

## Ethical challenges in cluster randomized controlled trials: experiences from public health interventions in Africa and Asia

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**Abstract** Public health interventions usually operate at the level of groups rather than individuals, and cluster randomized controlled trials (RCTs) are one means of evaluating their effectiveness. Using examples from six such trials in Bangladesh, India, Malawi and Nepal, we discuss our experience of the ethical issues that arise in their conduct. We set cluster RCTs in the broader context of public health research, highlighting debates about the need to reconcile individual autonomy with the common good and about the ethics of public health research in low-income settings in general. After a brief introduction to cluster RCTs, we discuss particular challenges we have faced. These include the nature of – and responsibility for – group consent, and the need for consent by individuals within groups to intervention and data collection. We discuss the timing of consent in relation to the implementation of public health strategies, and the problem of securing ethical review and approval in a complex domain. Finally, we consider the debate about benefits to control groups and the standard of care that they should receive, and the issue of post-trial adoption of the intervention under test.

Une traduction en français de ce résumé figure à la fin de l'article. Al final del artículo se facilita una traducción al español. الترجمة العربية لهذه الخلاصة في نهاية النص الكامل لهذه المقالة.

### Introduction

“I am because we are and because we are I am. A person is not a separated and isolated individual but a community of related individuals. Despite all this, an individual has the right to self determination and authorization.”

Joseph Mfutso-Bengo, Malawian bioethicist.<sup>1</sup>

This paper describes ethical discussions arising from our attempts to improve public health evidence in low-income settings. It considers two overlapping issues: the ethics of testing social interventions and the ethics of cluster randomized controlled trials (RCTs). We are not ethicists but public health practitioners who work on maternal and newborn survival, and our interest in ethics arises from operational challenges. We started our first cluster RCT a decade ago, and currently work on six: one in Bangladesh, two in India, one in Malawi, and two in Nepal (Table 1).

### Ethics of public health research in low-income countries

Recent papers on public health ethics in the *Bulletin of the World Health Organization* identify a need to reconcile the claims of individual and mass approaches,<sup>2–4</sup> a need encapsulated in the quotation with which this paper begins. The current emphasis of research guidelines on individual autonomy – the protection of the vulnerable – is primarily a reaction to historical tragedies.<sup>5–9</sup> It draws on the ethical tradition of de-

ontological morality: the question of whether research treats participants as they ought to be treated or as they have a right to be treated.<sup>5,10</sup> This accords with the Hippocratic obligation to benefit the individual patient and its hallmarks are consent to participation and the right to non-interference.<sup>11–14</sup> There are other possible perspectives. Public health research lends itself to utilitarian morals within which it should maximize health or happiness for the greatest number of people:<sup>5</sup> an action may be justified by its overall results rather than by its effects on the individual participant. This perspective, known as consequentialism,<sup>10</sup> is attractive but difficult because it reminds us of the very abuses that led to the drafting of the existing guidelines. Nevertheless, a focus restricted to individual self-determination does not necessarily resonate with our experience of social life, the connectivity between people and the public health agenda. We hesitate to generalize but it is worth floating the idea that the individualistic perspective is at least partly a product of European enlightenment thinking and that this may not always coincide with traditions of thought in other societies.

Discussions about research ethics in low-income countries have been dominated recently by concerns about trials of drug regimens to prevent mother-to-child transmission of HIV.<sup>15</sup> Contentious issues include the use of placebo control groups, the testing of interventions that are likely to be less effective than current best practice (with substantial discussion on how far best practice implies a global standard of care) and post-trial access to therapy.<sup>16–19</sup> Although the resulting

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(Submitted: 14 January 2008 – Revised version received: 10 October 2008 – Accepted: 6 January 2009 – Published online: 24 July 2009)

controversy has been beneficial – airing concerns about “North–South” relationships and inequity – it gives a limited impression of public health research partnerships in low-income countries.

It is easy to see that trials of public health interventions involve a tension between individual autonomy and potential public benefit.<sup>20</sup> Some interventions leave little option for voluntary participation, others more. Our work, for example, aims to improve the experience and outcomes of maternity. Much of it involves testing the effects of community women’s groups on morbidity, care seeking and mortality (Fig. 1). The intervention model is a cycle in which the groups discuss maternal and child health, identify problems and successes they and their neighbours have faced, prioritize issues for action, design strategies to address them, enact the strategies (either as groups or within the wider community) and evaluate their success (Fig. 2). The intervention is made on a background of sub-optimal health-care provision and usage, the point being that we are testing strategies to improve quality and uptake of appropriate care in a situation where health system best practice is an aspiration rather than a reality. The intervention requires participants to opt in: individuals have to make an effort to access it by joining and attending a community group and involving themselves in its activities.

## Cluster randomized controlled trials

The use of RCTs to test public health interventions is increasing, a predictable development given their importance as a source of evidence. The defining feature of a cluster RCT is that the unit of allocation is a group rather than an individual.<sup>21</sup> Cluster trials are important to public health for four reasons. Many public health interventions are delivered to groups, areas, institutions or systems collectively rather than individually; testing the delivery of an intervention to an individual might raise concerns if others are not included; individually-delivered interventions might spread among family, friends or the wider community; and we are often interested in the mass effectiveness of interventions that will be rolled out to the public with varying degrees of quality, uptake, adherence and response,

Fig. 1. A women’s group in Dhanusha, Nepal



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even if they have been shown to be efficacious in individual cases.<sup>22</sup> We will not discuss the issues of design,<sup>23</sup> analysis<sup>21,24,25</sup> and reporting of cluster RCTs,<sup>26–28</sup> but we think that researchers have an ethical responsibility to be aware of them, to seek advice and to report on the basis of appropriate analyses.<sup>27,29–31</sup>

## Challenges and responses

### Group consent

Cluster RCTs involve two levels of consent:<sup>28</sup> for the involvement of the group and the individual. Commonly, local guardians or representatives – elected leaders, community elders or group heads – act as cluster guardians who consent to participation. In communities in which collective decision-making is customary, communal leaders may express the collective will. To do this, they have to decide that participation is in the best interest of the community, a utilitarian judgement that may also be contested given that communities are usually amalgams of smaller communities.<sup>29,32</sup> In a complex society, how do we identify individuals – or groups – who speak for the many? How far can we say their guardianship extends to such a decision? We need to bear in mind that representatives will almost never have been appointed for the context in which we seek their assent and so their fitness for this role may be questionable.

We have found group consent challenging. At the minimum, we need to document the choice of representatives and the reasons for approaching them.<sup>33</sup> In all our trials, we have tried to make the process of cluster consent as open as possible. Since it is unlikely that one type of person can represent a community, we have sought agreement from a range of stakeholders. In most cases we have held community meetings at which the idea of the trial has been discussed and consent for it sought (Table 1 and Box 1). This has not always been written consent, which tends to have been reserved for elected representatives and village heads, but it has at least been inclusive.

Three examples provide food for thought. When the MIRA Makwanpur trial began in rural Nepal, we were able to engage the district development committee and village development committees in the process of cluster selection, randomization and allocation. However, as the crisis of governance associated with Nepal’s Maoist insurrection developed, the legitimacy and responsibilities of these institutions were contested. By degrees, the realities of running a trial in an area with two governments – each considered illegitimate by the other – became clear. We speculate that politics embodies the idea of cluster guardianship writ large, since it involves claims that individuals, parties and movements speak for larger groups. Indeed, the suggestion that a given leader might not be able to give

consent for the involvement of his or her constituency could be seen as an affront to such claims.

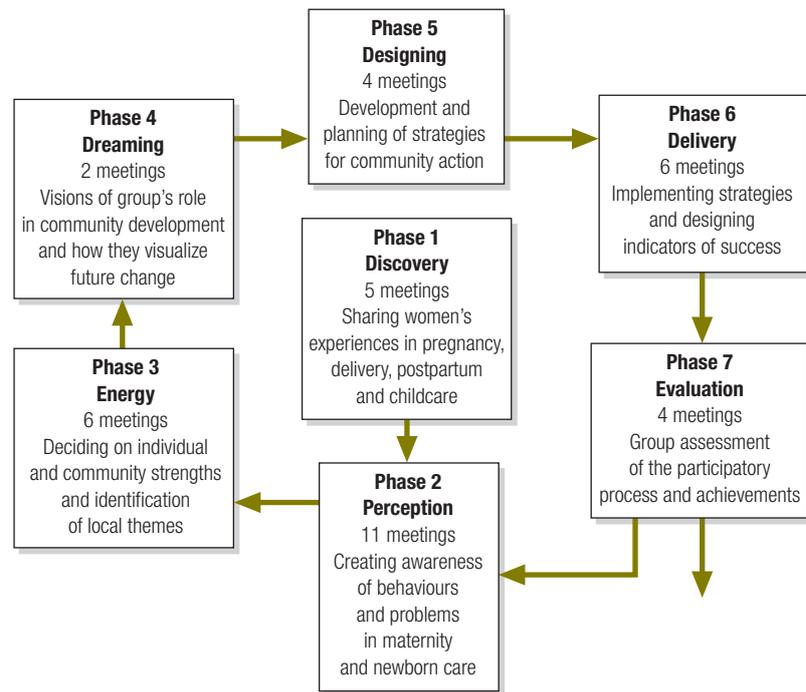
Difficult though this issue is, it becomes more confusing if the definition of a “cluster” is not based on existing geopolitical demarcations. In Mumbai, India, we work within vulnerable urban slum areas. This means that the boundaries of clusters are not obvious and they do not necessarily represent existing political or sociocultural spaces. Who gives consent for the inclusion in a trial of part of an urban agglomeration of densely packed but diverse humanity? Certainly, we have consent from municipal health service providers but, since one of the intrinsic problems is the lack of access to their services, it would be hard to say that they speak for a cluster. We have to fall back for permission on political and cultural leaders, elected members and community organizations, bearing in mind that it is always best to avoid associating public health interventions with specific political incumbents.

And what if the intervention under test aims to change the status quo? The Ekjut intervention in Jharkhand, India, tries to help women in underserved communities to take charge of their health needs. The process itself raises (at least conceptual) notions of empowerment and agency that could be seen as socio-politically destabilizing. How would potential cluster guardians deal with this possibility? More provocatively, how ethical is it to take consent from (mostly male) guardians who embody the social structure within which the participants will be manoeuvring? On balance, we feel that the opt-in nature of the interventions under test relieves us of at least some of the burden of anxiety. Cluster guardianship is less critical if individuals are able to decide for themselves whether to be physically involved in the trial; but perhaps this allows us to skirt the issue.

### Individual consent

Group consent is not a substitute for individual consent, which we think should follow similar lines to individualized studies. Participation may be related to the intervention itself and to data collection. Community members should be made aware of the trial and asked if they would like to participate. An individual's right to refuse to participate should be respected, despite

Fig. 2. Example of an intervention model: sequence of community group activities in the City Initiative for Newborn Health, Mumbai, India



consent at the representative level,<sup>32</sup> and trial documentation should clarify the opportunities for cluster members to avoid the risks associated with an intervention.<sup>33</sup>

All our trials require verbal consent for data collection. Participants are informed of the reasons for the exercise, the scope of the questions involved and the likely time required for an interview, as well as the fact that the decision not to participate will not be penalized. We have not so far been concerned about verbal consent in this context. From the intervention perspective, things are less concrete. In the Ekjut trial, for example, the agenda of the first women's group meeting is to seek consent for future meetings. This is obtained after explaining the approach that will be followed, that participation in meetings is voluntary and groups can decide not to meet. In the MaiMwana trial, Malawi, women's informed voluntary participation in intervention activities is considered to imply consent. We confess to some variation in the degree to which participants in women's group activities are aware of the study design or the existence of control groups. They tend to be invited to participate in the unmasked intervention and are informed that they are involved in testing a new approach which will be

compared with other areas that do not have women's groups.

### Timing of consent

Consent after randomization is common in cluster RCTs. Because of the scale of work, it is often easier to choose a population, define and draw a random sample of clusters in which the trial will be done, randomize the allocation, then seek consent from cluster guardians.<sup>34</sup> This conforms in general terms with Zelen's approach to individually randomized designs, in which consent is taken after randomization.<sup>35,36</sup> In an individualized trial, we seek consent for participation and explain the process of randomization so that the participant is aware that she may or may not receive the intervention under test. Presumably a similar approach should apply to clusters: we should seek consent from cluster guardians for inclusion in the trial and explain that data collection will be done across all study clusters, but that allocation will be random.

Table 1 shows that we have sought cluster guardian consent pre-allocation in several cases, but not in all. In our experience, community representatives have been able to grasp the idea of randomization easily: stakeholders in Makwanpur rapidly conceived the trial design as a lottery. One way of looking

Table 1. Six cluster randomized controlled trials conducted by the partnership for Population Science of Maternal and Child Survival

	Perinatal Care Project	Ekjut Project	City Initiative for Newborn Health	MaiMwana Project	MIRA Makwanpur	MIRA Dhanusha
<b>Country</b>	Bangladesh	India	India	Malawi	Nepal	Nepal
<b>Area</b>	Bogra, Maulvi Bazaar and Faridpur districts	Jharkhand and Orissa states	Mumbai municipality	Mchinji district	Makwanpur district	Dhanusha district
<b>Population</b>	480 000	228 000	300 000	170 000	170 000	417 000
<b>Clusters (intervention: control 1:1)</b>	18	36	48	48	24	60
<b>Cluster population</b>	25 000	6333	6250	3500	7000	7000
<b>Cluster parameters</b>	Villages making up a union	8–10 villages Residents classified as tribal or other backward castes	1000–1500 households in vulnerable slum area	Aggregated villages and group village headman areas	Village development committee	Village development committee
<b>Project partners</b>	Diabetic Association of Bangladesh (DAB) Women and Children First (United Kingdom-based charity)	Ekjut Government of India PRADAN (national voluntary organization) UCL Centre for International Health and Development	Society for Nutrition Education and Health Action (SNEHA) Municipal corporation of Greater Mumbai ICICI Centre for Child Health and Nutrition UCL Centre for International Health and Development	MaiMwana Malawi Government Ministry of Health Lilongwe Central Hospital UCL Centre for International Health and Development	Mother and Infant Research Activities (MIRA) Nepal Government Ministry of Health District Development Committee District Public Health Office UCL Centre for International Health and Development	Mother and Infant Research Activities (MIRA) Nepal Government Ministry of Health Local Development Committee District Public Health Office UCL Centre for International Health and Development
<b>Source of ethical approval</b>	DAB Ethical Committee	Independent ethics committee	Mumbai Independent Ethics Committee	Malawi National Health Sciences Research Committee Institute of Child Health Ethics Committee	Nepal Health Research Council Institute of Child Health Ethics Committee	Nepal Health Research Council Institute of Child Health Ethics Committee
<b>Pre- or post-allocation consent</b>	Post-allocation	Post-allocation	Pre-allocation	Pre-allocation	Pre-allocation	Pre-allocation

UCL, University College London.

at – and presenting – the situation is as a pilot test of an intervention in the first phase of roll-out. It is undoubtedly true that some representatives of control areas have been unenthusiastic by the fact that their areas are not to receive the intervention under test until a later date, and it would be disingenuous of us to claim that the process has been smooth sailing. However, if the idea of the RCT is rendered overt, consensus can usually be reached.

### Ethical approval

We have faced two particular challenges to ethical review.<sup>13,15</sup> First, it may not be easy to find an ethical committee to

which to put the case for an RCT. This is not the usual business of governmental public health. For example, although the City Initiative for Newborn Health was undertaken in partnership with the Municipal Corporation of Greater Mumbai, we struggled to find an ethical committee with sufficient mandate to be able to cope with review of a trial that involved operational research and social interventions: most ethical committees deal with clinical trials. A second problem is the blurred line between public health interventions and trials, particularly when trials are conducted as part of incremental changes in health services or community action.

When a trial is conducted in a sector with few precedents for ethical review, individuals within the system may not see it as necessary to apply for approval from an ethics committee or to seek group or individual consent. On the other hand, the Nepal Health Research Council, which reviewed the Makwanpur and Dhanusha trials, has a national role across the spectrum of health and has developed a great deal of experience. Members of the Council and the Ministry of Health also sit on the trial Data Safety Monitoring Boards. The same was true in Malawi, which has an active National Health Sciences Review and Ethics Committee.

**Box 1. Examples of ethical challenges faced****Consent from cluster guardians**

In all trials, the design of the cluster RCT was explained to cluster guardians before initiation.

Bangladesh: we held meetings and took verbal consent from community leaders, religious leaders, local chairmen, and elected administrative union heads.

India (Jharkhand, Orissa): we held open community meetings with village elders, opinion leaders and headmen. Written permission was granted by village elders. Clusters roughly corresponded with *panchayats*, although the project is spread across two states. In Orissa, *panchayats* have elected *sarpanchs* who acted as cluster guardians. In Jharkhand there had not been *panchayat* elections for some years and the debate about whether to hold them or to continue with the traditional system of governance involving village headmen is sub-judice: we obtained consent from traditional village headmen.

India (Mumbai): we held community meetings and took verbal consent from general practitioners, community-based organizations, non-government organizations, municipal representatives, health-post personnel, representatives of the Integrated Child Development Services, political officers of major parties and self-declared social workers. We explained to representatives what the community might contribute to the work: assistance with mapping, help to identify households, births and deaths, nominating community members to join the team and attending periodic meetings. In one area, we were advised to seek permission from a political leader (*bhai*), but were unable to meet him over 8 visits. A local general practitioner kindly discussed the trial with him and permission was granted.

Malawi: we held community meetings with district assembly members. We took signed consent from the District Commissioner, traditional authorities, group village headmen and village headmen.

Nepal (Makwanpur): we held open community meetings and took signed consent from heads of village development committees. Initially, one chairman asked for a donation to each village development committee before approval could be given. Chairpersons also applied pressure for us to employ personally recommended staff. Both these issues were resolved by a combination of resilience, a clear position and the support of the chairman of the district development committee, who emphasized the importance of the trial and our lack of financial wherewithal.

Nepal (Dhanusha): we held open community meetings and took signed consent from secretaries of village development committees.

**Consent by individuals**

In all trials, attendance at community group meetings is voluntary and group members have been told that the findings of their work will be compared with other areas in which groups are not active.

In all trials, verbal consent to data collection is taken after reading out an explanation. Participants are told that we hope that the data will contribute to the improvement of maternal and child health. The Jharkhand and Orissa trial Data Safety Monitoring Board recommended signed or thumbprint consent for individual data collection, and this has been introduced. We have disseminated baseline study findings to government and local stakeholders through programmes of meetings.

In Nepal, women in intervention clusters were told about the formation of community groups to identify the problems of women and children and to find local solutions. This information was conveyed both in women's groups and in households when interviewers visited to collect data. In control clusters, women were told that they happened to be in the control group by chance, and that only information on pregnancy, delivery, births and deaths was being collected in their area, while women's groups would be formed in other villages. They were also told that once the first phase of the trial was over, a similar intervention would be started in their villages. This was the earliest of our trials and the intervention was introduced in control areas in 2005.

We face some problems in clarifying the nature of the trial for individual women in control clusters. Since some of the trials involve a single visit for postnatal interview, interviewers explain that data are being collected to find out about maternal and child health to benefit local communities. Field staff have said that they find it difficult to put across the idea that somewhere else women are attending voluntary groups, but not in the respondent's area, and that the areas will be compared. In reality, the conceptual notion of denial of an intervention to the control area is manifest only in the lack of a (novel and controversial) local women's group, which the participant might not want to attend if it existed. Field staff have said that explaining this is challenging.

In Mumbai, although the trial involves a partnership with government, being identified too closely with government programmes can be a liability for participation. For example, family planning programmes do not have a good reputation among our participants, and we have found it necessary to assure them of our independence.

**Benefits to control areas**

Bangladesh: we undertook training in maternal and newborn care for health service providers and traditional birth attendants. Pregnant women were encouraged to use health facilities. Women's group members and trained traditional birth attendants accompany women to the facility as a result of which women get medical attention more readily.

India (Jharkhand, Orissa): we engaged with area health committees and conducted appreciative inquiry workshops for auxiliary nurse midwives. We helped to set up health committees in all clusters, to improve the links between communities and frontline public sector health providers.

India (Mumbai): as part of the wider City Initiative for Maternal and Newborn Health, we helped to upgrade health post structure and equipment, conducted appreciative inquiry workshops at maternity homes and undertook a programme of quality improvement at public sector hospitals in partnership with the municipal corporation.

Malawi: we undertook training in newborn care for health service providers and strengthening of the programme for prevention of mother-to-child-transmission of HIV, through multiplier funding.

Nepal (Makwanpur and Dhanusha): we undertook training in newborn care for all district health workers, community volunteers and traditional birth attendants. We provided equipment for all district health facilities and essential drugs for primary health centres and health posts.

(Box 1, cont.)

**Requests by participants**

Rural women's groups requested funds for travel and refreshments, common practice in non-government organization work (in Bangladesh and Nepal). We argued that the aim was for groups to be sustainable after withdrawal of support, and that such a provision was unlikely to be sustainable. In Nepal, since a small block grant was available for each group, we suggested that group members should decide on expenditure themselves.

Rural women's groups requested ambulances, building of roads and health facilities (in all rural projects to some degree). We emphasized that solutions had to come from the community, and that it was not within our capacity to offer these services. We developed linkages with providers and were able to advise participants on how and where to make a case for provision.

Urban women's groups requested medicines and fertility treatment (Mumbai, India). We developed guidelines and contact details for sources of care, which were provided by group facilitators.

RCT, randomized controlled trial.

**Benefits to control groups**

In the fall-out from the HIV research debate, advisory bodies have struggled with the question of what constitutes the appropriate standard of care for control groups.<sup>7,37</sup> In addition, because public health interventions are usually not masked, the possibility of “resentful demoralization” in members of control groups is high.<sup>38</sup> It seems to us, however, that the current debate has been limited to a technological frame of reference: testing a new protocol of care for a specific disease against optimal implementation of an existing protocol. Public health interventions may be conceptually different if what we are trying to do is improve the general quality and uptake of care in a situation of vulnerability, limited resources, inequity and system weaknesses. It makes little sense to test an improvement in a system against the best possible version of the existing system, since that is precisely where the problem lies.

The issue turns, we think, on equipoise – a state of uncertainty about the pros and cons of either therapeutic arm. If we genuinely do not know if a change in health services or community action will lead to better outcomes than the status quo, a trial is a sensible option, and it is reasonable for the individuals in control groups to experience existing health-care norms.<sup>39</sup> Failure to test interventions against current realities could deprive disadvantaged populations of incremental improvements in health. This is not an exemption clause: we believe that control groups should receive benefits for participation, although the scope of reasonable benefits is uncertain.<sup>14,40</sup> Provision of care that is not directly linked to the research question (*ancillary care*) is particularly important in low-income settings, and is a current topic of debate for the Malawi National Health Sciences Review

and Ethics Committee. As a research team, we hold to the maxim “no survey without service” and, in all of our trials, control groups receive benefits, summarized in Box 1. These extend to a duty of care for people in control clusters when data collection teams identify risks to health. We are happy to break protocol if individuals are at risk, assisting them, for example, with transport and negotiations for emergency medical care.

**Post-trial adoption**

As we have said, we see a cluster RCT as a first step in the roll-out of an intervention that may benefit public health. The intervention is introduced in a limited number of groups, its effectiveness is evaluated and, if the trial suggests that it is effective, it is rolled out to the control groups, with modifications based on experience. If the trial suggests that it is ineffective, control group individuals are protected from wasteful intervention. Participants in RCTs should have the opportunity to access superior care if the trial shows that one intervention is more effective than another, and communities involved in studies should benefit in the long run. If only things were this simple. First, we have found the cluster RCT to be less of a gold standard than it might appear. Trials often require replication to deal with questions about generalizability or simply to develop a groundswell of conviction. Health care involves politics, and so does research, and trial findings are exposed to a wide range of interpretation. Second, research funding bodies are generally not in the business of roll-out. This puts the onus on researchers to try to leverage uptake by (usually) the public sector. Again, if there is buy-in at a high level in the initial stages the process may be easier, but there is a difference between notional agreement and the

commitment of resources. Involving many partners in identifying, developing, conducting and disseminating research is one way to leverage such commitment. One of the issues for all our trials is the sustainability of the community women's groups after the trial ends. Withdrawal demands extensive discussions with group members. In all cases, we have agreed to give the control clusters the benefits of the intervention if it is shown to be effective. In some cases (Bangladesh, Jharkhand and Orissa, Mumbai), we have assurances of financial support for this from existing funders. In others, we are trying to negotiate a roll-out plan with government representatives.

**Conclusion**

We support the use of cluster RCTs of public health interventions in low-income countries. The current move towards more rigorous evaluation has occurred because it is increasingly agreed that public health research has not delivered credible evidence as often as it could have. We should also consider the ethics of not doing research. If less than 10% of current global funding for research goes to diseases that afflict more than 90% of the population (the “10/90 gap”), this gap is itself an ethical issue.<sup>13</sup> Good research tells us if things work – or if they do not – and ethics may be served equally by protecting people from exposure to costly and ineffective interventions.<sup>14,41</sup> ■

**Acknowledgements**

We thank all the community groups and stakeholders in the trials discussed, and Glyn Alcock, Sarah Barnett, Sonia Lewycka, Joanna Morrison, Mikey Rosato and Naomi Saville. We thank the coordinators of the projects involved in our collaboration. At the Ekjut project,

Nirmala Nair; at the City Initiative for Newborn Health, Neena Shah More; at the MaiMwana project, Tambosi Phiri; at the MIRA Makwanpur project, Kirti Tumbahangphe; and at the MIRA Dhanusha project, Bhim Shrestha.

**Funding:** Most of the authors are members of Towards 4+5, a Research Programme Consortium funded by the United Kingdom (UK) Department for International Development. David Osrin is funded by a Career Development Fellowship from The Wellcome

Trust. In Bangladesh, the Perinatal Care Project is funded by the UK Community Fund and the UK Department for International Development. In India, the Ekjut study is funded by the Health Foundation and the City Initiative for Newborn Health by the ICICI Centre for Child Health and Nutrition and The Wellcome Trust. In Malawi, the MaiMwana project is funded by Saving Newborn Lives (Save the Children USA), Effective Interventions, and the UK Department for International Development. In Nepal, the MIRA

Makwanpur trial is funded by the UK Department for International Development, the World Health Organization, the United Nations Fund for Population Activities, and the United Nations Children's Fund; and the MIRA Dhanusha trial by a Swiss foundation and the United States Agency for International Development. The funding bodies played no part in the development of the article or the decision to submit it for publication.

**Competing interests:** None declared.

## Résumé

### Problèmes éthiques rencontrés dans les essais contrôlés randomisés en grappes : expérience apportée par des interventions de santé publique en Afrique et en Asie

Les interventions de santé publique s'opèrent habituellement au niveau des groupes plutôt qu'à celui des individus et les essais contrôlés randomisés (RCT) en grappes constituent un moyen d'évaluer leur efficacité. En utilisant ceux-ci six de ces essais menés au Bangladesh, en Inde, au Malawi et au Népal, nous évoquons notre expérience des problèmes éthiques intervenant dans la réalisation de ces essais. Nous replaçons les RCT en grappes dans le contexte plus large de la recherche en santé publique, en mettant en avant les débats sur la nécessité de concilier autonomie individuelle et bien commun et sur les aspects éthiques de la recherche en santé publique dans les pays à faible revenu en général. Après avoir brièvement introduit les RCT en grappes,

nous avons évoqué les difficultés particulières que nous avons rencontrées. Ces difficultés portaient notamment sur la nature - et sur la responsabilité - du consentement collectif et sur la nécessité que les individus au sein des groupes consentent également à l'intervention et au recueil des données. Nous avons examiné le moment où devait intervenir le consentement dans la mise en œuvre des stratégies de santé publique et les difficultés pour garantir un examen et une approbation éthiques dans un domaine complexe. Enfin, nous avons débattu des bénéfices pour les groupes témoins et de la norme de soins à leur appliquer, ainsi que du problème de l'adoption de l'intervention testée après l'essai.

## Resumen

### Dilemas éticos en ensayos controlados aleatorizados por conglomerados: experiencias de intervenciones de salud pública en África y Asia

Las intervenciones de salud pública inciden por lo general en grupos más que en individuos, y los ensayos controlados aleatorizados (ECA) por conglomerados son un instrumento para evaluar su eficacia. A partir de ejemplos de seis ensayos de ese tipo llevados a cabo en Bangladesh, la India, Malawi y Nepal, analizamos nuestra experiencia en cuanto a los dilemas éticos que plantea la realización de esos ensayos. Situamos los ECA por conglomerados en el contexto general de las investigaciones de salud pública, resaltando los debates sobre la necesidad de compaginar la autonomía individual y el bien común, y sobre la ética de las investigaciones de salud pública en los entornos de ingresos bajos en general. Tras una breve introducción a los ECA

por conglomerados, examinamos los problemas particulares que hemos encontrado, entre los que cabe citar la naturaleza del consentimiento colectivo -y la responsabilidad de obtenerlo- y la necesidad de consentimiento de los individuos, dentro de los grupos, respecto a la realización de la intervención y la recogida de datos. Analizamos el momento del consentimiento en relación con la aplicación de las estrategias de salud pública, así como los problemas que surgen para garantizar el examen ético y la aprobación en un dominio complejo. Por último, se considera el debate sobre los beneficios para los grupos de control y el nivel de atención que deberían recibir, así como el tema de la adopción de la intervención sometida a ensayo una vez concluido este.

## ملخص

### التحديات الأخلاقية في التجارب العشوائية المضبوطة بالشواهد: خبرات مكتسبة من تدخلات الصحة العمومية في أفريقيا وآسيا

المضبوطة بالشواهد في سياقها الأوسع لبحوث الصحة العمومية؛ مع توضيح الجدل حول الحاجة لتوفير الاستقلال الذاتي مع المنافع المشتركة وفي ما يتعلق بأخلاقيات الصحة العمومية في الأماكن المنخفضة الدخل بشكل عام. وبعد مقدمة موجزة للتجارب العشوائية المضبوطة بالشواهد يناقش الباحثون التحديات الخاصة التي واجهوها. وتشمل هذه التحديات طبيعة

تعمل تدخلات الصحة العمومية عادةً في مستوى المجموعات أكثر مما تعمل في مستوى الأفراد. وتعد التجارب العشوائية المضبوطة بالشواهد إحدى الوسائل لتقييم فعالية هذه التدخلات. ويناقش الباحثون خبراتهم المكتسبة من ست تجارب من بنغلاديش والهند ومالوي ونيبال حول القضايا الأخلاقية التي قد تنشأ خلال تنفيذها. وقد وضع الباحثون التجارب العشوائية المضبوطة

النهائية في مثل هذا المجال المعقّد. وفي الختام، يستعرض الباحثون الجدول القائم حول المنافع التي تقدّم لمجموعات الشواهد ومعايير الرعاية التي ينبغي أن يتلقوها وقضية تبني التدخل الذي كان موضوع الاختبار، بعد انتهاء الدراسة.

الموافقة الجماعية وما يترتب عليها من مسؤوليات، والحاجة إلى الحصول على موافقة الأفراد ضمن الجماعات بالنسبة للتدخل ولتجميع المعلومات، ثم ناقش الباحثون توقيت الموافقة فيما يتعلق بتنفيذ استراتيجيات الصحة العمومية ومشكلة ضمان إجراء مراجعة أخلاقية والحصول على الموافقة

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