

**«Les enjeux méthodologiques,  
opérationnels et éthiques»**

**«Methodological, operational and  
ethical challenges»**

***JC Desenclos, Institut de Veille Sanitaire & ANRS AC25***

# Why this seminar ?

- **ANRS « Actions coordonnées » : to promote the emergence of research projects from the research community on priorities or insufficiently covered needs**
- **AC25, AC18 & AC 12 : hard to promote community intervention trials !**
- **Why not a research seminar ?**

# Why doing community health intervention trials ?

- Health interventions applied on a community-wide basis have been increasingly used in public health research over the past several decades
- Community-based interventions efficient way to increase the generalizability of public health program benefits
- Needs to demonstrate to health policy makers the positive impact of health intervention beyond that based on individual-based clinical trials
- The emergence of community health intervention trials is a shift in health research from studies that focus primarily on the individual to those that focus on community groups.
- The emphasis on interventions focusing on communities has created new methodological, operational and ethical challenges

*D'après Atienza & King, Epidemiol Rev, 2002*

# Why this seminar for ANRS ?

- **Innovative actions are needed to reduce hepatitis and HIV infection and their health & social impact to individuals and communities**
- **Biological, clinical & epidemiological and social sciences research :**
  - improve our understanding of the processes that contributes to the spread and the health & social impact of these infections
  - new tools, strategies & policies for prevention & intervention
  - new opportunities to reduce further their health and social impact
- **Innovative tools or health social strategies must be evaluated at community level through community-based intervention trials**
- **However, community-based intervention trials under utilized by the French public health research community**

# Our aim !

- **Foster the development of the experimental evaluation of innovative prevention & health, behavioral and social strategies among the French researchers for research promoted by ANRS in France and internationally**
- **En donner le goût !**

# Methodological - scientific issues (1)

- **Two components**
  - definition of the experimental social intervention or program to bring desired changes and health improvement
  - research design to evaluate / assess / quantify interventions outcome and impact
- **Although relatively similar to clinical trials for basic principles, quite a few methodological, operational and ethical issues**

# Methodological - scientific issues (2)

- **Definition and conceptualization of the intervention**
- **Is a community control trial needed ?**
- **Enough evidence to get into a trial ?**
- **Definition of the community of interest**
- **Randomization ?**
  - if yes how ?
  - Individual vs cluster ?
- **Statistical power ?**
- **Monitoring the delivery of the intervention and adherence**
- **Outcome measurements (subjective vs objective...)**
- **Cohort vs cross-sectional analysis**
- **Accounting for secular trends**
- **Statistical issues for the analysis of community trials**
- **...**

# Methodological - scientific issues (3)

- **Understanding how community-based interventions improve health is as critical (if not more) than evaluating the outcome**
- **It requires the specification of conceptual or theoretical models**
- **Need for a strong interaction between social sciences and quantitative epidemiology**

*Atienza & King, Epidemiol Rev, 2002*

# Operational challenges

- **Balancing scientific methodology and feasibility**
- **Trial organization & planning**
- **Identify and recruit appropriate communities**
- **Resources and funding**
- **Information & communication**
- **Political, institutional and social issues...**
- **Community involvement...**
- **Recruitment & training of study personnel...**
- **Mono-centre vs. multi-centre trials (multi-country)**
- **Quality control and quality assurance**
- **Data collection**
- **Interim analysis**
- **Scientific monitoring (steering, scientific boards...)**
- **...**

# Ethical issues (1)

- **Follow principles for clinical trial, however, specific issues**
  - the behavioral & social nature of the intervention
  - community vs individual approach in intervention delivery
- **Ethical consideration (1, 2)**
  - Autonomy/informed consent
  - beneficence
  - non-maleficence
  - assessment of the risk
  - risk – benefit ratio
  - justice
  - access to care
  - confidentiality
  - community involvement & partnership

*1. Peter Cleaton-Jones: the first randomization trial of male circumcision: what were the ethical issues  
Plos Med; 2005;2:e287*

*2. MIMH Collaborative HIV/STD prevention trial group. Ethical issues. AIDS 2007;21:S69-S80.*

# Ethical issues (2): Challenges specific to international collaborative research

- **Sponsor-funding of trial in poor countries by rich countries**
- **Potential to exploit vulnerable international population**
- **Should be independent of any moral or ideological value from sponsoring country (ies)**
- **Should address needs of host population and nation**
- **Acceptable level of care**
- **Secure access to intervention if conclusive after trial is over**
- **Contribute to capacity building of host country**
- **Moving research into policy practice**

*MIMH Collaborative HIV/STD prevention trial group. Ethical issues. AIDS 2007;21:S69-S80.*

# Seminar organization

- **Conferences : 3 introductory & 1 methodological**
- **Five 2 hours thematic sessions**
  - sexual issues (2)
  - screening and care strategies (2)
  - prevention challenges among drug users
  - based on experience in the North and South
  - A « table ronde » on role of institutions
- **For each session:**
  - a coordinator
  - three invited speakers
  - a discussant that focuses on methodological and ethical issues and the impact on policy decision
  - a moderator to keep the time and write a synthesis of the session, including issues discussed

# Aknowledgements

- **Organizing committee: François Dabis, Jean-Paul Moatti, Nathalie Bajos, Patricia Carrieri, France Lert, Bertrand Nalpas, Caroline Semaille, Emmanuel Château, Nadine Job Spira, Véronique Doré, Brigitte Bazin**
- **Speakers**
- **Moderators**
- **Discussants**