMPACT AS BEING IN THE LONGER TERM, IN COLLABORATION WITH CLINICIANS/OTHER STAKEHOLDERS AND THE RESEARCH AND PRODUCTS OF THAT RESEARCH. MAY ALSO BE FINANCIAL ISSUES WHERE THE PUBLIC/TAXPAYERS HAVE A RIGHT TO A SAY..

Introduction

Biobanks do not operate in isolation. They exist within a diverse "ecosystem" of stakeholders which includes the public, patients, healthcare workers, scientists, government, funders, healthcare providers, ethicists, regulators and others. The sheer variety of stakeholders involved in maintaining biobanks reflects the diversity of biobanks themselves (1). Biobanking operators such as hospitals, research institutes, pharmaceutical companies and patient organisations translate their own biobanking activities differently, very often according to the background of the founding organisation and the particular context in which the biobank is embedded.

Point: THE GEOGRAPHICAL LOCATION AND WHETHER LOCAL, NATIONAL OR INTERNATIONAL IS ALSO IMPORTANT.

The role of patients and the public in biobanking activities has been viewed traditionally as biobank participants rather than as collaborators in the design, development and ongoing operation AND GOVERNANCE of biobanks.

Definitions

The term ‘patient’ in this article refers to the patient, his/her relatives, or patient advocates as collaborative or representative voices of patients.

The term “patient involvement” in this article refers to ‘involvement in research’ (i.e. being actively involved in the research process itself, rather than being participants or subjects of the research).

DEFINITION OF PUBLIC AND THEIR ROLE?

WHAT IS THE DEFINITION OF A ‘PATIENT ORGANISATION’ AS IN THE EXAMPLES INCLUDED IN THIS PAPER?

MAY NEED SPOME EXPLANATION, INCLUDING FUNDING (so people around the world can understand)

Unless otherwise stated, the term “biobank” in this article refers to disease-based, human, tissue, cell or DNA banks and associated clinical data.

NEEDS MORE DETAIL/CONTEXT? (AS DETAILED AT THE BEGINNING OF MY COMMENTS) – AND HERE WOULD BE A GOOD PLACE TO HAVE IT (ALLOWS TEXT TO PROVIDE THE BROADER OVERVIEW WHICH AT PRESENT IT PROVIDES)
ALSO NEED A DEFINITION OF A REGISTRY WITH THE DIFFERENCES CLEAR?

6. Discretionary changes:

Main Theories and Background

Evolution of patient and public involvement (PPI) in research

PPI can contribute to the broader democratisation of research, through participatory forms of involvement that encourage partnership in research (18,19,20). This increased appreciation of early and sustained engagement and involvement of patients in research can be summarised by the following quote from Kish (21):

“Actually, it’s surprising that it has taken us this long to focus on patient engagement because the results we have thus far are nothing short of astounding. If patient engagement were a drug, it would be the blockbuster drug of the century and malpractice not to use it.”

Leonard Kish – Principal and Co-Founder of VivaPhi (US)

Re quote: DOES NOT EXPLAIN IN WHAT WAY – SO NOT PARTICULARLY HELPFUL?

Key Messages

Patient and public involvement in biobanking activities

I: Emergence of patient-led biobanks

Although an ever-increasing number of patient organisations are establishing their own biobank, the emergence of patient-led and patient-run biobanks began only relatively recently. Individual patients, and representative patient organisations, many unsatisfied with the speed of research into their respective conditions, established their own biobank, primarily to enable them to provide a greater contribution and influence on research in their disease area.

THIS MAY BE A GOOD PLACE TO SAY SOMETHING ABOUT THE PATIENT ORGANISATIONS THAT ARE ACTIVE IN THIS AREA (OR REFER TO IN AN APPENDIX OR THE LIKE); AND IT WOULD BE REALLY HELPFUL IN PROVIDING AN UNDERSTANDING OF ‘THE DIFFERENT ‘TYPES’ OF PATIENT GROUPS’ AND THEREFORE THE DIFFERENT ROLES (WHICH ARE REALLY CLEARLY SET OUT HERE)

Three case studies of patient-led biobanks in the USA, Germany and Italy are provided in this article as examples in this regard. LIST – AS IS NOT THE IMMEDIATE FOLLOWING TEXT

Another example worth highlighting is the Génénthom DNA and Cell Bank driven by the French patient organisation Association Française contre les Myopathies (AFM). AFM become active in genetic research in the 1980s
HOW/IN WHAT WAY?

IV: Education and Training

It is commonly accepted that in order to ensure that biobanks are developed and used to their full potential, it is essential that both researchers and other stakeholders associated with biobanking have access to the best possible training and career development opportunities at all stages of their professional life. Therefore, in order to facilitate active participation of patients and patient organisations in biobanking activities,

IN PARTNERSHIP WITH HEALTHCARE SERVICES/CLINICIANS (AND RESEARCHERS)?

A number of ongoing patient-led training initiatives in this area are helping to raise awareness of the contribution that patients and the public can make as partners in research. The European Patients’ Academy (EUPATI)

NEED A BIT ABOUT WHAT IT IS AND HOW FUNDED/ITS GOVERNANCE STRUCTURE

Case Studies

Patients’ Tumor Bank of Hope (PATH Biobank) run by the PATH Foundation, Germany

1. The PATH board consists of breast cancer survivors (ALL ARE SURVIVORS? (ALSO SEE LAST SENTENCE OF THIS PARA)? THIS IS HOW IT READS AND SO DOES NOT AGREE WITH THE FOLLOWING SENTENCE: According to its statutes, at least two members of the PATH board have to be breast cancer survivors. In addition to the representation (e.g. at conferences and towards scientific partners), the board guides the activities and direction of PATH biobank. As breast cancer survivors, all board members have an inherent motivation to contribute to the cure of this disease.

Chordoma Foundation Biobank, USA

FUNDING/GOVERNANCE?

Italian Biobank AHC, Italy

PARTNERSHIP MODEL – FUNDING?

Patient involvement as part of biobank governance – IN THE MEDICAL MODEL?

7. Wales Cancer Bank, United Kingdom

QUITE A BIT OF DETAIL – TOO MUCH?

Nottingham Health Science Biobank, United Kingdom SIMILARLY
Level of interest: An article of outstanding merit and interest in its field

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

No competing interests to declare