



OWNERSHIP, CUSTODIANSHIP, ACCESS AND USAGE- AN ACADEMIC PERSPECTIVE

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OUTLINE

- My background
- The value of studying primary cells in academia
- Success criteria for a biobank
- Access requirements
- Conclusions



MY BACKGROUND

- Medically qualified Haematologist
- Research active for 20 years
- Main research interest: drug resistance mechanisms in childhood leukaemia
- Director, Newcastle Cancer Centre and Northern Institute for Cancer Research, Newcastle University
- Designated Individual for the Newcastle Medical School HTA research licence
- Chair of the CRUK Biomarkers and Imaging Discovery and Development committee



RESEARCH WITH HUMAN TISSUES

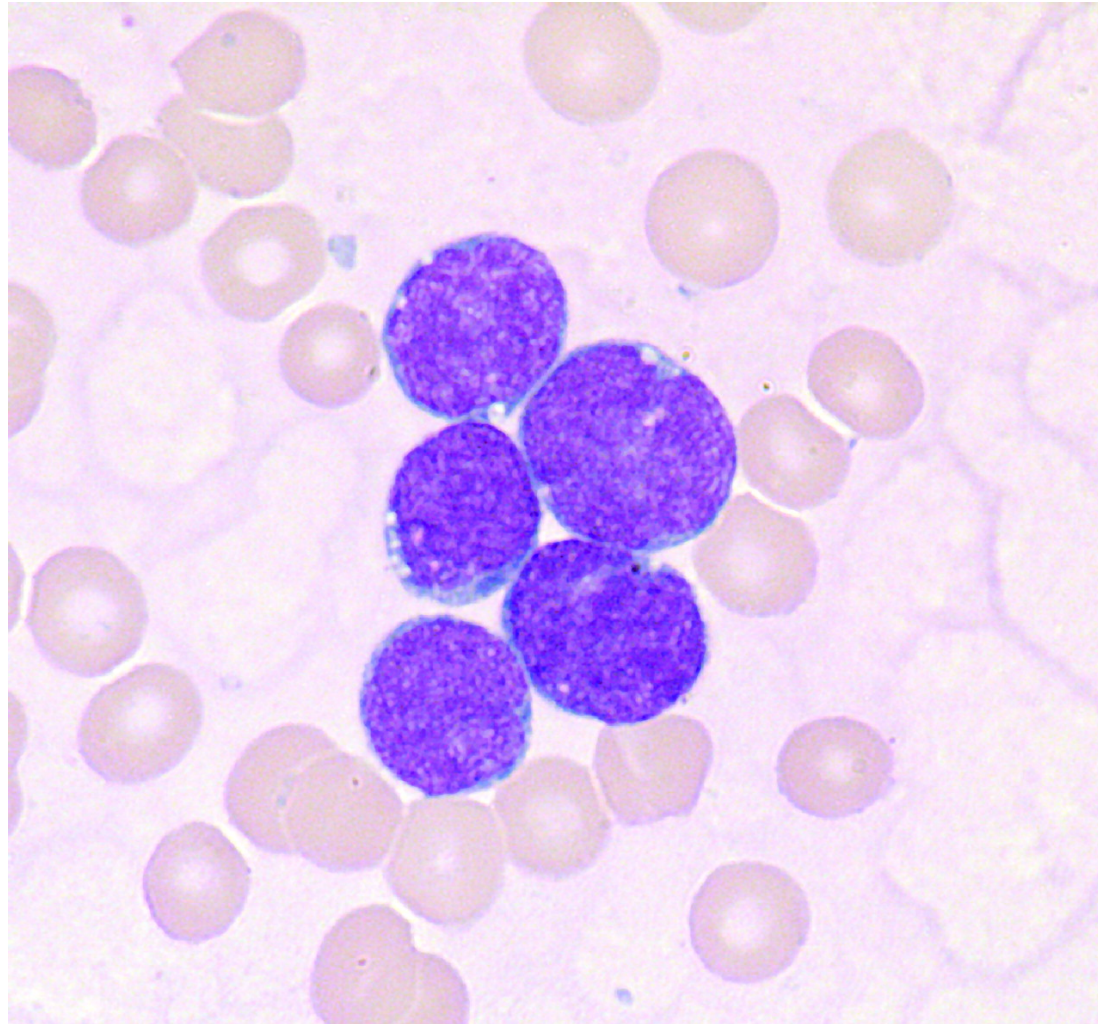


BENEFITS OF USING HUMAN TISSUES FOR RESEARCH

- Direct benefit to patient
- Direct benefit for other patients
- Improved understanding of diseases
- Development of new treatments
 - Surgical techniques
 - New medicines



Precursor B-ALL: A high power view reveals coarse chromatin with an irregular nuclear contour



Maslak, P. ASH Image Bank 2007;2007:6-00053



STUDIES OF STEROID RESISTANCE IN LEUKAEMIA

- Childhood acute lymphoblastic leukaemia usually very chemosensitive at diagnosis
- 10-20% of patients relapse
- Steroids are key agents in therapy
- Cell line studies indicate that mutations in the glucocorticoid receptor are a major cause of resistance prednisolone- but these are not commonly found in patient material
- Why?-Mismatch repair defects are common in lymphoid cell lines but NOT in primary samples- hence the relative frequency of GR mutations



DEFINITION OF A RESEARCH BIOBANK

- A collection of samples taken from patients for the purposes of research, or excess to diagnostic requirements, **and** (usually) associated clinical data
- Usually samples are of little use without high quality, anonymously linked, data



WHAT MAKES A GOOD BIOBANK FROM AN ACADEMIC USERS PERSPECTIVE (1)

- Established on a sound legal and ethical footing: appropriate consent, HTA licence in place etc.
- Ideally generic ethics approval in place as well
- Samples must be “fit for purpose”- Although this is best defined by defining the purpose at the onset (not always possible) basic quality assurance measures should be in place (eg DNA/RNA quality, sample purity, viability etc)
- Good quality, appropriate data on sample quality- histological/immunological characterisation
- Appropriate, high quality clinical data set



WHAT MAKES A GOOD BIOBANK (2)

- Good quality catalogue, with well described samples- readily available for scrutiny
- Transparent application process
- Rapid response to request
- Fair review process
- Rapid release of samples
- Reasonable cost-recovery model



WHAT MAKES A SUCCESSFUL BIOBANK- THE DONORS AND FUNDERS PERSPECTIVE

Ultimately the success of a biobank should be defined by the USAGE of samples not the storage- samples should be accessible to people best placed to do the best research- this is not always the same as the people who collected the samples!



HEREIN LIES A BIG PROBLEM!



(Apologies- I don't have a picture of me with an elephant in the room)

“OWNERSHIP” V “CUSTODIANSHIP”

- Human tissues are not commodities that can be bought or sold
- Researchers must act as “custodians”
- Responsibilities as custodians under the HTA relate to ensuring appropriate consent is in place, that samples are stored appropriately and destroyed in a sensitive manner if not used.



ACCESS

- Access arrangements are not set out under the HTA but may be scrutinised by ethics committees
- To date access has largely been left to the discretion of the individual custodians
- Input from funders has been limited, and largely confined to gentle exhortations



PROBLEMS WITH ACCESS

- PIs, as individuals or acting in cartels, often act more as owners than custodians- retaining collections for their own exclusive use or trading them for academic benefit
- If this is unacceptable- how are researchers to be incentivised?



BIOBANKING MODELS

- UK Biobank;
 - Direct collection from volunteers
 - Large amount of central funding
 - No vested interest on part of collection team
- National disease biobanks: Leukaemia and Lymphoma Research Childhood leukaemia
 - Linked to clinical trials
 - Samples surplus to diagnostic test used in patient stratification
 - Central collection
 - Independent access committee
 - Ideal for rare diseases
- OnCore model
 - Virtual collections linked by central organisation
 - Needs strong driver to make it work (?money)



RESEARCH CARTELS



RESEARCH CARTELS

- Multicentre clinical trials usually set up by leaders in research field with strong vested interest in using samples
- Access committees often not properly established or supported
 - Slow to respond
 - Non-transparent criteria for acceptance of proposals
 - Concerns about confidentiality
 - Poor quality of samples
 - Sometimes demand authorship/high cost recovery



THE BIDD EXPERIENCE

- Supports sample collections linked to clinical trials in patients with Cancer
- Applications range from 10s to 1000s
- All cancer types covered
- Sample collection rates often wildly overestimated in applications
- Promises made by applicants regarding open access are not monitored- non-compliance is not penalised or compliance rewarded



POSSIBLE SOLUTIONS

- Milestone payments for collection
- Milestone payments for sample release
- Centralised storage by third party agency (eg by UK biobank)
- Centralised access committees
- Funding linked to trial costs



(SADLY) MONEY IS THE KEY!



CONCLUSIONS

- Good quality biobanks of human samples are vital for translational research
- The HTA is a good thing (if rather cumbersome)
- Better quality access arrangements need to be in place to ensure the maximum returns on the generous donations of tissues and of money for research
- Linking access to funding is probably the only way to drive this process

