

**Ethics in randomized clinical trials in  
Cameroon :  
Theoretical and practical issues**

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# Background :

- 2 RCT on Nonoxynol-9 carried out in Cameroon between 1996-2000
- **Objective** : To assess the effectiveness of different formulation of N-9 in preventing male-to-female transmission of GC, CT and HIV.
- N-9 formulations were :
  - 70 mg N-9 (28%) in 5X5 cm film
  - 100 mg N-9 (4%) in 3.5 ml gel
- **Study population:**
  - Female Sex Workers
  - Women from the general population at risk for STIs
- Trials conducted under GCP and GLP

# **Administrative and Ethical Approvals :**

- **Cameroonian Health Authorities**
- **Cameroonian National Ethical Committee**
- **Family Health International IRB**
- **Ad hoc IRB (Yaoundé School of Medicine)**
- **Quarterly meetings of the DSMB**

# **Main principles underlying these studies (1)**

- **GCP and GLP**
- **Written Informed consent at screening and at enrolment**
  - **Witness if participant not educated**
  - **Voluntary participation**
  - **Possibility of withdrawal during the study**
- **Participants willing to use study product or placebo and to know their HIV test result**
- **Non-spermicide lubricated male latex condoms to participants**

## **Main Principles underlying these studies (2)**

- Participants with curable STIs given free treatment according to international or national guidelines if any
- HIV positive participants referred for psychosocial support
- Transportation fees to and from the study site reimbursed
- Possibility of asking any question at any time about study and their rights

☞ Despite all these Ethical considerations put in place, many preoccupations and challenges arose from :

- Health Authorities,
- Local Ethical Committee,
- Study Participants,
- Colleagues,
- Local and International AIDS activists,
- Journalists,
- Etc.

# **1. Health Authorities Misgivings on Phase III RCT**

- \* Why only in DCs ?
- \* Is it really for our interest ?
- \* N-9 increases HIV transmission
- \* Promote male condoms instead

- **Advocacy for female controlled methods**
- **Provide state-of-the-art information**
- **Have them involved from study planning**

**2. Moral and psychosocial support to HIV positive participants not enough**

**\* ARV drugs and drugs for OIs**

**AIDS Activists, PLA, Colleagues**

- **ARV is related to clinical stages**
- **Expensive, Side effects, etc.**

With a more than 90% reduction in the costs, some provision should be made to refer HIV positive participants to treatment centers for initial FU. Question : What is next ?

### 3. « Guinea pigs » issue

- \* Researchers real intention ?
- \* How relevant for us and our communities ?
- \* Sudden interest to us with such resources
- \* Rely on researchers explanations ?
- \* Whose benefit is been served ?

- Informed consent required
- Voluntary participation
- Study product in the market for decades
- Study product available in local pharmacies and in FP clinics
- Other sites involved

## **4. Fear of being refused medical services if does not enroll**

- Voluntary participation
- Part of your fundamental rights
- Withdrawal at anytime
- Will still have access to the health center if does not enroll

## **5. Accidental needle pricks reported with apprehension**

- Afraid of being blamed
- No provision made for medical attention
- Do not want to know HIV status

- Training and information on PEP
- Making ARV available
- Encouraging staff for HIV testing

## **6. Informed HIV positive participants spreading the infection**

- Men reluctance for male condoms
- Need money
- Did not ask to be infected

- Good counseling
- Explain need for condom use
- Might get infected with a more virulent strain

## **7. Participants feel used and frustrated at the end**

- What is next ?
- Wait for the next trial ?
- What if study results not conclusive ?
- Will product be accessible if efficient ?
- What to do between trials ?

 **« THE TRIAL IS OVER, HEALTH PROBLEM PERSISTS »**

- **HIV prevention is a global challenge**
- **IEC provided**
- **HIV incidence drastically reduced**
- **Hope products will be accessible if proven to be efficient**

## 8. « Negative rumors » about the study

- \* Easy access to participants
- \* Reduced costs
- \* Less stringent regulations
- \* Exploitation of indigenous population
- \* Investigators corrupted
- \* Blood collected to be sold abroad
- \* Not altruistic, etc.

- Proper information on HIV epidemiology and risk factors
- Provide accurate information on study objective and methodology
- Study approved by Health Authorities and Ethical Boards

**9. How am I sure participants are using the Study Product ?**

## **In conclusion :**

- Research on Microbicides is crucial to reduce the spread of HIV infection especially in sub-Saharan Africa
- RCT will involve ethical challenges that need to be addressed accordingly