Eliminating epidemic meningitis as a public health problem in sub-Saharan Africa

Ethics and Community Perspectives during the MenAfriVac® clinical trials

22 February 2016 – The MVP Closure Conference

Prof. Samba Sow, CVD Mali
Lionel Martellet, PATH
Presentation outline

1. MenAfriVac Clinical Sites
2. Understanding our responsibilities
3. Community permission
4. Informed Consent
5. Confidentiality in study procedures
6. Healthcare provision
7. Health risk prevention and post-trial access
8. Community Feedback
MenAfriVac Clinical sites

West Africa
- Centre pour le Développement des Vaccins, CVD, Bamako, Mali
- Navrongo Health Research Centre, Ghana
- Institut pour la Recherche et le Développement, IRD, Niakhar, Senegal
- Medical Research Council, Basse Field Station, The Gambia

India
- Shirdi Saibaba Hospital, Vadu Rural Health Program, Pune District, India
- Seth G.S. Medical College & KEM Hospital, Mumbai, India
- T.N. Medical College & BYL Nair Ch. Hospital, Mumbai, India
- Nizam Institute of Medical Sciences, Hyderabad, India
**Understanding our responsibilities**

**International level**

**International guidelines**
- Declaration of Helsinki, World Medical Association
- International Conference on Harmonization of Good Clinical Practices (ICH-GCP)
- Medical and Epidemiological Guidelines from the Council for International Organizations of Medical Sciences (CIOMs)

**Ethics Committees outside country sites**
(WHO-ERC; PATH REC, etc.)

**Country level**

**National Health & Regulatory Authorities**
Clinical Trial Regulations – Ghana & India

**Local Ethics Committees**
- Ghana Health Service Ethics Review Committee (GHS-ERC), Accra, Ghana
- Navrongo Health Reserch Center Institutional Review Board (NHRC IRB), Navrongo, Ghana
- Comité d’éthique de la Faculté de médecine de pharmacie et d’odonto-stomatologie (FMPOS), Bamako, Mali
Understanding our responsibilities

The Community
- Village Chiefs and Elders
- Religious Leaders
- Women’s Associations
- Town Criers
- Doctors and nurses of the Health Care system
- Private doctors
- Midwives
- Traditional practitioners

The Family
- Head of the household
- Husband/Wife
- Brothers-Sisters
- Children
- Uncles-Aunts
- Cousins
- Grand-parents

The Participant
- Age
- Gender
- Health status
- Languages spoken
- Economic status
- Literacy
- Etc.

Community liaisons

Study Team
- Principal Investigator
- Study doctors
- Pharmacist
- Study nurses
- Field workers
Obtaining community permission

Community meetings prior to starting the trial

- Sharing the objectives and purpose of the research
- Creating dialogue and discussion
- Understanding expectations
Informed Consent and Language

A signed informed consent required for each subject enrolled

Challenges

- Multiple dialects
- Low to medium literacy levels
- Official written language different from the common verbal language
- Difficulty in obtaining a written informed consent in the local language which can be understood even by the study team
Informed Consent as an interactive process

Approaches followed at our study sites:

- **Validated tape recordings** in the local languages of the informed consent form
- **Training of field workers** in communicating the informed consent form
- **Sharing copies** of the informed consent form in the field with potential participants, their families and their literate relatives
- **Leaving time for deliberation** at home for the participant after conveying the informed consent (at least one day and night)
- **Presence of an Impartial Literate Witness** during informed consent discussion
Confidentiality in study procedures

Pregnancy testing in Mali for study PsA-TT-006

- **Validated SOP** approved by ECs for pregnancy testing
- **Mid-wife individual counseling office** next to the study clinic
- **Systematic** consultation for **all** women entering the study
- **Confidential** screening for pregnancy according to site SOP

Result

- Discretion well accepted in the community
- Protection of minors was safeguarded
- Mid-wife consultation on popular demand among the community
Provision of Care

- Any acute illness during the study: medical support and the national standard treatment free of charge
- For chronic disease or condition, free treatment will not be offered beyond referral stage

- Identified serious chronic illness/accident during study trial
  - Leukemia
  - Paraplegia following a tree fall
  - HIV-infection
Prevention and post-trial access

- **Rise in malaria cases** in Ghana – response: contribution to the mosquito bednets distribution program in the study area – observed reduction in malaria cases

- **Alert on malnutrition** (Ghana and the Gambia) - support to the nutrition program

- At study closure, **offering** the licensed **vaccine**/study vaccine to control groups and/or subjects who did not attain protective thresholds
Community Feedback Meetings

- Sharing results of the research and its outcomes
- Sharing recommendations and conclusions
- Answering any follow-up questions
- Thanking the communities for their participation
What we learned

- Ask permission and continuously inform the Community
- Conducting Informed Consent as a process
- Ensure confidentiality in counseling & study procedures
- Monitor health issues at subject and community level
- Sharing between Ethics Committees
- Refining best practices & guidelines protecting participants
- Bridging universal principles and local specificities
Acknowledgements

- The Communities
- Investigators and their Site Teams
- DSMB
- Ethics Committees
- National Health Authorities
- MVP Clinical Team
- MVP Team at large at PATH and in WHO
- SIIL Team
- DiagnoSearch & AARSH Teams
- MVP Advisers and Consultants
- MVP Advisory Group and Expert Panel
- The Bill & Melinda Gates Foundation
Thank you!