Research Benefits for Hypothetical HIV Vaccine Trials: The Views of Ugandans in the Rakai District

BY CHRISTINE GRADY, JENNIFER WAGMAN, ROBERT SSEKUBUGU, MARIA J. WAWER, DAVID SERWADDA, MOHAMMED KIDDUGAVU, FRED NALUGODA, RONALD H. GRAY, DAVID WENDLER, QIAN DONG, DENNIS O. DIXON, BRYAN TOWNSEND, ELIZABETH WAHL, AND EZEKIEL J. EMANUEL

Table 1. Study Population

Group name	*Recruitment*	*Characteristics*	*Details of group*
Rakai Cohort Surveillance Study (RCSS)[a]	300 randomly selected (100 from each of three communities) from over 12,000 participants.	Males and females. Not receiving study compensation.	Research participants in an HIV surveillance study. Possible cohort for HIV prevention trials.
Molecular Epidemiology Research (MER)	125 males randomly selected from >600 seroconverters.	Males only. Receiving financial compensation (15,000 Ush (~$8USD) plus travel if appropriate for each cycle).	Research participants in a substudy to characterize HIV- subtypes and viral set points among recent HIV seroconverters identified through the RCCS.
Bacterial Vaginosis Etiology & Natural History Study (BV)	125 women randomly selected from 273 participants.	Females only. Receiving financial compensation (~2000 Ush per visit for a total of 8000/month (~$4 USD).	Research participants in a natural history and sexual transmission study of bacterial vaginosis.
Unaffiliated Participants	100 randomly selected from a census of three communities not involved in RHSP studies.	Males and females. Not receiving study compensation.	Members of communities not previously invited to participate in Rakai Project studies.
Decliners	125 randomly selected from 406 who declined further participation in the RCSS.	Males and females. Not receiving study compensation.	Individuals who declined to participate in at least one round of the RCSS study.
Opinion Leaders (OL)	150 opinion leaders identified through SOLnet and 50 randomly chosen community mobilizers.	Males and females. Not receiving study compensation.	Community opinion leaders in three Rakai District community clusters who were identified through a separate sociometric survey (SOLnet study) and/or selected based on their local council leadership status.

a. Formerly Community HIV Epidemiology Research (CHER).

Table 2. Characteristics of the Study Sample

	Total (n = 915)	*RCSS[a] (n = 251)*	*MER[a] (n = 123)*	*BV[a] (n = 143)*	*Unaffiliated[b] (n = 103)*	*Decliner (n = 100)*	*Opinion leader (n = 195)*
Mean age, years	31.3	30.2	31.6	28.1	30.9	30.2	35.6
% female	50.2	52.6	0.0	100.0	58.3	46.0	39.5
% married	72.2	70.1	77.2	68.5	72.8	71.0	74.9
% Catholic	65.2	66.9	69.1	61.5	68.9	53.0	67.7
% with less than a primary education	61.7	64.1	70.0	69.3	58.2	69.0	46.1
% with iron sheet roofing	92.7	92.4	91.9	91.6	92.2	92.0	94.9
% with no electricity	91.9	89.6	94.3	88.8	84.5	97.0	96.9
% whose primary water source is a well	43.8	33.9	39.0	31.5	68.9	49.0	52.8
% with bicycles	64.7	61.0	63.4	57.3	55.3	61.0	82.6

a. RCSS= Rakai Cohort Surveillance Study, MER = Molecular Epidemiology Research, BV = Bacterial Vaginosis.
b. Unaffiliated: residents of communities not involved in RHSP research studies.

Table 3. Compensation for Individual Research Participation in a Hypothetical HIV Vaccine Trial

Survey (n = 915)	*%*
Subjects *should* be compensated in research	73.0%
Types of compensation suggested[a,b]	(n = 668)
Money	54.8%
Food	15.1%
Healthcare	22.5%
A Health Care Item	5.7%
Type of compensation selected for hypothetical HIV vaccine trial[c]	(n = 915)
Reimbursement for travel	6.6%
A small Uganda shilling (Ush) payment	5.7%
Health/hygiene-related item	22.2%
Reimbursement for travel and a small Ush payment	21.6%
Reimbursement for travel and a health/hygiene-related item	43.9%

a. Percentages do not add to 100, as we did not include 'Other' category in table.
b. Open-ended question.
c. Multiple-choice question.

Table 4. Posttrial Benefits to the Community

Survey Questions (n=912)	%
Researchers should provide some benefit to everyone in the community	79.7%
Type of benefit suggested:[a]	(n = 729)
Vaccine tested	16.0%
Food	19.1%
Health care	59.3%
Money	27.8%
Other social services[b]	25.2%
Other[c]	32.6%
Type of community benefit chosen from a list:	(n = 912)
Free vaccine for HIV-negative individuals	44.2%
Free opportunistic-infection drugs for HIV-positive individuals	5.5%
Free HIV/AIDS drugs for HIV-positive individuals	20.9%
Free general medical care for everyone in community	29.2%
% responding that vaccine should be provided in addition to previously specified benefit	41.2% (74.0% of 511)[d]

a. Open-ended question, total is less than 100% as some respondents suggested more than one type of benefit.

b. Other suggested social services included hospitals, clinics, schools, and safe water sources.

c. Specific alternative benefits suggested by respondents included soap, mosquito nets, health education, and home items.

d. The question was not asked of the 404 who chose 'free vaccine' in the previous question

Table 5. Distribution of HIV/AIDS Vaccine If Found To Be Safe and Effective

% that said the most fair method of vaccine distribution would be:	*Total (n=915)*	*Males*	*Female*
Vaccine available to more people at some cost	85.8%	85.0%	86.9%
Vaccine available to fewer people for free	12.3%	12.6%	12.2%
No exception; Rakai Project should provide the vaccine to everyone free of charge	1.6%	2.4%	0.9%
% that said the cost of vaccine should be subsidized by:			
Drug/pharmaceutical company	9.9%	8.4%	11.6%
Ugandan government	50.1%	56.4%	44.0%
Local or international aid organization	39.8%	35.2%	44.4%