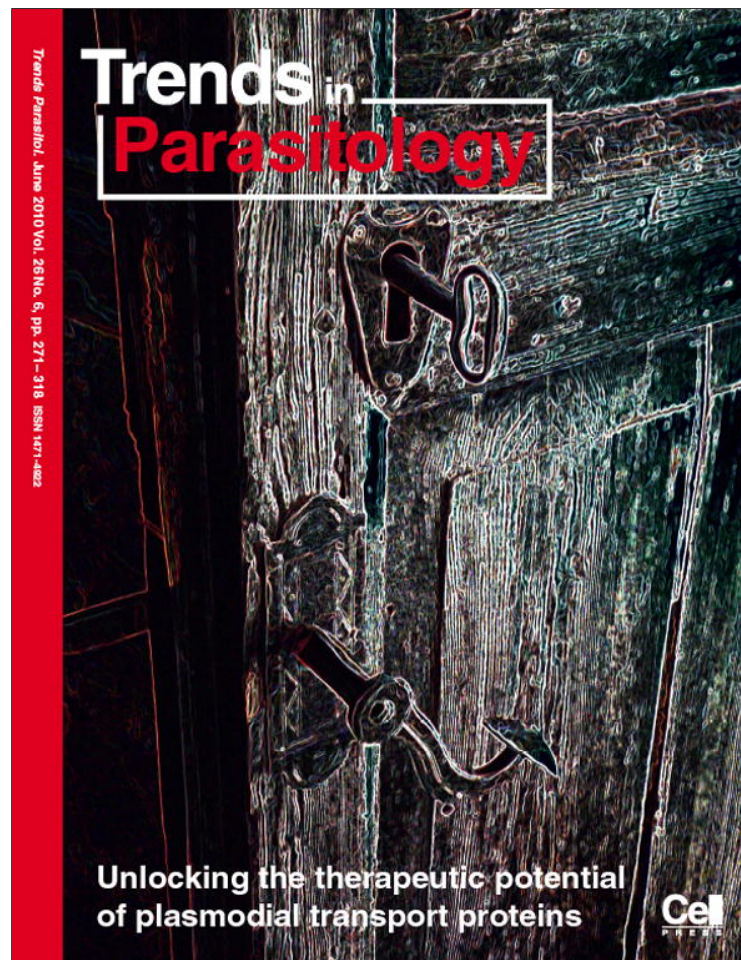


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Towards a framework for community engagement in global health research

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New technologies for global public health are spurring critical evaluations of the role of communities in research and what they receive in exchange for their participation. Community engagement activities resulting from these evaluations are most challenging for novel scientific ventures, particularly those involving controversial strategies and those in which some risks are poorly understood or determined. Remarkably, there is no explicit body of community engagement knowledge to which researchers can turn for guidance about approaches that are most likely to be effective in different contexts, and why. We describe here a framework that provides a starting point for broader discussions of community engagement in global health research, particularly as it relates to the development, evaluation and application of new technologies.

Community engagement in research

There has been an evolution in thinking during the past decade about the role of communities in research projects, and the protections and benefits owed to them in exchange for their participation [1]. Insights into how communities can be harmed or exploited, intentionally or otherwise, and a growing recognition of the political, economic and cultural assumptions that shape the global discourse and practice of 'development' [1–4] have fostered greater attention to the process and substance of community engagement (CE) in research [5–7], particularly in developing countries and aboriginal communities [8–12].

CE is a central theme in the women's health movement, environmental health activism and more broadly in mobilizing communities for political action [13–15], but its impact to date on biomedical research has been modest. Although there is increasing awareness and attention to practices, and reporting and critical evaluation are becoming more common [5–7,10], there is a dearth of literature to guide researchers in the effective application of CE activities. Thus, CE practices remain as much art as science and

what makes them effective is still determined largely by a combination of intuition, experience and opinion. Yet, while the science and practice of CE matures [5–7,16], investigators must engage communities in their research because failure to do so might have both ethical and scientific costs.

We describe here a framework based on principles and 'points to consider' that was developed to guide CE in a collaborative study in Mexico involving genetically engineered mosquitoes to prevent dengue virus transmission [17]. Funded under the Grand Challenges in Global Health (GCGH) initiative [18], this project studies genetic strategies to prevent infection by reducing the density of the principle mosquito vector *Aedes aegypti* and/or limiting the ability of the insect to transmit viruses. The CE framework was developed collaboratively with the Advisory Service of the Ethical, Social and Cultural (ESC) Program for the GCGH [19]. Although this framework evolved from a specific research project, our larger objective was to provide a starting point for a broader discussion of the purpose and effectiveness of CE in global public health research, particularly as it relates to the testing and introduction of new health technologies. Our intent was to achieve the highest-quality and most-respectful CE with the collaborating communities, and thereby contribute more generally to the developing dialogue about such activities in research. By making our assumptions explicit, publicly available and open to scrutiny, we invite attention and response that might strengthen both our approach and conceptual basis of CE in biomedical research in general.

Effective community engagement: a framework

The 12 'points to consider' (Box 1) evolved from published reports with an emphasis on those that avoid exploitation in research [3,5,11,20]. Important concepts came from community development, sociology, anthropology, agriculture, environmental health, public health, political science, civil society and non-academic literature. An on-going challenge is to ensure that relevant insights and experi-

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Box 1. 'Points to consider' for effective community engagement

- (i) Rigorous site-selection procedures
- (ii) Early initiation of community engagement activities
- (iii) Characterize and build knowledge of the community, its diversity, and its changing needs
- (iv) Ensure the purpose and goals of the research are clear to the community
- (v) Provide information
- (vi) Establish relationships and commitments to build trust with relevant authorities in the community: formal, informal and traditional
- (vii) Understand community perceptions and attitudes about the proposed research
- (viii) Identify, mobilize, and develop relevant community assets and capacity
- (ix) Maximize opportunities for stewardship, ownership, and shared control by the community
- (x) Ensure adequate opportunities and respect for dissenting opinions
- (xi) Secure permission/authorization from the community
- (xii) Review, evaluate and if necessary, modify engagement strategies

ences of these disciplines contribute progressively to the development of high-quality CE. Although many points function at multiple stages in the process, the framework was ordered temporally to emphasize the step-wise development of CE activities.

Site-selection procedures

Site selection is important for determining whether candidate communities have the capacity to be active participants in research and a sustained CE program, rather than being simply passive, and perhaps reluctant, hosts [21]. In addition to biological and epidemiological criteria, the existence of national regulations or guidelines for research involving genetically modified organisms, internationally recognized expertise in insect vector control and a strong research capacity to ensure meaningful leadership from the collaborating scientists and institutions are important for the project. We identified the appropriate administrative authority in the proposed field-site jurisdiction, legal ownership of the preferred field sites and risks that the research would displace individuals or communities. Conditions were assessed for on-going negotiations and interactions with the community, existing data on community views regarding genetic engineering, the appropriate balance between informed consent with individual community members and other forms of collective community authorization, and existence of an adequate infrastructure for public engagement.

Early initiation of community engagement activities

Early initiation helps avoid putting communities in situations in which they are pressured to make hurried and perhaps ill-considered decisions solely to meet timelines of investigators. Although there is no accepted set of criteria for what constitutes early initiation, we coupled our activities to commencement of site-selection procedures. This allows sufficient time to make evaluations of the natural environment, social conditions and local infrastructure, to help identify relevant community stakeholders, and to set

in place plans to ensure that their perspectives are sought throughout the early stages of the project. This stepwise approach is important for developing appropriate CE activities.

Characterize and build knowledge of the community, its diversity and its changing needs

One of the greatest challenges is identifying the relevant community. In the absence of a consensus about what constitutes a community for the purposes of a research project, or how to identify its members, we adopted two principles proposed by Brunger and Weijer [2]. First, the community comprises at least those individuals who share identified risks associated with the proposed research project. Second, that the community is not pre-existing and established, but rather takes form progressively in response to specific aspects of the research and to CE activities associated with the project. Characterizing the community identifies the individuals, groups, organizations, and agencies that have legitimate interests in the research so that they can be engaged effectively and in a timely manner. For example, the need to acquire land for the experiments in Mexico required that we present the research proposal to the *ejidatarios*, the stewards of the land, within the system of communal ownership of agrarian lands [22]. This point also allows for the on-going assessment of community needs and anticipation of changes within the community that might affect the outcome of the research or require adjustments in the CE approaches.

Ensure the purpose and goals of the research are clear to the community

The goal of our project in Mexico is to improve dengue prevention using approaches meant to complement existing vector-control strategies. This goal is emphasized during the provision of other information necessary to the community because it can be easily lost in the complexities of the scientific jargon of new and poorly understood technologies, and it helps to frame and justify the relevance of research activities. Familiarity with this goal contributes to a sense of community involvement and ownership of the research and facilitates modification of CE activities in response to community feedback.

Provide information

Information dissemination is critical when communities are invited to participate in research and take on any research-related risks. Communities must have adequate information about the project to permit a reasoned judgment about whether the research warrants community support and participation. Well-conducted site-selection procedures reveal the familiarity of the community with the problem being addressed. In our case, extensive interactions with a wide range of community stakeholders informed us of how the community understood the challenges of effective mosquito control and the relevance of testing alternative control strategies. It has helped ensure that the materials describing the research reflect local knowledge and are accessible to the general public. Information should include regulatory requirements, accounts

of risks and potential benefits of the research. When there is little likelihood that the research will result in direct health benefits for the community, it is essential to explain the importance of the work for establishing proof-of-concept for future initiatives that might hold greater promise of benefit.

Establish relationships and commitments to build trust with formal and informal authorities in the community

All communities have some form of authority for collective decision-making or action, and relationships of trust must be established with key individuals and groups. These authorities may be formal (municipal, state and federal governments) or informal (key opinion leaders, civil society or faith-based organizations). In many developing countries, there may also be traditional authorities who serve the community. The involvement of authentic leaders and institutional collaborations provides the community with a sense of familiarity, ownership and security, and establishes the basis for mutual trust. For example, because mosquito traps for our research might be distributed around and inside homes and other structures, introductions of the project supervisors and field staff that monitor them helps avoid the misunderstanding and apprehension that arises when unfamiliar people are suddenly present in unusual ways in the community. Similarly, if these relationships are established early, field workers will be more likely to trust insights and guidance from community members that arise in the course of their work.

Understand community perceptions and attitudes about the proposed research

This point reduces implementation of research practices based on poorly founded assumptions of relevance to the host community and taking community acceptance for granted. There is an inescapable tension between scientific interests, which aim to develop and test interventions that can improve health, and community concerns that their needs and interests will be treated as less important than the research itself. This concern stems from the relatively poor record of international research to bring about health improvements in host-country communities and close the health gaps between developed and developing countries [23]. Rather than assuming that community attitudes can be anticipated in advance, as would be required to prepare surveys of perceptions, attitudes and experiences [24], we believe it is better to establish citizen councils [25] or focus groups that allow community members to express their perspectives in their own terms, rather than relying solely on the concepts and pre-determined questions of the investigators. By beginning this process with key informants from within the community, it is possible to utilize methods of sequential referral sampling (whereby key informants suggest subsequent key informants, especially those with different perspectives) to identify positive and negative perspectives within the community. This approach can help refine understanding of social structure and community dynamics, especially when it is employed across different socioeconomic strata. Furthermore, we are concerned that current survey methodologies [26] could raise unrealistic expectations about the extent to which the

research activities can alleviate the health problems under investigation. Experience from clinical research shows that therapeutic misconception (confusing the primary purpose of research with therapy [27]) can engender feelings of abandonment and betrayal if the efforts do not result in the expected benefits. Although little is known about how this type of effect might work in contexts beyond the clinic, careful attention to site-selection, including well-planned site visits, can provide insights into community perceptions and minimize the impact of unmet expectations.

Identify, mobilize and develop relevant community assets and capacity

It is important to reveal the presence or absence of specialized skill sets or relevant context-specific knowledge. This point helps identify individuals or groups with project-relevant talents and skills that can be recruited to join the project. For example, our early activities reinforced the complexity of the CE challenge, and a local anthropologist was recruited to expand (in collaboration with the community) an earlier version of the framework into a more complete strategy, one that is aligned more closely with the regional cultural background.

Maximize opportunities for stewardship/ownership/control by the community

Investigators should seek opportunities to invite active leadership from within the community and among the collaborating scientists. Local leadership can promote community adoption and control of some project activities. The research project, no matter how scientifically sound, sensitively conducted and genuinely relevant, is still imported into the community, and, as such, has the potential for some disruption. Participation by community members in meaningful ways helps limit the disruptive effect, to some degree, by naturalizing the research. The involvement of the *ejido* [22] in the selection, negotiation and completion of land purchase for field site development is an example of how the community has been encouraged to take ownership of key aspects of the project in Mexico.

Ensure adequate opportunities and respect for dissenting opinions

It is important to strive for the difficult balance between promoting potentially valuable science and respecting and deferring to the will of the community. One of the most controversial aspects of CE is whether communities are ever truly able to say 'no' to research proposals. Soliciting a full spectrum of views from the community reveals dissenting views and opposition either to the proposed research or to the more general aspects of the technology. To enhance the ability of the community to make informed decisions, mechanisms must be established to engage opposing views and ensure appropriate deliberations.

Secure permission/authorization from the community

Authorization is at the center of a contentious debate in the research ethics literature about how and whether informed consent practices designed for individual research partici-

pants can be applied in studies involving communities [28,29]. Despite the fact that the concept of 'community consent' has become part of the research ethics vernacular, there are no clear models of how to achieve it in practice. Current approaches involve collections of individuals from whom informed consent has been sought, or explicit permission or authorization from community leaders [30], or a combination of both. The combined approach is often linked to compliance with the relevant regulatory requirements. Although democratic deliberation is proposed to 'promote the legitimacy of collective decision-making' [31], this approach has yet to be influential in research. We assert that more can be done using focus groups, citizen councils, and other creative means [25] to elicit the advice of the community and, in particular, determine whether individual informed consent is necessary or even appropriate under these circumstances. Improving the authenticity and legitimacy of community decisions in research is expected to require increased emphasis on deliberative methods and should be viewed as an on-going aspect of the relationship between the community and the research team. Throughout the research, mechanisms incorporating community-defined criteria should be developed to re-visit and confirm permission and/or authorization.

Review, evaluate and, if necessary, modify engagement strategies

This point reflects our belief that CE is a complex social phenomenon that defies simple description or mechanization. As such, the requirement for continual review and evaluation by both investigators and communities is a key feature of the framework. A commitment to on-going review and evaluation serves to remind all participants of the complexity of CE and the poorly developed understanding of what constitutes effective activities [5]. It also provides an on-going platform for incorporating a wide variety of community perspectives into the research, especially critical feedback that can improve the CE process. This type of strategy can encourage new scholarship on CE in research and greater attention to literature in cognate fields, thus expanding the available insights on the topic.

Developing and implementing the framework

The process of developing and implementing the framework presented here illuminated the scarcity of CE guidance for the introduction of new technologies and the potential for risky divergence between researchers and communities on fundamental issues related to research trials. Although we have embraced this framework as a reasonable starting point for our own activities, we expect its greater contribution might lie in providing an early 'target' for others currently considering these issues to make recommendations for improving CE. Regardless of its specific shortcomings, this framework serves as an example of how global health investigators can more meaningfully and effectively engage with the communities who host their studies. Despite a growing emphasis on collaboration and inclusion of communities in research, the accompanying CE activities, if any, fall far short of most of the principles and practices described here. We suspect

that too few researchers authentically grapple with questions about what the precise nature of a given research community is, what constitutes fair and meaningful authorization by a community, whether dissenting voices should be afforded a fair opportunity for expression, or whether some control of important aspects of a research project can truly be ceded to the community without compromising the quality or integrity of the research. These and other issues reflected in this framework could have important implications for the way research is funded, investigators are trained, and obligations to communities are conceptualized and codified in guidance. As research ethics moves inexorably towards greater appreciation of the relationship between global disparities and collaborative obligations of investigators [19], investigators who embrace these challenges will contribute to the long-term goal of developing ethically sound and increasingly effective practices in community engagement in research.

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References

- 1 Weijer, C. and Emanuel, E.J. (2000) Protecting communities in biomedical research. *Science* 289, 1142–1144
- 2 Brunger, F. and Weijer, C. (2006) Politics, risk, and community in the ICBG-Chiapas case. In *Ethical Issues in International Biomedical Research: A Casebook* (Lavery, J.V. et al., eds), pp. 35–42, Oxford University Press
- 3 Gbadegesun, S. and Wendler, D. (2006) Community exploitation. *Bioethics* 20, 248–253
- 4 Escobar, A. (1995) *Encountering Development: The Making and Unmaking of the Third World*, Princeton University Press
- 5 Tindana, P.O. et al. (2007) Grand Challenges in Global Health: community engagement in research in developing countries. *PLoS Med.* 4, e273 DOI: 10.1371/journal.pmed.0040273 (www.plosmedicine.org/)
- 6 MacQueen, K. and Cates, W., Jr (2005) The multiple layers of prevention science research. *Am. J. Prev. Med.* 28, 491–495
- 7 Marsh, V. et al. (2008) Beginning community engagement at a busy biomedical research programme: experiences from the KEMRI CGMRC-Wellcome Trust Research Programme, Kilifi, Kenya. *Soc. Sci. Med.* 67, 721–733
- 8 National Bioethics Advisory Commission (2001) *Ethical and Policy Issues in International Research* (Vol. 1), NBAC. (<http://bioethics.georgetown.edu/nbac/human/oversumm.html>)
- 9 Nuffield Council on Bioethics (2002) *The Ethics of Research Related to Healthcare in Developing Countries*, Nuffield Council on Bioethics
- 10 HIV Prevention Trials Network (2007) Community involvement toolbox. (http://www.hptn.org/community_program/community_involvement_toolbox.htm)
- 11 Canadian Institutes for Health Research (2007) *CIHR Guidelines for Health Research Involving Aboriginal People*, CIHR. (http://www.cihr-irsc.gc.ca/e/documents/ethics_aboriginal_guidelines_e.pdf)
- 12 National Health and Medical Research Council (2003) *Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research*, NHMRC. (http://www.nhmrc.gov.au/files_nhmrc/file/health_ethics/human/conduct/guidelines/e52.pdf)
- 13 Ferree, M.M. and Martin, P.Y., eds (1995) *Feminist Organizations: Harvest of the New Women's Movement*, Temple University Press
- 14 Lavery, J.V. et al. (2003) Ethical issues in international environmental research. *Int. J. Hyg. Environ. Health* 206, 453–463

- 15 Freire, P. (2000) *Pedagogy of the Oppressed*, (30th Anniversary edn), Continuum
- 16 Newman, P.A. (2006) Towards a science of community engagement. *Lancet* 36, 302
- 17 Grand Challenges in Global Health (2008) Genetic strategies for the control of dengue virus transmission. (<http://www.gcgh.org/ControlInsect/Challenges/GeneticStrategy/Pages/DengueTransmission.aspx>)
- 18 Varmus, H. *et al.* (2003) Grand challenges in global health. *Science* 302, 398–399
- 19 Singer, P.A. *et al.* (2007) Grand Challenges in Global Health: The ethical, social and cultural program. *PLoS Med.* 4, e265 DOI: 10.1371/journal.pmed.0040273 In: www.plosmedicine.org
- 20 London, A.J. (2005) Justice and the human development approach to international research. *Hastings Cent. Rep.* 35, 24–37
- 21 Lavery, J.V. *et al.* (2008) Ethical, social, and cultural considerations for site selection for research with genetically modified mosquitoes. *Am. J. Trop. Med. Hyg.* 79, 312–318
- 22 Wikipedia contributors (2008) Ejido. (<http://en.wikipedia.org/wiki/Ejido>)
- 23 Macklin, R. (2001) After Helsinki: unresolved issues in international research. *Kennedy Inst. Ethics J.* 11, 17–36
- 24 Macer, D. (2003) Ethical, Legal and Social Issues of Genetically-Modified Disease Vectors in Public Health. Social, Economic and Behavioural Research. Special Topics No. 1, TDR/WHO. (<http://www.eubios.info/gminelsi.pdf>)
- 25 Smith, G. and Wales, C. (2000) Citizen's juries and deliberative democracy. *Polit. Stud.* 48, 51–65
- 26 Koenraadt, C.J.M. *et al.* (2006) Dengue knowledge and practices and their impact on *Aedes aegypti* populations in Kamphaeng Phet, Thailand. *Am. J. Trop. Med. Hyg.* 74, 692–700
- 27 del Melo-Martin, I. and Ho, A. (2008) Beyond informed consent: the therapeutic misconception and trust. *J. Med. Ethics* 34, 202–205
- 28 Molyneux, C.S. *et al.* (2005) Even if they ask you to stand by a tree all day, you will have to do it: community voices on the notion and practice of informed consent for biomedical research in developing countries. *Soc. Sci. Med.* 61, 443–454
- 29 Chokshi, D.A. *et al.* (2007) Valid consent for genomic epidemiology in developing countries. *PLoS Med.* 4, 636–641
- 30 Diallo, D.A. *et al.* (2005) Community permission for medical research in developing countries. *Clin. Infect Dis.* 41, 255–259
- 31 Gutmann, A. and Thompson, D. (1997) Deliberating about bioethics. *Hastings Cent. Rep.* 27, 38–41