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Original Article

Engaging community to support HIV prevention research

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Abstract. Actively engaging communities in effective partnerships is considered critical for ethically robust and locally relevant HIV prevention research. This can be challenging in developing countries that have little prior experience in this area. This paper summarizes processes and lessons learnt while setting up the Community Involvement Plan of National AIDS Research Institute, Pune, India. Formal partnerships were established with voluntary agencies. The focus was on using strategies adapted from participatory learning and action techniques. The community program was implemented through peer educators specifically identified from the communities where partner non-governmental organizations function. At the grass root level, peer educators imparted education to the common people about research studies and helped to implement community based recruitment and retention activities. The focus was on facilitating periodic interaction between the outreach workers of the research team and the peers and modifying the strategies till they were found locally implementable and appropriate. Through adequate time investment, mutually beneficial and respectful partnerships with community based organizations and grass root level workers, the community became actively involved in clinical research. The program helped in developing a sense of partnership among the peers for the research conducted by the research organization, widening the net of community education and identification of research participants. By building trust in the community and implementing research within an ethical framework, culturally sensitive matters were appropriately addressed. The community involvement process is long, laborious and ever-evolving. Effective community engagement requires institutional leadership support, adequate funding and commitment by researchers. It is possible to sustain such a model in a resource limited setting.

Key words: Community involvement, community advisory board (CAB), HIV prevention, partnership, research, trial, NGO

1. Introduction

Participatory action research can be defined as community-based ethnography; it denies the authority of an individual researcher to determine the purpose, processes, and products of investigation. The basic principle of the participatory approach is to explore not only "what" is the best way to study but also "how" can it be done the best way. This type of research places value on equal participation of community members and researchers (1, 2). The process of community involvement is likely to promote new institutional approaches to conduct research in an ethical framework. Actively engaging communities in effective partnerships is considered vital to the successful conduct of ethically robust and locally-appropriate clinical trials in developing countries (3).

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National AIDS Research Institute (NARI) in Pune, India has been working on epidemiological, clinical, basic science and social science research related to HIV/ AIDS since 1992. NARI has also been participating in HIV prevention and therapeutic research sponsored by National Institutes of Health (NIH), USA in the last 15 years and has conducted HIV sero-prevalence studies, incidence (cohort) studies and clinical trials.

As many of these studies are multi-centric and multi-national, maintaining uniformity in participant recruitment, protocol implementation and informed consent processes across participating sites located all over the world can be a challenge.

With a suggestion of involving the community in externally sponsored research and a growing felt-need of going beyond the clinic-based recruitment of participants and exploring community oriented approaches to meet the stiff enrollment targets of Phase II and III trials, scientists at NARI worked on development of a

multi-dimensional model of community engagement.

We describe and discuss a significant initiative of NARI in community involvement through the establishment of partnerships between NARI, a Government institute working in the public sector and non-governmental organizations (NGOs) and community based organizations (CBOs), both representing the private sector to conduct real world grass-root level work. This initiative was called as Community Involvement Plan (CIP). This paper describes steps and experiences in establishment of Community Involvement Plan of NARI and lessons learnt in this process.

2. Meterial and methods

Following advice from the Community Advisory Board (CAB) of NARI, the Community Involvement Plan of NARI was drafted. It was decided to involve NGOs or CBOs to create a community support structure for the research studies conducted by NARI. The program was initiated in the year 2000 with the primary objectives of active involvement of stakeholders in the field to support clinic and community based clinical research. In the last 8 years, the CIP of NARI has expanded in its scope and nature.

The process of NGO/ CBO identification: Nearly 25 -30 NGOs/ CBOs operating in Pune city were invited to participate in two rounds of exploratory meetings. The objectives of these meetings were to discuss NARI's Community Involvement Plan with these agencies working in the private sector and assess their willingness to partner with NARI (4, 5). The focus was on promoting a mutually beneficial relationship between NARI and NGOs/ CBOs and formalizing the same by signing a memorandum of understanding (MoU). It was proposed that NARI would provide training to NGO employees, HIV counseling and testing facilities for their community and technical assistance for writing grants. The NGOs/ CBOs would work with outreach workers of NARI to gather a profile of the community, educate the community about HIV/ AIDS, ongoing research and means of prevention and help to identify individuals who could be directed to participate in various ongoing studies of NARI.

Each NGO is expected to contribute to the CIP by providing two employees as 'Supervisors' who look after the administrative issues (maintaining attendance records, paying honoraria), conducting refresher training and helping in identification of new peers. The supervisors are paid employee of the concerned NGOs who act as liaisons between peers, NGOs and NARI. One field worker of NARI is assigned to one partner organization to oversee program implementation in the respective NGO area. The supervisors liaise with NARI outreach workers in allotting and supervising duties of peer educators.

Program implementation through Peer Educators: The central theme of the CIP is to identify up to 20 peers per NGO/ CBO. Being educated is not an essential criterion for selecting a peer. Peers are identified based on their quick comprehension, keen interest in social and community work, time commitment, communication skills and general knowledge of the locality where they live. A structured peer identification process is devised for selection of new peers. We have defined core competencies among the peers as ability to 1) work among people and influence people, 2) understand the importance of research and develop appropriate messages for common people, and 3) build relationships between NARI, concerned NGO and the community. All the peer educators are given pre-induction training of a minimum of sixty hours spread over two weeks which is later reinforced through periodic refresher trainings at NARI. The curriculum includes training in communication skills, human subject research and ethics, and differences between research and treatment. They are also made familiar with research sites through visits to clinics and observation of activities and are sensitized to matters related to confidentiality and their actual role in the community program of NARI. Our peers commonly represent the following groups in the community: house maids, house wives, youth leaders or unemployed youth, elderly persons or Anganwadi workers (social workers employed as teachers in the government sponsored Integrated Child Development Program for children in the pre-school age-group).

After training, the peers from the partner NGOs become adequately empowered to facilitate community based activities, initially jointly with outreach workers of NARI and later independently. The expectation is that they spend up to two hours every day for the activities assigned as a part of the NARI CIP. They are provided an honorarium by NARI through the partner NGOs. Although the peers are under the administrative control of the NGOs, their day to day program is supervised by NARI outreach workers.

Specific strategies have been developed to sensitize community covered under the CIP network of NARI. The program involves two components: 1) Core program and 2) Protocol

oriented program. The "core program" is the ongoing community contact program aimed at creating HIV/ AIDS awareness, conducting house to house surveys, promoting voluntary counseling and testing, educating community about the need and concepts in biomedical research and sensitizing communities about research related issues. This program functions throughout the year even when no active community based recruitment is taking place in any particular research study. The household coverage by peers is expected to be documented using a simple census form that captures the demographic profile of the household members in the area. The second component of CIP is "protocol oriented program". This specially designed time bound intensive program aims at sensitization of the community through peers about specific research protocols designed to result in referral of the participants to the clinical research sites for possibile enrollment in research studies. Based on the requirements of specific protocols, various strategies are considered. For microbicide trials approaches to reach women and their husbands or partners are required. Approaches in reaching healthy and low risk populations for participation in Phase I HIV vaccine trials are completely different than those required for recruiting HIV sero-discordant couples in a Phase I or III HIV prevention trial.

Referrals from the CIP to various research sites of NARI are identified by tracking referral cards called 'Care Cards'. Care cards are issued to peers in the weekly peer meetings. The care card has records of names of the strategy, peer, NGO and the NARI outreach worker. There are two parts of care card. When used, one part is retained by the peer to be submitted to NARI and the other part is handed over to the potential participant with an instruction to hand over the same to the counselors in the referral clinic. The cards distributed in the community and collected at clinical research sites (CRSs) are matched daily in the computerized system to track the outcome of referrals.

Monitoring and evaluation: A peer evaluation plan has been prepared in consultation with NGOs. Weekly peer meetings are facilitated by NARI personnel to share experiences and understand and solve problems faced by peer educators and NGOs/ CBOs in the community. They also serve as administrative meetings where all peers provide weekly planner and submit weekly reports. The weekly reports are entered in the NARI CIP activity data base that helps in generating monthly reports of the peer activity. The peer activity report is shared with the respective partner NGO for further improvement of the program.

The following indicators are employed for evaluation of the CIP through the peer program: 1) Attendance of peers at weekly meetings and refresher training programs; 2) Contribution to ongoing core and program activities like number of individual, couples and group meetings conducted, contacts with health care providers and practitioners, telephone contacts, key person identification; 3) Specific/ special contributions like rumor eradication or suggesting new strategy and 4) Successful referrals of potential participants to Clinical Research Sites.

3. Results

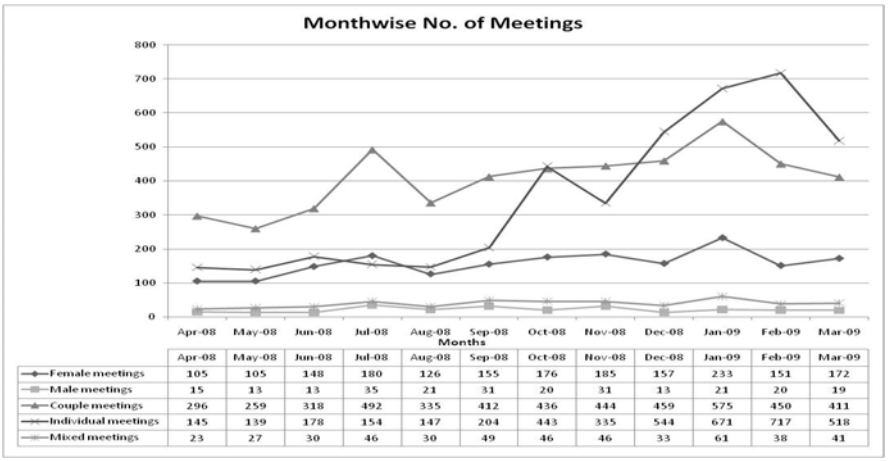
The concept of engaging the community in clinic and community based research right from design up to implementation was untried in India when we began work. However, over the last 15 years, with sustained effort and by the process of experiential learning, we were able to involve the local community in a meaningful manner. One of our partner NGO Directors commented: ***"****I am born and brought up in this slum. To reach to the community is my responsibility and local community has trust in me. The community responds and gives respect to my representatives".* This reflects the willingness of the community to accept the opinion of the local community leaders and the need to involve community representatives in research. Work was initiated with five NGOs and one CBO and later two additional NGOs were inducted in the Community Involvement Plan. Currently NARI has a working partnership with eight NGOs that primarily work in the area of HIV/AIDS (Table-1).

Presently a total of 92 peers from six partner NGOs are operating and peer identification process is ongoing in case of two recently inducted NGO partners. Almost all (91/92) peers are women and none of the 92 peers is illiterate. The majority of them have studied middle to high school (59/92, 64.1%) and 9/ 92 (9.8%) have completed their graduation. Two are pursuing their post-graduation; while two more have completed their post-graduate education. Nearly half of the peers are Anganwadi workers employed in the Government's program for pregnant women and pre-school children (41/92, 44.6%). In addition, 22 out of 92 (23.7%) peers are active social or community workers simultaneously employed in other Government or NGO projects. Among the others, 14 (15.2% are housewives and 15 (16.2%) are employed elsewhere.

Table 1. Profile of NGO/ CBO partners of NARI's community ınvolvement plan

Name of NGO/ CBO partner	Basic area of work	Year of induction in CIP	No. of peers
Community Aid and Sponsorship Program (CASP)	Sponsorship program for children and AIDS orphans, adult education	2003	18
John Paul Slum Development Project (JPSDP)	Awareness, Nutrition, DOT Centre for tuberculosis, Targeted intervention for commercial sex workers	2003	13
Snehdeep Jankalyan	Education for children [balwadi], Clinic, Parent Education, Child care	2003	08
Deepgruha Society	HIV / AIDS , Nutritional centre for children [balwadi], Clinic, Hospice, HIV/ AIDS	2003	25
Bahujan Hitaya	Women self help group, Women empowerment, Medical aids, Sure start program for hospital delivery of pregnant women	2006	16
Swadhar	Nutrition for HIV infected children, legal advice related to HIV issue, HIV support group	2005	12
Pasaydaan	HIV/ AIDS awareness, Education	2009	Peer identification process ongoing
Mahila Vikas Kendra	Empowerment for house maids, Savings group, Micro credit system	2009	

As part of Community Involvement Plan, NARI keeps adding partners to carry forward the agenda of community involvement in research. Currently there are 8 partner NGOs and 80 peers under this program and peer identification process at the two newly inducted NGO partners is ongoing.



	Apr-08	May-08	Jun-08	Jul-08	Aug-08	Sep-08	Oct-08	Nov-08	Dec-08	Jan-09	Feb-09	Mar-09
Female meetings	105	105	148	180	126	155	176	185	157	233	151	172
Male meetings	15	13	13	35	21	31	20	31	13	21	20	19
Couple meetings	296	259	318	492	335	412	436	444	459	575	450	411
Individual meetings	145	139	178	154	147	204	443	335	544	671	717	518
Mixed meetings	23	27	30	46	30	49	46	46	33	61	38	41

Fig. 1. Attendance in individual and couples' meetings.

Participation in male and female group meetings and mixed meetings involving members from both genders remained the same during April 2008 to March 2009. However, participation in couple meetings and individual one-to-one meetings showed a steady increase demonstrating an evidence based change in strategy for recruiting HIV discordant couples at Pune, India site.

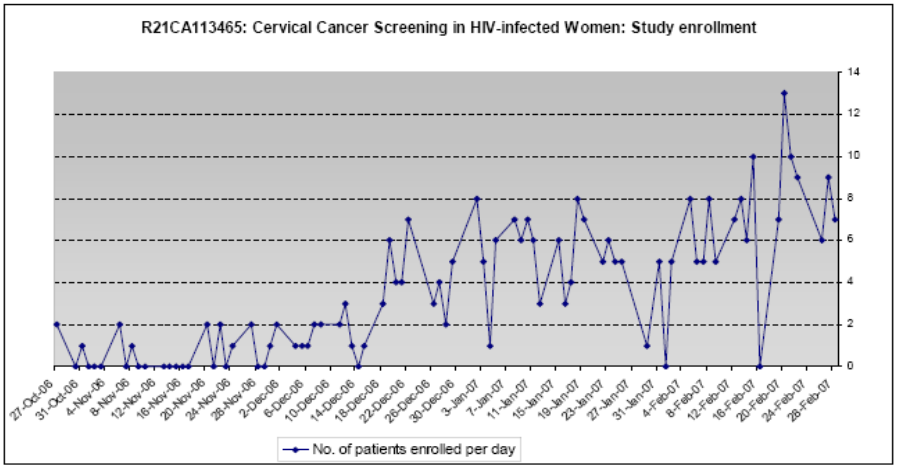


Fig. 2. Enrollment in cervical cancer screening study showing effect of introduction of community based referral with significant deficit in enrollment targets following clinic-based enrollment by December 2006, community based outreach activity supported through core CIP, was planned to identify and inform HIV positive women about the study. After initiation of this activity in December 2007, targeted enrollment was rapidly completed.

The CIP of NARI helped in building enabling environment in the recipient communities. Over 50,000 households were covered by peers using door to door approach for community sensitization and education over a period of six years (2003 -2009). A large number of individual, couples and group meetings were conducted and data for the year ending March 2009 is presented (Figure 1). It was observed that response to male and female group meetings and mixed meetings involving members from both genders remained the same throughout the year. However, when we started focusing on couples' meetings and individual one-to-one meetings, the participation in these meetings increased.

A cross sectional study on cervical cancer screening conducted by NARI initially focused on clinic-based recruitment. With significant shortfall in enrollment targets after 2 months of study initiation, community based outreach activity was planned to identify and inform HIV infected women about the study. After initiation of this activity in December 2007, targeted enrolment was rapidly completed (Figure 2). The results of referrals and enrollment of HIV sero-discordant couples in one of the studies of NARI (HPTN 052 study) are summarized in Table 2.

The CIP alone resulted in very few referrals in the study. Many additional strategies were employed to recruit HIV discordant couples in that study. Study referrals of HIV sero-discordant couples were received from Integrated Counseling and Testing Centers (ICTC), Voluntary Counseling and Testing centers (VCTCs), doctors and organizations working for HIV positive people. Thus, although Core Program of CIP might not have significantly helped in sero-discordant couples' enrollment, it has indirectly contributed in self-referral of patients to NARI clinics who would have eventually participated in the study. Between April 2008 and June 2009, the client turnover at the clinical research sites of NARI ranged between 388 and 723 (Table 3). Focused increase in 'Couples' HIV counseling and testing' was implemented by the end of September 2008. Correct information on requirement of HIV discordant couples was passed on to the community. Consequently the discordant to concordant couple ratio decreased and more and more HIV sero-discordant couples were referred to the study clinics.

4. Discussion

Although NARI began efforts in engaging grass roots community in the mid 1990s for the NIH sponsored extramural research, it became an institutional commitment by the year 2000 and the concept was extended to all institutional research activities. The Community Involvement Plan of NARI emphasizing partnerships between local NGOs and NARI was formalized following a specific recommendation from the Community Advisory Board. The goal of CIP of NARI was to create awareness about HIV/ AIDS, ethical issues and specific research studies including Phase I, II and III clinical trials; identify and train

Table 2. Strategies used for community outreach for identification and referral of HIV discordant couples (April 2008 – March 2009)

Recruitment Strategies	No. of community contacts made	No. of referrals to NARI clinics (couples)	No. of screenings	No. of enrollments	Screening/ enrollment ratio
CIP core program					
Meetings by peers	4827	413	04	04	1:1
Protocol oriented or study specific program					
Meetings by peers and NARI staff to encourage referrals from ICTC centers	372	105	22	14	1.6:1
Meetings and follow-ups by peers and NARI staff with doctors	725	59	07	06	1.1:1
Meetings and follow-ups by peers and NARI staff with organizations working for PLHA	589	40	11	05	2.2:1
Self-referral of people from the coverage area to VCT	-	476	44	25	1.7:1
Contacts made by NARI with past study participants	Peers not involved	-	06	04	1.5:1
Other sources	-	-	07	02	3.5:1
Total		1093	101	60	1.7:1

Note: CIP – Community Involvement Plan, ICTC – Integrated Counseling and Testing Centers, VCT – Voluntary Counseling and Testing

Table 3. Client turnover, couple referral and HIV discordance and concordance ratio

Time Period	Client turnover at CRSs[α]	VCT clients	Couples referred	HIV discordant : HIV concordant (ratio)
April 2008	562	358	102	21: 73 (1:4)
May 2008	723	495	114	29: 78 (1:3)
June 2008	661	441	110	42: 71 (1:2)
July 2008	689	459	115	41:79 (1:2)
August 2008	555	385	85	23:72 (1:3)
September2008	526	412	57	19:40 (1:2)
October 2008	397	275	61	21:45 (1:2)
November 2008	558	406	76	21:45 (1:2)
December 2008	560	420	70	27:41 (1:1.5)
January 2009	609	455	77	19:46 (1:2)
February 2009	543	415	64	25:40 (1:2)
March 2009	505	367	69	20:40 (1:2)
April 2009	436	312	62	17:44 (1: 2.5)
May 2009	482	376	53	15:35 (1:2.5)
June 2009	388	278	55	25:28 (1:1)

[α] CRS: Clinical Research Site

Focused increase in 'Couples' HIV counseling and testing' was implemented by the end of September 2008. Subsequently the discordant to concordant couple ratio decreased. Correct information on requirement of HIV discordant couples was passed on to the community

community based peers, and educate people to know more about ongoing HIV prevention research. Also, as research on HIV/ AIDS has significant sensitivity and potential stigma, it was envisaged that community involvement would help to significantly minimize these. Clinical research exposes patient participants to unproved methods and research procedures in order to gather generalizable knowledge to benefit others (6). Community involvement helps to make this process transparent, ethical and trustworthy. Hence, the ultimate indicator of community engagement in research indicative of empowerment could be self-decision making based on self-acquired knowledge about research studies and self-referral by community members in research studies.

Examples of engaging NGOs / CBOs in biomedical research are very rare in India. Although increasing awareness about research ethics and good participatory practices (7) will demand this in the years to come, motivation and commitment of researchers to make this happen will remain a challenge. Hence sensitization of researchers will have to be made an ongoing process. It is also important to make the communities research literate first. The lay community and its representative members should understand the public health significance of clinical research and make learned decisions about research participation and ask questions if they need any additional information. Thus educating the community on a continuous basis using friendly strategies is another challenge. Other key challenges in engaging community in a sustained manner include significant time investment by the researchers in building and maintaining community networks, uninterrupted and perseverant efforts by the researchers and funding to support the peers' program. Retaining the trained peers is another key challenge because the work is voluntary and has limited remuneration. Peers in the lower socio-economic strata tend to be mobile and often engage in better paid jobs to support their families. Keeping them interested by discussing their contributions in research and providing incentives such as sending for some meetings or providing opportunities at local, national and international levels to make presentations can help in sustainability of this program. Community engagement in biomedical research can be a long, slow and non-uniform process and its benefits can, not only be apparent and direct, but also indirect. Significant investments of time and funds may be necessary to support the community program particularly when the level of literacy is low and poverty prevails with a lack of infrastructure. There is a need to keep a continuum of contact with the community by sustaining some baseline activities under the core program even if no study specific focused activities are being actively implemented. Thus it is important to ensure adequate financial support to the ongoing community oriented activities. It is critical to maintain a visible presence and contact in the community for the success of future trials. A strong data management support can ensure that the community engagement activities are providing appropriate inputs in the research program and yielding the desired results.

Peer educators constitute the mainstay of the CIP of NARI. In addition to formal trainings, some of the peer educators and NGO partner representatives also had an opportunity to meet and have discussions with their global counterparts. Sharing of local experiences at a global level is a kind of development practice (8) that can result in significant capacity building. Peer educators also benefitted through their interaction with the individuals affected/ infected by HIV who have been associated with research studies of NARI as workers of partner NGOs or CAB members. It has been commented that involvement of such faces of the community is central to a complex understanding of the nature of the epidemic and to the utilization of the knowledge gained and they should be fully integrated into research processes from the start (9). Lo & Bayer have suggested that it is important to build partnerships with various agencies for clinical research and trials and that research protocols should be reviewed by beneficiaries before the implementation of the proposals (10). The requirements of some of the early international prevention study protocols have conflicted with local cultural norms (11, 12). Therefore, researchers even in the resource limited settings have started to involve community leaders and stakeholders in research planning and implementation. It is important to accept this good practice of community engagement and extend the same to clinical research of national and local relevance as well.

We have discussed a model of community engagement for clinic and community based research through establishment of formal working partnerships between NGOs and CBOs in private sector and a Government research institute in public sector. Our site has been able to engage community in a meaningful manner over a decade of partnership. The partner NGOs did not ask for any monetary assistance for supporting or sustaining this partnership other than provision of

honoraria for their peer educators. We have not presented cost effectiveness analysis of the CIP in this paper. This kind of Government-NGO partnership model has not been reported elsewhere in the field of clinical trials in India. This model is suitable for resource poor settings because the cost outlays are reasonable and the model is based on active participation of the people from the community who have a desire to work for the community.

NARI's role in bringing NGOs and CBOs in the process of making research visible to the community resulted in increase in uptake of VCT at the Clinical Research Sites (CRSs) and also helped to build enabling environments for community involvement in clinical research in Pune. Researchers need to understand that by reaching out to a large number of susceptible people and creating awareness among them, it may be possible to reduce the disease transmission in the community. Additionally this effort might also facilitate study participants' recruitment and retention. The community partners should review protocols for cultural sensitivity, help to develop culturally sensitive education material and assist researchers address concerns of the community. Our work in community engagement has been appreciated at the international level and has resulted in finalization of several reports and policy briefs (13-17).

Creating research literacy in the community can be challenging. It is important to make community understand the difference between 'research' and 'treatment'. The community partners can contribute by explaining to the community the real meaning of research participation, clearly emphasizing that their right to health care and treatment cannot be linked to research participation. Research participation emphasizes internalization of responsibility in terms of time commitment, adherence to study protocols, retention and partnering with researchers to ensure adherence to study protocols. A strong commitment is required to empower and build capacities of the least empowered sections of the society such as the less educated, poor people, children and women. It is important to fund community partnerships as an integral part of clinical trials and adequate financial support to train scientists, research staff, and members of ethics review committees, community partners and Community Advisory Boards (18-21). Community preparedness activities should be funded at least one year prior to study initiation and study sites should ensure developing corpus funds / NGO support to continue with community level work even after the study is over. Appropriate skill development for carrying out these processes efficiently and strategic questioning might help to avoid inappropriate peer behavior during community sensitization in sensitive areas (22,23). We engaged the peers from the community in which research was taking place and generally, the peer educators in CIP represented lower and weaker sections of the society. The CIP helped in building the capacity and skill-sets of otherwise non-income producing groups or meager income

Table 4. Key messages for community involvement in clinical research

Building partnership	A GO-NGO partnership is possible if there is symbiotic relationship and working arrangement based on common goals defined by mutual interests.
Training	Training requires comprehension of privacy/ confidentiality related issues and technical information about research protocols. Training enables peers to adopt community friendly approach to deliver community friendly messages.
Peer identification	A good peer has to possess leadership qualities, access to households of the served community, ability to network with key persons/ leaders in the area and motivation for social work. Education is not that important.
Communication skills & perseverance	Communication skills and perseverance among peers can be an asset in outreach activities related to clinical research.
Monitoring & Evaluation	Researchers should define measurable indicators for CIP evaluation prior to its initiation and closely monitor the outcomes. Work of peers in the CIP needs to be closely monitored. Client and peer centric tracking tools can be useful monitoring tools.
Generalizability of program	Community Involvement Plan (CIP) contributes to capacity building of local human resources and helps to develop community literacy among the researchers. With methodical application and appropriate investment it can be practiced by any research organization.

producing groups. CIP is an example of sharing manpower resource between NGOs and research organization. Research conducted at NARI almost invariably has a community component. We have been able to successfully engage the community. Some of the key messages from this program are enlisted (Table-4). There is institutional support to community program. Institutional decision makers visit the community, attend meetings and provide technical support to partner NGOs in conducting health camps, developing new projects and providing resource persons for trainings. The evaluation of community involvement program is critical to judge the success of the partnership and gain continued support from sponsors and administrators. After its annual evaluation of the peer activity, NARI had to discontinue one NGO partner in 2006 that was not performing optimally. Recently, one more partner NGO expressed inability to continue to work as a partner in CIP owing to shortage of their own staff. However, new partnerships with two new NGOs have been formalized recently. The parameters that can be used to assess the performance of the peers include door to door surveys conducted, group meetings conducted, referrals made to the clinical trial research sites, attendance at weekly peer meetings and special inputs such as advice on community issue. We observed that the performance of the peers was non-uniform. The provision of specific training sessions designed to enhance the preparedness of peers and NGO representatives to participate effectively in the CIP, combined with on-the-field training and performance appraisal can possibly help to increase the efficiency of the community intervention. It will be important to identify measurable indicators for community involvement. However, it is important to remember that the benefits of CIP may not always be directly measurable. The CIP can act as a solid foundation for any future research endeavor.

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