AsPac J. Mol. Biol. Biotechnol. 2010
Vol. 18 (2) : 247-250

Achieving precaution through effective community engagement in research with genetically modified mosquitoes

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Received 17th July 2009 / Resubmitted 6th March 2010 / Accepted 31st May 2010

Abstract. The testing and introduction of new biotechnologies are often controversial, especially because of uncertainty about their risks and potential benefits. One of the main concepts dividing proponents and opponents of GMOs is the "precautionary principle", the idea that new technologies should not be introduced until their risks are identified and thoroughly understood. In this paper, we draw on the arguments of Welsh and Ervin to argue that early and effective community engagement can satisfy some of the fundamental aims of precaution, and promote innovation to improve safety and effective implementation, without imposing a moratorium on promising research. The precaution through experience approach implies that affected non-scientists can provide critical insights that can help scientists improve their technologies and/or help illuminate the necessary social pathways that may help ensure the effective and ethical testing and implementation of their technologies. Conducting community engagement effectively and early in the process of technology development, may represent a valuable new application of the precautionary mindset, to identify issues from a range of stakeholder perspectives and encourage innovation early enough in the process that it can actually make a difference.

Keywords: Community engagement; Modified mosquitoes; Precautionary principle; Precaution through experience.

INTRODUCTION

The testing and introduction of new biotechnologies are often controversial because of a lack of theory and evidence for policy decisions (Welsh and Ervin, 2006), especially uncertainty about their risks and potential benefits. These conditions have been true, in general, for genetically-modified organisms (GMOs), and in the case of GM crops, the conflict has resulted in deeply entrenched positions and the virtual absence of shared frameworks for effective decision-making (Falkner and Gupta, 2009).

One of the main concepts dividing proponents and opponents of GMOs is the "precautionary principle", the idea that new technologies should not be introduced until their risks are identified and thoroughly understood. Although precise definitions vary, the precautionary principle is, in effect, an expression of prudence in the face of uncertain risk (Morris, 2000). In general, prudence is a reasonable approach to uncertainty. But in global health the sheer magnitude of the background and health problems can make a prudent approach look reckless (Miller and Conko, 2001). For example, when Zambian president Levy Mwanawasa cited the precautionary principle as grounds for his country's refusal to accept GM corn as emergency food aid during the severe food shortages of 2002 (Bohannen, 2002), his decision placed millions of people at risk of preventable starvation. Precaution in one direction exposed a huge vulnerability in another direction.

As innovative vector control technologies move into contained field-testing, and ultimately open release trials, there is potential for underlying tensions to be exacerbated. In fact, as recently as 2005 50% of the malaria research and control community assembled at the 4th meeting of the Multilateral Initiative on Malaria (MIM) in Cameroon reported that they believed "stakeholder tension [will] undermine the ability to solve ethical, legal and social issues related to the release of GM mosquitoes" (Knols et al., 2007).

In this brief commentary, we propose that there is an opportunity arising, as innovative vector control strategies

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mature to the point of caged field trials and open-release trials, to reflect on lessons from the global controversy surrounding the testing and introduction of other GMs, such as GM crops, to improve on both the ethics and impact of these introductions for global health. We draw on the arguments of Welsh and Ervin (2006) to argue that early and effective community engagement can satisfy some of the fundamental aims of precaution, and promote innovation to improve safety and effective implementation, without imposing a moratorium on promising research.

Re-purposing precaution. A defining feature of approaches to technology assessment and regulation informed by the precautionary principle is that they accept input from non-scientists as valid and informative (Welsh and Ervin, 2006). In addition to arguments that the precautionary principle may actually be worse for global public health than more aggressive deployment strategies because it can delay, or even prevent, the introduction and refinement of potentially beneficial technologies (Miller and Conko, 2001), some have also argued that it may limit the kind of social learning that arises from trial and error and is required to identify problems and innovative solutions (Wildavsky, 2000).

Rather than clarifying key questions to help forge social consensus around new technologies, science has become a tool for division in some politically sensitive areas, such as climate change and the testing and introduction of GM crops, creating factions, often with economic and political interests, that have become entrenched, leaving little space for constructive dialogue and deliberation (Jasanoff, 2000). Welsh and Ervin have proposed an approach to move beyond this type of impasse, which they call precaution through experience (Welsh and Ervin, 2006). Their approach involves a trial and error strategy for the introduction of new technologies, but advocates an early involvement of the public or other interested stakeholders, so that precautionary concerns can be utilized to drive innovation early in technology development (Jasanoff, 2000), rather than imposing the precautionary principle at the point of commercialization or implementation, when there are "sunk" costs and enormous time pressures to recover them. Introducing non-scientist perspectives at this later point is likely to be seen as obstructionist, even if the input is valid and potentially valuable (Welsh and Ervin, 2006), and is also likely to be seen by non-scientist stakeholders as tokenism.

The precaution through experience approach requires, in particular, that one cornerstone dimension of the precautionary principle be taken seriously, namely that affected non-scientists have unique knowledge and can provide critical insights that can help scientists improve their technologies and/or help illuminate the necessary social pathways that may help ensure the effective and ethical testing and implementation of their technologies. For the benefits of this approach to accrue, however, non-scientists must be taken seriously and the processes started early, before costs and pressures mount.

Focusing on communities. An ecological view of health recognizes that individuals are part of social, cultural, economic and political systems that have a profound impact on their health and well-being. It provides a framework for critical reflection about the 'community' context as an important determinant of health outcomes (Marmot et al., 1995) and as the ultimate context for the introduction of new biotechnologies.

Collaborative partnerships with communities are now widely recognized as an important strategy for successful public health interventions (CDC, 1997). In international collaborative research, partnership with communities has been recognized as a fundamental ethical requirement (Emanuel et al., 2004). In this context, community engagement serves as a tangible expression of respect for host communities. But it also reflects the recognition of the inherent ethical tension that is common in global health, when research programs are introduced from high-income countries (HICs) to low and middle-income countries (LMICs), often with inadequate preparation for the full range of potential social implications (Apffell-Marglin and Marglin, 1990; Benatar, 2001).

There is also increasing evidence that health initiatives are most likely to succeed if they receive support, input, guidance, and collaboration from the communities involved (Campbell and MacPhail, 2002; Campbell, 2003; Minkler, 2004; Speed, 2006). However, despite increasing emphasis on community engagement and community partnerships as pre-requisites for the ethical conduct of international collaborative research in LMICs (PATH, 2009; Marsh et al., 2008), current research ethics guidelines offer little practical guidance for investigators and communities, beyond the need for voluntary participation and informed consent, fairness in the distribution of harms and benefits and post-trial agreements. International research ethics norms remain ambiguous, at best, about how early or how actively host communities should be involved in the planning and implementation of research activities, and about the kinds of formal and informal authorization processes that are required from communities for research to be undertaken ethically.

Similarly, the inclusion of explicit socioeconomic considerations in the Cartagena Protocol on Biosafety has proven to be a contentious issue, with limited agreement about how they should be operationalized (Falck-Zepeda, 2009). Consideration of this type of impact does not mean that studies of new biotechnologies inevitably involve social disruption, or that all disruption of social structures is destructive, any more than the requirement to conduct toxicity testing in clinical drug trials entails that all drugs are toxic. Rather, fair consideration of potential social implications through engagement with host communities can provide important insights about community values and interests, as well as av-

enues to address potentially detrimental disruption. Importantly, these insights can offer concrete grounds for dialogue and creative collaboration, which, in itself, is likely to reduce any potentially disruptive impact of new technologies and enhance their positive impact.

Embracing community engagement in modified mosquito trials to drive precautionary innovation. Community engagement must be recognized as a key process in the testing and introduction of modified mosquitoes for the control of vector-borne diseases (Lavery et al., 2010). Empirical research to examine and illuminate community engagement practices and begin to understand what makes community engagement effective and ethical is a crucial first step (Tindana et al., 2007). We are currently engaged in a series of 10 case studies in a range of global health research contexts, including trials of modified mosquitoes, and expect to begin publishing the results of these case studies early in 2010. The cases each examine various aspects of community engagement and aim to elucidate community engagement practices that are effective from a range of stakeholder perspectives. A better understanding of what makes community engagement effective may also offer insights about the wide range of community interests that underlie research collaborations, such as the desire on the part of the community for meaningful responsibility and stewardship opportunities in the introduction of new technologies or programs. Moreover, it may help to identify mechanisms and strategies such as ways of securing community authorization for research, or models of research governance that may help ensure that effective technologies are taken up by the public health system, or successfully commercialized in ways that benefit the host communities.

Scientists are already burdened with many non-strictly-scientific responsibilities (Lavery, 2004) and they are rightly wary of lengthy processes that hinder, rather than facilitate their research. But conducting community engagement effectively and early in the process of technology development, may represent a valuable new application of the precautionary mindset—to identify issues from a range of stakeholder perspectives and encourage innovation early enough in the process that it can actually make a difference (Knols et al, 2007; Singer et al., 2007). Welsh and Ervin's approach may also increase the likelihood that safe and effective new technologies will be embraced by their target populations, since the type of active community engagement they envision is already known to be beneficial in several important ways (Campbell and MacPhail, 2002; Campbell, 2003; Minkler, 2004; Speed, 2006). Their model represents a potentially important step forward in the science of community engagement (Newman, 2006), which we believe should be pursued vigorously alongside the science of modifying mosquito vectors for disease control.

Of course, effective community engagement alone will not ensure success, since many conditions must be satisfied for technology development to function effectively (Singer et al., 2007). But we agree with Welsh and Ervin that a repurposing of precaution by the authentic and early inclusion of non-scientist perspectives in the technology development process can improve the likelihood that these new technologies will be tested and introduced with greater attention to their potential benefits and less suspicion and controversy.

FUNDING

Funding for this project is from a grant from the Bill & Melinda Gates Foundation through the Grand Challenges in Global Health Initiative.

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