**Methods description**

Extracted from publication:

Hate K, Meherally S, Shah More N, Jayaraman A, Bull S, Parker M, and Osrin D. Sweat, Skepticism, and Uncharted Territory: A Qualitative Study of Opinions on Data Sharing Among Public Health Researchers and Research Participants in Mumbai, India. Journal of Empirical Research on Human Research Ethics July 2015 10: 239-250, doi:10.1177/1556264615592383

Method

Setting

Within the remit of the collaborative study, we aimed to interview people drawn from two pools: Employees or participants in research conducted by SNEHA, augmented by researchers from other organizations with experience of either data sharing or the ethical issues around it. We tried to cover a spectrum, from community members who had taken part in studies, through field data collectors, data entry officers, analysts, and research designers, to organizational executives. Many of the data collected by SNEHA relate to health issues for women and children in urban informal settlements. Around 40% of Mumbai’s residents live in informal settlements with attendant constraints on finances, space, water and sanitation, and access to adequate health care (Officer of the Registrar General & Census Commissioner, & Director of Census Operations Maharashtra, 2011). These constraints lead to aspirations for themselves and their communities that might inform interviewees’ responses to questions about data sharing. There is substantial diversity within informal settlements in terms of longevity, place of origin, religion, language, and cultural mores. A minority of women are involved in formal sector work, and many have limited control over resources and limited agency. Daily life involves a negotiation between the opportunities of urban modernity and the persistence of traditional norms.

Interviewers

Two full-time female interviewers (K.H. and S.M.) collected the data through semi-structured interviews and focus group discussions. Both have postgraduate degrees and experience of collecting and analyzing qualitative data. All the participants were familiar with the organization and its work, if not with the interviewers themselves. More than half of them worked with the organization, and all but one of the others were recruited through the authors’ personal and professional contacts or those of community outreach workers.

**Table 1.** Participants.

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| --- | --- | --- | --- |
| Stakeholders | SNEHA | External | Data collection method |
| Managers or decision makers | 2 | 0 | Interview |
| Project implementers | 2 | 0 | Interview |
| Senior researchers | 1 | 4 | Interview |
| Mid-level researchers | 3 | 0 | Interview |
| Junior researchers or assistants | 6 | 1 | Interview |
| Ethics committee members | 0 | 3 | Interview |
| Field data collectors | 24 | 0 | Focus group discussion |
| Community members | 0 | 20 | Focus group discussion |
| Total | 38 | 28 | 66 |

*Note.* SNEHA = Society for Nutrition, Education and Health Action.

Participant Selection

A mix of purposive and convenience sampling was used. Participants for semi-structured interviews were selected for their level of familiarity with data sharing. Table 1 summarizes the sample. It was easy to find people within the organization who had no experience of data sharing, but interviews with experienced people tended to be outside the organization. We grouped interviewees by their level of involvement in the process and ethics of research, as senior, mid-level, and junior biomedical and social science researchers, program implementers, policymakers, and ethicists. The focus groups were conducted with field-workers involved in community mobilization and with women from the communities in which the organization worked. We contacted interviewees by email and telephone, field-workers by telephone or face-to-face, and community members through field-workers who already knew them. Two potential interviewees did not respond to email invitations.

When not responding to specific examples posed by interviewers and focus group facilitators, it is likely that participants associated with SNEHA (either as researchers or as community members) would have been thinking about research that involved collection of interview data about maternal and newborn health, nutrition, sexual and reproductive health, or gender-based violence. Ethicists were drawing on their experience of social science research, and external senior researchers were involved in descriptive studies, laboratory work, and clinical trials on communicable diseases and mental health.

Interview Arrangements

We interviewed participants at a time and place convenient to them: one at home and the rest at their workplaces. Two focus group discussions with field-workers were conducted at program offices and two with community members at outreach centers. When interviewees were outside Mumbai, we communicated through Skype and used third-party software to record the interviews (www.ifree-recorder.com). Interviews were in English, Hindi, or Marathi, depending on interviewees’ proficiency and comfort. With help from a participant information sheet, the interviewers explained the reasons for the study and the aims of the interview. K.H. and S.M. led interviews alternately—one as primary interviewer and the other as an observer—apart from three solo interviews. They were also co-facilitators for the focus group discussions. We held two focus groups with field-workers and two with community members. Three field-workers attended the community discussions because we thought that their presence would reassure the participants. They had similar backgrounds and we did not think that their presence would hinder open discussion.

Interview Content

Topic guides were based on a structure agreed across the collaboration, reordered on the basis of experience and natural flow. We began by asking interviewees about their research experience and areas of interest, organizational roles, and history of collaboration. We asked what they understood by data, sensitive data, and data sharing. We asked about their experiences of data sharing—access or provision—and agreements and obstacles to it, their ideas of the advantages and disadvantages, the kinds of data that should or should not be shared, and their views on current policies, barriers, and recommendations for good practice. We explored their views on researchers’ responsibilities and how participants’ interests could be protected during the process and on data sharing across cultures and research contexts, particularly on sharing data between higher- and lower-income countries. We asked about existing consent processes, their views on broad and explicit consent, and any constraints that participants might put on secondary uses of their data. We concluded by asking for their views on sharing data from the interview itself.

For focus groups, we developed a series of scenarios that drew on their previous contributions to research. We began by describing a scenario in which data on the prevalence of malnutrition and tuberculosis might be shared with other entities. These entities were presented in steps, beginning with local or foreign students and broadening organizationally and geographically to researchers and national and international organizations. We also presented scenarios with increasing sensitivity, for example, information about family planning or violence in the case of a woman who might not want her family to know about it.

Interviews and focus group discussions were audio-recorded and transcribed verbatim. Discussions in Hindi and Marathi were subsequently translated into English. Field notes described observations of participant behavior and responses. Transcripts were given to participants who were interested in reviewing them, and we are not aware of any concerns. Interviews lasted an average 51 min (range: 14-91). Focus group discussions lasted 42 min (range: 28-60).

Data were collected in two phases. In the first, 12 interviews and two focus group discussions were conducted and coded broadly. In the second, we tried to sample and probe on the basis of information gaps and emerging themes. We discussed data saturation continually from the latter part of the first phase and felt that we were accruing no new responses by the final interviews.

Theoretical Framework

We used framework analysis because we already had an idea of the terrain of data sharing, a set of a priori questions, specific objectives for outputs (recommendations for ethical considerations in data sharing policy and practice), and an agreed sample size and timeline for deliverables (Ritchie & Spencer, 1994; Srivastava & Thomson, 2009). Because the interviews followed a structured sequence and addressed issues that we already thought might be important, we agreed across the collaborating groups to begin with a list of general coding categories. In assigning information to these categories, we developed a series of subheadings (nodes), including new subheadings that reflected interviewees’ views and allowed us to think about themes that emerged from the data (Lacey & Luff, 2007; Pope, Ziebland, & Mays, 2000; Smith & Firth, 2011).

Analysis

Transcripts were imported into NVivo 10 (www.qsrinternational.com), in which coding and analysis were done. The coding tree was developed collectively in sessions during which pseudonymized transcripts were projected. Beginning with the consensual tree for the multisite study, we added sub-nodes without disrupting the general framework of parent nodes. From halfway through the first phase, initial coding was done by K.H. and S.M., after which it was reviewed by the other authors. Nodes were annotated with descriptions, and a second round of coding reviewed the exhaustiveness and utility of the coding tree. We mapped concepts and explanations through several iterations (Attride-Stirling, 2001) and discussed them with the wider collaborative group at an international meeting, through a shared electronic repository, and at fortnightly teleconferences.

Ethics Review

The multisite study was approved by the Oxford Tropical Research Ethics Committee (OxTREC 1051-13). The India study was approved by the Multi-Institutional Ethics Committee, Mumbai.