BIOBANKING, BIOSECURITY and LEGAL FRAMEWORK
Banking highly infectious Pathogens in Public Health Emergency scenarios

• The current outbreaks of EIDs, can generate a great number and variety of biological samples.

• Such samples constitute a precious, non-renewable resource, and if managed judiciously, afford a unique opportunity to increase our knowledge and improve interventions for disease control now and in the future.
The Problem. A Biosecurity Threat

- There is no inventory of how many infectious samples exist, where they are being held, how they are leaving affected countries and under what conditions they have been held.
- The facilities in which the samples are currently kept are inconsistent with the international standards for storing dangerous pathogens.
- The biosecurity and biosafety aspects of most labs are insufficient, and need to be seriously upgraded. Staff need to be trained and appropriate Standard Operating Practices (SOPs) need to be updated and or implemented.
- There is a reluctance to help these countries develop capacity and as a result the recommendations are to either remove the remaining samples or destroy them.
- Governance and laws are non existent or weak.
Why Implement a Regional and National Biobanking Biosecurity Programs?

- Improve security
- Increase emergency preparedness
- Protect reputation/image
- Mitigate liability exposure
- Protect public health
- Protect employees
- Protect research
Focus areas

• Immediate action required to securely store samples and data
• Verification of quantity, quality and location of samples
• Options for storing and using samples, including regional cooperation
• The need for National action plans and biosecurity agendas.
Instruments of the Biosecurity Conventions.

- BWC Articles and Confidence building mechanisms
- UNSCR 1540
- 11 Packages of the GHSA
- IHR
- PVS
- One Health Agenda
Concrete Solution:
One Health Marshall Plan for Africa!

We need to move from reaction to preparation and planning.

Cant have such paradoxical diametrically opposing standards in such close proximity
Philosophical paradigm shifts

• No need to reinvent the wheel, EU and North America have learned how to communicate to Policy makers.

• **Understand the dynamics of the Health-Policy intersect.**

• Move away from continental or regional towards global initiatives
WHO Proposed Action Plans

• Strengthening agreements on the use of samples, such as through a biospecimen data access committee and an established evaluation criteria and hierarchy of access;
• Identifying which samples need to be banked;
• Requirements for storing and using samples, including the purposes and infrastructure required;
• Appropriate ethical oversight, including key ethical issues, governing documents, and legislative integration;
• Linking biobanking to broader public health efforts;
• Community engagement; and,
• Financing.
Components of the Plan:

• High Level Advocacy
• SDGs
• Deep bilateral collaboration between North and South with bidirectional free flow of samples, data and technology under fair trade agreements.
• Synchronizing activities on ground
• Heavy component of training and human capital development.
• Harmonization of governance, SOPs, algorithms and platforms.
Who will own this and who are the stakeholders?
HELLO?...HELP! WE NEED YOUR ... HELLO?
CAN YOU HEAR ME?
HELLO00?

AFRICA

EBOLA FATALITIES:
1000+
Some Concrete projects on ground
Strengthening National Internal Governance

- **National Constitution:**
- **Health act** as it relates to science and ethics of Biobanking and list of dangerous and routine public health goods and materials
- **Environment Protection Agency Act** as it relates to prohibition waste management and disposal without authorization
- **Customs Law** as it relates to specific measures in place to prevent the unauthorized or cleverly disguised transfer of (dangerous) biological goods and toxins
- **Anti Money Laundering and Combating of Financing of Terrorism Act** as it relates to misuse of biologicals
- **National Security and Central Intelligence Act** as it relates to suspected misuse of dangerous biological agents and toxins.
Progress in Sierra Leone and Lagos

• Legislative review
• Biobanking and Biosecurity Policy and agenda
• Governance council
• CE and Civic Engagement
• Consolidation of samples and data, LIMS!
• BSL2 and 3 biocontainment
• Research ideas rapidly growing
Biospecimen and Data Access Committee

• Will function as an affiliated governance body of the Biorepository Program, consisting of X members. This will include senior representatives from the following fields: (i) scientists involved in research, (ii) scientists with specialist expertise in biobanking, (iii) a data expert, (iv) individuals qualified/well versed in ethical aspects of research into human health, (v) the legal fraternity and possibly (vi) a community representative.

• Will review new Biospecimen and Data Access Applications from qualified researchers and notify applicants.
H3Africa Data Sharing, Access and Release Guidelines
Model to Consider

**Timeline for processing from raw data to validated/quality controlled data set and transfer to H3ABioNet**

- **Bin #1 Genomic data**
  - Genomic data generated, quality controlled & validated (to be defined)

- **Bin #2 Phenotypic data**
  - Phenotypic clinical data associated with clinical sample
  - Clinical data reviewed (to be defined)

- **Bin #3 Role of H3ABioNet**
  - Timeline for transfer of phenotypic data to H3ABioNet

- **Bin #4 Ethics and informed consent**
  - Ethics guidelines and study specific informed consent reviewed (to be defined)

- **Bin #5 EGA**
  - Data held at H3ABioNet for 9 months before it is transferred to EGA
  - EGA Controlled Access Database
  - 12 month publication embargo

- **Bin #6 EGA data access and release**

**21 MONTHS**

**Protection of the rights and privacy of human subjects**
Access to data and samples during Public Health Emergencies
Governance
Governing Documents

• Local and regional laws on R & D in Health/Env
• Consent Guidelines
• MTA guidelines
• Minimal Data sets to accompany biospecimen
• Biospecimen Submission policy
• Data and Biospecimen Access Committee
• Biospecimen Release Policy
• Data Release Policy
Specifically consent and governance must address:

- Who owns the samples and data
- Storage in biobanks and data base into posterity
- Conversion of samples into cell lines
- Movement of samples out of bank to unknown sites globally for secondary use
- Data access
- Commercialization
- Return of results
- Beneficiation
CONNECTING BIOBANKS INTERNATIONALLY

International community

![Map of Africa with marked regions]

FIG. 1. The relationship between the types of attributes. *highlights attributes relevant for studies only.

Jan-Eric Litton et al., 2011
“Forcing” Harmonization

How do you get…

• Hundreds of Sites to register…
• Tens of Services which creates…
• Millions of biologicals which are sent to…
• Hundreds of Investigators for…
• Global Studies without…

Losing your mind or your samples!
Sustainability
Developing cost effective Biobanks and Bio-containment hybrid facilities that are specialized facilities required for rapid control and research in Public Health Emergencies
Advocating for Appropriate Technology

Hybrid Power Systems
Combine multiple sources to deliver non-intermittent electric power

- PV Modules
- Generator
- AC or DC
- Load
- Wind turbine
- Battery bank
- Regulation and conversion

www.thegreenmechanics.com
$90 Million to date and going into 2\textsuperscript{nd} Five year funding cycle
Euros 5 Million: For first 3 year funding cycle ending 2018.

B3Africa: 2015
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E-3Kit:LIMS/Database/HER/Bioinformatics
Global Emerging Pathogens Treatment Consortium

Help Logistics Infrastructure Mobilised Experts Support Samples Healthy
3rd African Conference on Emerging Infectious Diseases and Biosecurity, 2017

16th - 18th August 2017
Accra, Ghana

Theme: Pandemic preparedness. Biosecurity and Infrastructure in the wake of the Ebola outbreak.
Thank you.
Akin Abayomi
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Pandemics cause havoc

- Bubonic plague: 1346. 30-40% of Europe dead
- Spanish flu: 1918. 50-100 million dead (~5-10% of the world population)
- 1855 Third Flu pandemic killed 12 million
- 1968 Hong Kong flu killed 1 million
- HIV: 1981-present. 60 million infected. 30 million dead
• There are 50,000 vertebrates on earth, each of which harbors about 20 different viruses and host of bacteria and parasites.
• That gives in excess of 1 million vertebrate pathogens.
• We only have an understanding of about 2,000 to date.
• Therefore over 99.8% have not yet been discovered!
• Expanding human populations and manipulation of the ecosystem.
• The zoonotic pool is very large – providing many opportunities for new human infections to emerge if the setting is right
Black Death has long been portrayed as a cataclysmic event—a plague that wiped out 30% to 60% of Europe’s population, young and old, rich and poor.
Spanish Flu 1918

At least 50 million died worldwide.
“Ebola” is a Category A pathogen

Category A pathogens are those organisms/biological agents that pose the highest risk to national security and public health because they can:

- be easily disseminated or transmitted from person to person usually with no specific treatment
- Result in high mortality rates and have the potential for major public health impact
- Cause public panic and social disruption
- Require special action and infrastructure for public health preparedness and drains existing resources
- May be acquired by non state actors for aggressive intention
The need of an integrated solution
Transporting DNA Samples to NSB-H3A at **Normal Ambient Temperature** from Satellite Sites in Africa

* DHL – 1kg
Sustainability

- Difficult to find Business minds with biological background
- Funding models are not in keeping with reality of establishing biobanks
- Logistics and cost of transportation is prohibitively expensive in Africa
Strategy: Business plan

• Develop committed biobanking human capital expertise

• Application for supporting grants and equipment

• Develop contractual relationships

• Solicit other projects to patronize the biobanking facilities

• Develop excellent reputation and accountability for samples and data