Personal and community benefits and harms of research: views from Rakai, Uganda

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Objectives: To assess what individuals in low-income countries perceive as benefits and harms of population-based HIV/STD research.

Design: A total of 811 research participants, research decliners, and community opinion leaders in the Rakai District, Uganda were surveyed. Types of personal and community benefits and harms, as well as rates of reporting great personal and community benefit were assessed.

Methods: Using logistic regression, demographic characteristics, participant and opinion leader status, use of Rakai Health Sciences Program (RHSP) services, and perceived research effects were entered as predictors of reported great personal and great community benefit.

Results: Most respondents thought that RHSP research was of great personal (85%) and community (88%) benefit. The perception that the RHSP was a great personal benefit was correlated with female sex, post-secondary education, frequent use of RHSP-sponsored medical services, health knowledge gains, and increased hope for future health improvements. Persons of non-Baganda ethnicity and 30–39 year-olds were less likely to believe research was personally beneficial. Regarding research as a great community benefit was associated with reported health knowledge gains, greater hope for Rakai residents' future health, and local economic benefit. Decliners were the most likely to report a personal harm, while community opinion leaders identified community harms at the highest rates.

Conclusions: The majority of Rakai residents report that HIV/STD research has enhanced their own and their communities' welfare. Different factors were associated with the belief that research is a personal versus community benefit. Variations in participant, decliner, and community opinion leader perceptions highlight inadequacies of current community consultation mechanisms.

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Introduction

The recent rapid growth of biomedical studies in resource-poor countries has re-ignited concerns that such research may exploit global disparities. Fears that such research unfairly exposes individuals to the risks of experimentation without sufficiently benefiting them have been compounded by the perception that certain

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communities in low-income countries are ‘overused’ and are experiencing ‘research fatigue’ [1–3]. In response, bioethicists assert that a favorable risk-benefit ratio for *communities* is integral to the ethical conduct of research [4–6]. Some research ethics guidelines, including those promulgated by UNAIDS and the HIV Prevention Trials Network, recommend that clinical trials provide community benefits (e.g. medical and scientific capacity building, post-trial access to the tested intervention) and engage in a process of community consultation [3,7–12].

These guidelines have thus far, however, been developed in the absence of data about what individuals in low-income countries perceive as the benefits and harms of clinical or prevention trials. Nor do we know if individuals distinguish between personal and communal benefits and harms, or if these views differ between groups within a community.

The present study is a first attempt to answer these questions. We examined the perceived impact of population-based research on HIV/AIDS and sexually transmitted diseases (STDs). Our results give voice to research participants, research decliners, and community opinion leaders in the Rakai District, Uganda.

Methods

Study population

Life expectancy at birth in Rakai, a rural district in southwest Uganda, is 43 years. In 2003, Uganda’s income per capita was US$ 250; national healthcare expenditure per capita averaged US$ 12 [13–15]. Under 40% of Rakai’s approximately 500 000 inhabitants lived within walking distance of a hospital or clinic [13,14,16]. Rakai has been a nexus of HIV/AIDS epidemiological and clinical research since 1988, when Ugandan and American researchers established a community cohort study in the District. Several HIV prevention and STD treatment trials have since been nested within the 50 cohort communities, including a 1994–1999 cluster–randomized study of mass STD treatment on HIV prevention [16,17].

In 2003, the RHSP conducted seven studies and provided primary care, family planning, STD treatment, HIV palliative care, and prophylaxis for HIV-associated opportunistic infections via fixed and mobile clinics. The RHSP also offered voluntary HIV counseling and testing (VCT), couples VCT, condoms, and HIV and STD prevention education. These services were free or highly subsidized for all cohort community residents, whether or not they participated in research. Antiretroviral therapy was not available until June 2004, after this survey was conducted.

The Perceptions of Benefits and Harms of Research (BAHR) survey sampled adults aged 18–49 from three groups: (1) research participants; (2) research decliners; and (3) community opinion leaders (COLs). Research participants were randomly selected from three ongoing, longitudinal RHSP epidemiology trials: the Rakai Community Cohort Study (RCCS), the umbrella for all RHSP studies; the Bacterial Vaginosis study (BV); and the Molecular Epidemiology Research study (MER), which enrolled RCCS participants who had recently acquired HIV [18,19,20]. These three minimal risk trials involve periodic questionnaires and provision of biological samples. MER and BV participants received financial compensation for each study visit; households participating in the RCCS were offered a bar of soap. To maintain a balanced overall sex ratio, the BAHR survey sampled female BV and male MER subjects.

Between 1994 and 2003, 11.0% of RCCS subjects discontinued their participation after at least one round of data collection [21]. Individuals who withdrew during the most recent RCCS cycle were considered ‘decliners’ for the BAHR study. COLs included RHSP mobilizers ($n = 96$) and persons identified as COLs during a prior unpublished sociometric survey ($n = 99$). Thirty-six (18.5%) COLs had never participated in a clinical trial: their responses are included only in the community benefits and harms analyses.

Procedures

Designed by NIH and RHSP investigators, the BAHR survey comprised: (1) research participation experience; (2) perceptions of benefits and harms from RHSP research; (3) attitudes toward investigators’ obligations in a hypothetical HIV vaccine study; and (4) sociodemographic characteristics [Grady *et al.* submitted,.]. The survey was pilot-tested in 2002 and fielded in 2003.

A complex stratified sampling mechanism structured around the extant 11 RCCS community clusters ensured respondent representation from peri-urban, rural, and deep rural regions [17]. To avoid biasing responses in favor of the RHSP, the RHSP hired independent interviewers to obtain written consent and administer the 45-min-long BAHR survey. Respondents received 2500 Uganda shillings (~ US$ 1.50) for lunch and travel.

The present article reports respondents’ perceptions of the RHSP’s effects, most beneficial and most harmful aspects, and overall benefit or harm. *Perceived effect* questions probed plausible research benefits identified in the pilot study or debated in bioethics literature: knowledge of the seven principal RHSP medical services (free condoms, VCT, couples VCT, family planning services, primary care clinic, STD clinic, HIV clinic); personal use of the first six RHSP medical services; acquaintance with someone treated at the HIV clinic; gains in health knowledge (STD prevention, HIV

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prevention, and family planning); improved medical professional expertise; local economic benefit (job creation and local economic growth); and increased hope for Rakai residents' future health status and care access (HIV vaccine availability, HIV drug access, HIV prevalence, and quality of life).

In response to open-ended queries, BAHR participants identified the aspects of research they found *most beneficial* and *most harmful* to them personally and to their communities. *Overall benefit or harm* questions asked whether respondents thought that RHSP had helped them 'a great deal', helped them 'a small amount', 'neither been helpful nor harmful', harmed them 'a small amount', or harmed them 'a great deal'. A parallel question addressed perceived help or harm for the community.

Statistical analysis

Statistical analyses were conducted with SAS version 9.1.3 (SAS Institute Inc., Cary, North Carolina, USA).

A total of 811 individuals completed the BAHR survey: 517 research participants (63.6%), 100 decliners (12.3%), and 195 COLs (24.0%). One respondent did not finish the survey due to its length; her answers were excluded from the analysis. Response rates for all items were close to 100%.

To avoid collinearity in the multivariate analyses we created unweighted indexes of health knowledge gain, economic benefit, and hope from multiple survey items. Since most individuals reported that the research helped them (84.9%) or their communities (87.9%) 'a great deal', these responses were dichotomized into the categories 'great benefit' and 'not a great' benefit (all other responses). To complement the use of weekly per capita expenditure as a measure of short-term income, we conducted a principal components analysis to develop an asset index proxy for household wealth ([22,23] Available asset data included type of roof, walls, and floor, latrine facilities, access to electricity, drinking water source, and ownership of land and durable goods (radio, bicycle, and motorcycle). The asset index was weakly correlated with per capita weekly expenditure (rho = 0.24, $P < 0.0001$). Both were retained as variables.

Using χ^2-tests and *t*-tests for continuous variables, we calculated between-group (participants, decliners, COLs) differences in sociodemographic characteristics, rates of reported RHSP effects, and rates of describing aspects of the RHSP as the *most beneficial* and *most harmful*.

We conducted parallel analyses to determine factors associated with perceptions of *overall great personal benefit* and *overall great community benefit*. Cross tabulations and χ^2-tests assessed correlations between great benefit and respondents' group status, demographic characteristics, and perceived RHSP effects. There was minimal to moderate correlation between variables and between each variable and the outcomes. Multivariate logistic regression models were adjusted for group status, demographic characteristics, and covariates identified as statistically significant ($P < 0.15$) in univariate analysis. We report odd ratios and 95% confidence intervals for variables estimated to be significant at a univariate or multivariate level.

Results

Demographics

Table 1 reports respondent characteristics. Nearly half (47.3%) had participated in more than one RHSP study. Compared to decliners and participants, COLs were more likely to be male, older, and Baganda; have some secondary or upper-level education; be government employees, clerical workers, or teachers; support a dependent and have more dependents; and possess the highest level of household assets. Decliners were more likely than COLs and participants to be Muslim.

Perceived benefits of research

Effects of research

The majority thought that RHSP had greatly benefited the local economy (59.6%) and greatly improved local health workers' expertise (79.3%) (Table 2). Half (50.9%) stated that research had greatly increased their hope for Rakai's future health. One-third (37.4%) reported learning a 'great deal' about HIV prevention, family planning, and STD prevention. Health knowledge gains were most frequently reported by COLs (44.6 vs. 35.1%; $P = 0.0163$). Awareness of RHSP medical services was high: 63.4% knew about all seven primary services. COLs were the most (72.8 vs. 60.4%; $P = 0.0017$) and decliners the least (42.0 vs. 66.4%; $P < 0.0001$) aware of RHSP services. Although decliners were the least likely to use five or six medical services (5.0 vs. 22.8%; $P < 0.0001$), two-thirds (66.7%) of them had used two or more.

Greatest personal benefits

All but five respondents identified one aspect of the RHSP as most personally beneficial: VCT (42.7%), outpatient clinic treatment (30.7%), and health education (20.0%). Participants were less likely than decliners and COLs to name health education (16.8 vs. 27.5%; $P = 0.0005$) but were more likely to report home-based HIV care (7.30 vs. 0.4%; $P < 0.0001$) as the most important personal benefit.

Greatest community benefits

In the survey, 98.3% named a greatest community benefit: clinic treatment (44.9%), health education (23.2%), and VCT (23.1%). Decliners were more likely than other respondents to perceive clinic treatment (57.0 vs. 43.2%; $P = 0.0093$) and less likely than COLs to identify health

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Table 1. Demographic and socio-economic characteristics of the Perceptions of Benefits and Harms of Research survey population and subgroups.

	Total ($n = 811$)	Research participants ($n = 516$)	Decliners ($n = 100$)	Community opinion leaders ($n = 195$)
Age, mean (SD)	31.3 (7.6)	29.9 (7.2)	30.2 (8.3)	35.6 (6.7)†
Percentage male	413 (50.9%)	241 (46.7%)	54 (54.0%)	118* (60.5%)‡
Marital status				
Single	126 (15.5%)	82 (15.9%)	20 (20.0%)	24 (12.3%)
Married/long-term consensual	585 (72.1%)	368 (71.3%)	71 (71.0%)	146 (74.9%)
Widowed/divorced	100 (12.3%)	66 (12.8%)	9 (9.0%)	25 (12.8%)
Religion				
Catholic	525 (64.7%)	340 (65.9%)	53 (53.0%)*	132 (67.7%)
Protestant	138 (17.0%)	91 (17.6%)	18 (18.0%)	29 (14.9%)
Muslim	124 (15.3%)	71 (13.8%)	25 (25.0%)*	28 (14.4%)
Other/none	24 (3.0%)	14 (2.7%)	4 (4.0%)	6 (3.1%)
Percentage Baganda ethnicity	705 (86.9%)	435 (84.3%)	84 (84.0%)	186 (95.4%)†
Dependents				
Percentage with dependents	758 (93.5%)	476 (92.3%)	91 (91.0%)	191 (98.0%)‡
Number of dependents, mean (SD)	5.4 (3.5%)	4.9 (3.2%)	4.8 (3.4%)	7.0 (4.0%)†
Education				
Primary or less	504 (62.2%)	345 (66.9%)	69 (69.0%)	90 (46.2%)†
Some secondary	183 (22.6%)	102 (19.8%)	21 (21.0%)	60 (30.8%)‡
Some post-secondary	124 (15.3%)	69 (13.4%)	10 (10.0%)	45 (23.1%)‡
Primary occupation				
Agricultural/housework	451 (55.6%)	285 (55.2%)	59 (59.0%)	107 (54.9%)
Trade and vending	150 (18.5%)	98 (19.0%)	18 (18.0%)	34 (17.4%)
Government/clerical/teaching	73 (9.00%)	41 (8.0%)	5 (5.0%)	27 (13.9%)‡
Construction	42 (5.2%)	25 (4.8%)	5 (5.0%)	12 (6.2%)
Other	95 (11.7%)	67 (13.0%)	13 (13.0%)	15 (7.7%)‡
Wealth quintile using asset index				
Lowest	168 (20.7%)	113 (21.9%)	29 (29.0%)	26 (13.3%)‡
Low	161 (19.9%)	99 (19.2%)	17 (17.0%)	45 (23.1%)
Middle	155 (19.1%)	98 (19.0%)	16 (16.0%)	41 (21.0%)
High	163 (20.1%)	108 (20.9%)	23 (23.0%)	32 (16.4%)
Highest	164 (20.2%)	98 (19.0%)	15 (15.0%)	51 (26.2%)‡
Per capita expenditure				
Lowest	156 (19.2%)	100 (19.4%)	23 (23.0%)	33 (16.9%)
Low	137 (16.9%)	81 (15.7%)	15 (15.0%)	41 (21.0%)
Middle	191 (23.6%)	116 (22.5%)	28 (28.0%)	47 (24.1%)
High	166 (20.5%)	117 (22.7%)	15 (15.0%)	34 (17.4%)
Highest	161 (19.9%)	102 (19.8%)	19 (19.0%)	40 (20.5%)

Data are expressed as: number (% of total or subgroup). χ^2 and *t*-test comparisons of decliners versus participants and decliners versus community opinion leaders (COLs): $^{*}P < 0.05$. χ^2 and *t*-test comparisons of COLs versus participants and decliners $^{\dagger}P < 0.0001$, $^{\ddagger}P < 0.05$.

education (17.0 vs. 28.2%; $P = 0.0339$) as the most important community benefit.

Perceived harms of research

Greatest personal harms

Two-thirds (68.8%) reported that RHSP research posed no harms to them personally. Among the remaining respondents, the most commonly described personal harms were minor: discomfort during venipuncture and biological sample provision (10.1%); interview time and inconvenience (9.3%); infrequent, distant, or inadequate RHSP medical treatment (3.7%); and embarrassment or invasion of privacy during interviews (3.2%). Decliners were the most likely to identify a greatest personal harm (49.0 vs. 28.6%; $P < 0.0001$).

Greatest community harms

Only 25.2% reported any community harm from the RHSP: stigma (6.0%); discomfort providing a biological sample (4.8%); interview time (3.7%); and treatment side effects (2.3%). Complaints about fairness (2.2% of all respondents, 5.9% of COLs) included RHSP's focus on communities near main roads despite equal need in rural regions, the exclusion or dis-enrollment of willing participants due to funding constraints or study conclusion, and the provision of financial compensation to only some subjects. COLs were the most likely to identify community harms (36.9 vs. 22.0%; $P < 0.0001$).

Perceived overall impact of research

Overall personal benefit

Most respondents (85.0%) stated that RHSP research had, overall, helped them a 'great deal'; 11.2% reported a 'small amount' of help, 1.7% neither help nor harm, 1.8% a 'small amount' of harm, and 0.1% a 'great deal' of personal harm. Table 3 reports univariate results. In a multivariate logistic regression model, female sex, post-secondary education, use of more than three RHSP services, hope for future health improvements, and high levels of health knowledge gains were significantly associated with perceptions of great personal benefit (Table 3). Controlling for all other factors, non-Bagandans

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Table 2. Reported rates of perceived Rakai Health Sciences Program (RHSP) effects by participant status.

	Total $n = 811$ (%)	Research participants $n = 516$ (%)	Decliners $n = 100$ (%)	Community opinion leaders $n = 195$ (%)
Highest health knowledge gains	303 (37.4)	186 (36.1)	30 (30.0)	87 (44.6)[†]
Knowledge of availability of all seven RHSP services	514 (63.4)	330 (64.0)	42 (42.0)[*]	142 (72.8)[†]
Personal use of five or six RHSP services	167 (20.6)	117 (22.7)	5 (5.00)[*]	45 (23.1)
Knew someone who was treated at the Rakai Project HIV/AIDS clinic	330 (40.7)	204 (39.5)	32 (32.0)	94 (48.2)[†]
Great local economic benefit	483 (59.6)	320 (62.0)	57 (57.0)	106 (54.4)[‡]
Great improvement health worker knowledge	644 (79.3)	418 (81.0)	80 (80.0)	146 (74.9)[‡]
Great hope for the future health of Rakai residents	413 (50.9)	268 (51.9)	44 (44.0)	101 (51.8)

Data are expressed as: number (% of total or subgroup).
[*] $P < 0.0001$ Decliners vs. participants and opinion leaders.
[†] $P < 0.05$ Opinion leaders vs. participants and decliners.
[‡] $P < 0.10$ opinion leaders vs. participants.

and 30–39-year olds were less likely to report great personal benefit.

Overall community benefit

Most respondents (88.0%) believed that the RHSP greatly benefited their community; 9.5% reported a ‘small amount’ of community benefit, 0.5% neither a harm nor benefit, 0.9% a ‘small amount’ of harm, and 0.3% a ‘great deal’ of community harm. Table 4 includes the results of the univariate analyses. In multivariate analysis, only perceived great local economic benefit, hope of future health benefits, and health knowledge gains were significantly associated with regarding RHSP research as a great community benefit (Table 4).

Relationship between overall personal and community benefit

Most respondents had concordant beliefs about the personal and community impact of the RHSP: 79.5% thought both had benefited a ‘great deal’ while 6.2% believed that neither had benefited a ‘great deal’. The remainder had discordant perceptions, with 8.8% reporting a great benefit to the community but not to them personally, and 5.6% the converse.

Discussion

This is the first published study assessing perceptions of individuals from a low-income country about the risks and benefits of biomedical research. An overwhelming majority of Rakai respondents regarded ongoing population-based HIV/AIDS and STD studies as a great benefit to them personally and to their community. Less than one-third of respondents identified any personal or community harms; the majority of the harms described were transient inconveniences or discomforts.

Within its cohort communities, the RHSP creates substantial positive ‘spill-over effects’ for individuals who do not participate in research. Decliners were less likely to interact with the research team, decreasing their awareness and use of RHSP health services. Nearly all had used more than one such service, however, and were as likely as participants to report learning a great deal of health knowledge. Although decliners identified personal harms from research more frequently than participants and COLs (49.0 vs. 28.6%), after controlling for other characteristics, they were equally likely to believe that the RHSP was an overall great personal and community benefit.

Furthermore, most respondents believed that the RHSP had boosted the local economy (59.6%) and improved health worker knowledge (79.3%). These perceptions are consistent with international guidelines’ attention to the importance of developing long-term local medical and research capacity [3,9,12,24]. These and other spill-over effects contributed to optimism that the RHSP would enhance the quality of life, decrease HIV prevalence, and improve access to HIV vaccines and drugs in Rakai.

As the BAHR survey did not sample subjects in treatment studies and focused on future benefits to the entire community, the high levels of hope are unlikely to reflect a widespread therapeutic misconception. Nevertheless, the correlation between frequency of RHSP-sponsored medical services use and reported great personal benefit suggests that the availability of primary and supportive care increases support for ongoing research. The complexities of providing such care in the context of community-based research merits further attention, particularly in light of the recent debate about researchers’ obligations to offer ancillary care to subjects and their communities [25,26].

Despite the high concordance in *types* of greatest benefits reported at the personal and community levels, the multivariate results indicate that respondents weigh different aspects of research when evaluating the overall personal versus community impact of the research. Individual characteristics (ethnicity, sex, age, education) and personal use of RHSP services were significantly correlated with great personal but not with great community benefit. It may be harder for respondents’ to identify and articulate the factors that influence their

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Table 3. Factors associated with perception that the Rakai Health Sciences Program (RHSP) is a 'great' personal benefit: Proportions of each group reporting 'great' personal benefit, unadjusted and adjusted odds ratio (OR) values, and 95% confidence intervals (CI).

	n (% reporting benefit)	Unadjusted OR (95% CI)	Adjusted OR (95% CI)
Group			
Participants	445 (86.2)	1.00	1.00
Decliners	69 (69.0)	0.36 (0.22–0.58)†	0.65 (0.33–1.25)
Community opinion leaders	145 (91.2)	1.65 (0.90–3.02)	1.47 (0.65–3.32)
Sex			
Male	389 (82.5)	1.00	1.00
Female	386 (87.6)	1.49 (1.00–2.23)†	2.38 (1.37–4.13)†
Religion			
Catholic	428 (86.1)	1.00	1.00
Protestant	118 (87.4)	1.12 (0.63–1.98)	1.41 (0.70–2.85)
Muslim	96 (78.7)	0.60 (0.36–0.98)†	0.58 (0.29–1.15)
Other	17 (81.0)	0.69 (0.22–2.10)	0.93 (0.23–3.79)
Ethnicity			
Baganda	581 (86.5)	1.00	1.00
not Baganda	78 (75.0)	0.46 (0.28–0.76)†	0.45 (0.24–0.86)†
Age group			
< 20	50 (87.7)	1.00	1.00
21–30	296 (85.1)	0.80 (0.34–1.85)	0.40 (0.14–1.18)
31–40	216 (83.4)	0.70 (0.30–1.66)	0.26 (0.08–0.83)†
41–50	97 (87.4)	0.97 (0.37–2.56)	0.39 (0.11–1.42)
Education			
Primary or less	403 (83.3)	1.00	1.00
Some secondary	147 (85.5)	1.18 (0.73–1.92)	1.16 (0.60–2.23)
Some postsecondary	109 (91.6)	2.19 (1.10–4.37)†	4.52 (1.58–11.23)†
Proximity to the main RHSP clinic in Kalisizo			
Non-Kalisizo	619 (84.6)	1.00	1.00
Kalisizo	40 (93.0)	2.43 (0.74–8.00)	0.48 (0.12–1.86)
Personal use of RHSP services			
1 or less	56 (64.4)	1.00	1.00
2	130 (76.0)	1.76 (1.00–30.8)†	1.56 (0.76–3.19)
3	165 (88.2)	4.15 (2.22–7.76)†	4.26 (1.89–9.58)†
4	148 (90.8)	5.46 (2.74–10.9)†	4.39 (1.72–11.23)†
5 or 6	160 (95.8)	12.65 (5.28–30.3)†	8.21 (2.70–24.91)†
Knowledge of RHSP services			
4 or less	24 (66.7)	1.00	1.00
5	54 (73.0)	1.35 (0.57–3.20)	0.73 (0.24–2.5)
6	138 (81.7)	2.23 (1.01–4.93)†	0.56 (0.19–1.66)
7	443 (89.3)	4.18 (1.98–8.84)†	0.64 (0.22–1.86)
Know someone treated at the HIV clinic			
Not used	382 (82.9)	1.00	1.00
Used	277 (88.2)	1.55 (1.02–2.36)†	0.84 (0.49–1.46)
Health worker expertise			
No, minimal, or moderate expertise gains	109 (71.2)	1.00	1.00
Great expertise gains	550 (88.4)	3.08 (2.01–4.73)†	1.35 (0.73–2.52)
Hope			
No or minimal hope	83 (64.8)	1.00	1.00
Moderate hope	206 (82.1)	2.48 (1.53–4.03)†	2.95 (1.56–5.58)†
Great hope	370 (93.4)	7.72 (1.50–13.22)†	6.50 (3.18–13.31)*
Local economic benefit			
Minimal or no local economic benefit	83 (70.9)	1.00	1.00
Moderate local economic benefit	150 (79.8)	1.62 (0.95–2.76)†	1.17 (0.57–2.37)
Great local economic benefit	426 (90.6)	3.97 (2.39–6.58)†	1.84 (0.90–3.81)
Change in health knowledge			
Least knowledge gain	82 (66.1)	1.00	1.00
Less knowledge gain	76 (71.7)	1.30 (0.74–2.28)	0.87 (0.42–1.81)
Middle knowledge gain	105 (82.0)	2.34 (1.30–4.20)†	2.06 (1.00–4.26)
High knowledge gain	115 (95.0)	9.82 (3.99–24.2)†	7.34 (2.60–20.75)†
Highest knowledge gain	281 (94.9)	9.60 (5.07–18.2)†	7.07 (3.22–15.52)*

Hosmer-Lemeshow $\chi^2 = 0.936$, adjusted $r^2 = 0.43$.
*$P < 0.0001$,
†$P < 0.05$.

community benefit assessments, compared to the relative psychological availability of aspects of personal benefit. Researchers may need to ask explicitly about hope, economic benefit, and health knowledge gains to fully assess the extent of a study's perceived community benefits.

COLs identified different primary personal benefits than participants and were more likely to describe community harms – especially those related to fairness – than other groups. As sources of advice, COLs may be the most likely to learn about the experiences of others, increasing

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Table 4. Factors associated with perception that the Rakai Health Sciences Program (RHSP) is a 'great' community benefit: Proportions of each group reporting 'great' personal benefit, unadjusted odds ratio (OR) values, and 95% confidence intervals (CI).

(n = 811)	n (%)	Unadjusted OR (95% CI)	Adjusted OR (95% CI)
Group			
Participants	457 (88.6)	1.00	1.00
Decliners	83 (83.0)	0.63 (0.35–1.13)	1.03 (0.51–2.11)
Community opinion leaders	174 (89.2)	0.80 (0.63–1.81)	1.05 (0.55–2.01)
Sex			
Male	359 (86.9)	1.00	1.00
Female	355 (89.2)	1.24 (0.81–1.90)	1.31 (0.79–2.18)
Religion			
Catholic	464 (88.4)	1.00	1.00
Protestant	126 (91.3)	1.38 (0.72–2.64)	1.60 (0.78–3.30)
Muslim	106 (85.5)	0.77 (0.44–1.36)	0.83 (.043–1.62)
Other	18 (75.0)	0.39 (0.15–1.03)	0.54 (0.17–1.70)
Ethnicity			
Baganda	629 (89.2)	1.00	1.00
not Baganda	85 (80.2)	0.49 (0.29–0.83)[†]	0.60 (0.32–1.12)
Age group			
<20	52 (89.7)	1.00	1.00
21–30	308 (86.3)	0.73 (0.30–1.78)	0.72 (0.25–2.03)
31–40	244 (88.4)	0.88 (0.35–2.21)	0.94 (0.31–2.88)
41–50	110 (91.7)	1.27 (0.44–3.68)	1.22 (0.34–4.35)
Education			
Primary or less	440 (87.3)	1.00	1.00
Some secondary	166 (90.7)	1.42 (0.81–2.50)	1.44 (0.73–2.84)
Some post-secondary	108 (87.1)	0.98 (0.55–1.77)	1.07 (0.51–2.25)
Proximity to the main RHSP clinic in Kalisizo			
Non-Kalisizo	672 (87.5)	1.00	1.00
Kalisizo	42 (97.7)	6.00 (0.82–44.1)[†]	3.07 (0.39–24.12)
Personal use of RHSP services			
1 or less	90 (81.1)	1.00	1.00
2	154 (86.0)	1.44 (0.76–2.71)	1.39 (0.66–2.91)
3	168 (88.4)	1.78 (0.93–3.41)	1.30 (0.61–2.79)
4	145 (88.4)	1.78 (0.91–3.49)	1.04 (0.45–2.42)
5 or 6	157 (94.0)	3.66 (1.65–8.12)	1.65 (0.63–4.35)
Knowledge of RHSP services			
4 or less	28 (73.7)	1.00	1.00
5	66 (80.5)	1.47 (0.60–3.64)	1.16 (0.40–3.34)
6	154 (87.0)	2.39 (1.03–5.56)[†]	1.36 (0.49–3.77)
7	466 (90.7)	3.47 (1.59–7.57)[†]	1.36 (0.50–3.72)
Know someone treated at the HIV clinic			
Not used	417 (86.7)	1.00	1.00
Used	297 (90.0)	1.38 (0.88–2.16)	1.00 (0.59–1.71)
Health worker expertise			
No, minimal, or moderate expertise gains	129 (77.3)	1.00	1.00
Great expertise gains	585 (90.8)	2.92 (1.86–4.58)[†]	1.14 (0.64–2.05)
Hope			
No or minimal hope	95 (71.4)	1.00	1.00
Moderate hope	232 (87.6)	2.81 (1.67–4.75)[†]	2.40 (1.32–4.37)[†]
Great hope	387 (93.7)	5.95 (3.45–10.29)[†]	3.26 (1.71–6.22)[†]
Local economic benefit			
Minimal or no local economic benefit	95 (73.6)	1.00	1.00
Moderate local economic benefit	167 (83.9)	1.87 (1.08–3.22)[†]	1.72 (0.92–3.21)
Great local economic benefit	452 (93.6)	5.22 (3.06–8.91)[†]	3.23 (1.68–6.21)[†]
Change in health knowledge			
Least knowledge gain	103 (76.3)	1.00	1.00
Less knowledge gain	91 (80.5)	1.29 (0.70–2.37)	1.18 (0.57–2.44)
Middle knowledge gain	119 (89.5)	2.64 (1.34–5.22)[†]	2.37 (1.09–5.15)[†]
High knowledge gain	118 (92.9)	4.07 (1.86–8.93)[†]	3.45 (1.43–8.36)[†]
Highest knowledge gain	283 (93.4)	4.40 (2.41–8.03)[†]	3.11 (1.54–6.28)[†]

Hosmer-Lemeshow $\chi^2 = 0.600$, adjusted $r^2 = 0.23$.
[*] $P < 0.0001$;
[†] $P < 0.05$.

their ability to discern differential treatment. They may also be better at verbalizing community concerns about the distribution of the benefits and harms of research. Exclusive engagement with COLs during community consultation could lead to an incomplete understanding of the relative importance of various research benefits and harms, underestimation of decliners' concerns about personal harms, and overestimation of the degree to which research is generally perceived as being a community harm.

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Our study has several limitations. First, survey results may not be generalizable to other resource-poor countries or communities less accustomed to research. Individuals in urban settings may have less positive views of research, particularly if overlapping projects make it more difficult to establish integrated medical services. Perceptions of benefits and harms may differ in treatment trials or research on conditions other than HIV and STDs.

Second, due to the high percentage of respondents reporting great personal and community benefit, odds ratios should be interpreted as qualitative indicators rather than point estimates of relative risk [27]. Third, the survey may have been under-powered to demonstrate the statistical significance of some highly suggestive between-group differences in reported greatest benefits and harms. Fourth, COL responses were not linked to their recruitment criterion; we were therefore unable to compare the attitudes of RHSP mobilizers with those identified through the sociological survey. Fifth, our study describes self-reported perceptions rather than actual changes in behavior, economic indicators, or health status. We did not assess the views of policy makers, local medical practitioners, or non-RHSP researchers. Other studies, however, document increased rates of VCT, [28] greater condom and hormonal contraceptive use, [29] and decreased HIV prevalence in Rakai during the last decade, indicating that respondents' perceptions are not entirely groundless.

The present study elucidates the factors affecting assessment of personal and community benefit in biomedical research, highlights the complex relationship between personal and community benefit and harm, and offers potential improvements to community consultation processes. The pervasive perception that the RHSP generated personal and community benefits in Rakai, a region that has been the subject of nearly 100 peer-reviewed scientific and medical articles, suggests that concerns about 'research fatigue' may be misplaced.

Ethics approval

The BAHR survey was reviewed and approved by institutional review boards at the National Institute of Allergy and Infectious Diseases, the Uganda Virus Research Institute, and the Uganda National Council for Science and Technology.

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