Working with Concepts: The Role of Community in International Collaborative Biomedical Research

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The importance of communities in strengthening the ethics of international collaborative research is increasingly highlighted, but there has been much debate about the meaning of the term 'community' and its specific normative contribution. We argue that 'community' is a contingent concept that plays an important normative role in research through the existence of morally significant interplay between notions of community and individuality. We draw on experience of community engagement in rural Kenya to illustrate two aspects of this interplay: (i) that taking individual informed consent seriously involves understanding and addressing the influence of communities in which individuals' lives are embedded; (ii) that individual participation can generate risks and benefits for communities as part of the wider implications of research. We further argue that the contingent nature of a community means that defining boundaries is generally a normative process itself, with ethical implications. Community engagement supports the enactment of normative roles; building mutual understanding and trust between researchers and community members have been important goals in Kilifi, requiring a broad range of approaches. Ethical dilemmas are continuously generated as part of these engagement activities, including the risks of perverse outcomes related to existing social relations in communities and conditions of 'half knowing' intrinsic to processes of developing new understandings.

Introduction

Guidelines for the ethical conduct of biomedical research ethics increasingly emphasize community engagement as a core ethical requirement in international collaborative research (Nuffield Council on Bioethics, 2002, Emanuel et al., 2004). This requirement is supported by a wider literature that highlights the potential roles of community engagement in strengthening the protection, respect and empowerment of participant communities as well as enhancing the relevance and quality of research (Marshall and Rotimi, 2001; Lavery, 2004; Doumbo, 2005; Tindana et al., 2007; Marsh et al., 2008b). As a consequence of its importance in international guidelines and in the bioethics literature, the concept of community and practice of

community engagement are also increasingly the subject of academic debate and critique. There are, for example, well-recognized debates around the specific normative roles that communities can play in strengthening the ethics of research (Weijer and Miller, 2004). The special edition that this article is contributing to has arisen from a satellite meeting of the World Congress in Bioethics in 2010 specifically geared towards exploring this normative role.

In this article, we argue that the concept of community plays an important normative role in biomedical research because of the existence of morally significant interplay between the concept of community (and its enactment in 'community engagement') and that of the individual, itself a foundational concept for internationally recognized bioethical values, such as those associated with 'informed consent'. Drawing on our experience of working in community engagement in an international collaborative health research setting in rural Kenya, we discuss and illustrate two morally significant features of the relationship between individual and community and identify some of the normative work potentially done by the concept of community.

Broadly speaking, the first of the two ways in which we explore the interplay between individuals and communities as normatively relevant in this article arises out of the ways in which individuality itself is generated through wider interactions within a surrounding culture. In this case, the ability of individuals to make free informed decisions about participation in research, a key ethical requirement, must always relate to the wider understandings, attitudes, beliefs and practices of the communities to which that individual belongs. The 'community' in this instance is the group of people who surround and influence the everyday lives of individual research participants. Although such a community is likely to be heterogeneous and changing, a notion of indivisibility between individual and community suggests both substantive and procedural roles for the latter in normative decision making in health research. Challenges to a pre-eminent value for individual autonomy in research have been widely made, particularly from communitarian, often non-Western, perspectives (Doumbo, 2005) and in public health ethics (Jennings, 2007). We draw on similar thinking to emphasize that generating a context in which consent to research participation can reasonably be considered free and informed will often require engagement with communities as well as individuals, and that this will be based on both understanding and trust (Lavery, 2007).

The second kind of normatively relevant interplay between the concept of the individual and of the community which we explore here arises out of a recognition that in participating in research individuals are drawn from wider communities, such that risks, harms and benefits may potentially be generated that have traction beyond the individual. Therefore, an assessment of benefits and costs to individuals focuses too narrowly to capture the wider ramifications of research. Social science research and engagement within a wider community may become an essential process to understand the benefits and risks of individual participation for communities, as well as for individuals. In this instance, the definition of a relevant community would depend on specific features of the research and the context in which it was being conducted. This relationship between individual and community is the basis of one argument for the ethical importance of community review or consultation in research (Sharp and Foster, 2000; Emanuel *et al.*, 2004; Weijer and Miller, 2004; Marsh *et al.*, 2008a). Further, researchers' obligations to assess these implications of participation are articulated as professional codes for research and medical ethics, particularly where research and treatment occur together (CIOMS, 2002).

In this article, we first explore the concept of community itself, aiming to illustrate that this is not fixed but contingent on goals and context, and that the process of defining a community is itself normative and therefore not ethically neutral. The following sections explore the two main themes outlined above for considering community and individual as either indivisible or overlapping; supporting individual free and informed decisions about participation, and assessing community and individual benefits and risks of participation in research. At the same time, we discuss the way in which these conditions help to balance the limitations of each.

The discussion in this article draws upon practical experience, based on two published case studies (Boxes A and B) and on our ongoing participation in efforts to strengthen community engagement for a diverse range of studies conducted at an international collaborative research programme in Kenya, while acknowledging that alternative and additional analyses of the normative role of 'community' are possible. Based on our analysis, the final section of this article addresses important practical issues for community engagement, including the importance of trust in informed consent, the broad approaches to community engagement that may be needed to address diverse theoretical goals and that new ethical dilemmas may be generated, highlighting the role of social relations and processes of learning in engagement activities.

Box A. Community perceptions in a genomic epidemiological study

In late 2007, a genomic epidemiological study in a rural area of Kenya began recruiting 12,000 healthy children under the age of 12 months across a district with a population of around 250,000 people, aiming to assess the relationship between inheritance and susceptibility to many of the commonest causes of childhood mortality, through links to hospital in-patient surveillance data. Predictive testing for a serious and relatively common inherited condition, sickle cell disorder (SCD), was included in this study, with the provision of counselling and long term management at the local government hospital for children found to be affected. Local government administrative leaders and community representatives were consulted initially, and leaders worked with research staff to conduct public meetings and small group discussions with village elders and religious leaders across the community to explain and respond to questions about the study (Marsh *et al.*, 2010). Community engagement and informed consent processes included information-giving on SCD since the disorder was not well recognized in the community. A team of eight field workers, local residents with at least 12 years schooling working full time for the research programme, visited and continue to visit homes included within a research demographic surveillance system (Cowgill *et al.*, 2006) to seek consent for participation of children, after reporting of a new birth. Participation involves the collection of a 0.2 ml capillary blood sample from the heel along with data on risk factors. Field workers reported that most prospective participants found testing for SCD both more interesting and easier to understand than the genomics study; during a subsequent household survey, many were unable to recall the main research aims. In its early stages, the study attracted concerns, primarily over safety of the mode of blood sampling and associated issues of trust in the research institution. Over time, field workers report that concerns have diminished, with some parents claiming no need for further study information during recruitment where other children have previously participated from the same household.

Box B. Community perceptions in a malaria vaccine trial

In 2006, a malaria vaccine study in a small group of villages within Kilifi district invited participation from 400 families with young children, including intervention and control groups. For eligible children whose parents were consented, procedures included a photograph for identification on visits, vaccine administration in three injections over three visits to the local dispensary, check-ups after each vaccination, and home visits and blood tests to check for malaria over a year. In order to ensure that all health related events in study children were documented, parents were encouraged to contact field staff based in the study villages in the case of any illness in study participants. The FW could then communicate with the PI by mobile phone in the case of an emergency, or directly with the dispensary, to ensure the child received treatment. This was free of charge for the one year study period. The MVT used a multi-step informed consent process, including discussions with local administration and dispensary committees, large-scale community sensitization meetings, household visits and group discussions at the health facility where the study was being discussed. Over time, tensions reportedly developed between participant and non participant families in these villages, in part over access to study benefits (Gikonyo *et al.*, 2008). Participant families expressed strong feelings that rumours about safety and misplaced trust were being fuelled and spread by non participants. When consulted about the mechanisms for feedback of findings at the end of this trial, study participants refused to agree to information being given to non participants.

Concepts of 'community'

As suggested by the preceding paragraphs, the term community is recognized as an amorphous, fluid, culturally constructed identity that groups individuals together. In its most straightforward definition, community refers to 'a sense of belonging together' (Weber *et al.*, 1978). It may refer to a group of people living in the same locality, religion, race, profession or with other common characteristics (CDC/ATSDR, 1997, Tindana *et al.*, 2007, Ragin *et al.*, 2008). Social scientists, geneticists and community-based

participatory researchers have identified a number of structural characteristics associated with communities that strengthen the normative role of the concept. These include relative stability, social interactions and established community institutions, such that there is 'sufficient social interaction, structure and permanence to allow an individual to identify themselves as a member of a community' (Ragin *et al.*, 2008). Only occasionally have researchers explored community members' own definitions of community (Ragin *et al.*, 2008; Shagi *et al.*, 2008). Clearly, there are challenges in drawing boundaries around communities, made more complex by considering the perspective of the 'boundary-drawer' as well as the heterogeneity most recognized communities encompass, captured by the concept of nested communities (Sharp and Foster, 2000). Membership within a community can be by choice or based on innate personal characteristics, such as age, geography, shared interests, values and experiences (CDC/ATSDR, 1997). Ultimately, definitions of community are likely to be linked to the reasons that groups of people are being termed as communities, either internally or externally. Internal definitions may arise for reasons of empowerment, including as part of community-based participatory research. In much international collaborative research, definitions are more commonly made externally in relation to the goals and the context of a study, including community structure.

Where ways of interacting with a community, or community engagement, are linked to researchers definitions of community, the types of questions typically asked are 'What are we trying to achieve through community engagement *in this situation*, and why? And given this, which communities should be involved, and how?' Common externally drawn boundaries include kinship for genome research, people with a certain disease or risk-factor, geographical locality, those served by a particular health facility or groups with a commonly identified or legitimately elected leadership (Goodman *et al.*, 1993; Couzos *et al.*, 2005; Vallely *et al.*, 2007; Upshur *et al.*, 2007; Cargo and Mercer, 2008; Minkler *et al.*, 2008; Ragin *et al.*, 2008; Shagi *et al.*, 2008). Research institutions can also be said to create communities of participants (Mitchell *et al.*, 2002; Vallely *et al.*, 2007; Marsh *et al.*, 2008a). An example of a community of research participants was given by the malaria vaccine trial presented in Box B and will be discussed in more detail later, showing the way that the act of participating in research established mechanisms for information sharing and created bonds between members, while excluding others in the wider village community. Given all of this fluidity, the drawing of boundaries around communities will often itself be a normative process, with its own ethical implications. Key among these issues are considerations of whose perspectives may be privileged when boundaries are drawn (Benatar, 2002), and with what effect.

Communities in Kilifi: The KEMRI–Wellcome Trust research programme, Kenya

The experiences drawn on in this article have been generated through the authors' involvement in health research at the KEMRI Wellcome Trust Programme (www.kemri-wellcome.org), an international multidisciplinary biomedical research programme started in 1989 as a collaboration between the Kenya Medical Research Institute (KEMRI) and the Wellcome Trust, UK. V.M., D.K. and S.M. have worked in this setting for over 15 years, with an important focus on research and implementation policy and practice around community engagement since 2001. The research centre is situated in the District General Hospital (KDH) of this relatively poor, rural district. The community referred to comprises the geographic population of approximately 250,000 local residents who access health services at KDH, primarily subsistence farmers belonging to the Mijikenda ethnic group, with <20% migration from other parts of Kenya. Local tourism, petty trading and employment in nearby larger towns provide cash income. Local administration is the responsibility of chiefs, working through assistant chiefs and village elders. Chiefs are civil servants with at least 12 years of schooling, drawn from the ethnic community they serve. They are seen by community members as essential gatekeepers for community activities, but not necessarily as their representatives. The centre works in close collaboration with KDH, and ensures that a consistently high standard of treatment is available to all inpatients in many departments, including the children's general and intensive care wards, regardless of their participation in research. The research centre and the local community have been described elsewhere in more detail (Molyneux *et al.*, 2002, 2007; Marsh *et al.*, 2008a).

Community engagement at the Kilifi centre is supported by a centralized group of full time community facilitators and draws on action research principles of continuous evaluation and adaptation (Marsh *et al.*, 2008a). A summary of community engagement activities is presented in Table 1. In common with other

Table 1. Examples of goals, approaches and activities for engaging communities in Kilfi

Goals	Approach	Activities
Strengthen general awareness and understanding of biomedical research concepts and activities	Wide outreach of information, targeting community of all potential participants in any research (geographic community around KDH)	Public engagement, e.g. through schools, public meetings and events in community Regular interactions with opinion leaders, including community leaders and government health staff, who are in continuous contact with wider community Training and support supervision of all interface research staff Coordination and implementation through group of skilled community facilitators at centre
Building appropriate levels of trust	Supportive interactivity between researchers and community to promote visibility, accountability, reliability and perceived fairness	Public meetings in community attended by senior staff and administrators Visibility of partnership with government health sector Staff training and supportive supervision, including ancillary staff, drivers; value of ICF templates and SOPs Welcoming the public into the centre Having institutional policies that are responsive to community needs, including internal communication (e.g. support consistency) Participatory workshops/discussions to ensure opinion leaders and other intermediaries are aware of national/international scientific and ethical guidelines and practice for research
Understanding how general or specific research project activities/actors/context may interfere with freedom of choice (including existence of alternatives)	Consultation/deliberation with typical community members and opinion leaders. Role of social science research	Meetings with community 'representatives', empowered to support deliberative discussions (participatory methods, separate workshops on research, regular meetings to build relationships) Mechanisms to document outcomes of discussions and take into account wider context in time and place (e.g. research done previously, other research being done at same time, other relevant contextual circumstances)
Building awareness of specific studies	Narrow outreach, targeting only potential participant groups for study	Small-scale meetings of invited groups Project staff training and supportive supervision, including field workers and drivers
Understanding how research activities/actors/context may generate 'hidden' costs or benefits	Consultation/local discussions or debates Role of social science and benefits to ensure balance is fair in practice	Meeting/discussions with 'typical' representatives and opinion leaders Note: Gaps remain in understanding how exactly this can be achieved. Need for accountability, transparency and representativeness as well as understanding how to work with differences in opinions. Important role of social science research.
Ensuring validity of science	Consultation/local discussions Role of social science	As above

health research programmes working in settings where experience and understanding of health research are limited, action and empirical research have demonstrated challenges in communicating about research, including common confusions about the centre's overall research aims and the purpose and nature of many research activities (Mitchell *et al.*, 2002, Molyneux *et al.*, 2005a, 2005b; Leach and Fairhead, 2007; Molyneux and Geissler, 2008; Marsh *et al.*, 2008a). A therapeutic misconception of research, defined as a belief that what is being proposed is for the benefit of the individual person and has a reasonable chance of success, contributes to the mix of community perceptions around research in Kilifi. This phenomenon has been widely reported elsewhere for research settings in both more and less developed countries (Appelbaum *et al.*, 1987).

Concept of Community #1: Supporting Free and Informed Individual Decisions about Participation in Research

In research involving people, there is widespread agreement on the principle of respect for persons, linked to acknowledgment of the central value of individual autonomy and freedom of choice. The source of this principle in research ethics is a more fundamental set of universal human rights expressed in the 1948 United Nations Declaration, notwithstanding lack of universal agreement on their application. To support the principle of respect for persons, international research ethics guidance (CIOMS, 2002; Nuffield Council on Bioethics, 2002) promotes the concept of individual informed consent based on three widely agreed conditions of (i) researchers adequately explaining the proposed study, or disclosure; (ii) prospective participants understanding what is being proposed, including the social value of the research as well as procedures, benefits and costs amongst other well defined issues; and (iii) prospective participants making a free, competent informed choice about joining the study, without undue incentives or coercion. We also argue that these steps can only support valid informed consent processes when underpinned by relationships based on appropriate levels of trust (Lavery, 2007). Further, and specific to the main argument in this paper, that building both understanding and trust must recognize the influence of community on individuals, or their indivisibility.

There is an important debate in bioethics that challenges the concept of individual autonomy as one of the universally predominant principles, given the role of communal, rather than individual, decision making in some cultures (Emanuel *et al.*, 2004; Doumbo, 2005). In a similar vein, it is our experience that individuals considering taking part in research are strongly influenced by the prevailing beliefs and attitudes of the communities in which they live. In describing the way that individual ethical–moral development takes place from a psychology perspective, Mkhize (2004) describes that 'Self understanding emerges against the background social practices provided by the culture at large'. In a less fundamental way, people's beliefs and attitudes are shaped at any given time by those of others considered significant. Particularly where there are important paradigmatic differences between researchers and participants in relation to the nature, goals and activities in research, it may be very difficult, arguably impossible, to bridge these through interactions with individual prospective participants. Failure to address these gaps leads not only to challenges in participants' understanding of proposed research, but to concerns and rumours that may undermine trust in research as an institution and in the people who represent it. This conclusion underpins one normative role for 'community' in research ethics; building a foundation of wider understanding and trust that allows individual informed consent to become a valid process.

We recognize that in relation to individual informed consent there are potential risks in building a foundation of wider trust, including contributing to an environment in which research institutions and individuals are not questioned and challenged, and in which decisions about research participation are based on an unreflective belief that individual and community needs will be prioritized in any research endeavour (Melo-Martin and Ho, 2008). Conversely, mistrust, where based on misinformation and rumour, can lead to automatic rejection of studies, with negative implications for both researchers (in terms of negative perceptions of studies and low recruitment rates) and for community members (for example unnecessarily heightened concerns about procedures and automatic rejection of studies with valued benefits) (Molyneux et al., 2005a, 2005b). In the normative role for community in research ethics, there is therefore a need to build *appropriate* levels of trust (Molyneux *et al.*, 2005a. 2005b). Exhibiting aspects of behaviour and attitudes known to be important in trusting relationships, such as openness, truth-telling and respect (Gilson, 2005), should support a healthy questioning of research staff

and institutions among communities, and a reasoned assessment of the information discussed as part of research-related decision-making.

A genomic epidemiological study in Kilifi, described in Box A, provides an illustration of the way that beliefs and attitudes prevalent within a community, including trust, are linked to individual informed consent processes, with potential effects of both supporting and discouraging participation. The genomics study aims to generate greater understanding of inherited factors influencing resistance and susceptibility to serious causes of childhood disease in this and other similar areas. A qualitative study exploring social and ethical issues around genomics research was also conducted, including individual and small group interviews with the group of eight male field workers responsible for informed consent and sample and data collection, and 22 families participating in the research (Marsh *et al.*, 2010). During these discussions, the relationship between community and individual perceptions of the study was central to the way that the informed consent process was described, including acting as a source or as a means of checking information:

> Because most of the time . . . in these barazas (public meetings) women are in large numbers, in every location you see this there, and when they get that information they share it with their friends back home. That is how they get to know the information. And really, because sometimes they do not ask those questions in the meetings but when they are back home, they try to see some community figureheads in that community, whether it's the chief or somebody who is very much elite, and try to ask them questions. And when they get that information its happily stuck in their heads. (FW 01, 34 years)

> Because maybe where they get the information, they get it from a wrong person so they don't really get it clear and know what it really is about or . . . so you will visit the homestead you end up getting a refusal just because somebody has misinformed this person you followed, so you go there, you try to explain, somebody will just say no, no, because something else is planted inside. (FW 06, 31 years)

> I asked where he was going to next, to a neighbour's home, so that I could go and ask if he did the same there as he did here. I asked the name of the next child to be followed and he told me. It was a neighbour I know so I went later to ask and found out that her child had also had blood taken from the heel. So I knew that many children

will be done the same (mother of child in genomics study, 39 years, 8 years schooling)

A form of encouragement to participation arose through a phenomenon close to a therapeutic misconception of research. Therapeutic misconceptions have been particularly described as an important influence in communities where biomedical research is an unfamiliar activity, different models for health and illness between researchers and research participants are common and many people have had little exposure to formal education. As these conditions and the quotes above illustrate, therapeutic misconceptions can therefore often occur across communities, and not just at the level of individuals within that community. In the genomics study, this misconception emerged in the form of a 'health check' rather than 'treatment'. Additionally, the phenomenon might be more accurately represented here as a form of 'crowding out' than 'misconception'; more interesting and easily understood information about SCD seems to have been prioritized over more arcane issues around genomics research, both by individuals and the wider community. All the genomics field workers talked about this bias, saying for example that:

> You'll just find most of the questions are being asked in the sickle cell part, when you are reading that sickle cell part. But at the end of the consent you'll then ask questions to see if they have understood the whole thing [and] you'll find most of the questions or the answers are just from the sickle cell part. (FW 02, 34 years)

> Even if you go deep and talk about the genetic study, still at the end of the day go back to that participant, he or she will tell you about sickle cell.' (FW 03, 27 years)

Greater interest in sickle cell testing than the genomics research was also described in relation to the value placed on immediate, as opposed to long term, benefits:

> There are some who are going to agree because there are those who know what research is all about, and there are those who join research because of sickle cell. So there are two groups of people, those who know about the research and those who join research activities just because of the immediate benefits.' (FW 07, 33 years)

Conversely, discouragement from participation often resulted from rumours described as prevalent within the community, which could change over time:

> And when you give the consent, is kind of afraid of signing, it's like the rumors around are like to sign the document is like, now you have offered

the kid to them so it's all up to you . . . so she is comfortable with consenting and pricking and everything, but putting a signature . . .? (FW 02)

It took me a lot of time to explain to the mother because she had already understood some fake stories about a kid being pricked by KEMRI people and then the kid becomes sick, yea . . . (FW 06)

People were, they were afraid of the prick, where that prick is being done . . . most of these people, these communities, they were not used to the heel prick. But I think they have come to realize that the heel prick is not that different from the finger prick, so that question is not being asked any more, the community has come to understand more about the prick than before (FW 05, 30 years)

[Sighing] There have been some places whereby [in] the neighbouring homestead we were told that when you pricked the child, the next day the child became sick . . . [but] you find that there are some parents in fact that come in and tell the others that even if this child had not been recruited, maybe this illness was already coming (FW 07)

While health check misconceptions or biases could be seen as important ways in which informed consent is undermined towards undue influence to participate, community rumours about research can equally present undue influence on individuals away from participation. This 'false' discouragement can be argued as an important loss of a right to participation, particularly where research offers an opportunity to test for a serious disorder, affecting 1% of young children in the area. We could consider this dilemma compounded by the decision on participation being taken by a parent on behalf of a minor.

However, while community perceptions have a strong influence on individual informed choices about research participation, there are well recognized challenges to arguments that relying on informed choice alone would support ethical outcomes (Benatar, 2002). First, there may be a limit to the amount of information shared with potential participants to support such a choice, particularly for research which is highly technical. While working towards ensuring that all the information required by guidelines is included, researchers and reviewers may also privilege components they believe are most important to take into account before making a decision about participation. In practice, this is influenced by awareness that attempts to convey all the details of planned research during an informed consent process can interfere with participants' understanding of the most important implications of participation (Molyneux et al., 2005b). The decision on what information to present, to whom and how, while aiming to act as the basis for a participant's 'free choice', is therefore one generally taken by researchers and review committees. The same pertains to information shared with communities or their representatives as part of a community engagement process. Second, even where complete individual understanding could be achieved, there may be conflicts between a participant's informed choice and the researcher's perceptions of that person's best interests. In a clinical trial, for example, researchers are required to exclude an established participant from a study if they develop a new condition that increases the risks of their participation. Where participation in a trial secures provision of free medical care for the duration of the study, and this would otherwise be less freely available, the researcher's duty of care may conflict with a participant's choice to accept a small or theoretical increase in risk. These professional obligations towards research participants generate a requirement for researchers to consider the real impacts that participation may have on a person's health and wellbeing, as well their informed choices on involvement. In this example, the researcher could frame the participant's choice as having been unduly influenced by a study benefit of access to medical services. Thus, while concept #1 highlights one fundamental role of 'community', autonomy has well recognized and important limitations in supporting ethical practice when considered alone. Concept #2 of community describes a second and complementary role for community that contributes to addressing this limitation.

Concept of Community #2: Assessing Benefits and Risks to Communities of Individual Participation

An important second way in which the relationship between individuals and communities can have normative significance arises out of the fact that the involvement of individuals in health research can have wider consequences for communities. This relationship is particularly recognized in genetic or genomics research (NCOB, 2006), where links between individuals and their wider families or related communities are inherent to the subject of study, and for non genetic research that

may generate community risks by association, for example, stigmatization of linked groups in studies including individuals at high risk for HIV/AIDS (Morin *et al.*, 2003). These concerns contribute to arguments for considering community consultation (Sharp and Foster, 2000; Marsh *et al.*, 2008a) and even sometimes consent (Diallo *et al.*, 2005) as a critical step in planning and implementing some types of research, including supporting decision making about types and levels of information that should be given to individuals and communities. In practice, community consultation and social science research in Kilifi indicate that a less debated consequence of individual participation can be the generation of intra-community tensions between participants and non participants in research, directly linked to the nature of individual costs and benefits.

A malaria vaccine trial conducted in Kilifi, described in Box B, provides an illustration of the potential risk of generating intra-community tensions as a result of individual participation in research, as well as the way that community-wide benefits can act to minimize this effect. In this research, the provision of medical care for study children was an indirect benefit of participation and highly valued (Gikonyo *et al.*, 2008; Molyneux *et al.*, 2008). Parents of participant children repeatedly highlighted these benefits over any altruistic interest in contributing to the global pool of knowledge on malaria prevention as the main reason for joining the trial:

> What attracted us [was that] we knew our children will receive treatment for a whole year in every disease they suffer. If you have a problem and visit the people concerned, a call is made to the [PI] he brings a vehicle and [the sick person] is carried away [to hospital]. In fact it's something we should be happy about because nobody can bring you a vehicle that easily. (Mother 2, FGD 3)

A potential concern in such a context is for such improved access to medical care in research to act as a form of undue inducement. In contrast, in this trial, better access to medical services generated unforeseen complications of intra-community tensions. Participants in FGDs described non-participants as jealous of the benefits that they were receiving, and that these non-participants were fuelling rumours about the trial in order to encourage participants to drop out.

> 'It is said [by non participants] that we joined KEMRI and photographs were taken, blood was removed and both will be taken there [to KEMRI] . . . later they will cut the photo up and the child will start fitting . . .' (Mother 8, FGD3)

> P3: Yes, the child will fit [i.e., have a seizure] [laughter] . . . and die . . . so KEMRI are devil worshippers! (Mother 3, FGD 3)

> 'They [non-participants] are out to worry us . . .'.(Mother 4, FGD 3): It's a conflict between those who attended and those who didn't, so it's upon us to educate them so that they don't convince the ones participating to withdraw . . . '(Mother 8, FGD 3): When they see us boarding the free vehicles they shout 'a lazy person takes advantage of any chance' (Mother 12, FGD 3).

The circulation of these rumours and concerns were potentially detrimental to wider community cohesion and the completion of the trial (Gikonyo *et al.*, 2008). Regarding the latter, many parents described struggling to ignore the 'nonsense' being circulated:

> 'the [vaccine] for malaria is still new in our place that's why they are doing it [the trial] using our children. And a lot of nonsense has been going round. We are fighting to cross over [to truly believing that all of the rumours are nonsense] but after [the trial] you should think about us because we are in the middle of water!' (laughter) [i.e., the ones taking the risks] we don't know whether we'll drown or what . . . .we are in the middle of the sea. (Mother 2, FGD 2)

The pressures and worries that participants felt they had to cope with, in large measure fuelled by non-participants' reported 'rumour-mongering', influenced participants' views on what should happen at the end of the study. Regarding results, many participants were keen that there be separate information giving for those who were in the trial and those who were not, and in several groups it was strongly felt that non-participants should not be given any direct feedback. One person even mentioned that non-participants should be given the feedback 'that makes them feel bad'. Some felt that non-participants should not be able to access any benefits at the end of the trial:

> The rabies vaccine [control vaccine] should be given to those who participated only but not to those that refused to participate. Even if a dog bites one, they shouldn't tell them there is the vaccine at the dispensary. They should go to Kilifi [Kilifi district hospital] because this vaccine is for those that participated [in the study] (Mother 2, FGD 4).

Discussions with non-participants on the other hand revealed concerns about not being involved in the study once it was underway. They noted that they did not have much information on the status of the study or any

information on what the participants received and that they had to wait and ask their friends and relatives who had children in the study. Others stated that they were not interested in what had gone on.

> I won't ask you, in fact I will refuse to know what you have. I don't want you to tell me what you have been told there, eeh. (Mother 4, dropped out/refused FGD 1)

Overall, a dispensary committee member's comment may have given a good general indication of how many non-participants felt: 'it is like the community members were starting to group themselves and were taking themselves to be that the study people are the 'important' ones and those not in the project should not benefit again because they refused it at the beginning' (IDI 6).

It is unclear how serious the intra-community tensions really were, and for how long after the completion of the trial they continued. Nevertheless, in this situation, increasing access to medical services *for the wider community* through collaboration with government health providers is a potentially important strategy to reduce the risks of both intra-community conflict as well as undue inducement for individual participants. As a longstanding research institution, this partnership with government medical providers has been possible in Kilifi and routinely supports provision of medical services to many research communities, particularly where longitudinal cohorts are recruited. Although the intra-community tensions involved in this case study might be considered unique to this particular type of study or context, we have noted similar issues in mixed methodology social science studies conducted in both Kenya and South Africa, where the importance of providing community-level benefits was also highlighted (Molyneux *et al.* 2009). In so doing, it was recognized that new potential concerns arise, including defining who the relevant communities are, what the appropriate levels and types of benefits are, who should provide those benefits and how individual interest in joining studies is maintained through compensating participants for the time and inconvenience involved.

We have illustrated a negative consequence for communities arising out of individuals' participation in studies, with potentially positive implications in terms of strengthening the focus on 'community wide benefits' to avoid such problems. There may also be more direct positive community-level consequences arising out of individual's participation in studies, which are more typically recognized by researchers. For example an individual participating in an HIV trial which involves significant information-giving about the disease and available support groups may contribute to participants sharing that information with other community members and to improved health and strengthened social networks. Another example is that in-depth interviews about health financing policies may lead to greater discussion, awareness, and possibly even advocacy among wider communities for change in policy or practice.

It follows that researchers have a responsibility both to support participants' free informed decisions about involvement in research and also to assess the ethical implications of these decisions, taking into account other issues such as risks and benefits both to the individual participant and to the community of which they are a representative. Further, engagement (for example, see Table 1) with a wider community will often be an important process to support informed consent and understand community benefits and risks in practice. In the next section, we address this procedural role of 'community', highlighting the breadth of approaches used in Kilifi to support individual choice and assess community risks and benefits in research. We also point to challenges in this process that can in our experience lead to perverse outcomes, primarily related to communication and the fundamentally social nature of many engagement activities.

Working with Concepts: Community Engagement Goals and Activities in Kilifi

We described earlier that researchers will often identity communities that can support individual free informed choice or assessments of the benefits and risks around participation in research in relation to the type of research and the wider context for a study, including the particular groups of people who may become involved in its implementation. As an illustration of the breadth of approaches that this may involve, Table 1 outlines the types of goals that have commonly been defined for research in Kilifi, the communities involved and the range of activities currently put in place to work towards these goals. Given the central role of trust in this engagement process, it has been particularly important to build understanding of the research programme as an institution, ensure transparency and accountability in its policies (for example, concerning employment and science training opportunities) and build coordinated supportive policies on staff training and monitoring as well as community engagement itself.

The community engagement activities described have been developed over a period of time, linked to the findings of linked action and empirical social science research. These experiences and studies have strengthened our understanding of the issues and dilemmas that can interfere with the pathways between planned community engagement activities and their intended ethical goals. Further, that new ethical issues can be generated through these initiatives. Based on our experience of supporting research teams to develop and implement community engagement plans, we offer three examples of such perverse outcomes around dilemmas on who to engage with and dangers of 'half knowing'.

Dilemmas on who to engage with

Based on a recognition of the importance of building understanding and trust of research among communities as well as individuals, and of the potential value of consulting community representatives in early discussions on the potential risks and benefits of research, researchers involved in a current vaccine trial included in their pre-trial community engagement activities chiefs, village elders and community health workers (CHWs), among many others. Although this was essential and there were many positive consequences of doing it, two important dilemmas emerged. First, it became apparent that one of the chiefs—in his capacity as an administrator—was taking it upon himself to organize meetings about the trial, and to put significant pressure on parents with eligible children to enroll their children. In a famine prone area he had reportedly threatened to remove tickets for free food rations from eligible families who did not enroll. For this study, these threats were reported with significant laughter by community members, and efforts were re-doubled by the research team to emphasize the voluntary nature of trial participation. Nevertheless, the incident highlighted that engagement with community members always involves engagement with existing social relations and hierarchies, and that this can have perverse consequences, in this case potentially for individual informed consent and for intra-community relations. A second dilemma was that on engaging with CHWs, as strongly suggested by Ministry of Health collaborators, it became clear that CHWs themselves would like to assist with the study, in part in order to receive some payment for their work and therefore benefit from the study. This was an understandable interest, given that few CHWs following selection and training by MoH have been supported to implement their training due to resource shortages. A challenge became if and how to involve CHWs in

addition to the existing trial team, whether to pay them, at what level, and the potential implications for informed consent and community relations. There was a concern that payment of any form might lead to tensions within communities, and others involved directly or indirectly in the study requesting payment. On amount to pay, there was a concern that if this was based on numbers of people recruited there might be inappropriate levels of pressure on parents of eligible children, but on the other hand that a flat payment for example per day may lead to unfairness between CHWs and between CHWs and others involved in the trial. An appropriate resolution appeared to be payment on the basis of numbers of people CHWs brought to the study clinic to learn more about the research. However, these issues highlighted complexities regarding who to consult, at what stage and how, and that community representatives' own needs might feature as much in discussions as those of potential participants and the wider community.

The dangers of 'half knowing'

The effect of low understanding of research and greater familiarity with medical services in generating therapeutic misconceptions has been described as an important ethical rationale for building greater awareness of research, including through community engagement. We have observed in Kilifi that, in practice, understanding is not only challenging to achieve but that incomplete levels of understanding, or 'half knowing' are almost an inevitable accompaniment of communication efforts. Further, there are dilemmas created around 'half knowing' about research that engagement strategies have to respond to. For example, efforts to explain research, and the difference between research and treatment, have included messages about the voluntary nature of research participation and the availability of standard care for non participants, for example, in clinical trials. Where understanding enables research to be recognized as *different* to medical care, rumours and concerns can arise where alternative, more accurate explanations are not available or understandable. In this paper, we have discussed a range of these rumours and concerns in Kilifi and elsewhere, linked for example to doubts about researchers' motives and the safety of procedures. Consequences may be community tensions, the inability to generate social value through research and loss of rights of participation. A further outcome of 'half knowing' can be that recognition of the voluntary nature of research, accompanied by challenges in differentiating between specific examples of research and

treatment, can lead to rejection of treatment. In a relatively well-resourced research centre, more complex diagnostic procedures are often available than would be the case in typical public health care facilities. At KDH, we have experienced that diagnostic procedures, important to the wellbeing of a patient, have been refused on an assumption that this is part of research, voluntary and non-essential. The danger of 'half knowing' here is the potentially negative consequences for clinical care, or more likely and more subtly, of unnecessarily raised concerns about standard clinical care procedures. Ultimately, there is a potential risk of patients avoiding key public health facilities in which research is happening, in order to avoid research altogether. Community engagement strategies that continue to build not only understanding of research but also mutual trust have an important role in addressing these perverse outcomes. However, again, we acknowledge that an increased but still incomplete level of 'knowing' could contribute to the inappropriately high and unreflective levels of trust referred to earlier in this article. We continue to resolve these issues through for example refining messages, and through communication skills support to health workers and study teams. However, the dilemma is that while community engagement has the potential to strengthen individual informed consent, and to reduce the likelihood of 'therapeutic misconceptions' or 'crowding out' of key research-related information, the concept of research and of different studies remains difficult to get across. 'Half knowing' will almost inevitably be an outcome and the implications of this at individual and community level need to be continuously taken into account.

Conclusions

In considering the normative role of communities in international collaborative research, we highlight the contingent nature of a community, such that applying definitions is itself a normative process with ethical implications, often related to the perspectives of the 'boundary-drawer'. Drawing on experience of working with local residents in a rural setting in Kenya, we identify two normative roles played by communities in this setting. First, that taking individual informed consent seriously involves understanding and addressing the influence of communities in which individuals' lives are embedded. Second, that individual participation can generate risks and benefits for communities as part of the wider implications of research, and that these should also be taken into account. Community engagement

is an important process to address these issues, but may require a broad approach to build mutual understanding and trust between researchers and community members. We emphasize the challenging nature of these communication efforts, including the need to continually work towards understanding and addressing the risks of perverse outcomes, using examples related to the influence of existing social relations and the inevitable complications of 'half knowing'.

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