

## Qualitative methods within large programmes: The example of the Microbicide Development Programme

### Sources:

Montgomery, C.M., Lees, S., Stadler, J., Morar, N.S., Ssali, A., Mwanaza, B., Mntambo, M., Phillip, J., Watts, C. and Pool, R. (2008) 'The role of partnership dynamics in determining the acceptability of condoms and microbicides', *AIDS Care*, 20(6): 733-40.

Stadler, J., Delaney, S. and Mntambo, M. (2008) 'Women's perceptions and experiences of HIV prevention trials in Soweto, South Africa', *Social Science & Medicine*, 66: 189-200.

The Microbicide Development Programme is an international partnership set up to evaluate and test vaginal microbicides to prevent HIV transmission. MDP301 is a large, randomized, double-blind, placebo controlled trial of the microbicide gel PRO 2000/5, designed to prevent vaginally-acquired HIV infection. The trial intends to recruit around 9,000 participants from six sites located in South Africa, Zambia, Uganda and Tanzania, to test the efficacy and safety of the microbicide. This is a complex programme, involving several local teams of researchers, community mobilization teams (to lead recruitment) and workers and participants across different sites, all of which are multilingual. The trial design included social science research from the outset to: contribute to feasibility studies; collect more detailed data on key topics relating to sexual behaviour; assess the acceptability of the gel and its applicator; assess the validity of trial data through triangulation using qualitative methods; and also to study participants' own understandings of the study itself, including the consent procedures.

Qualitative data from feasibility studies for the trial generated evidence for understanding how women perceived participation in the research, which is essential for planning appropriate recruitment and information strategies. In a feasibility study in Soweto, South Africa, Jonathan Stadler and colleagues discuss the widespread fear and denial of AIDS in the community, and the negative connotations medical research might have in the South African context. Lack of community involvement can impede the successful roll out and completion of a trial, and understanding the social and cultural contexts in which products such as microbicides are being investigated is crucial to not only understanding trial findings, but also to the likely success of the trial. In the feasibility study, focus groups were first conducted within the community, before any trial recruitment began. These included a range of participants, including students, traditional healers and those from community health committees. The second phase involved interviews and focus groups with a random sample of women who were recruited for the trial feasibility study. This enabled the researchers to understand better how the participating women understood the consent procedures of the trial, and what effect their participation might have on them. For most of the women, participation was a positive experience. Not only did it provide health care services they might not otherwise receive (e.g., screening for sexually transmitted diseases), but the testing and counselling received as part of the trial were reported as empowering, in that they gave the women knowledge about their health, and an added confidence in discussing sexual health with their partners.

Catherine Montgomery and colleagues reported on interviews with 320 women and 45 male partners, as part of the pilot study for the trial in four of the participating countries. Women were asked about their attitudes to the gel, and about the

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involvement of their partners in deciding to take part in the trial. Analysis of interviews with women and their partners suggested that women used a process of persuasion to overcome the resistance their partners often had to their participation in the trial, and men reported using this resistance to gain more knowledge about their partners, and the new technology. Although the microbicide gel could be considered a 'female controlled' technology, in practice it might be difficult to use covertly in relationships because of the changes it produced in how the vagina felt. However, it emerged that the 'meaning' of microbicide gel within relationships was very different from that of condoms. Whereas condoms were associated with a lack of trust (and were therefore difficult to use in long-term relationships), the gel was associated with sexual pleasure (in part, because using it involved intimacy) and with greater communication within relationships, thus making it suitable for long-term relationships.

The roles of qualitative research in large trials such as the Microbicide Development Programme are complex. First, the research (in the examples here, from feasibility and pilot studies) generates useful data in its own right, addressing questions about how sexual health is experienced in the context of relationships and health care provision. Information about the different ways that microbicide gel and condoms are perceived in terms of 'trust' is extremely useful information that could be used, for instance, in planning rollout campaigns for the product if the trial does show that microbicides are effective and safe. Second, such data also have to function as 'useful' for the primary purposes of a large quantitative trial, in which adequate recruitment and retention, and the reliability and validity of trial methods, are crucial. This potentially raises problems if the qualitative data are not consistent with data from other parts of the trial. Third, there are issues of integrating findings from the quantitative and qualitative components during the analysis.

In this case, qualitative interviews and focus groups helped in the design of the trial's quantitative instruments, especially in terms of clarifying key concepts and the range of ways in which they were understood locally. This included defining terms such as 'long-term partner' or 'penetrative sex', which may be difficult to standardize across study settings. They also aided in designing recruitment strategies that maximized informed consent and ethical participation. Finally, interviews and focus groups provide essential information on the *process* of the trial, and on issues such as how women completed the diaries developed to monitor adherence through the trial and how their answers to study questionnaires may change over time as a result of their participation in the project.

### Reflective questions

Imagine you have been asked to oversee the qualitative component of a large complex trial. What kinds of issues might you wish to agree with your co-investigators in advance? What kinds of analysis might be appropriate for your data?

### Feedback

Crucially you might want to agree how any discrepancies between the qualitative and the quantitative findings will be dealt with or reported. For the analysis, it will depend on which aspect of the data you are dealing with. If you are looking for information regarding the *implementation* of the policy you might want to use Framework analysis. If, however, you are looking at perceptions and understandings of the participants then you might prefer an approach based on the principles of grounded theory.

### Public transport and young people's well-being: The qualitative contribution to a mixed methods study

#### Sources:

Jones, A., Steinbach, R., Roberts, H., Goodman, A. and Green, J. (2012) 'Rethinking passive transport: Bus fare exemptions and young people's wellbeing' *Health and Place*, 18: 605-12.

Goodman, A., Jones, A., Roberts, H., Steinbach, R. and Green, J. (2013) "'We can all just get on a bus and go": Rethinking independent mobility in the context of universal provision of free bus travel to young Londoners', *Mobilities*.

The contribution of 'active transport' to physical activity levels has become the subject of public health policy in many high income countries, with a concern that reliance on private cars for transport has a detrimental impact on health by reducing the amount of exercise people get through walking or cycling. The role of public transport in encouraging exercise is debated. In contexts where there is high car use, providing better public transport might encourage more walking, in order to get to transport hubs. However, where there are already high levels of cycling and walking, better public transport may replace these and decrease the amount of activity undertaken. Transport does not, though, only impact on health by affecting levels of exercise. Transport systems and policies also affect road traffic injury rates, levels of pollution, and how easily different groups in the population are able to access the determinants of health, such as goods and services. In London, UK, a mixed methods study was conducted to evaluate the impact of one public transport intervention – a scheme to provide free bus travel for young people – on the public health.

The overall design of the study was experimental, with an evaluation of a 'natural experiment' (see Chapter 2), using travel diaries and other data to compare the distances young people walked before and after the scheme was introduced, compared with differences in other population groups not exposed to the scheme. However, alongside these quantitative data, a qualitative study also used in-depth interviews, focus groups, observational data and participatory research with young people to explore the broader impacts of free bus travel for well-being.

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The findings from the qualitative component of the project intersected with the quantitative findings in different ways.

First, travel diary data suggested that although young people's use of bus travel had gone up after the scheme was introduced, the distance that they walked had not changed. The qualitative data helped explain this finding, in that young people talked about a range of additional journeys that were undertaken because their travel was now free. They were therefore making more journeys, and even though many of these were on the buses, these generated additional walking and opportunities for exercise.

Observational data also suggested that using the bus was not a 'passive' mode of travel, in that young people typically spent time running between buses, and moving around on the buses. The second contribution of qualitative data is then that it helped refine one of the indicators of 'active travel', and suggested that walking and cycling were not the only ways of getting exercise within a transport system.

Third, qualitative analysis broadened the perspectives of public health impact that were considered, in also identifying what was important to young people. Public health practitioners focused on exercise, whereas young people (although recognizing that this was important for health) prioritized aspects of social well-being, such as being with friends, opportunities to participate in social life, and feeling as if they 'belonged' to a city. Providing free bus travel also provided an important public space simply to be in, given that there were few other spaces in which young people could socialize.

Finally, the qualitative design, because it could explore behaviour in context, also shed light on why the scheme had particular effects on health, in this context. In summary, young people stressed that because the scheme was universal (all young people living in the city were eligible), and because travel preferences in general were to travel together, with friends where possible, this meant that bus travel became the 'default', simply because all members of a peer group could then go together. Further, London was a city recognized as having an efficient and accessible public bus network. This was an important precondition of the scheme's effects. The importance of this was shown by a 'deviant case' in the analysis: the views of young people with disabilities. Unlike their able bodies peers, these young people described bus travel as difficult to access and unreliable, and rather than a 'default' mode that made them feel included as part of the population, bus travel was a key indicator of their exclusion.

Whereas the quantitative components of the project enabled the research team to demonstrate that free bus travel did not have any observable impact on the distances walked by young people in this setting, the qualitative component therefore helped with transferability of study findings by identifying the key elements of the system that enabled public health effects to accrue from free travel, i.e. a universal scheme, accessible to all, and provided in a city with a good bus service.

The challenges of integrating findings from different types of design within one study arise from the different logic of an experimental design and a more inductive qualitative design. In public health, good practice in evaluation advocates publishing a detailed analysis protocol at the outset of a study, with the expected direction of change, and the hypotheses to be tested clearly stated. This is to offset the risk of 'data dredging' where large numbers of quantitative results can be searched for anything 'significant'. However, within a more iterative qualitative design, a grounded theory approach (see Chapter 9) relies on the ability to refine the research questions and plans for data generation and analysis in the light of early findings. If different methodologies (rather than different sources of data) are used simultaneously, they are likely to have both synergistic and

antagonistic relationships, with (for instance) qualitative data providing context and explanation for associations found, but also potentially suggesting critique of quantitative indicators, or a reframing of the original study questions.

## Reflective questions

In your view, is it ever truly possible to ‘marry’ research findings from different epistemological perspectives or are they doomed always to be ‘unhappy bedfellows’? What steps might a research team take to minimize the effects of this?

## Feedback

The two case studies in this chapter provide some examples of productive mixed methods approaches, despite some tensions. One way of minimizing the impact of fundamental epistemological difference is to agree in advance whether or not to address this in the research output and to agree how far (if at all) acknowledgement of this should be taken. It might be feasible to agree in advance that the pragmatic findings should be published without discussion of this in public health policy/health services research journals but that more reflexive, theoretical/philosophical papers be written up for social science specialist journals as well.