How and What are the Conditions to Develop Best Science and Best Practices in Africa?

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The National, Regional, and International Health Environment

1) Tropical parasitic diseases are still in the 21st century important cause morbidity and DALYs in SSA: Malaria, Schistosomiasis, Filariasis, Geo-Helminths, Neglected Tropical Diseases with viruses and bacterial diseases such as HIV-Aids, Tb. Chronic Diseases are becoming Public Health Concerns: Cancer, Cvx Disorders, Diabetes, Mental illness…..

2) Current Tools for control are efficient for most of these diseases, but need to reach >=80% of the target population and access to clinical laboratories and best practices are real issues in SSA.

3) More and more competitive research teams for health are needed in SSA ➞ best patient care, evidence-based health strategies ➞ knowledge research ➞ Health care system improvement

 ➞ How to build an enabling environment for capacity building in clinical research and best science to reduce African Scientists and Health workers’ “ Brain Drain ”?
Malaria death/year in Africa = 3 sunamis => Ethical Issue

Malaria control → elimination → eradication
All about: Prevention & Treatment with Effective tools/ interventions available
Political will & support: Paradigms change!!

Looks simple …
But isn't:
Slow progress

P. Olliaro, WHO, Seoul 2005,
Malaria in the world: 
*P. falciparum* endemicty distribution

- 50% of all malaria
- 70% of *falciparum* malaria
- 2.8B fever cases/y

Outside transmission
Unclassified
Hypoendemic
Mesoendemic
Hyper- & Holoendemic

750 Millions

3 Billions

Other human species:
*P.vivax*
*P.malariae, P.ovale*
*P.knowlesi?*

214-365M *falciparum* cases / year
~1.5 million deaths/y (?) 

Snow et al, Nature 2005

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CONDITIONS of SUCCESS For Best Science and Best Practices in Africa

BEST SCIENCE AND BEST PRACTICES

FUNCTIONAL HEALTH CARE SYSTEM
CRITICAL MASS AND COMPETENT PERSONAL

POLITICAL COMMITMENT
DEMOCRACY SYSTEM
ICH/GCPs are standards for:

- Designing
- Conducting
- Performing
- Monitoring
- Auditing
- Recording
- Managing and Analyzing
- Reporting data for clinical trials

⇒ Subject protection and Evidence based Practices and Public Health Strategies

Training and retention of top level scientist in Africa: MRTC-NIAID/NIH Experience in Mali

1] Selection Process of Msc and PhD trainees,
2] Training strategies: The MRTC PCR type strategy,
3] Mentorship strategies both locally and oversea,
4] PhD research questions links to Malian’s needs,
5] 95% of retention of Msc and PhDs, since 1992,
6] Career path within university of Bamako,
7] Autonomy, research management and science, production and NIAID long term support,
8] Local Buying in! Government, local Institution community
9] Clinical Trials associated with Basis Research,
10] Usage of research results to inform policy.
NIH

Extramural:
- NIAID/DMID/FIC
- MRTC/DEAP/FMPOS
- University of Bamako
- WRAIR
- MRTC/DEAP/FMPOS
- University of Bamako
- NMCP

USAID/CDC

Government of Mali/Uni-Bko/MOH

AIEA

EU grants:
- BioMalPar network
- EDCTP

MIM/TDR/WHO

Intramural:
- MVDB, LMVR

CVD Maryland

Pharma:
- Sanofi-Aventis, GSK, Novartis,
- Dafra, Pfizer, Mepha, Mérieux

AMANET

WRAIR

Institut Pasteur

Universities:
- Marseille, Angers, Bordeaux, Lyon, Paris,
  Oxford, Stockholm, Nijmegen, Tulane,
- Dakar, Ouagadougou, Abidjan,
- Conakry, Cotonou, Libreville

Professeur Philippe Ranque

Pr C. Soucko

Pr A. Diallo

Pr Y.T. Touré

Pr A. Tournaka

Pr O.K. Doumbo

Professeur ENSUP

Vice Recteur Univ. Bko

OMS-Geneva

Doyen FMPOS

Directeur PER/MRTC

F1.1

A. Dolo

O. Kota

K. Djimde

E. Doumba

M. Diallo

M. Théra

S. Diop

S. Sou

F. Traoré

B. Traoré

Prof ag.

Direktur LMBA

Chef Unité MEDRU

Chef Unité GSRS

Chef Unité Dig. Panel.

Chef Unité MVU/BMP

Expert OMS

Chef Unité Anthro/Serolo

Directeur CVD-Mali

Chef Unité Phar-Priv.

Chef Unité PREMA

F1.2

A. Dicko

D. B. Toure

M. Drakité

S. Podoungou

M. S. Sissoko

I. Sagoné

K. Koyentaré

A. Thaore

B. Baé

L. Sangané

Chef Unité Epistat/Stat.

Chef Unité Bioinformatique

Chef Unité Gérontiq

Expert Milieu Village

PI - essai Vaccin Sotuba

PI - essai Vaccin Bancoumana

PI - Prema Kambila/Sikasso

Biostatistiques

Chef Unité MEDRU

Chef Unité LBMA

En formation Mali, Afrique, Europe, USA.
Insights: Impact of Training and Career Development

- **Milieu** – Rich with NIH grants, technology used in transfer of data
- Opportunities to work with NIH-MRTC investigators

- University integrated with research

- Compliance with MOH’s need for Health Information System

- Peer reviewed publication record of trainees
IMPORTANCE OF CONNECTIVITY AND NETWORKING FOR GCP IN AFRICA

Network of MRTC Clinical Laboratory: CLSI Certification

Lab Director
DAD

BANDIAGARA
2 Lab-Tech

BAMAKO
2 Lab tech
1 freezer work tech
Lab Manager and Lab supervisor

BANCOUMANA
2 Lab-tech

DONEGUEBOUGOU
2 Lab-tech

Lab personnel
Continuous Training
Field Clinical Laboratory

MRTC-MVDB-CLSI collaboration in Clinical Laboratory building in Mali.

- 1) Careful process of lab personnel selection: working together, in the field and Bko = building trustful relationship.
- "We are partners"

- 2) Selection of adapted lab equipments for tropical countries (by listening and documented experience) and continuous training plan responsible and accountable.

- 3) Space organization, electricity system, fire system, SOPs documentation… lab governance improvement

- 4) Communication and participation in real time lab activities during clinical studies in the field "Open mind and listening"

- 5) "We are learning together for sustainability"
Countries using ISO 15189: Mali on the Next list of Certification=CHALLENGE

Harold E. VARMUS, Nobel Prize in Medicine 1989 for his discovery of the cellular origin of retroviral oncogenes.

Us Agency for International Development have established a Malaria Research and Training Center (MRTC) that is staffed mainly by Malian scientists and technicians, has good internet connectivity, serves as a regional institution for training, receives its own grant money from the NIH, and hosts scientific visitors from NIH and Tulane University for collaborative projects. The center is well known and well respected by the political leadership of Mali, is a source of public pride, and offers a positive view of health research to students at the adjacent school of medicine. The Lancet. Volume 360 Supplement 1, 21 December 2002, Pages 1-4
Informatics in Africa for best science and best practices: Distance Learning

- Capacity Development and Sustainability
- Critical Mass per country
- Career path and continuous training
- Technology Transfer and maintenance
- Link with Health information Network at the MOH
- Evidence based decisions in public health
- Maintaining research and training link with the overseas mentor.

Bandiagara
Donéguébougou
Sotuba
Bancoumana
QUALITY OF STUDIES SITES IN AFRICA: ICH/GCP COMPLIANTS

Qualité des Capacités de Gestion des “SAEs”

- Equipements pour les Urgences Médicales,
- Disponibilité de Kits de prise en charge
- Disponibilité d’Urgentistes Compétents
- Disponibilité d’une possibilité d’Evacuation en cas de Problèmes Médico-Chirurgicaux.
In case of emergency: SAEs⇒ Standard of Care +++
IMPORTANCE OF COMMUNITY DOCTORS NETWORK FOR PHARMACOVIGILANCE (N=115)

- Région de Tombouctou: 2 médecins de campagne
- Région de Kayes: 26 médecins de campagne
- Région de Ségou: 24 médecins de campagne
- Région de Koutiala: 1 médecin de campagne
- Région de Gao: 1 médecin de campagne
- Région de Mopti: 1 médecin de campagne
- Région de Sikasso: 37 médecins de campagne

IMPORTANCE OF PUBLIC PRIVATE, COMMUNITY PARTNERSHIP
NEEDS AND CHALLENGES FOR THE MRTC and AFRICAN COUNTRIES

- Maintenance of lab equipment for emergencies,
- Calibration of equipment “Metrology”,
- Easy access to lab reagents,
- Power (electricity) problem and impact on the equipment,
- Training opportunities in Africa and the lack of south-south collaboration,
- Common training platform in clinical lab and feedback system
- Important component of support come from foreign grants ➔ need to increase government and partners long term support in the development and sustainability of clinical laboratories.
- Language barrier (Mali is French speaking country) and the need of translation of the clinical lab materials
- Successful trainee and job attraction ➔ critical mass!

IMPORTANCE OF TRAINING, MONITORING, QA/QC AND EVALUATION, MRTC-AMANET REGIONAL WORKSHOP FOR GCP/ETHIC/DATA MANAG.
EVIDENCE BASED STRATEGIES TPIp with SP
Kayentao et al., JID2005

Semaine de gestation

Conception

Dose 1
16 sem

Dose 2
Avant 38 sem

Mouvement

Naissance

10

20

30

CQR et Model GRI =⇒ ACTs Djimdé, Doumbo et al., The Lancet, 2001, Djimdé et al., NEJM, 2001
DEVELOPMENT OF BASIS RESEARCH IN AFRICA: THE HbC HISTORY

- β6: Glu → Lys
- Focus in West Africa
- HbC protect against CM
  - Blood, 2000,
  - Nature 2001,
  - Nature 2005

Dynamics of blood stage antigen diversity at a vaccine testing site in Mali

- 100 children followed 3y
- MSP-119 genotyped by Pyrosequencing
- 17 haplotypes among 1,363 infections
- Frequency distribution similar over time, season, age groups
  - Suggests balancing selection
- 3D7 vaccine strain prevalence: 16%

Takala et. al PLoS Medicine 2007
The political climate is changing in Africa +++

The political climate changes for Best Practices in Africa

- Millennium development goal (MDG) #4 = reduce under 5 mortality by two-thirds by 2015
- Roll Back Malaria (RBM) initiative (1998)
- Abuja declaration of African Heads of State, 2000
- Global Fund for HIV, Tuberculosis & Malaria
- Bill & Melinda Gates Foundation (BMGF) malaria conference 2007 = call for the 'eradication' of malaria (by 2050). The MalEra initiative agenda
- G8 Gleneagle summit, 2005: pledge to double aid to Africa by 2010
  - initiative to 'eradicate malaria in ~30 years' (Birmingham communiqué, 17 May 1998, G8 Bulletin 2(10))
- UN Secretary General: timetable for comprehensive malaria control in Africa by end of 2010
- AU? ECOWACS? UEMOA? SADEC? === to be engaged for best science and best practices funding in Africa
Best Science and Best Practices are Network of International Team With Transparency and Mutual Trust