Consent and Community Engagement in diverse research contexts: Reviewing and developing research and practice

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ABSTRACT: consent and community engagement (CE) in health research are two aspects of a single concern—that research is carried out in a respectful manner where social value is maximized. There are important overlaps and interdependencies between consent and CE; for example, CE can provide insights into how best to tailor consent to context and can be an important component of consent processes. Engaging communities can also have intrinsic and instrumental value beyond consent; for example, as a means of showing respect and identifying appropriate ways of working respectfully. In this paper we critically examine how CE and consent processes are characterized, conducted, and evaluated in diverse health research contexts, and propose a preliminary research agenda to support future learning in these critical areas.

KEY WORDS: Consent, community engagement, research, Africa, Asia, research ethics

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Consent and community engagement (CE) are two aspects of a single concern—that research is carried out in a way that is respectful to individuals and communities, where social value is maximized. Consent is more clearly defined in the literature than CE, but there are important overlaps and interdependencies between the two concepts, and the way they are applied in health research practice. In both cases, effective and appropriate processes require the balancing of internationally recognized standards of good practice with responsiveness to the local context (Bull, Farsides, & Tekola Ayele, 2012). However, there are relatively few published data on how this might be done, particularly in CE in "traditional," nonparticipatory, biomedical research contexts. Newman (2006) notes:

> Engaging vulnerable community stakeholders in medical research is less of a controlled and predictable science than we might wish. Nevertheless, it seems curious that we invest millions of dollars in product development, clinical training, design and building of facilities … but often leave vital processes of CE largely to trial and error (p. 302).

In order to share literature, ideas, experiences, and needs regarding CE and consent for health research, we organized a four-day international collaborative workshop in Kilifi, Kenya, in early 2011. The workshop brought together groups engaging in research and practice with CE and consent in collaborative global health research from universities and research centers in South Africa, Malawi, Kenya, Botswana, Brazil, Uganda, Burma/Myanmar, Cambodia, Thailand, Peru, Bangladesh, Canada, and the United Kingdom. A breadth of disciplinary backgrounds and perspectives were represented, including bioethics, philosophy, law, anthropology, human geography, psychology, tropical/clinical medicine and clinical trials, science communication, education, gender and development, theology, and health policy. Under the broad topics of CE, consent, or cross-cutting issues, participants either gave conceptual talks based on literature, or presented new empirical research and experiences. Theoretical, methodological, ethical, and research implications of the presentations were discussed. Thus the workshop served as an opportunity for a diverse range of actors to evaluate the current state of knowledge regarding consent and CE, based both on the literature and on experience from a number of key sites. Over the course of the workshop, consensus on key lessons, challenges, and research needs began to emerge.

This paper draws on both the literature and workshop discussions to present an overview of current thinking about, and experiences with, consent and CE in health research. Following introductory material about consent and CE and the interplay between them, the paper is divided into three thematic sections, concerning consent, CE, and cross-cutting issues in turn. We conclude with proposals for research and action that we hope will encourage discussion and input from others.

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CONSENT AND CE IN HEALTH RESEARCH

Consent and CE are frequently dealt with separately in health research literature. Consent has long been considered as a core requirement for the ethical conduct of biomedical research. The concept is relatively clearly defined, with valid consent to research with competent adults entailing: (1) researchers adequately explaining the proposed study; (2) prospective participants understanding what is being proposed; and (3) prospective participants being able to make a free choice about joining the study (Nuffield Council on Bioethics, 2002). Challenges to achieving these components have been observed all over the world (Edwards et al., 1998; Flory & Emanuel, 2004; Mandava et al., 2012), and are potentially exacerbated in low-income settings by greater inequities in resources, power, and information among stakeholders in research (Nuffield Council on Bioethics, 2002; United States National Bioethics Advisory Commission, 2001). There are also differences in cultural practices around communitarian and individual decision making that can impact the conduct of consent processes for specific participants.

Community engagement has long been promoted in health delivery, and is a core value in *participatory* health research. Recently, and partly in response to challenges arising when seeking consent, CE has begun to be promoted as an important component of the research process in more "traditional," nonparticipatory research (Tindana et al., 2007). CE is promoted in these situations as a potential approach to strengthen the protection of, respect for, and empowerment of participant communities, and to improve the relevance and quality of research (Doumbo, 2005; Emanuel et al., 2004; Marsh et al., 2008; Marshall & Rotimi, 2001; Tindana et al., 2007). There is no universally accepted definition of CE. Descriptions range from efforts to simply improve information sharing and transparency in communities, through more active consultation, to initiatives aimed at ensuring greater control or partnership by community members (Tindana et al., 2007). Some definitions of CE *require* more than simple information giving. For example, Tindana et al. (2007) note:

> In our view, the concept of engagement in research … is the process of working collaboratively with relevant partners who share common goals and interests. This involves "building authentic partnerships, including mutual respect and active, inclusive participation; power sharing and equity; mutual benefit or finding the 'win–win' possibility in the collaborative initiative" (p. 1452).

UNAIDS (2011) recommends defining CE as interactions with those from a particular subgroup or geographical community from which trial participants will be drawn, as opposed to other stakeholders. CE can take place at various and multiple stages of research, from study conception and design, through pre-study information giving, to feedback and communication of results. Research centers may also run program-wide CE activities that are not linked to specific studies. Although CE is increasingly promoted in health research, the concept itself, and the way in which it is best implemented in practice, is understudied and contested.

INTERPLAY BETWEEN CE AND CONSENT

There are multiple forms of interplay between CE and individual consent. Marsh et al. (2011) recently described the links between communities and individuals. They argued that community understandings, beliefs, and attitudes influence perceptions of personhood, independent decision making, and views on risks and benefits of research. They also noted that individual participation in research can generate risks and benefits for communities as part of the wider implications of research. For example there may be identification and stigmatization of those linked to individual participants through research, either directly or by association (Marshall, 2004; Morin et al., 2003; Tekola et al., 2009a). Also, benefits given to individual participants within communities may cause intracommunity tensions. Such tensions can have an impact on individual participants' views and comfort within studies (Gikonyo et al., 2008; Marsh et al., 2010; Molyneux et al., 2012).

These points suggest that (1) consent processes may need support from or be influenced by CE activities and (2) CE may be needed to develop appropriate consent processes. Given these overlaps between CE and consent, CE is often promoted as an essential supplement to consent processes (Doumbo, 2005; Molyneux, Peshu, & Marsh, 2005; Tindana et al., 2007). The Good Participatory Practice guidelines for HIV prevention trials illustrate the potential overlap and mutual support between community sensitization, community consultation, and consent activities (UNAIDS, 2011).

Overlap and interplay between CE and consent are critical to this paper, and the practical ethical challenges presented by these two complementary aspects of good research practice are often cross-cutting. CE activities may aim to inform and strengthen consent processes, and consent may be seen as a multilayered process incorporating CE activities during recruitment. However, CE has far greater potential value than simply supporting consent processes; it has the potential to contribute to a broad range of intrinsic and instrumental goals in research. We first present literature and workshop discussions on consent and CE separately, before returning to

interrelationships and cross-cutting challenges in the final section.

Seeking Consent to Research: Examining Processes and Responding to Issues

In contrast to CE, there is national and international guidance and regulation to define how consent to research should be sought. In particular, consent processes must contain appropriate information, information must be provided in an understandable way, and participants must be free to accept or decline to take part in research (Nuffield Council on Bioethics, 2002). Despite broad support for these aims, obstacles to the achievement of these requirements exist in practice.

This section outlines challenges that have been identified when seeking to ensure that consent to participate in research is "genuine," "valid," "true," or "authentic." We discuss issues relating to information provision, supporting understanding, and voluntary decision making in turn, before discussing approaches to strengthen consent processes. We argue that some of the challenges can potentially be addressed through CE.

PROVIDING INFORMATION ABOUT RESEARCH

There is a lack of consistency in guidance and regulation about what information is essential for research participants to know. Guidelines range from giving general instructions, to providing detailed lists of over 25 items of which participants must be informed (Council for International Organizations of Medical Sciences & World Health Organization, 2002; International Conference on Harmonisation, 1996; World Medical Association, 2008). Topics on which there is widespread agreement are: the purpose of the study; the research procedures involved; the duration of participation; potential risks; potential benefits; participants' rights to decline to take part or to withdraw from research without penalty; treatment and compensation available for research-related harms; and confidentiality. There is also awareness that the above items do not provide an exhaustive list of topics that participants may want or need to be informed about (see Figure 1). Research teams may need to draw upon previous or ongoing research and CE activities to identify additional information of importance to potential participants and communities. For example, significant amounts of basic healthcare information may need to be provided to enable participants to make sense of details of a specific study (Boga et al., 2011; Bull et al., 2012).

There is some debate about how much information should be supplied about each topic in the consent process (Berger et al., 2009; Lynoe & Hoeyer, 2005), and about how much variation is necessary or appropriate for different sites in a multicenter study (de Vries et al., 2011; Marshall, 2008). It has been argued that "fully informed consent" is neither a possible nor desirable goal when recruiting participants (Nuffield Council on Bioethics, 2002). Instead, researchers have an obligation to ensure that appropriate information is provided in a comprehensible manner. Recent trends of longer and increasingly legalistic consent forms have raised concerns among researchers (Berger et al., 2009; Nuffield Council on Bioethics, 2005). A particular concern is that overloading participants with information may impair their understanding of aspects of the research of particular importance to them (Molyneux, Peshu, & Marsh, 2004). In addition, it may be difficult to engage with participants about aspects of research that researchers consider important but that participants consider to be of relatively little interest and relevance (Ndebele et al., 2012; Tindana et al., 2012).

> Informed consent materials and processes are often designed to convey information to potential research participants about the procedures they will go through in order to ensure that data requirements of studies are met, as opposed to assisting participants in understanding the reasons for studies and procedures, and the personal implications of research participation. An informed person is one who appreciates why research is conducted, why the particular study is being conducted, which procedures are being used and why they are being used, and the implications of their involvement (Ndebele, Wassenaar, Munalula, & Masiye, 2012)

FIG. 1. Explaining the rationale of research.

Another important aspect of information sharing concerns who is providing the information. Those who might best be able technically to give out the information (for example, clinicians) may not be the people best able to communicate with the potential participant in terms of age, gender, or awareness of the sociocultural background of the person (Fitzgerald et al., 2002).

UNDERSTANDING

Empirical ethics research in resource-poor settings has identified a number of issues arising in practice relating to participants' comprehension of study information and factors affecting comprehension (Bhansali et al., 2009; Kass, Maman, & Atkinson, 2005; Pace, Emanuel et al., 2005; Pace, Talisuna et al., 2005); effects of interventions to improve comprehension (Joseph et al., 2006; Ndebele et al., 2012; Penn & Evans, 2010; Sarkar et al., 2010; Vallely et al., 2010); means of evaluating comprehension (Lindegger et al., 2006; Molyneux et al., 2007); and participants' and communities' understandings and perceptions of research.

These studies demonstrate that there is often limited understanding among research participants about specific

aspects of a study and, in some cases, of the entire purpose of the activity. Thus, for example, "therapeutic misconceptions"—where research activities are incorrectly perceived to be primarily for the benefit of the individual research participants—have been widely documented around the world (Appelbaum, Lidz, & Grisso, 2004; Molyneux, Peshu, & Marsh, 2005). A related concept is "crowding out," where elements of research are understood but not prioritized by participants who may be more concerned with immediately relevant or understandable healthcare elements of research (Marsh et al., 2011). Where there is crowding out of research information, participants over time may come to describe the research activity as more of a health check (Craig, Reilly, & Bland, 2012). Participants' inaccurate descriptions of research are not necessarily due to a lack of understanding of the nature and purpose of a study, but to a complex interplay of factors including type of research, broader contextual issues such as poverty and constrained public healthcare services, and participants' hopes, previous experiences with research and healthcare, and other psychological factors (Glannon, 2006).

Research participants' understanding can be improved by including explanations of the differences between research and routine care, and of research procedures to be used, as well as their justification and personal implications. In a study conducted in Malawi among women of low literacy, it was demonstrated that trial participants' understanding was improved by relating research and research procedures to daily life (Ndebele et al., 2012).

There is some ambiguity in the international guidelines about whether researchers' responsibilities are limited to providing information in an understandable way or whether they should also assess understanding of a study before consent is obtained (International Conference on Harmonisation, 1996; World Medical Association, 2008). Approaches taken in practice have ranged from those that require no formal review of participants' understanding before consent is obtained, to those requiring prior assessment of understanding via a standardized test. Researchers have noted that assessing understanding in many research contexts may not be straightforward. Means of assessing understanding may be unfamiliar and confusing for participants (Krosin et al., 2006; Molyneux et al., 2007), and the choice of method used to assess understanding may significantly affect the results received (see Figure 2). When assessment of understanding is required, issues arise about whether participants should be excluded from research that offers some benefit but minimal risk if they are unable to answer key questions about the study (Kamuya et al., 2013; Molyneux, Kamuya, & Marsh, 2010; Molyneux et al., 2007).

Bioethics literature has also drawn a distinction between understanding and acceptance (Beauchamp & Childress, 2001). While participants may adequately understand the information that is transmitted to them, they may not necessarily believe or accept this information, thus invalidating consent. In a study in Nigeria authors found that approximately 25% of participants understood that they were in a clinical trial of an antiretroviral drug, but found it hard to believe that good doctors would provide them with a medicine that was not already known to be effective (Manafa, Lindegger, & Ijsselmuiden, 2007).

> Assessment of understanding has commonly been through the use of forced choice questionnaires. However, these methods of assessment are often culturally foreign and risk assessing short-term memory of rote learning of technical concepts (Lindegger & Richter, 2000). The HIV/AIDS Vaccine Ethics Group (HAVEG) in South Africa conducted a study comparing various methods of assessment of understanding (Lindegger et al., 2006). The study used scenario-based and narrative methods of assessment which were more culturally familiar. The findings suggest that forced choice questionnaires often overestimate levels of understanding. The study is currently being repeated in Zambia, Uganda, and Kenya, and preliminary findings also show overestimation. There were initial concerns among researchers that these alternate assessment procedures may be time consuming and expensive, but ongoing research has shown that this is not necessarily the case. Feedback from research participants has shown a marked preference for these alternate assessment methods. Feedback from researchers trained in the alternate method has ironically also been that the method allows researchers to obtain a better understanding of what aspects of trials are most difficult for potential participants to understand. The latter suggests that appropriate assessment of understanding may, in fact, become an additional means of CE.

FIG. 2. **Field experiences: Developing alternative methods of assessing understanding.**

VOLUNTARINESS, MOTIVATIONS, AND DECISION MAKING

A further challenge identified is that of ensuring that consent to research is *voluntary*. Voluntariness involves intention and (perceived) freedom from control by external factors (Bull & Lindegger, 2011). Factors that can impact on voluntariness include social and gender norms. Such factors are problematic to consider in consent evaluations: cooperative decision making among spouses may be voluntary, or a wife may feel she has no choice but to hand over decision making to her husband (Kamuya, Marsh, & Molyneux, 2011). Concerns also arise when senior community members purport to consent to research on behalf of a community, rather than considering their role as authorizing recruitment among community members (Tindana, Kass, & Akweongo, 2006). Economic constraints can also lead to participants wishing to join studies to access study-related benefits, in some cases despite significant reservations or with only a limited

understanding of some aspects of the research (Leach et al., 1999).

There are a number of examples of research evaluating voluntariness of participation and social and economic factors affecting voluntariness (Abdool Karim et al., 1998; Barsdorf & Wassenaar, 2005; Kass et al., 2005; Marshall et al., 2006; Pace, Emanuel et al., 2005; Pace, Talisuna et al., 2005; Woodsong & Karim, 2005). Further studies examine decision-making processes and the involvement of others in these, and motivations for consenting or declining to take part in research (Kass et al., 2005; Masiye et al., 2008; Mfutso-Bengo et al., 2008; Molyneux et al., 2005; Mtunthama et al., 2008; Nabulsi, Khalil, & Makhoul, 2010; Tindana et al., 2006; Woodsong & Karim, 2005).

Emerging from these studies is the conclusion that subjective experiences of social and economic constraints on voluntariness are neither uniform nor necessarily predictable. Guidance requires that researchers do not deliberately seek to restrict participants' voluntary decision making via coercion or undue inducement. However, the extent of researchers' responsibilities to assess subjective experiences of other economic and social constraints on participants' decision making is not so clear (Bull & Lindegger, 2011). Moreover, determining what decisions have actually been made, and how to respond to nonverbal communication, can be far from straightforward, as illustrated by the concept of "silent refusals" (Kamuya et al., 2013) (Figure 3).

Questions also arose at the workshop about whether and how researchers should respond to some modes of decision making by individuals and communities. Examples discussed included community leaders requiring certain conditions to be met prior to recruitment, such as employment of particular individuals, and individuals seeking to join studies by approaching researchers and asking to whom they can sell their blood (Figure 4).

> The term "silent refusals" is used in Kilifi to describe a situation where participants appear not to want to participate in research but do not say so (Kamuya et al., 2013). Rather than saying "No," appointments are made and broken, nonverbal communication expresses disinterest or concern, or research staff are requested to return later to discuss a study further with other family members. Staff find it difficult to know how to respond. Should it be assumed that research—and any associated benefits—is being declined? Are reasons given to miss appointments genuine issues or are they polite ways of saying "No"? Does a mother really have to defer to her husband or is that a strategy to decline participation? How much follow-up is appropriate before individuals feel under pressure to take part in research? Silent refusals illustrate the important but highly complex power relations between research staff and participants in contexts where researchers are keen to do research and participants wish to gain study-related benefits but may also want to avoid some or all research procedures.

FIG. 3. Field experiences: Silent refusals.

> Community-based cohort studies often require permission from local authorities, including traditional, civic leaders and government bureaucrats. Communicating to such gatekeepers that their permission should not be contingent on family members or other nominated individuals being employed as research staff is difficult and may cause offense. Local authority permission also potentially affects decision making about research in individuals who are expected to participate in things deemed "good" by their leaders. Fieldworkers are often drawn from the same communities and are expected to follow the wishes of their leaders. These expectations must be balanced with the need to respect voluntary decision making by potential participants, and the fact that participant recruitment rates may factor into fieldworkers' performance evaluations (Reynolds, Cousins, Newell, & Imrie, 2013).

FIG. 4. Field experiences: Interactions with gatekeepers.

RESPONDING TO RECOGNIZED CHALLENGES

Attendees at the Kilifi workshop discussed how researchers should respond to challenges to ensuring appropriate information is provided, that understanding is facilitated, and free decision making is supported. Suggestions are summarized for the different stages of research in Table 1, and include careful consideration of the design of consent processes and engagement with communities from the outset.

DESIGNING CONSENT PROCESSES AND SUPPORTING THE STAFF WHO IMPLEMENT THEM

There is significant variation in the modes of design of consent processes, from researchers being asked to use information sheets and consent forms developed for overseas populations, to researchers designing a consent process from scratch. The development of templates which incorporate contextually relevant and needed information for specific settings can help (see, for example, Boga et al., 2011). In practice, consent processes are often developed with minimal resources, because limited funding is available before ethical approval is received, or there are limited resources for such development in the research budget. Such constraints may also limit the amount of training that recruiters receive before a study begins. The quality of consent processes will depend on recruiters' ability to explain and discuss research (Kamuya et al., 2013; Madhavan et al., 2007).

In designing consent processes and in training recruiters, it is useful to distinguish between legal and ethical conceptions of consent. Faden, Beauchamp, and King (1986) argue that legalistic notions of consent create a potentially adversarial relationship between doctor and

TABLE 1. Strategies to Strengthen Consent Processes Prior to and During Recruitment, and Over the Course of Research.

Prior to Recruitment	During Recruitment	During Research
• Engaging with community advisory groups and recruitment staff to determine the appropriate design of consent processes • Seeking to understand how local or indigenous knowledge makes sense of research in general, or particular research projects • Discussing the research with research ethics committees and seeking approval of designs • Negotiating amendments to consent processes developed in different contexts where relevant • Building capacity within recruitment staff to explain the research and answer questions appropriately • Discussing and publicizing agreed research via meetings, leaflets, flyers, loudspeakers, television, and radio	• Discussing research with and providing information sheets to potential participants and, where appropriate, others such as family members and communities • Ensuring that research makes sense to participants and that the implications of participation are understood	• Determining whether participants are still willing to take part in research • Continuing to engage with the communities and other stakeholders where relevant to identify and respond to emerging concerns

patient, in which consent is seen as a mechanism to provide the doctor or researcher with legal indemnity. By comparison the ethical conception regards consent as a shared decision-making process, which is the embodiment of a higher level of moral commitment. The latter focuses on empowering people to make good decisions about participation that they do not later regret (Lindegger & Richter, 2000).

CONSIDERING COMMUNITY-WIDE ACTIVITIES PRIOR TO AND FOLLOWING RECRUITMENT AS KEY TO CONSENT PROCESSES

Critical prerequisites to recruitment may include seeking advice and permission from community representatives, such as community leaders and elders, or community advisory groups. These groups may also advise on the design and content of the consent processes, including information-sharing activities with potential communities and participants. Discussions about a study prior to recruitment should ideally involve a two-way learning process. Researchers learn about the relevant communities and the implications of the research for communities and community members. Potential participants learn about the value and procedures associated with the research, and the implications of taking part.

Researchers may need to conduct formative research to strengthen their understanding of issues and local communities before embarking on any recruitment initiatives. They may also need to add additional engagement activities with communities as questions and concerns about research emerge (see Figure 5).

In addition to engagements relating to specific studies, some research institutions conduct activities aimed at improving general understanding between researchers and community members. For example, a team of community facilitators at the Agincourt Health and Socio-demographic Surveillance System in South Africa have coined the term "building a research-savvy community" to describe their work of continuous coordinated interactions between facilitators and community members over the course of multiple studies. A research-savvy community is seen as a community that is well informed about research, and that is able to engage in an informed way with specific consent processes and the wider research institution. This is ultimately aimed at contributing to high-quality, locally important research that can be sustained over time.

Community Engagement: The Spectrum of Activities and Emerging Issues

There is a long history of community participation and engagement in health delivery, and CE is the core value in participatory health research. However, there is relatively little guidance available on what CE is, and how

> The Mafessta study examined HIV and sexually transmitted infections in fishing communities in Mangochi, Malawi, and assessed the transmission dynamics and feasibility of conducting future preventive trials. In the study adult participants had 10ml samples of blood taken on each of three monthly follow-up visits. Before and during the study, some community members were suspicious that the blood samples were inappropriately large, and therefore not being used for research purposes but for rituals and satanic sacrifices. Some participants were under pressure from family members and the wider community to withdraw from the study. Regular meetings were held with chiefs, opinion leaders, and community advisory groups, as well as participants, to discuss the importance of the samples. The trial team were advised to avoid any fieldwork activity in communities after dusk, and this was acted upon. These activities were felt by the team to alleviate concerns and support more informed consent processes.

FIG. 5. Field experiences: Blood samples and the Mafessta study in Malawi.

CE processes should be conducted in biomedical research contexts. Sites that have published their experience have highlighted significant benefits and challenges (Bandewar, Kimani, & Lavery, 2010; Brieland, 1971; Marsh et al., 2008; Marsh et al., 2010; Morin et al., 2003; Morin et al., 2008; Nyika, 2009; Reddy et al., 2010; Shubis et al., 2009; Strauss et al., 2001). Drawing on the workshop and on this literature, in this section we first describe the broad spectrum of activities that might be termed CE, followed by a discussion of the theory and practice of the concepts' core components. Given the complexity of terms and the range of potentially conflicting goals of CE, we end this section by highlighting the importance of clarifying the range and scope of goals in CE initiatives.

A BRIEF SNAPSHOT OF THE RANGE OF ACTIVITIES AT DIFFERENT LEVELS

"Community engagement" is an active area of work, encompassing a myriad of activities operating at various levels (Bandewar et al., 2010; Leach & Fairhead, 2007; Marsh et al., 2008; Marsh et al., 2010; Tindana et al., 2007; Tindana et al., 2011). Participatory (action) research is by definition a form of CE with associated ethical dilemmas and approaches (Bastida et al., 2010; Brugge, 2012; Shore et al., 2008), and there is much to learn about CE from participatory research approaches. However, as noted above, in this paper we are focusing on CE in more "traditional," nonparticipatory biomedical research contexts.

Many research institutions with a long-term presence in the geographical areas where they conduct their research conduct a diverse range of CE activities (Table 2). CE activities may be *institution wide* (such as those sharing information about research and the research institution with entire communities) or designed for *specific studies*. Program-wide and study-specific CE sometimes overlap. For example, during community meetings, information could be provided about the research institution and about a particular study. Several research institutions have a group of staff with CE as their main remit. Multiple materials may be used including leaflets, facts sheets, posters, videos, or other forms of "edutainment" (Treffry-Goatley, Mahlinza, & Imrie, 2013).

Beyond the geographical areas in which research institutions are based, involvement of communities also takes place at national and international levels through, for example, community members' involvement in the development of international guidelines. The 2008 Good Participatory Practice guidelines for HIV trials incorporated contributions from representatives of communities in multiple countries. Community members have also been involved in the design and review of studies, including the design of consent processes for those studies (see, for example, Cheah et al., 2010; Terry et al., 2007; Tindana et al., 2011; Vallely et al., 2010; Vanlerberghe et al., 2009).

DEFINING COMMUNITY

A key challenge emerging in discussions of CE relates to definitions of the core components: "community," "engagement," and "representation." Broadly, definitions of community can be based on geography, on special interests or goals, or on shared situations or experiences (Ragin et al., 2008). For individuals, community membership may be choice based (for example, membership in a women's group) or linked to characteristics (such as age or ethnic group). People are always members of multiple communities, with membership shifting over time and space. Membership of communities may be internally or externally defined.

In much healthcare research, relevant communities are often initially defined by researchers who are external to communities (Marsh et al., 2011). Definitions of communities are therefore often related to the nature of the research activity (e.g., does it involve a particular geographical area or illness group?) and location of the research institution (e.g., is it based in a rural or urban setting?).

A study or the CE for a study can lead to the disruption or the creation of communities (Bandewar et al., 2010; Gikonyo et al., 2008). For example, Bandewar et al. (2010) describe the creation of a community of sex workers in Nairobi, where no such community existed before. They note that the risks and benefits of research, including the social implications, can serve as the common bond that effectively turns disparate individuals into a community for the purposes of research.

At all levels, but particularly at national and international levels, the distinction between "CE" and "public engagement" is blurred. Depending on how communities are defined, any interactions with research stakeholders, such as Ministries of Health, ethics committees, policy makers, international organizations, the media, and universities, could be considered a form of CE.

DEFINING ENGAGEMENT

The brief snapshot of CE below (Table 2) points to a whole spectrum of approaches, mechanisms, and practices that might be termed "engagement." Engagement can include communities coming into research institutions or environments (e.g., visits, exhibitions, student placements), and institution staff going out to be with communities (e.g., participatory training, science cafes, drama, school visits). Activities can be continuous or one-off initiatives, and may be led or coordinated by members of a research team, by a group of community liaison officers or social scientists attached to the research center or by the communities themselves.

TABLE 2. An Overview of CE Activities and Reported Outcomes for Research Centers Participating in the Meeting.

CE Activities	Reported Outcomes
Consultation and opinion seeking • With "representatives" including opinion leaders (for example, chiefs and elders, women's group leaders), or typical members of the community, including through specifically established advisory groups • Through social science studies Interaction and information sharing with entire communities, including feedback • Public meetings in communities (for example, schools, health facilities, churches and mosques, community meeting areas or "cafes"), often including "edutainment" • Inviting community members and representatives into the research center or health facilities • Participating in traditional and local government council meetings regularly and on an ad hoc basis • Holding participatory workshops Targeted interaction and information sharing with potential participants for specific studies	Positive outcomes • For studies – better designed and communicated studies, and therefore more informed participants who are better motivated and less likely to withdraw • For participants and their communities – better understanding of studies and access to healthcare • Relationships – better mutual understanding between researchers, research institutions, and community members; and improved partnerships and relationships between researchers and community members, traditional leadership, and local government departments and authorities, including mutual respect and trust Perverse outcomes • Imparting incomplete knowledge – the potential for some information (for example, voluntariness in clinical research) leading to concerns about and refusal of standard clinical care procedures

Those who are "engaged with" include the range of communities described above, or more often "representatives" of those communities, and potential participants. Increasingly recognized is the importance of ensuring that engagement includes people who potentially have a key voice in communities, including local leaders, health providers and managers (Lang et al., 2011), and the research staff who interact with communities, such as doctors, nurses, and fieldworkers from local communities (Kamuya et al., 2013; Molyneux & Geissler, 2008; Nyika, 2009; Reynolds et al., 2013).

The Kilifi workshop highlighted the importance of informal "out of work" participation by research staff in community events (for example, weddings and funerals) as a form of engagement. Such forms of engagement are typically beyond the formal remit of CE plans, but are potentially important in shaping community members' views of research and research institutions. Thus, in addition to community liaison staff, fieldworkers and other institution staff often play an important role formally or informally at the "interface" between research institutions and communities (Kamuya et al., 2013; Molyneux, Peshu, & Marsh, 2005; Molyneux & Geissler, 2008; Molyneux et al., 2010; Reynolds et al., 2013).

Frameworks developed to evaluate community participation in healthcare (Arnstein, 1969; Loewenson, 2000) highlight that the creation of opportunities for involvement and consultation do not in themselves lead to community influence and control. In these frameworks the potential for "manipulation" or "token efforts" in initiatives is incorporated; a concern also raised by Slevin et al. in their background paper for AIDS2031 (Slevin, Morenike, & Lori, 2013). Concerns to avoid tokenism contribute to some definitions of CE *requiring* more than simple information giving, as noted in the introduction.

REPRESENTING COMMUNITIES

Cross-cutting the complexity of definitions of community and engagement is the different uses of the word "representation" in literature. Community representatives are often considered as central to learning about community priorities and concerns, either for specific studies or across studies (Morin et al., 2003; Morin et al., 2008; Quinn, 2004; Shubis et al., 2009). However the concept can be highly problematic. In some cases representatives are selected to "speak on behalf" of a particular community, in others individuals are considered as representatives in terms of having similar characteristics and views to others in the community (see Figure 6). When approaching potential community representatives it is important to be clear about the form of representation that individuals and groups are expected to have.

Important challenges for working with community representatives are: how to select representatives; how to balance motivation of representatives with independence from researchers in a way that facilitates critical and meaningful dialogue; how to ensure the most vulnerable groups and those least likely to be selected or vocal in representative groups are heard; and the potential for personal priorities and needs to dominate discussion (Bandewar et al., 2010; Brieland, 1971; Kamuya et al., 2013; Marsh et al., 2008; Marsh et al., 2010; Morin et al., 2003; Morin et al., 2008; Nyika, 2009; Reddy et al., 2010; Shubis et al., 2009; Strauss et al., 2001). To minimize these challenges, and to ensure interaction with multiple and diverse communities, many research institutions and studies engage with a range

The Tak Province Community Ethics Advisory Board
The Tak Province Community Ethics Advisory Board (T-CAB) was established on the Thai-Myanmar border in 2009. The T-CAB has 12–17 members who live in a range of different settings in the border area, both in Thailand and in Myanmar. The T-CAB goals are to advise on whether a study is acceptable to and perceived as beneficial by the communities in the region, to advise researchers on the ethical and operational aspects of proposed studies, and to act as a "bridge" between the communities and researchers. It provides communities with an opportunity to express views on proposed research and to influence and direct research aims, and also provides a means by which the researchers can feed the results of the research back to the community. The T-CAB members were selected pragmatically and so cannot be said to truly "represent" the community; rather, they are a diverse group of people who understand the border community well, have an interest in community work, are willing to serve voluntarily in the CAB, and, importantly, are literate in some of the languages used along the border, and are able to travel to meetings (Cheah et al., 2010; Khin Maung Lwin et al., 2013).

KEMRI community representatives (KCRs)
A network of 170 KCRs has been established in Kilifi, Kenya. KCRs are intended to be typical of the community residents in the areas where much research takes place, as opposed to being expected to speak on behalf of the community. KCRs are elected by local residents in an effort to ensure they come from a specific geographic area, are aware of ideas and concerns across the area, and are accepted by the people within it. This election process presents its own possibilities (for example, building relationships and a sense of collaboration between communities and the institution), but also presents challenges, such as community expectations that KCRs should be lobbying for greater research-related benefits and a possibility of KCRs being perceived as having "failed" if they do not do this (Kamuya, Marsh, Kombe, Geissler, & Molyneux, 2013).

FIG. 6. **Identifying individuals to speak on behalf of communities.**

of representatives, and proactively aim for some form of representation by gender, age, and geography. An emerging concern in approaching representatives in this way is how to deal with differences in views within and across different representative groups. Consideration of these issues highlights the importance of understanding CE not as a prefabricated set of activities that could apply to different settings, but as a dynamic and ever-changing set of negotiated relationships (Lavery et al., 2010).

THE IMPORTANCE OF CLARIFYING THE RANGE AND SCOPE OF CE GOALS

CE can simply be about how people behave when they encounter others in the host community, or about how to build on these encounters to achieve goals such as avoiding exploitation, ensuring fair benefits, and correcting historical malpractices. A range of goals were initially raised for CE initiatives in the workshop, including:

- Conducting successful research—for example, improving recruitment and retention rates
- Building relationships—trust and partnership
- Promoting understanding
- Strengthening capabilities for participants or communities
- Gaining permission and community consent
- Satisfying funders' requirements
- Satisfying intrinsic values such as respecting participants
- Identifying and addressing ethical issues
- Improving healthcare

The above goals or values can be broadly divided into those that are more instrumental, such as engaging communities to improve the quality of research (or simply satisfying funders), and those that are more intrinsic such as engaging communities to show respect or to ensure a sense of inclusion. There may be tensions between instrumental and intrinsic aims where intrinsically valuable community engagement does not achieve researchers' or research funders' instrumental goals. An example would be where responsiveness to community feedback leads to a decision not to proceed with a proposed study (Figure 7). Many workshop participants described a mix of both instrumental and intrinsic goals for their initiatives or strategies (see, for example, Figure 6) where the precise combination of aims was not always clearly articulated.

Over the course of the workshop the need for greater clarity on goals for CE emerged as important for three interrelated reasons:

1. There are potential tensions between differing aims. For example, in providing *improved healthcare* in response to community-identified needs for essential services, CE activities contribute to community perceptions of the research institution as a health

Changes have been made between the first and second version of the GPP guidelines for HIV prevention trials (UNAIDS, 2011). A key change was to highlight that while CE will ideally facilitate effective and collaborative research, in some cases, guidelines can also be drawn upon to determine whether or not to proceed with a particular study in a particular location. Reasons not to proceed might include: the community believes that proposed research is not responsive to local interests and demands; the sponsor does not support CE; or the sponsor does not recognize the value of reciprocity or the principle of respect for community autonomy.

FIG. 7. **Situations where studies may not proceed.**

provider, and therefore *undermine understanding* of research and of consent processes.

2. All CE has the potential to have a negative impact, at the very least through taking up people's time, but also through unintended perverse outcomes. Potential adverse outcomes include some individuals feeling obliged to take part in research through peer pressure, and raised expectations that cannot be met (Nyika, 2009; Reynolds et al., 2013). Another example is the danger of half knowing. CE is advocated to reduce therapeutic misconceptions and strengthen understanding of research and therefore informed participation in research (or informed refusal to participate). In practice, however, it can lead to deterioration in understanding through information being inadequately explained, or interpreted in unexpected ways. In Kilifi, for example, information sharing about the difference between research and clinical care, and about the voluntary nature of research, may have led to the rejection of much-needed clinical care on the assumption that the procedure was for research (Marsh et al., 2011).
3. There is clearly a limit to the ethical issues CE can resolve in research, including those related to historical and background injustices and inequities and poorly resourced health systems. The introduction of new or different benefits for individuals and communities, including improved health services, may be implemented on the basis of community members' recommendations made during engagement activities. However, it can be helpful to consider benefit sharing (including ancillary care debates) as separate from CE (Molyneux, Peshu, & Marsh, 2005; Molyneux et al., 2012; Tindana et al., 2011).

Beyond the above three reasons for clarity on goals, there is also the more pragmatic need to focus activities—both formal and informal—given the potential range and costs of CE.

Cross-cutting Issues: Relationships and Challenges in Evaluation

The previous two sections have indicated interplays between CE and consent. Throughout the workshop and in the literature, a series of interrelated cross-cutting ethical challenges to strengthening research practice can be highlighted, including complex social inequities, the key role of staff and volunteers working at the interface between researchers and communities, and the centrality of context, as discussed next. The importance and difficulty of including some of these aspects of CE and consent in evaluations are noted.

COMPLEX AND SHIFTING RELATIONS

Inequalities in social power permeate all CE and consent activities and discussions, including inequalities based on gender, class, age, generation, and color/race/ethnicities. These relationships work in complex and unexpected ways, and in ways that are constantly shifting over time (Cornwall & Jewkes, 1995). At an international level researchers have differential access to research funding and support, and differential abilities to negotiate for approaches to CE and consent that they consider are locally appropriate. At an institutional level, relationships between junior and senior research staff, and between researchers and service providers, can influence the nature and style of partnerships formed, and information shared and acted upon. Studies have shown, for example, that those with different roles in consent processes (e.g., principal investigators and research assistants) may have very different perspectives on consent and when it has been satisfactorily obtained (Lindegger & Van Loon, 2009). Politics can also play a pivotal role in CE and consent, with the nature and depth of engagement of particular communities in some settings depending on who has political authority locally.

Research staff and community representatives who work at the interface between research institutions and local communities constantly engage in and respond to complex power dynamics. For example, the gender of fieldworkers, and the ways in which they interact with different household members, can in some contexts shape the ways in which trust is built or dismantled (Kamuya et al., 2013). Within households and communities, gender roles and relations can also influence resource allocation, power and authority to make decisions about whether or not to consent to study participation, and attendance and inputs in different forms of CE activities (Lang et al., 2011; Molyneux, Wassenaar et al., 2005; Muhwava et al., 2007). Power relations can lead to complex discussions and negotiations within households about research participation (Kamuya et al., 2013); and power relations between patients and providers can lead to voluntariness being compromised.

The centrality of context—sociocultural, political, institutional, and study related (such as age and gender of participants)—is clear. Context influences what key communities might be, and how consent and CE activities might be defined, implemented, or perceived. For example, the history of an institution's (or senior individuals') engagement with a community will contribute to levels of trust, which will in turn influence community members' views about and willingness to participate in engagement activities and studies (Molyneux, Peshu, & Marsh., 2005). Whether a study is facility based or community based,

whether or not it involves a health intervention (and the form of the intervention), how sick potential participants are, and what procedures are involved, will all have important implications for power relations between front-line research staff and community members, and levels of stress and interest in research among individual(s) asked to make decisions (Mzimela et al., 2012). Whether communities and potential participants have access to healthcare, irrespective of research participation, will also have an important influence on decision making in some contexts.

CHALLENGES IN EVALUATING INTERVENTIONS

There are challenges to evaluating both CE and consent activities. Conceptual frameworks help identify what is expected to be affected and to develop appropriate methodologies. However, there is rarely a linear relationship between intervention implementation and impact, and it is often impossible to know what would have happened in the absence of what are often complex interventions or sets of interventions.

Although there is more published empirical research from low- and middle-income settings on consent than on CE, there is still relatively little information about the range of issues arising when seeking consent and how best to tailor consent processes to specific contexts. Rapid assessments incorporating a range of qualitative data collection methods such as direct observation, focus group discussions, and semi-structured interviews are a potentially valuable approach (Bull et al., 2012; Tekola et al., 2009b).

Recruitment rates are in themselves inadequate indicators of CE and consent "success," particularly in the absence of good-quality information on participants' or nonparticipants' understanding and voluntariness. Some key goals of interest—for example respect, autonomy, dignity, power, and trust—may be particularly difficult to measure using standard methodological approaches, and require careful conceptualization.

Indications of Best Practice

Different studies will raise different issues and concerns regarding consent, depending on the research design and context in which the studies are conducted. There are also differing implications for overlaps and relationships with CE. The goals for CE, including the links with consent, need careful consideration from the outset, and revision throughout the research process.

Relationship and contextual influences must be considered, and goals and planning of activities clearly articulated, to ensure that both CE and consent activities do not fall into the trap of becoming simplistic "tick-box" activities, or ritualistic initiatives that add relatively little value. Activities also have to be responsive to change in contextual influences, and therefore require monitoring and reflection over time.

Consent. CE and social science can provide insights into populations' priorities and needs regarding health and research, their understandings of research institutions and activities, the forms of information most needed, and the ways in which potential participants may interpret information about a study and make decisions (Mzimela et al., 2012). In some circumstances a case can be made for ensuring that core funding is available to support ongoing staff training and the staff that recruit participants. The design of resources such as consent templates and standard operating procedures (SOPs), and context-specific consent processes may also be supported. In strengthening consent documentation, it is essential to recognize that consent forms are only a small part of a substantial process including CE. Relevant relationships begin before a specific study is introduced, and change during and on completion of research.

CE. The importance of considering and revising goals before and throughout studies is essential to plan and evaluate CE activities. CE activities should not be seen as a prefabricated set of activities that could apply to different settings, or that are static and set at the outset of any particular study. CE activities should be seen as a dynamic and ever-changing set of negotiated relationships (Lavery, 2010).

Beyond consent and CE, access to medical care and other benefits for individuals and communities during and after studies needs careful consideration in research. These factors are key ethical issues in themselves, are often raised and discussed in community engagement activities, are important to understand as part of information provided about research, and feature strongly in community members' decision-making processes.

Toward a Research Agenda

Consent and community engagement (CE) are two aspects of a single aim, to support research that is respectful to individuals and communities where social value is maximized. At the Kilifi workshop it became clear during discussions of challenges arising in both CE and consent that achieving this aim in practice is not straightforward, and that many questions arise without simple answers. A need was identified for more social science research into how best to respond to the range of issues identified. Topics ranged from formative research to inform potential future initiatives, to research evaluating how well current initiatives are working. Methodological creativity and

innovation is much needed, including both quantitative and qualitative methods, and participatory, deliberative, reflexive, and philosophical approaches. For "empirical ethics" studies—where empirical data are combined with ethical analysis to allow normative claims—there is also scope for new approaches where normative argument and justification are incorporated directly into the process of collecting and analyzing data (Dunn et al., 2012). Community liaison officers and community representatives were underrepresented at the workshop, and so consultation with such key stakeholders will be critical when setting local research agendas.

A range of possible issues to follow up through empirical research have been highlighted in this paper:

Clarifying the goals and value of CE, and how these might differ in different contexts. Research could help describe the range of CE goals/values that have been identified, and inform debates on if and when CE should happen, and in what form. Recommendations are expected to differ for different types of research (e.g., emergency research versus community-based trials involving healthy children) and in different contexts (e.g., politically unstable or mobile populations versus relatively stable populations).

Comparing CE activities and impacts across different types of research and in different contexts. We need detailed descriptions of CE activities, and ways to evaluate their effectiveness. This will in turn require clarifying and comparing the goals and underlying values of activities, and the intended or expected outcomes. We need conceptual frameworks that consider depth of responsiveness to local populations/communities, and documentation of perverse outcomes.

Incorporating relational aspects of consent more centrally into consent plans and evaluations. Trust and power relations play a central but complex role in consent processes. These relational aspects of consent need careful attention, including asking: What are these relational influences? How do they work? What are the implications for consent processes? Do these relations influence who should be involved in consent processes and the support that they need? If so, why and how?

Examining the design and conduct of consent processes. Across many different settings, a range of innovative approaches are aimed at strengthening consent processes, facilitating understanding of studies, and supporting free decision making. These initiatives need to be documented and examined, and the findings shared and reflected upon.

Considering the deliberative spaces in which research institutions and studies operate. Researchers often work with community representatives. Clearer articulation of the similarities and differences between different representative groups is needed, in relation to goals of establishing or working with groups, forms of representation, and intended and actual use of deliberations with representatives in research practice. Specific questions include: Who is representing whom and in what way? How do we ensure that there are "authentic voices" in these discussions? What do we do with differences of opinion? What types of relationships are ultimately established between research institutions and communities? Reflection on experience with current practice would be a useful starting point, followed by carefully designed prospective studies.

Engaging with communities across multicenter studies. As multicenter studies continue to expand, there is an interest in documenting and researching the more specific issues and concerns that emerge from these studies from the perspectives of different actors involved. Innovative participatory approaches could include, for example, bringing together community liaison officers and community members/representatives from different sites to discuss on-the-ground realities, with inputs from ethicists and academics.

Educational Implications

We have focused on CE and consent at the level of interactions between researchers (and institutions) and study communities in international research contexts. The complex and contested nature of consent and especially CE is clear. Educational materials and activities need to clearly define the meanings of communities, engagement, and representation in relation to the goals of CE. Also to be highlighted are challenges to achieving "genuine," "true," or "authentic" consent, and therefore the need for innovative approaches to maximizing understanding and voluntariness in different contexts through carefully developing consent processes tailored to local contexts. It is essential to emphasize that neither CE nor consent can be a prefabricated set of activities that is static over time and place; both are dynamic and negotiated relationships. Researchers, ethics committee members, and community members have the potential to benefit from social science studies that incorporate methodological innovation.

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Authors' Biographical Sketches

Given the length of the author list, we have only included biographical sketches for the two main authors: Dr. Sassy Molyneux and Dr. Susan Bull. Dr. Molyneux prepared the first draft of the paper and Drs. Bull and Molyneux amended it extensively. The remainder of the authors contributed to the ideas expressed in the paper, and read and commented on the draft manuscript.

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