Building and Implementing TB Laboratory Capacity for Diagnostics, Vaccine Trials and Surveillance in Western Kenya

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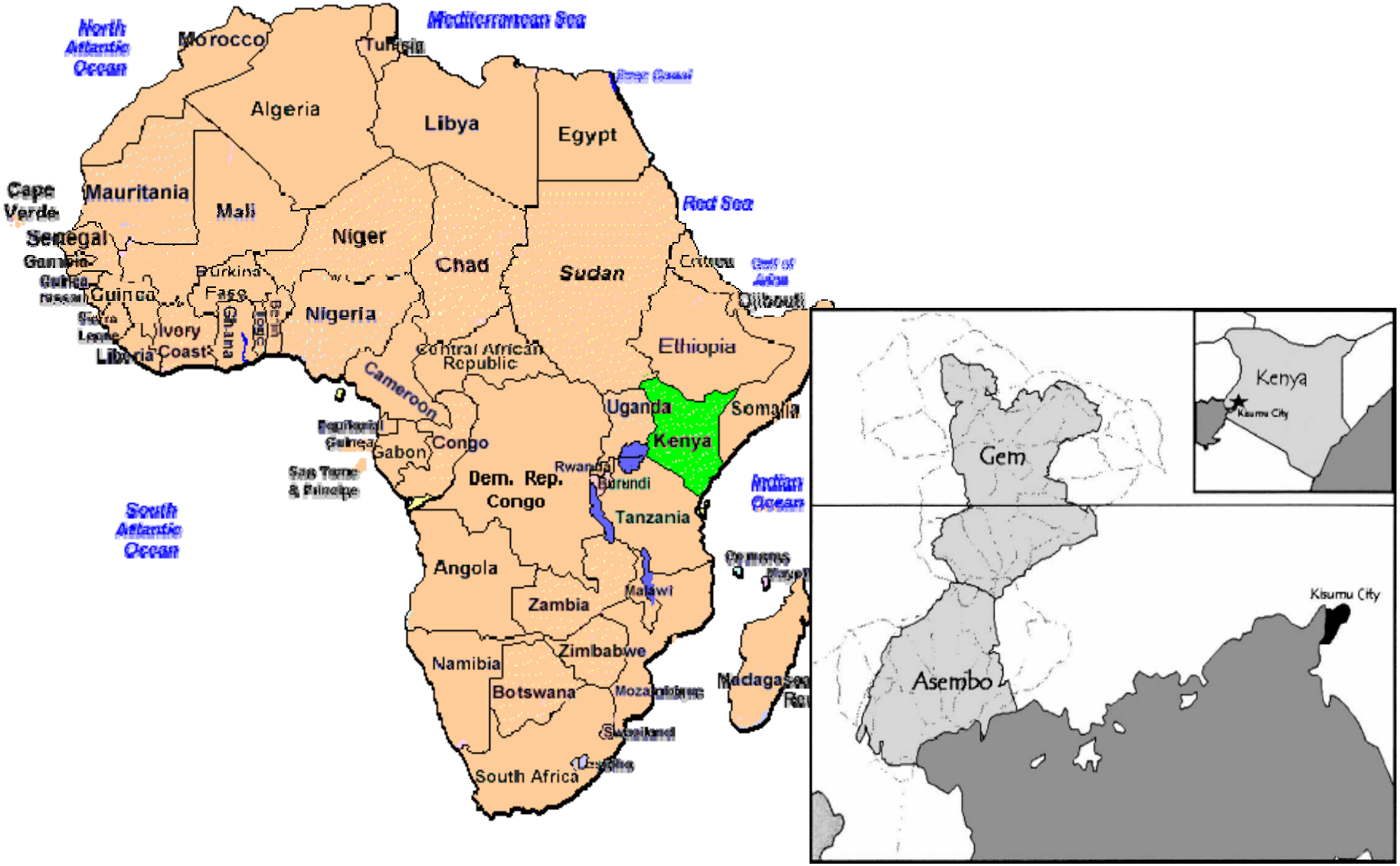
KEMRI/CDC Field Research Station Kisumu

- KEMRI/CDC program
  - Collaboration between
    - Kenya Medical Research Institute, Centre for Global Health Research, Kisumu, and
    - Centers for Disease Control and Prevention, Atlanta, USA
    - Started in 70-ies: entomology, parasitology
  - Expanded
    - 1990s: malaria epidemiology and intervention studies
    - 2000s: HIV programs and research, demographic surveillance, emerging infections work, tuberculosis epidemiology
  - TB epidemiology work
    - Collaboration between KEMRI (Centre for Respiratory Diseases Research, CGHR), CDC, Univ Amsterdam, KNCV, Aeras, SATVI, San Rafaelle Institute, and others

Location: Kisumu, Nyanza Province, Kenya



KEMRI/CDC Tuberculosis Laboratory Objectives

- Initiated to support tuberculosis epidemiology studies
- Objective is to establish a safe and high quality mycobacterial laboratory that is able to meet current and future research (and program) needs
- Established within an existing laboratory building
- Eventually: accreditation

Development in Phases

- Step I
  - Support a local TB prevalence survey
  - Lab that could handle ± 40.000 sputum samples
  - Sputum concentration, fluorescence microscopy, sample aliquotting
  - Biosafety level 2
- Step II
  - Support 2 cohort studies in preparation for TB vaccine trials
  - Solid and liquid mycobacterial cultures
  - Molecular identification tests
  - Meet biosafety level 3 requirements

Development in Phases

- Step III
  - Drug susceptibility testing (for cohort studies)
- Step IV
  - Support other studies / projects
  - Define role and relationship with national reference laboratory
  - Accreditation
  - Lab-based mycobacterial research?

Progress Step I

- Preparations and Activities
  - Started from 2004
  - Identify adequate room
    - Spacious because of volume
    - Building has controlled ventilation
  - Procure equipments / supplies
    - Biological safety cabinet
    - Autoclave in lab room
  - Staff recruitment and training
    - Experienced staff only available at other TB labs
  - Staff
    - 1 technologist in charge (higher Nat. Diploma)
    - 3 technologists (2 ordinary ND, 1 higher ND)
    - 2 technicians (certificate)
  - Sample processing from July 2006
- Cultures from survey were sent to KEMRI Centre for Respiratory Diseases Research TB lab in Nairobi (350 km)

Step I
-Support TB prevalence survey
-Handle ± 40.000 samples
-Sputum concentration, fluoresc. microscopy, sample aliquotting
-BSL 2

Progress Step II

Step II

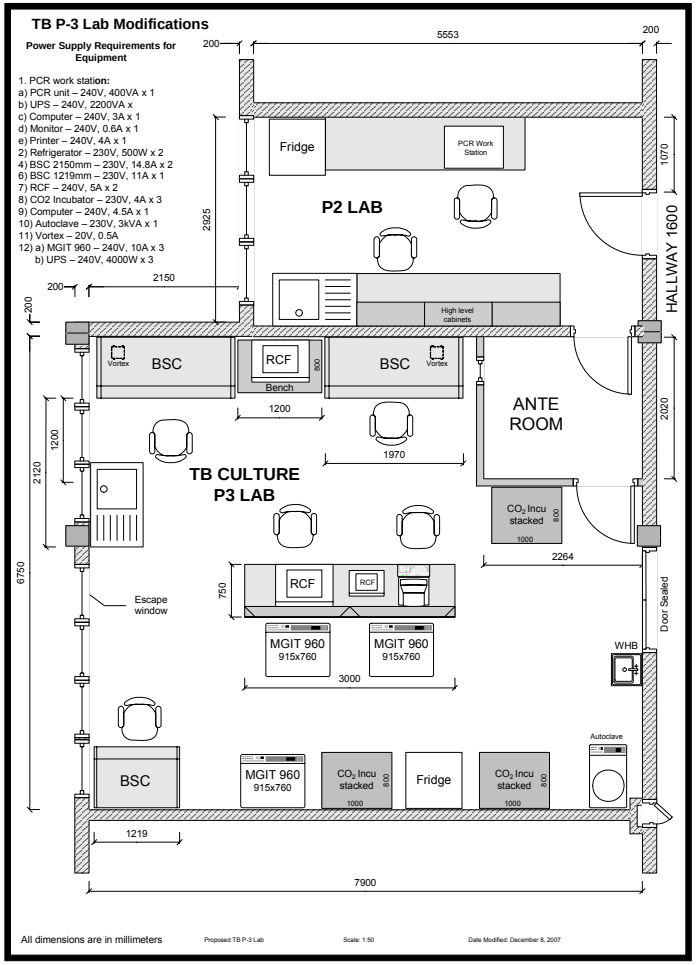
-Support 2 cohort studies in preparation for TB vaccine trials

-Solid and liquid mycobacterial cultures

-Molecular identification tests

-BSL 3 requirements

- Preparations and Activities
  - Planned renovation of existing space
    - Change airflow system, floor, layout
    - Include 2nd room
  - Temporary other space (BSL 2)
  - MGIT 960 machine, incubators etc. on-site
  - Staff training and start practice of culture techniques
- Meanwhile study samples are cultured at Eldoret TB laboratory (150 km)



Challenges and Considerations

1. BSL 2 or 3?
   - Standards for research samples, especially for phase III RCT?
   - Drug susceptibility testing
   - Costs
2. Renovation to meet BSL 3 requirements
   - What is the right advice?
     - ‘Good enough’ versus ‘Mercedes Benz option’
   - Who can give the right advice?
     - Scarcity of local expertise
     - Conflict of interest
     - Microbiology expert ≠ Construction expert ≠ expert in admin procedures
   - Tendering process
     - Burocracy, Transparency
     - Expertise to prepare bills of quantity and assess bids

Where is the Help Desk?

Challenges and Considerations

- Safety
  - Current: BSL-2 with controlled + filtered ventilation system, BSC, autoclaves in room
  - Access control + anteroom
  - 1 technologist is safety officer
  - General safety program in lab building

- Waste disposal
  - Autoclaved waste incinerated on compound
- Quality Control / Assurance
  - SOPs
  - 1 technologist is QA/QC officer
  - Re-checking of slides
    - Epi-studies: high volume, low % positive (<1%)

Challenges and Considerations

- Dealing with e.g. high MGIT contamination rates etc. still ahead
- Procurement of equipment & supplies
  - Takes time for procurement officers and local venders to understand needs and products
  - High prices compared to US, Europe, RSA
  - Reduced prices BD products
- Donor funds
  - Changing funding levels and priorities
  - Expiration dates

Challenges and Considerations

- Scope of this TB Laboratory
  - Only to support research? Programmatic support? Routine service – for culture? DST? Training and/or EQA for other labs?
    - 1% X-contamination between samples for DST and from epidemiological studies would hardly affect DST results but multiply incidence or prevalence estimates
  - KEMRI's mandate is research
  - Strict QA/QC requirements will have to apply to all samples handled

Lessons Learned

- Developing a TB culture laboratory tailored to the local situation appears to be a lengthy and complex process
- A ‘help desk’ for comprehensive advice on all aspects, tailored to the local situation, would be useful
- Importance to define scope / mandate

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