YRG CARE CAB and their role in research protocol development
Mission & Goals of YRG CARE CAB

Mission:
To relay the perspective of the host community to the researchers/Principal Investigators by providing them with informed commentary regarding the strategies to identify, recruit, educate and follow-up individuals in these studies.

Goals:
1. Provide community perspectives on issues likely to arise during the conduct of research studies.
2. Provide informed commentary on study protocols, informed consent processes, and informational, educational, and promotional materials.
3. Support recruitment efforts and promote referral arrangements associated with the studies.
4. Represent YRG CARE at regional meetings and other forums, when appropriate.
Key opinion leaders from various cross sections were identified and approached.

Mission and goal of YRG CAB was explained and they were invited.

Few self nominations and referrals occurred in the course of these various efforts to build an effective CAB.
Number of CAB members:

• Started with 10 members in 2000.
• Now grown to 22.

Term:

• Membership is for 3 years, renewable
• Membership in the CAB is a voluntary, honorary position.

Nature of Membership:

Includes Direct and Indirect Stakeholders.
Direct & Indirect Stakeholders

- Women in Prostitution…2
- Pimps……………………1
- IDU……………………1
- MSM……………………1
- HIV + …………………..1
- Transgender……………..1
- Community Housewives..4

TOTAL……………………..11

- Physician (Gynaecologist)……...1
- Religious leader (Catholic priest)……………………………………1
- Lawyers (Women’s rights activist & Corporate Lawyer)……………..2
- Public Accountant/Fin.Consultant..1
- Psychiatrist…………………………..1
- Rotarian…………………………...1
- NGO leaders………………………1
- Corporate Sector……………………1
- Hospital Administrator…………….1
- HIV-affected……………………….1

TOTAL…………………………..…11
General activities of the CAB

• Attend regular CAB meetings held bimonthly.
• Duration of meetings – 1.5 to 2 hours
• Held on – Saturdays (morning or afternoon)
• Held in – a hotel, where there is sufficient privacy and anonymity
• Agenda set by – the Research Manager and the CAB Coordinator in conjunction with CAB members
• Meetings conducted by – the two Co-Chairs.
• Meetings held till date: 39
Each study protocol is presented to IRB, CAB and prior to this, study team discusses with site PI
CAB members discuss protocols with PI and outreach team and this begins right from draft versions. Many informal meetings occur and community feedback is constantly provided.
Research team and CAB members identify areas of training needed and develop a plan to seek and learn mutually.
Training materials and community education tools are jointly created by CAB and outreach teams.
CAB members work with outreach teams in developing recruitment and retention plans for each protocol
Challenges, issues, problems and community expectations are constantly communicated to the research team and so CAB actually serves as their key informant.
Intrapartum single dose NVP with a 21 day course of antiretroviral therapy results in less frequent selection of NVP resistance than with a 7 day course.

The drugs used for tailing will not pick up any resistance of their own.
Study design: phase 2, prospective, randomized, open label study evaluating the effectiveness of three different antiretroviral (ART) strategies for the prevention Nevirapine resistance.

Objective: To determine whether a 21 day course of ART is more effective than a 7 day course.

Duration: mothers will be followed up for 96 weeks and infants for 12 weeks

Sample size: 420 mother infant pairs

Inclusion and exclusion criteria
Issues flagged by CAB

- 06 visits to the study center by mothers post delivery in year 01 is a big challenge culturally.
- Mothers also need to make joint visits with infants 03 visits.
- CAB suggested that unless mothers are provided transport allowances and for another attendant to help her, visit compliance may be low.
- To encourage mothers’ visits, CAB also recommended offering nutritional support to mothers and babies (formula feed).
Community education points recommended by CAB

- Travel support to mother, child and an attendant
- Diagnostic and medical support to mother and child during study period and referrals post.
- Nutritional support to mother and child
- Ensuring confidentiality is protected as this is a major issue for HIV positive mothers
- Effective counseling during and post delivery emphasizing the importance of study visit compliance.
Role of CAB in Research Methodology

CAB members review:

- Protocol
- Consent form
- Research methods
- Brochures
- Poster
- Leaflet etc.

- Certified in Human Subjects Research Education (Ethics) and Good Clinical Practices (GCP)
THANK YOU!!

YRG CARE
VHS CAMPUS
RAJIVGANDHI SALAI
TARAMANI, CHENNAI
WWW.YRG CARE.ORG
INFO@YRG CARE.ORG