



In cluster-randomised controlled trials, especially when an intervention can impact all households in a cluster and the surrounding area, ethical issues arise concerning not only the rights of individual subjects but also the fact that these individuals live in the same neighbourhood and constitute a community.

Existing guidelines such as the Helsinki Declaration [1], the Belmont Report [2] and Canada's Tri-Council Policy Statement [3] are mainly concerned with protection of individuals and their rights. Some guidelines speak of community participation in research. The Tri-council Statement has ethically nuanced special sections on research among indigenous communities. None of these manifests a consistent public health viewpoint.

Since the turn of the present century a growing number of voices have been arguing for adoption of a public health perspective in research ethics that takes into account not only risks and benefits to individual research participants but also those to the population as a whole [4–8]. The United Kingdom's Nuffield Council on Bioethics says that bioethical discussions should take ethical issues arising at the level of the population equally seriously and proposes a framework by which people can accept some personal restrictions in the interest of the wider population [9]. This framework is the "stewardship model", meaning mostly government stewardship. In the United States, the American Public Health Association adopted a set of Principles of the Ethical Practice of Public Health that seek to achieve a balance between the traditional concerns of public health with respect for the rights of individuals with the common good [10], while proponents of community-based participatory research have expressed dissatisfaction with the narrow focus adopted by some ethical review boards and called for new guidelines that protect not only individual research participants but also communities and populations [11, 12].

Here we discuss two ethical issues arising within Camino Verde, a cluster-randomised controlled trial of evidence-based community mobilisation for dengue control and prevention in Nicaragua and Mexico. The intervention had a positive impact on serological evidence of dengue virus infection in children, reported illness at all ages, and all dengue vector control indices [13]. The two issues arise from a particular approach adopted in the intervention and they concern the tension between individual and community rights and the tension that arises between researchers' responsibilities for ethical conduct of research and community autonomy in the conduct of an intervention.

In relation to the tension between individual and community rights, two ethical review boards for the Camino Verde trial questioned whether the intervention might lead to coercion and/or stigmatization of individuals.

The Oxford Dictionaries define coercion as the action or practice of persuading someone to do something by using force or threats [14]. Public health regulations such as quarantines, declaring certain locations to be smoke-free or requiring immunisations for entry into a country or a school, are coercive.

Erving Goffman famously called stigma "spoiled identity" [15]. Stigma links individuals to negative stereotypes, and stigmatisation can result in prejudice and discrimination [16].

Regarding the second tension, by community autonomy we mean that between researchers' responsibilities for ethical conduct of research and community responsibilities such as those to recruit new volunteers and train them not only in the technical aspects of mosquito control but also in respectful treatment of residents and obtaining individual informed consent for household visits.

From 2004 to 2007, the Nicaraguan office of the CIET Group, an international non-governmental collection of researchers, conducted a feasibility study of community mobilisation for dengue prevention in the capital city of Managua [17]. This study developed four main strategic elements that would guide the Camino Verde intervention: the use of community volunteers, called brigadistas; house-to-house visits, called *visitas de acompañamiento*; visits to schools, churches, shops, clubs and other organizations; and a wide variety of collective events.

While training the brigadistas to educate their neighbours about the dengue virus and the behaviour of the *Aedes aegypti* mosquito, researchers were also learning about the ethical climate already prevailing in these communities where neighbours had learned over many years to live with one another and cooperate under conditions of high residential density with severe limitations on water supply and other public services. These communities had long experience finding their own collective solutions to day-to-day problems. From the collaboration of researchers and brigadistas conducting household visits together, there developed an ethic of respect that was to guide the conduct of the Camino Verde trial in which 19 brigadistas from the feasibility study became the facilitators who trained the brigades that would be the trial's main driving force.

The Camino Verde trial was a collaborative effort between researchers at the University of California, Berkeley, two member organizations of the CIET Group

- the Centro de Investigación de Enfermedades Tropicales (CIET) at the University of Guerrero in Acapulco, Mexico and CIET in Nicaragua - together with 150 neighbourhoods: 60 of them in the Nicaraguan Capital, Managua, and 90 in three coastal regions of Guerrero state in southwest Mexico [13]. Data collection was limited to clusters of some 140 households in each neighbourhood but the intervention activities often extended beyond the cluster boundaries.

The baseline (August 2010–January 2011) and follow-up impact (August 2012–January 2013) surveys each included an entomological survey, collection of paired saliva samples before and after the dengue season to de-

should be done and how – seeking all the while to achieve consensus on the basis of free and informed decisions as to what can be done with the resources at hand. Through daily actions like these, learning occurs and an ethic of respect for others and their self-determination is built. –From an internal blog maintained by Nicaraguan investigators, facilitators and brigadistas [28].

Nevertheless, there are situations where community organisations are unable to engage in such a dialogue. This occurs especially with local businesses (stores, repair shops, scrap dealers, small factories, etc.) whose owners are inaccessible or uncommunicative. When all efforts at dialogue are exhausted, community leaders can and do call upon authorities to oblige the owners to control receptacles on their properties that are sources of contamination.

We believe that community mobilisation interventions such as the SEPA approach described here could become

A. Introduction

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Reference

Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans

Public health: ethical issues