Biorepository Survey

H3 Africa Consortium

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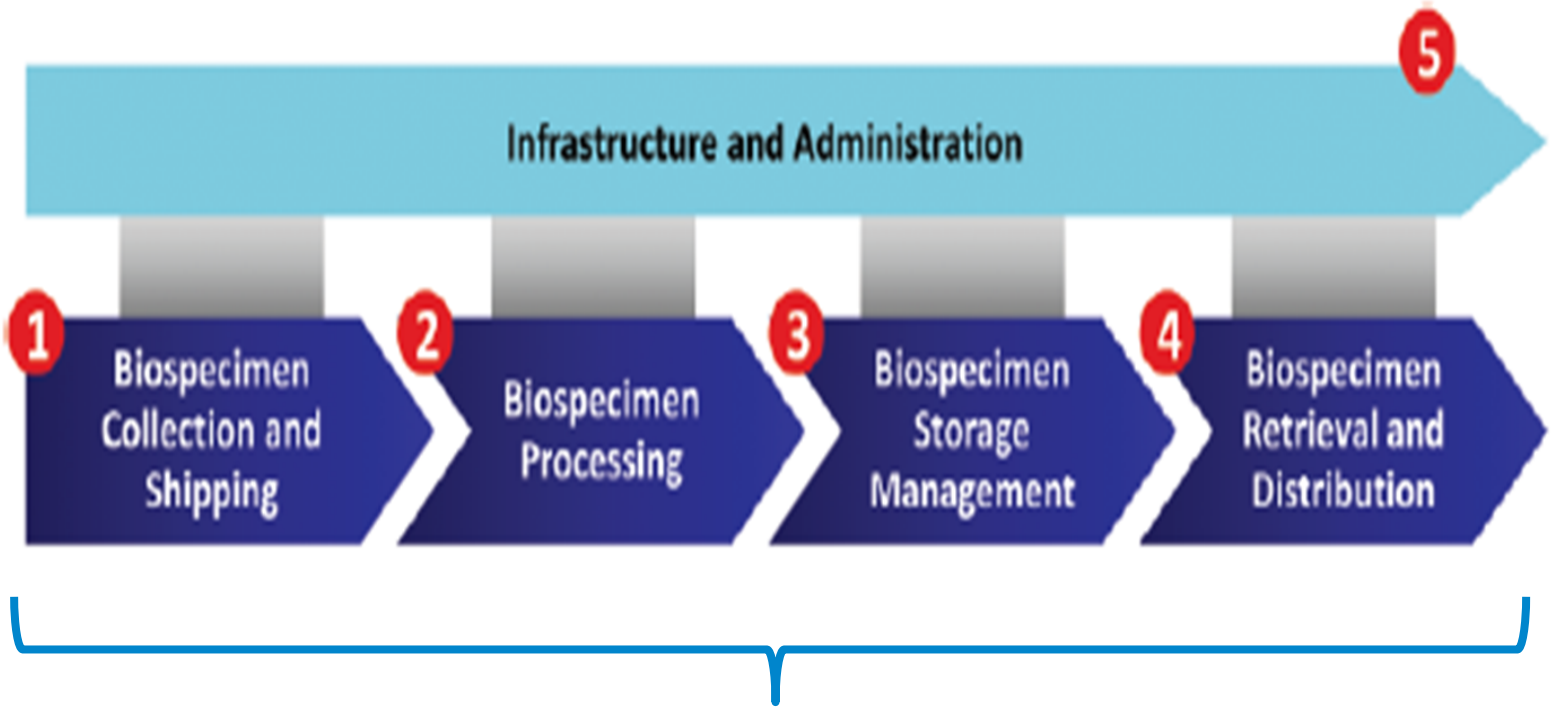
Introduction

- Traditionally research groups stored samples in there own freezers.
- Variations in collection, processing and storage methods – difficult to standardise methods and compare results.
- Example of Human Genome Atlas project – problems with glioblastoma samples – up to 99% were of unacceptable quality.
- Storing samples in a centralised facility allows standardisation and harmonization of methods as well as sharing of samples and related data.

Biorepository operations workflow



Aims of Biorepository Survey

1. Collect information from research groups on
   a) Types of samples sent
   b) Sample collection and processing requirements
   c) Sample transport (regulations, permits)
   d) Local laws & regulations governing sample sharing
2. Develop standardized SOPs/documents to ensure consistency and aid H3A research groups on best methods for
   a) Sample collection
   b) Sample processing
   c) Sample storage
   d) Sample transport

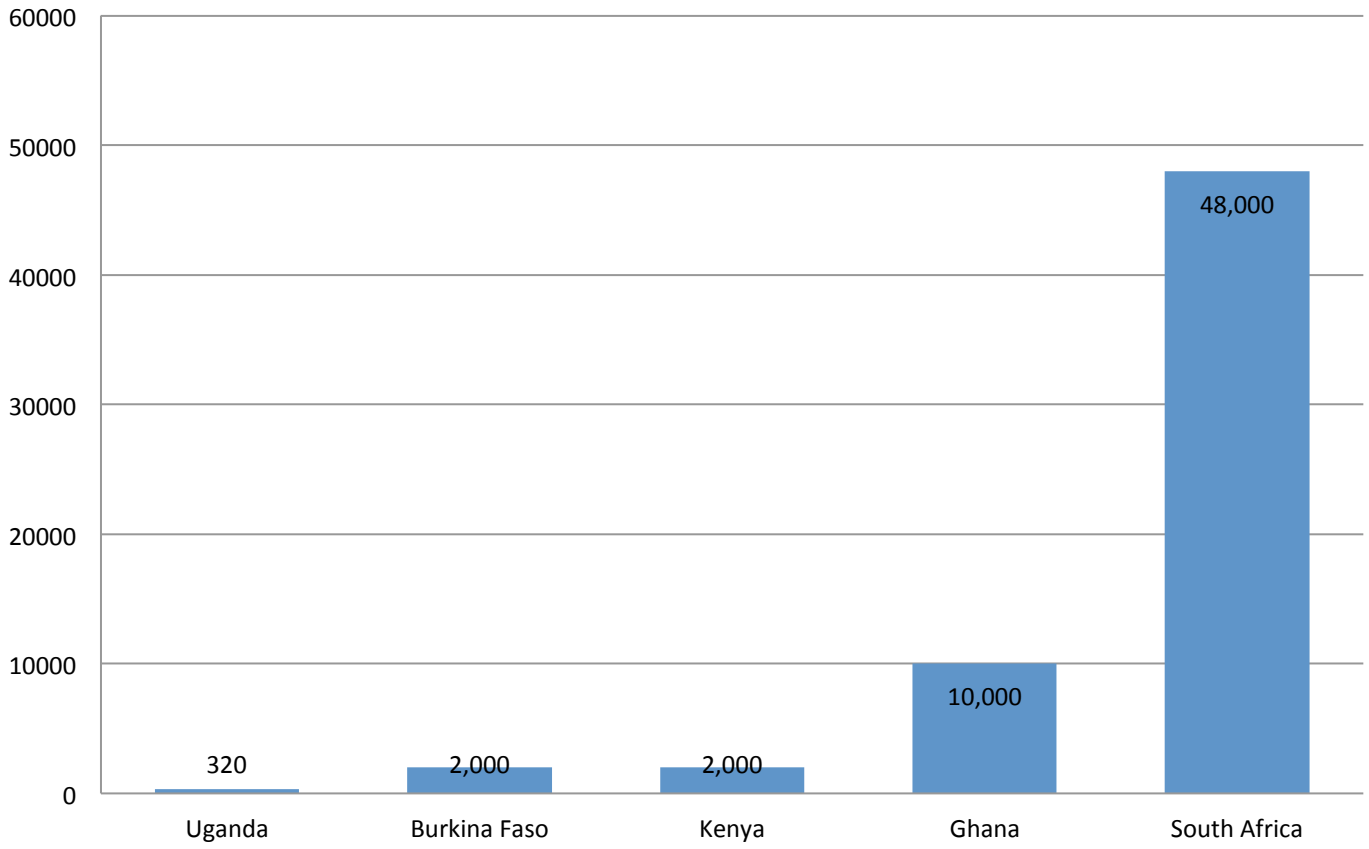
Aims of Biorepository Survey

3. Identify biorepository capabilities and infrastructural requirements for handling, processing, and storing samples types identified; devise strategies to address gaps.
4. Estimate number of samples to be received by the biorepository in preparations for supply forecasting, shipping contracts, infrastructure and overall capacity.

Biorepository Survey Responses: Sample Types & Required Processing

- Whole Blood
  - Plasma
  - Serum
  - DNA
  - RNA
- Oral Fluid
  - DNA
  - RNA
- Kidney tissue (potentially)

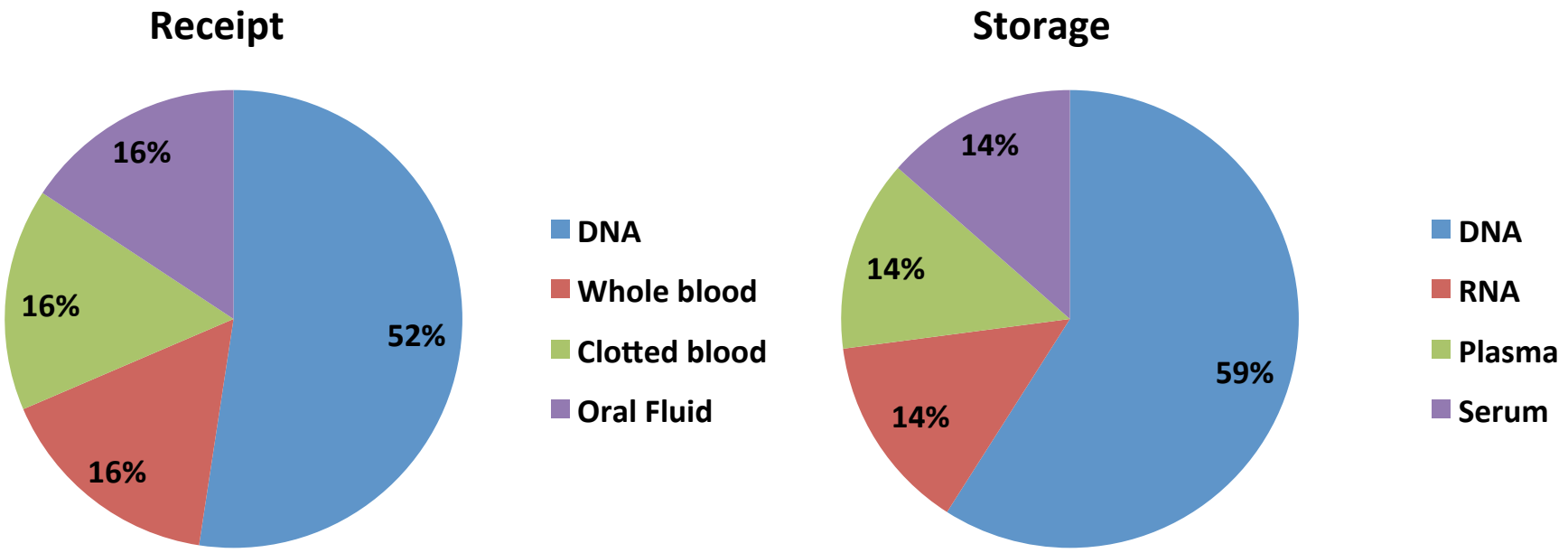
Number of Sample by Country



Biorepository Survey Responses: Summary of Sample Activity

	Receive		Store
Dr. Adu	**8,000 DNA**		**8,000 DNA**
Dr. Matuvo	**160 WB**	**Process →**	**160 DNA, 160 RNA**
Dr. Mayosi	**6,000 WB**	**Process →**	**6,000 DNA, 6,000 RNA, 6,000 Plasma**
	6,000 Oral Fluid	**Process →**	**6,000 DNA, 6,000 RNA**
	6,000 Clotted	**Process →**	**6,000 Serum**
Dr. Ramsay	**12,000 DNA**		**12,000 DNA**
Total	**20,000 DNA** **6,160 WB** **6,000 Oral Fluid** **6,000 Clotted**		**26,160 DNA** **6,160 RNA** **6,000 Plasma** **6,000 Serum**

Distribution of Sample Types



Biorepository Survey Responses: Documents

- MTAs from IHVN, Nigeria, as well as Wits and Stellenbosch University, SA (Country vs. Institute)
- Consent form from Matovu group, Uganda
- Ethics policies from Ramsay and Mayosi group
- Link to Uganda National Council of Science and Technology website (www.uncst.go.ug)
- Import/Export requirements for SA

Biorepository planning based on survey

- Investigate and develop SOPs for collection, transport, processing and storage of specific types of samples.
- Determine QC conditions & standards for specific sample types.
- Do cost-analysis of sample transport of various courier services at various temperatures according to sample type & PI locations
- Determine the best collection tubes and methods according to sample type and even analyte to be identified for certain downstream applications.
- Determine whether certain countries have ethical issues/ special requirements regarding sample import/export.

Current Developments: Sample Collection & Processing

- Identify the appropriate tubes, reagents and kits to use for collection of intended specimen types and associated processing.
- Develop/harmonize SOPs across the two biorepositories in accordance with best practices for sample collection, processing and manufacturers' recommendations.

Current Developments: Sample Transport

- Identified relevant IATA shipping regulations and requirements.
- Developing/harmonizing SOPs among the two biorepositories in accordance with best practices for sample transport and IATA regulations.
- Working closely with couriers to assist with import/export permits.
- We appreciate any information investigators have surrounding sample transfer requirements for their countries. (E.g. Nigeria MTA countrywide but in South Africa more institutionalized)

Current Developments: Sample processing and Quality Assurance

- We are developing/harmonizing SOPs between the two biorepositories in accordance with best practices and manufacturers' recommendations for sample processing and quality control.
- Prevent/minimise problems
- Detect problems – Implement monitoring procedures
- Take action in a timely + effective manner

Possible Shipping Conditions

- Ambient Temperature (+20°C to +30°C)
- Cold Packs (+2°C to +8°C or -20°C)
- Dry Ice (-70°C)
- LN_2 Dry Shippers (below -150°C)

Depends on:

- Intended Analysis
- Analytes /Molecules Measured
- Sample type
- Collection tubes

Why use the biorepository?

- Storage facility:
  - Reliable (backup power and emergency measures)
  - Secure
  - Sufficient capabilities and infrastructure for processing and storage
  - Centralization of sample storage.
- LIMS
  - Data security
  - Documentation of all stages of sample management & QC.
  - Sample tracking prevents sample mix-ups.
  - Sample inventories may be shared with investigators.

Why use the biorepository?

- Standardization
  - SOPs for all processes and activities.
  - Consistency among processes, which may not be achievable when performed by various clinics or without standardized measures.
  - High quality QC methods ensure sample integrity and quality.

Addressing User Concerns

- All policies will be developed within H3Africa and be approved by the Steering Committee.
- Confidentiality:
  - Minimal data set requested from Provider and given to Users.
- Ethical issues:
  - Proof of patient consent and REC approval required from sample Providers.

Addressing User Concerns

- Sample Release: (To be discussed in next presentation)
  - Conditions for sample release are dependent on MTA and contract between provider and biorepository
  - Biorepository release policy is binding document that governs biorepository activities and approved by H3Africa steering committee.
  - There will be a vetting process/committee for access of H3A samples and clinical information that decides whether investigators are authorized to use samples or data.
  - What happens to sample if time to use sample has ended? Will they be destroyed by end user or sent back to biorepository for destruc

Addressing User Concerns

- Security:
  - Samples will be stored in a secure location with limited access.
  - Sample information will be stored on the LIMS, with different access level given to different biorepository personnel.

Challenges

- Unsure if survey information received requires modification/is final
- Require additional information pertaining to sample transfer regulations etc. for other countries
- Require information on downstream applications.
- Standardize as far as possible based on currently available technology and applications.

What's next?

- Biorepositories need to educate researchers but, in turn, researchers need to educate biorepositories.
- Short term – survey feedback will allow us to develop SOPs for our pilot studies which will, in turn, help us to standardise conditions.
- We need ongoing feedback from researchers on your requirements for sample use.
- This information will allow us to continually work on harmonizing SOPs for sample collection, processing and storage.