

‘... in the project they really care for us’: Meaning and experiences of participating in a clinical study of first-line treatment for malaria and HIV in Tanzanian adults

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Critiques of biomedical research in low-resource settings typically centre on clinical trials and the ‘dissymmetries of power’ between the researched and those benefiting from the products of research. It is important to extend this critical lens to other forms of global health research. We conducted a qualitative study in Tanzania to explore meaning and experiences of participating in a clinical observational study evaluating the safety and efficacy of current practice for treating HIV and malaria co-infection. Focus group discussions and in-depth interviews were undertaken with 124 study participants, study staff and health workers. Participants’ understanding of the study’s research aims was limited, but the practice of participation – engaging with research staff and materials – appeared to facilitate interpretations of the study’s value, conceptualised as a ‘service’. For those peripheral to the study, however, interpretations of it reflected existing suspicions of experimental research. Our findings indicate the importance of considering the expectations, roles and responsibilities constructed through the practice of participation in different types of research, and how they relate to legacies of research. Understanding how networks of research practice intersect local social and historical contexts can extend discussions of collaboration and engagement with research in low-resource settings.

Keywords: Tanzania; research ethics; research participation; health care provision; low-income country

Background

The globalisation of clinical trials, in particular, drug trials conducted by contract research organisations, has led social scientists to engage with discourses of power and ethics to explore the meaning of conducting trials in low-resource settings (Lock & Nguyen, 2010). Outsourced clinical trials are typically conducted within communities that may not benefit directly from the outputs of the research, reflecting ‘dissymmetries of power’ (Farmer, 2004) between the researchers and the researched.

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In low-resource settings, participants are often considered to be particularly vulnerable to exploitation through research (Schüklenk, 2000) due to lack of access to routine health care and other social and material benefits that can be accrued through trial participation (Ballantyne, 2008). As such, there has been an increased focus on how participants' engagement with trials is shaped by social relations and expectations, and wider political-economic contexts (Fairhead, Leach, & Small, 2006).

Bioethics discussions have arisen around recruitment and informed consent procedures for trials in low-resource settings, frequently centring on the potential for undue inducement of participants to a trial situated in a 'landscape of constraint' (Lock & Nguyen, 2010). However, there is an ongoing need to explore the lived experience of research in low-resource settings to explore the empirical reality of engagement with a trial and how the 'embedded ethics' of research (Kelly, Ameh, Majambere, Lindsay, & Pinder, 2010) are experienced and understood by those involved.

These critical debates situating experimental trials in their social, ethical and political-economic contexts (Glickman et al., 2009) cannot be presumed to extend to other types of clinical research in low-resource settings. Analyses of the social lives of trials conducted by local research institutes, seeking to address health issues relevant to the local population, have been undertaken (Molyneux & Geissler, 2008). Here, attention has focused on the negotiation of social relationships around the consent process (Gikonyo, Bejon, Marsh, & Molyneux, 2008), methods for engaging with communities (Marsh, Kamuya, Rowa, Gikonyo, & Molyneux, 2008) and the perceived social value of such trials (Lairumbi, Parker, Fitzpatrick, & English, 2012). However, the exploration of other types of research carried out under 'global health' has been comparatively limited (Crane, 2010). Extending a critical lens to other research designs, including observational studies of existing local practice, is important given the growing numbers of such studies in low-resource settings.

We undertook qualitative research to explore experiences and conceptualisations of the meaning of participating in a clinical observational study which aimed to investigate the safety and efficacy of current national first-line treatments for HIV and malaria co-infection in Tanzania. The study offered an opportunity to extend consideration of the social critiques of biomedical research to a setting where research seeks to assess and inform routine local health care practice.

Our theoretical approach drew on work from the fields of critical medical anthropology (Singer, 1989), and science and technology studies (Latour, 1987), which consider research practice in terms of the contextual social and material dimensions that shape how it is conducted and understood (e.g. Kelly et al., 2010; Petty & Heimer, 2011). This work acknowledges that efforts to generate new biomedical knowledge through research also produce new forms of social relations (Geissler, Kelly, Imoukhuede, & Pool, 2008), particularly in a low-resource context where participation may represent a 'survival strategy' (Lock & Nguyen, 2010). We aimed to investigate how meaning and experiences of participation are conceptualised within an observational study, and how they interact with broader networks of social and economic relations. We hoped to generate deeper understanding of the expectations for health and care that may

shape, and be shaped by, engagement with research addressing local routine health care practice.

Methods

Study setting

This study was based at the district hospital in Muheza, a large, semi-rural town in north-eastern Tanzania. This area has an established history of research into malaria and other infectious diseases. The local research centre at Amani and the surrounding communities have long engaged in field research for malaria control, and more recently in clinical trials of antimalarial treatment and supportive therapies for children (Gysels et al., 2009; Mboera, Magesa, & Lemnge, 2000). The hospital in Muheza provides in- and out-patient care, with two specialist clinics providing care for HIV, among other conditions, and has hosted numerous local and international research projects for a range of diseases including malaria.

The clinical observational study

Our qualitative research was conducted alongside a clinical observational study, an international collaboration between a European institution and the National Medical Research Institute, Tanzania. This clinical study aimed to understand the safety and efficacy of current nationally recommended practice for concomitant treatment of HIV and malaria. Although these two diseases intersect widely in Tanzania and other sub-Saharan African populations (Brentlinger, Behrens, & Kublin, 2007), there is limited knowledge of the safety of taking antiretroviral therapy (ART) for management of HIV and artemisinin-based combination therapy (ACT) for treatment of malaria together.

The clinical study recruited HIV-positive people, both on ART (primarily nevirapine- and efavirenz-based combination treatment) and not on ART, and HIV-negative people, all of whom had tested positive for malaria, and a control group of HIV-positive people, on ART but with no malaria. To recruit participants, study staff were situated in the main hospital outpatients department and the two HIV clinics, to identify any people presenting with fever. Patients with fever symptoms were invited to be tested for malaria using a rapid diagnostic test. If testing parasite positive they were invited to participate in an observational follow-up after malaria treatment with the first line ACT, artemether lumefantrine (also known as 'Alu'), and informed consent was sought. If testing negative for malaria or not willing to participate, patients were transferred back to routine care at the hospital.

Consenting participants attended a series of follow-up appointments over 42 days to assess the efficacy of malaria treatment and record any adverse events. These appointments, lasting up to an hour, were held in a small building on the main hospital site, in close proximity to the HIV clinic buildings. The participants were attended by a clinical research team comprising one Medical Doctor, one Assistant Medical Officer and two nurses, all of whom were locally recruited and supervised by a medically trained research coordinator from Copenhagen. Recruitment and data collection began in July 2009 and were completed in October 2012, at which point a total of 830 patients had been enrolled into the study.

Qualitative study design

Our qualitative study addressed two research questions. Here, we present findings of the research question relating to perceptions of study participation. We will present elsewhere our findings of perceptions of taking antimalarial medication concomitantly with ART among HIV-positive people (Mangesho, Reynolds, Lemnge, Vestergaard, & Chandler, in preparation).

Sample

We sought to explore the experiences, and attributed meanings, of participating in the clinical observational study, with those who had participated directly in the clinical study. We sought to supplement this with the views of others surrounding this study, including health workers and those excluded from the clinical study.

We included three sub-groups of patients/participants. Two sub-groups comprised people who had successfully completed participation in the clinical study: group A were HIV-positive and group B were HIV-negative. The third sub-group (C) comprised HIV-positive people who had been screened for the clinical study but were not eligible, or were eligible but subsequently excluded, for example for having already taken antimalarial drugs for this episode of fever. We also included three sub-groups of health workers: clinical study staff members, health workers from the HIV care clinics at the hospital and health workers from the hospital. The sub-groups of the sample are shown in Table 1.

A combination of purposive and convenience sampling was used. Participants from the clinical study were recruited by systematically working through the study database, identifying eligible people and inviting them to participate. People not eligible for participation following screening were recruited prospectively during the

Table 1. Description of the sample sub-groups with number of FGDs/IDIs conducted.

Sub-groups of participants		Number conducted
Focus group discussions with patients/participants	A: HIV-positive; taking ART; screened positive for malaria and participated in study	Males 1 Females 3
	B: HIV-negative; screened positive for malaria and participated in study	Males 2 Females 2
	C: HIV-positive; taking ART; either ineligible for study, or began participation and excluded at a later date	Males 1 Females 4
		Total 13
		FGDs
In-depth interviews with health workers	Study staff carrying out face-to-face study activities with participants	4
	Clinic health workers from two HIV care clinics at the hospital	4
	Hospital health workers from other departments of the hospital	2
		Total 10 IDIs

period of the qualitative research. All study staff involved in face-to-face research activities with participants were invited to participate in this research, whereas health workers were selected purposively to include a range of cadres from the hospital and two HIV care clinics.

Data collection

We conducted focus group discussions (FGDs) with patients/participants, the method selected to offer a less inhibiting and more supportive environment for discussion. We also conducted in-depth interviews (IDIs) with health workers, to facilitate discussion of their practice in a more confidential setting. The FGDs were segregated by HIV status and gender, and were held at a location away from the hospital. Information about the qualitative study was relayed during recruitment and repeated prior to each FGD. Written informed consent was sought before each discussion commenced. The discussions were conducted in Kiswahili by a skilled moderator (P.M.), were audio recorded with participants' permission, and supplemented with notes captured by a note-taker.

IDIs were conducted by P.M. in a private office space on the hospital site, usually in Kiswahili or when preferred, in English or a mixture, and were audio recorded. Again, participants were given information at the first point of contact, and written consent was taken prior to the interview. All audio recordings were transcribed verbatim into Kiswahili (or English where appropriate), checked for accuracy and then translated into English following a meaning-based translation approach (Larson, 1984). Translations were checked by P.M. for accuracy and consistency of interpretation. Data were collected between July and November 2011, which corresponded with the beginning of the third, and final, year of the clinical observational study.

Data analysis

Translated transcripts and summaries of each IDI/FGD were organised and coded in QSR Nvivo 8 (QSR International Pty Ltd, 2009) using a bottom-up approach. Ideas were coded in the transcripts line-by-line, then grouped into themes and built up into theoretical constructs. This was an inductive process informed by the iterative approach of grounded theory analysis (Strauss & Corbin, 1998). Coding and analysis for this research question were conducted primarily by J.R., who also used an ongoing system of memos to capture overarching narratives as they were interpreted. These were later 'tested' against the data through various queries, to infer their saliency and to identify negative cases. Regular discussions were held between J.R. and P.M. to explore analysis with regard to the two different research questions, and to raise and address any issues of translation or cultural interpretation.

Ethical considerations

A key ethical challenge was the likely disclosure of people's HIV status in the group discussions. To address this, we segregated FGDs by HIV status and took care to make people aware of the potential disclosure of their status when inviting them to

participate. The study was approved by the ethical committee of the London School of Hygiene & Tropical Medicine (reference A216 5828) and the National Institute for Medical Research in Tanzania (reference NIMRIHQ/R.8a1Vol. IX/1150), and was conducted in accordance with universal ethical principles.

Results

Participants

Thirteen FGDs with a total of 114 participants were conducted across the 3 sub-groups of patients/participants, with 8–10 participants on average in each, except for one group C FGD for which only four participants attended. Recruiting participants for this sub-group proved difficult due to challenges in accessing up-to-date contact details. Across the FGDs, more women were recruited than men (76 women, 38 men), and although not deliberate in our sampling strategy, this was similar to the proportion in the clinical study. In total, 10 IDIs were conducted with the study staff team, clinic health workers (both clinicians and nurses) and hospital health workers (clinicians only). See Table 1 for a breakdown of participants by sub-group.

Overview of results

Perceptions of the value of the study reflected differing general understandings of research in general, conceptualisations of good health care and intersections between the study and broader social relations. The study was commonly interpreted as providing a ‘service’ and as such was subject to a perceived set of roles and responsibilities relating to a wider conceptualisation of access to resources.

How research is understood

There was a strong indication that clinical study participants’ understanding of the study’s aims was limited, conveyed through their responses to direct questions about the study and through narratives of participation. Some participants stated that they did not know, or had not been told about, the study aims. Others were able to relate the aims to malaria, although these explanations were often unspecific or centred on testing the effectiveness of different antimalarial drugs. Only a few participants indicated an understanding of the study investigating both HIV and malaria.

We also examined the ways in which participants conceptualised the clinical study more generally. The most common term used by participants to describe the study was *mradi*, meaning ‘project’. *Mradi* appeared linked to conceptualisations of the study as a care provider or programme, rather than research:

Participant (P) 05: Sincerely I am grateful to the project [mradi]. After joining, initially I tested for malaria, I went again to check TB, they gave me money [for travel fare] therefore I have been taking the TB dose and now I am ok. So the project has helped me much... (HIV-positive male, FGD-A3)

A few participants, however, used the term *utafiti*, meaning ‘research’, and uses of this term often reflected some understanding of the study’s investigative aims, and an

expression of the uncertainty framing the purpose of research in general. Among those who were screened but did not participate in the clinical study, there was little awareness or understanding of the study. However, a few were able to relate the study to previous malaria research projects that had taken place in the local community.

Conceptualisations of the clinical study were varied amongst the health workers. Study staff and one hospital doctor described the study's research aims, often employing the English terms 'study', 'clinical trial' and 'research' in their accounts. Amongst the other health workers, the term *mradi* was more common, and comprehension of the study and its aims did not often extend beyond how study activities related to their own practice, for example, in terms of assisting recruitment of patients.

Recruitment embedded within a clinical context

Participants' experiences of first engaging with the study seemed to be enmeshed with the clinical space in which they occurred. Narratives of the recruitment process by both participants and study staff were commonly framed around clinical activities; the acts of being tested and treated for malaria were central to these narratives:

P 09: I heard about this before from people but I didn't know how to join. On that day I went to the hospital because I had severe fever, after the test I was seen having malaria then I was taken to the project and I was asked some questions and I agreed to join and they gave me some drugs. (HIV-negative female, FGD-B1)

Here, the reported process of becoming a participant echoed strongly the logic of a typical clinical encounter in a health service setting: illness–testing–diagnosis–treatment. The act of recruitment appeared firmly embedded within that process, reflecting the position of participants at that time: as patients suffering with fever and attending the hospital for care.

Unsurprisingly, perhaps, the perceived need for treatment at the point of recruitment was a strong motivator for many participants seeking 'to get cured' (P 07, HIV-negative female, FGD-B2). The study was interpreted by many as a means to access treatment, thus achieving the expected, or hoped for, outcome of their clinical encounter. When asked about any concerns they had had prior to consenting, many participants indicated that due to their illness, they did not have any anxieties about participating. Several also indicated that the information given during recruitment had not been useful for their decision because of their illness state:

P 02: When you go there you have your diseases, therefore when you're told to participate you will agree for the aim of getting treatment, but most of us even if we are given the form we will put them in the cupboard without reading effectively to understand. That is why we don't have understanding even if we stay here till morning. (HIV-positive female, FGD-A2)

The expected functions of the recruitment and consent process – to facilitate weighing up of risks and benefits – seemed to be eclipsed by patients' expectations of the clinical encounter in which the process occurred.

Study staff articulated the importance of informing potential participants about the study aims and what would happen to them, reflecting a discourse of research

ethics. However, they also acknowledged that participants' expectations related to their illness:

We tell them what is in the consent [form] . . . this is the study whereby we are looking at the [drug] interactions but . . . the problem is you are talking to a patient who is sick, who came to the hospital looking for hope . . . So some they are volunteering to participate but to some it is their golden chance to get [better]. (Study staff member, IDI-07)

Although, study staff were separate from the team of health workers responsible for clinical care at the hospital, this example indicates how the clinical context and setting in which the recruitment was embedded may have influenced participants' understandings of, and expectations for, participation in the study.

Understanding through active engagement

Participant narratives of engagement with the study activities – the practice of participation – conveyed more complex interpretations of the study, however. A prominent feature was the identification of concerns about participation which were not articulated when participants were asked about the initial recruitment process. Participants recalled anxieties arising as they began their participation in study activities, commonly connected to blood taking for tests, and taking medication:

P 05: [I was concerned about] the drugs that are being investigated, what effects will they have on us, because on the first day when I saw the machines I was very worried.

P 01: In the first day I was a little bit anxious, when I came after 5 days I was told they are drawing a little quantity of blood and I should eat fruits, on the following day they also drew some blood and I started becoming worried. (HIV-negative males, FGD-B3)

Physical engagement with study activities, materials, space and staff appeared to facilitate participants' questioning of the meaning of participation for their bodies and lives. Blood taking was of particular concern for a number of participants, and was recognised by study staff and health workers, who linked the concern among HIV-positive people to their understandings of the infection and drugs' impact on their blood levels.

However, within these narratives of anxiety there was also a dominant theme of resolution. Narratives depicted participants' concerns arising and being explored within the study space, and eventually being resolved. For some this appeared to come through increasing familiarity with the study activities and context:

P 03: Worries had to be there, like me I used to squabble with them the way they were taking the blood, when I meet them I asked not [again]? Why are you taking a lot of blood, my blood will get finished . . . but they gave me a [good] service until I was getting used to it. (HIV-positive female, FGD-A1)

For others, resolution of concerns came from more direct engagement with study staff and their explanations of study activities. Study staff identified their role in negotiating participants' concerns; one described this as 'educating them better'

(Study staff member, IDI-10). This practice of participation appeared to be instrumental in facilitating participants' interpretations and articulations of the meaning of participation in the study.

The study provides a service

Experiences of participation were largely very positive, framed around a conceptualisation of the clinical study as providing a good 'service'. This construct of service comprised several elements: perceptions of the quality and accessibility of tests and treatments in the study; how the service was delivered by study staff, and comparisons between the study and usual hospital care. Monitoring tests were considered valuable as a means by which participants could 'know their health'. For some, this reflected an understanding through tests that they had no other health issues; for example, HIV-negative participants welcomed the opportunity to know that their 'blood is clean' (P 02, HIV-negative female, FGD-B1). For others, the benefits lay in the potential for tests to lead to further treatments, thus improving their health. Staff from the HIV clinics also articulated the value of tests for facilitating their monitoring of HIV-positive patients.

The conceptualisation of the service was also linked to participants' receipt of other resources, including travel fare and lunch. Study staff identified these material benefits offered in the study as means to facilitate participant attendance, recognising the financial challenges faced by many in travelling to the hospital. Beyond their obvious material value, participants saw these benefits as indicators of the individualised care being given in the study:

P 04: . . . with the project they care for the patients very much . . . you are asked about the cost of your to and from fare, some are coming there not having eaten anything, and perhaps the drugs are stronger; they care by giving you money or food. (HIV-negative male, FGD-B4)

Benefits were interpreted as being tailored to individuals' needs outside the clinical study setting, and thus became associated with the notion of care.

The role of study staff in delivering the service was emphasised by participants. Contrasted with experiences of routine hospital services – in addition to the availability of tests and treatments – the time spent with staff in the study appeared an important component of the perceived service received. The intensive focus of study follow up activities was frequently interpreted as evidence of the staff's interest in them as individuals, and as an expression of care:

P 08: What impressed me is how they care [for] their patients particularly we the infected [HIV+ persons], for the three days you are assigned to take the pills they must make a follow up if they don't see you, therefore they really care much. (HIV-positive male, FGD-A3)

It must also be noted, however, that some study staff reported negative reactions amongst a few participants to being sought by staff in their village as part of follow up, relating to fear of being seen to be involved in a HIV programme.

Participants' perceptions of the enhanced service extended to the notion of the study providing 'better' malaria treatment than available routinely. A number of

participants recounted having been cured from malaria as a result of being in the study, and not having suffered malaria since. These outcomes were often interpreted as indications of the superior quality of the study medication:

P 07: The ones [drugs] from the project are good, [better] than the ones I was taking because when I take the others after a short time like one month malaria is back again. (HIV-negative female, FGD-B1)

Although a few attributed the treatment's effectiveness to the type of antimalarial received – 'Alu' – other participants perceived the Alu provided in the study to be better quality than the (identical) Alu available from the hospital. This was linked to perceptions of their health following the study (in relation to malaria) as better than previous experiences following routine care.

Relations and responsibilities beyond the study

Accounts of experiences of participation in the study were expressions of how these experiences were linked to the broader social context. The relationships between participants, the study and the wider community were frequently identified, often in relation to perceived stigma arising from being recognised as a participant. For HIV-negative people in particular, the physical location of the study – seen by many as 'a place for HIV tests' – and the necessity of attending regular follow up sessions led to anxieties around how others viewed their participation as seeking treatment for HIV infection. In addition to the perceived stigma from associations between the study and HIV care, there were also indications that rumours of the study's 'real' purpose, and what happens to participants' blood, were circulating in the wider community. This was illustrated through description of a person's awareness of the study in one of the non-participant groups:

P 01: I was in my office at my salon when I was told there is a malaria project, I was told the project is taking our blood to sell it and I started becoming afraid . . . when they followed me I looked at him . . . with fear. (HIV-positive female, FGD-C3)

Rumours were also reported by study participants and staff, with the latter describing these suspicions as barriers to recruitment, whereby people perceived the research as 'a trap . . . [where] you make him die or take some things' (Study staff member, IDI-02). One study staff member linked this issue to a lack of understanding of the study in the wider community.

Alongside expressions of gratitude for the opportunity to participate in the study, participants conveyed a perceived sense of responsibility for facilitating access to the study's service for others in the community:

P 11: As we are lucky in [this] district, we have to come together and influence people to join the project [mradi]. (HIV-positive male, FGD-A3)

It was in these accounts that the description of the study as *mradi* – project – was most salient. Many participants stated that they would return to the study if they became ill again, and described actively recruiting friends, family and other

community members to attend the study site for a test, in the hope of accessing the service.

Participants also articulated a sense of responsibility on the part of those running the study to continue providing the service and increase access, saying ‘they have to continue’. Questions were asked by some participants as to where other people suffering from malaria would go ‘for this treatment if the project expires?’ (P 01, HIV-negative male, FGD-B4). This notion of responsibility towards continued service was further articulated by several clinic health workers, one of whom expressed concern for those not eligible to participate:

... we were told of the [necessary] criteria that patients ... are malaria positive after the test but it is impossible because [many] are children under 15. He is not enrolled or pregnant women or women who are breastfeeding, so, this is where they went wrong. I don't know how you are going to ... improve those who are [excluded]. (Clinic health worker, IDI-04)

The quotation suggests anxiety about the study not offering the same service to all patients, indicating an assumption about the study's responsibility to ‘improve’ the health of patients beyond the research objectives. Thus it seems that experiences of the service provided by the study created perceived responsibilities for its continuation in the eyes of those treated by, and providing care alongside it.

Discussion

Participants of a clinical observational study in Tanzania conceptualised their experiences of the study in a way that differed from the research perspective, and also differed from those people more peripheral to the study. The clinical context in which recruitment occurred appeared to shape motivations for participation, which largely centred on a perceived need for treatment. Only through engagement with study activities and study staff – the practice of participation – were participants able to make meaningful interpretations of the study and its implications for their bodies, health and lives beyond the study setting. Conceptualisations of the study as providing a ‘service’ underpinned participants’ perceptions of the value of the study and responsibility to increase access to this service. In contrast, on the periphery of the study, there were reports of suspicions of the study's aims in the broader community, and interpretations of the study reflected memories of a local landscape of research.

Ethics discourses of conducting clinical research in low-resource settings have highlighted the potential for the ‘landscape of constraint’ (Lock & Nguyen, 2010) – a context of limited health care resources – to unduly influence and even exploit people's motivation to participate in research (Schüklenk, 2000). This is encapsulated in the concept of the ‘therapeutic misconception’; the conflation of expectations for research participation with expectations for clinical care which may restrict ability to weigh the potential risks and benefits of participation (De Melo-Martín & Ho, 2008). Our findings suggest that many participants of the clinical study did conflate expectations of the clinical setting, and their desire for treatment for malarial symptoms, with the research described to them during the recruitment process.

On one hand this appears to correspond with the ‘therapeutic misconception’, with expectations for treatment potentially undermining patients’ ability to give full informed consent to study participation (Belkin, 2006). However, the notions of ‘risk’ that underpin ethical debates around consent differ from the risks involved in observational studies where participants are not allocated to comparison arms, as in an experimental trial. In our setting, the clinical study provided the same antimalarial drugs as current recommended practice in Tanzania, which were also available at the hospital site in which the study was situated. To frame questions of how potential participants can understand research before consenting only in terms of ‘risk’, therefore, may not capture the entirety of any ‘misconception’ that may take place. Rather, the misconception that participants may have held at the point of recruitment perhaps reflects a limited ability to distinguish the practicalities of participating in research from standard treatment-seeking, and the social and material relations that may arise from it.

The practice of participation – interactions with the physical research space, with research materials and activities, and with the team of research staff – was instrumental for participants’ understanding of the value of the clinical study, conveyed through the conceptualisation of the study as providing a ‘service’. Drawing on the use of actor-network theory for interpreting the construction of knowledge in scientific research (Latour, 1987), understandings of the study can be seen to derive from the network of relations between the material and social aspects of the study, within which participants were engaged. The longitudinal design of the clinical study in Tanzania – multiple follow-up sessions, involving a series of laboratory tests, over a period of six weeks – is likely to have played a significant role in establishing this network of relations. This points to the need to consider the extent, nature and timing of participants’ engagement with a study when thinking about how people interpret research, and construct meaning around its potential impact on their lives. As debates continue around how to define ‘informed consent’ and how it can be achieved and maintained (e.g. Corrigan, 2003; Molyneux, Peshu, & Marsh, 2004), these considerations could make a valuable contribution to deepening knowledge of how people make sense of research participation.

From the perspective of those on the periphery of the clinical study and its network of relations, levels of understanding and perceived value of the study were very different. Reported suspicions of the clinical study and its aims in the wider community resonate with theories of ‘rumour’ as expressions of resistance and uncertainty in contexts where clinical trials are being conducted (Fairhead et al., 2006). In this literature, rumours of blood stealing have been explained as local interpretations of the ethics of research, in particular, expressions of concern over the exchanges taking place within the study (Gikonyo et al., 2008). This literature in particular refers to the ‘dissymmetries of power’ inherent in the practice of clinical trials being conducted in low-resource settings that would not benefit from the outcome of the trials (Farmer, 2004). As such, the rumours and expressions of suspicion reported in our qualitative study suggest that the nuances of the clinical study seeking to inform local health care practice were negated by an existing landscape and legacy of research in the area.

Critical debates continue around the social value of research in low-resource settings (Stewart & Sewankambo, 2010) and how to engage communities in the research process in more collaborative, and locally relevant biomedical research

endeavours (Marsh et al., 2008). Our findings suggest that, without active engagement within the network of relations of research, understandings among those proximal to the study of its relevance and value to the broader local community and health service were limited. This indicates possible challenges for considering how to define, measure or increase the social value of clinical research in low-resource settings (Lairumbi et al., 2008) and for ongoing endeavours to engage communities in collaborative research, against a legacy of globalised clinical trials (Glickman et al., 2009).

Limitations

The majority of our sample of clinical study participants represented those who had completed the study and, therefore, may have had more positive perceptions of their experience than those who dropped out or chose not to participate in this qualitative study. The difficulties we faced in recruiting people who had been excluded from the study after beginning participation makes it difficult to draw firm conclusions about how their perceptions of the study differed from other participants. However, by including perspectives of study staff and health workers from the surrounding health service, we believe we explored a fuller picture of the differing experiences of engagement with the study.

It is possible that some participants' responses were mediated by what they perceived to be the aim of this qualitative work. As suggested elsewhere (Kelly et al., 2010), participants' positive interpretations of the study may have reflected their desire for the study – and its service – to continue, and they may have believed this qualitative study to play a role in making it happen. This reflection underscores our interpretation of participants recognising a responsibility to increase access to the service provided by the clinical study.

Conclusions

In this qualitative study, we identified the important role of participants' engagement with the network of research processes and relations – the practice of participation – for their understanding and interpretation of a clinical observational study. This highlights that more debate around the nature of 'informed' consent and what participants need to know about a study is required. Our findings also indicate a disconnect between the construction and interpretation of value of research by those engaged with it, and those external to a study, underpinned by legacies of previous research studies in the locality. The relationships between networks of research practice and how they intersect the social and historical contexts in which they operate should remain a key focus of considerations of clinical research from ethical and critical perspectives. This will be important for contributing to, and extending, discourses of collaboration and community engagement in research in low-resource settings, and of the social value of clinical research.

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