

# Mass public health programmes and the obligations of sponsoring and participating organisations

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The obligations of organisations associated with policy formation and implementation of international mass public health programmes are explored. Lines of responsibility are considered to become unclear because of the large number of agencies associated with such programmes. A separation of the relevant obligations among the bodies responsible for the formulation (usually an international non-governmental organisation) and those responsible for the implementation of the policies (usually national bodies) is suggested. The continuing oral polio vaccine campaign against poliomyelitis in India is used to illustrate the general argument. Although the aim of the programme is legitimate and laudable, unnecessary harm is currently being caused to some children as a result of elements of the policy and this should be rectified immediately. Such mass programmes should take care to ensure that people are not unnecessarily sacrificed in the drive to attain the desirable ends of the policy.

programme-related harm can be provided. We reason that procedures for reviewing policy formulation and implementation, as well as clear lines of responsibility for all aspects of the programme, should be included as explicit components of such policies. A danger exists that complex multinational funding and management structures mean that responsibility is unclear, and that as a result unnecessary harm may be perpetuated.

## MASS PUBLIC HEALTH PROGRAMMES: COSTS AND BENEFITS

In this paper, we explore the respective obligations of international NGOs, other participating organisations and national bodies arising from their participation in mass public health programmes. We begin by asserting that the fact that a large population has clear health needs (as is the case in many parts of the developing world) and that such programmes will produce some benefit is not enough—on its own—to justify such interventions. If there is insufficient assessment of the potential harms before such programmes begin, insufficient monitoring of potential problems during the active phase of the programmes and no action in response to problems detected, the relevant organisations run the risk of undermining the acceptance of public health programmes as a whole. This, in turn, will probably result in long-lasting negative consequences, producing unnecessary harms and a rise in situations where people fail to take up a potential benefit.

This paper is about public health programmes that are focused on improving the health of large groups of people or whole populations. Such an approach can prove to be very effective in improving the whole population's health or in reducing the risk of disease or other sources of harm to the population. Good examples of such programmes include the worldwide eradication of smallpox and the marked reduction of other infectious diseases through the use of mass preventive vaccination programmes.<sup>1</sup> Many mass public health population-based programmes, however, also carry a considerable risk of harm as a result of the proposed intervention. This is because even a small risk of harm to a small percentage of people will be magnified because of the large numbers of people who receive the

This paper explores the obligations of organisations associated with policy formation and implementation of international mass public health programmes. In such cases, it is common for a policy to be formulated by an international non-governmental organisation (NGO) such as the World Health Organization (WHO), but for other organisations to provide funding, materials or personnel to aid the implementation of that policy in a regional or national context. National bodies may also be associated with such programmes through the implementation of the policy (as formulated by the international NGO) and the management of the resources (as supplied by the other participating organisations).

The issues that we discuss in this paper are of general relevance throughout the world. We have, however, chosen to use the continuing oral polio vaccine (OPV) campaign against poliomyelitis in India as an example of a mass population-based intervention to illustrate the general argument because it provides an excellent example of the benefits, and also some of the problems, of such mass campaigns. In this case, unintended but foreseeable harm has been caused to some of the participants. It would, however, be possible to revise elements of the programme to take account of these facts. The risk of harm can be reduced for at least some participants and compensation for

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intervention.<sup>2</sup> In public health programmes, such harms cannot be dismissed, because the intervention is carried out in an asymptomatic population. Although the intention is clearly to benefit that population's health, it is relevant that the individual participants do not seek out help for a problem themselves: the onus is elsewhere. This fact can be taken to impose a strong obligation on those associated with the intervention to ensure that the benefits clearly outweigh any possible harm.

A favourable ratio of benefits to harms may not, on its own, be enough to determine that the intervention is ethical. For example, the risks and benefits of such interventions may be distributed unequally, with clear population-level benefits (the health of the population is clearly better as a result of the intervention), but some people may be made worse off. If any resultant harm is temporary or of a very low order, this may be more easily justified, although possibly, on some occasions, it may be appropriate and justifiable to run higher risks to gain clear population health benefits. In general, however, and other things remaining equal, it is unjust if the benefits and burdens of a population intervention fall on different groups.<sup>3</sup>

After this general discussion on the nature of harms and benefits of mass public health programmes, we now turn to one such example.

### OPV-BASED PREVENTIVE POLIO VACCINATION PROGRAMMES IN INDIA

Poliomyelitis is a devastating disease that can result in permanent paralysis and even death. The eradication of polio is clearly a worthwhile goal and would be of benefit to the whole world. Despite some setbacks, the international mass preventive vaccination programme has meant that the disease is close to being eradicated, in line with the commitment of the World Health Assembly resolution of 1988 (WHA 41.28).<sup>4</sup> Worldwide, the number of cases has dramatically reduced (despite some recent setbacks).<sup>5, 6</sup> Even in endemic countries such as India, the reduction in the number of polio cases has been dramatic (although some problems remain).<sup>7</sup>

The best treatment for polio is prevention through prior vaccination. Two different vaccines with different properties are available to prevent polio. OPV is absorbed through the digestive tract. It is, however, a live vaccine, and is commonly excreted from the vaccinated children into the environment. This means that non-vaccinated children may develop immunity to polio through coming into contact with the vaccine through the faecal-oral route. In other words, OPV can provide a secondary protective benefit beyond that provided to those vaccinated.<sup>8</sup> The alternative vaccine, inactivated polio vaccine (IPV), is an injectable vaccine, made from the killed virus. It does not have the secondary community benefits provided by OPV. The WHO recommends and funds only OPV for its eradication programme for areas such as India, where the disease is endemic.

Although OPV has undoubtedly benefited many children, the programme can also result in harm. Many different issues arise in relation to the programme,<sup>9</sup> but we will concentrate on the issue of vaccine-associated paralytic poliomyelitis (VAPP). VAPP occurs because of the development of mutant neurotoxic vaccine polioviruses called vaccine-derived wild-like polioviruses. Mutant neurotoxic vaccine polioviruses can cause polio in vaccine recipients (known as recipient VAPP) and in non-immune contacts through secondary spread (known as contact VAPP). In other words, OPV, by the production of VAPP, can actually cause polio. It has been estimated that 60–75 VAPP cases are expected to occur every year in India.<sup>10</sup> Although the official annual number of VAPP cases is much higher (between 120 and 206 for the years

1998–2002), estimates by Paul<sup>11</sup> suggest that the true figures are in fact still higher, at around 300 VAPP cases each year. Although the exact figures remain disputed, this means that in some years, the number of VAPP cases in India may have been up to five times that expected.

Given the benefits of OPV, these VAPP cases may be viewed as an acceptable “cost” of the programme. Whatever the exact figures, however, it is certain that at least some of the cases of VAPP can easily be prevented. Although anyone who is given OPV (or coming into contact with OPV in the environment) may develop VAPP, the risk of developing paralysis after giving OPV is much higher than normal when children have a compromised immune system, and this is one reason for the very high rate of VAPP in India. It is therefore standard practice to give immunocompromised children IPV instead of OPV<sup>12</sup> because IPV cannot cause VAPP. IPV, however, is not available in India in the routine polio eradication programme. As a result, OPV is given to all children up to 5 years of age, including those with compromised immune systems. This is partly responsible for the unacceptably high incidence of VAPP in India.<sup>13</sup> This means that some children are knowingly placed at increased risk of VAPP, although a safe and effective alternative vaccine (IPV) exists. In the absence of any other explanation, we can only assume that this is on the grounds of cost (as OPV is less than a tenth the price of IPV).<sup>14</sup> Introducing IPV for this relatively small subgroup of the population, however, would not add much to the overall cost of the programme. We suggest that it should be made available immediately in the routine eradication programme for those who need it.

In summary, the OPV vaccination programme in India results in harm to some of the participants. Although some such harm may just have to be accepted as a necessary cost for the success of the programme as a whole, at least some of this harm is unnecessary and easily avoidable (if IPV were provided for immunocompromised children as a routine part of the programme).

### CONFUSED STRUCTURES AND UNCLEAR RESPONSIBILITIES

Determining who is responsible for the different elements of a mass public health programme involving international NGOs is often complicated. This problem certainly exists with the OPV programme in India. Polio eradication is an international project carried out according to strategies formulated by the Global Polio Eradication Initiative, an NGO spearheaded by the WHO, the US Center for Disease Control and Prevention and Unicef, with national bodies in the respective countries carrying out the implementation of the programme. In India, for example, the National Polio Surveillance Project is responsible for the implementation of the polio eradication programme on behalf of the Indian government. The national programme in India is supported in turn by 12 partner agencies such as the Canadian International Development Agency (CIDA, Canada); Center for Disease Control and Prevention (CDC, USA); Cooperazione Italiana (Italy); Core Group Partners Project (CGPP) in India (USA); Danida (Denmark); Department for International Development (DfID, UK); Japanese International Cooperation Agency (Japan); Rotary International; UN Foundation; Unicef; United States Agency for International Development (USAID, USA); and the World Bank.<sup>15</sup>

It is laudable that so many organisations are willing to be a part of such efforts. Given such a complex network of bodies, however, it needs to be clear who is responsible for the planning, running and consequences of the programme. Where so many agencies are associated with this programme, such activities may be difficult to determine, and so should be

made explicit during the development of the programme. Does responsibility for the programme lie with the funding organisation or does it lie with the organisations charged with the implementation of the policy? Do these different bodies have different responsibilities? We may reason that the international NGOs and the national bodies have different roles and, consequently, different obligations. On this view, it may be argued that the international NGOs have responsibility for the design of the programme (and so must take most responsibility for the balance of harms and benefits arising from the programme as a whole), whereas the national bodies must always have the best interests of the individual participants as their primary focus when they implement the policy. In this case, the two groups may potentially come into conflict. More can be said about these differing obligations.

### **OBLIGATIONS OF INTERNATIONAL NGOS**

Those with the responsibility for the formulation and planning of such mass programmes, such as the sponsoring organisations, have an obligation to not only determine in advance what the relative benefits and harms of the proposed intervention may be, but also maintain a regular monitoring of the implementation and conduct of the programme to ensure that the initial calculations in favour of the programme continue. If they change, then it may be appropriate to suspend or even end the programme. Of course, the harm resulting from the programme is not intended, but it is often foreseeable. As was mentioned before, it is important that where there is knowledge of potential harm, the benefits of the programme must clearly outweigh any such harm. Such harm is of special concern when it is iatrogenic (caused by medicine itself). Sometimes it is an unavoidable result of the intervention itself (eg, even the safest vaccines will occasionally cause side effects). This does not mean that the programme should not be implemented or maintained (if the benefits are worthwhile). What is problematic is when the harm from the programme is the result of mismanagement of the programme or when the harms are potentially avoidable but the relevant action to prevent or end the harm is not taken.

Virtually any programme will carry some degree of risk of harm. The point is not that risk can be avoided, but that it should be monitored and evaluated, and that the presumed benefits of the programme continue to outweigh any actual harm. There are several reasons for this approach. The first is that this is the only fair way to conduct such public health programmes. For example, we will not be able to identify in advance those people who will be harmed. It may also prove difficult to inform the whole population of any risks owing to the expected costs (both in terms of money and time). Resources may be better spent on extending the main programme instead. Providing information may not be the priority, given the limited budgets. Secondly, by failing to approach the implementation of programmes in this way, we may run the risk of damaging the public's trust in such a programme and other public health interventions, trust that is easy to lose and difficult to regain.

### **OBLIGATIONS OF NATIONAL BODIES**

If we now consider the obligations of the national bodies associated with such mass programmes, a suitable starting point would be that governments have the primary responsibility for the welfare of their people. It is surely one of any government's most important obligations to ensure that any intervention carried out with the intention of benefiting the population's health is done without causing any unnecessary harm. National governments (often through their appointed proxies) will almost always have a gate-keeping role in

relation to such mass programmes, controlling the access of international NGOs to the relevant populations. This gives governments the opportunity to influence and shape the implementation of any programmes under their geographical control. There might be some limits on this, however. For example, representing the interests of a nation's patients is a difficult job. Often, finance for the mass programmes will have strings attached by the relevant donors: they will give the money, support or services with the clear expectation that a programme with certain qualities will emerge. Difficult political issues may have to be dealt with if a national body does not believe that the NGO's policy is appropriate for its country. A policy formulated by an international NGO will impact differently across the world. Countries may choose to ignore such recommendations (in the way that the UK ignores the WHO recommendations in relation to hepatitis B vaccination).<sup>16 17</sup> Other countries, however, may be less able to resist or question the policy of an international NGO. Where healthcare resources are limited, as in the developing countries, any access to funded resources is likely to be welcomed. Although the primary obligation of national bodies will be to their own people, it must be realised that it may be difficult in some circumstances to turn aid away even when given with restrictions.

If responsibility for the mass programmes is clearer, as suggested earlier, it may mean that officials implementing the policy at the national level are in a stronger negotiating position before the inception of the programme. They may be able to argue that unnecessary harm may result from the programme, but that something can be done to minimise this. If the issue has been noted but such funds have not been provided despite a known risk of harm, clearly, the funders are at least partly responsible for the subsequent harm.

Within national boundaries there will also be other agencies with relevant responsibilities, such as the national bodies representing doctors and other healthcare professionals. For example, where such bodies are aware of any unnecessary harms resulting from such programmes, it is arguably their responsibility to bring this to the attention of the national government and the international NGOs sponsoring the programme. The population can reasonably expect doctors to emphasise the interests of the patients and ensure that those interests are not forgotten while focusing on the ends of any mass public health campaigns. Harm may result from such programmes, but even if this is considered to be a necessary and acceptable cost, the population needs to be assured that someone is looking out for their interests if they are to continue to support such programmes. Organisations representing doctors are likely to have a powerful voice if they choose to express any concerns about such interventions. It will be hard for national governments and international NGOs to ignore them if they choose to be associated with such debates. Given the role that such national bodies can have in representing the interests of patients, it should be incumbent on international NGOs such as the WHO to include them in the development and implementation of mass public health programmes, in a local context.

### **ORGANISATIONS, OBLIGATIONS AND THE POLIO ERADICATION PROGRAMME IN INDIA**

We can now turn our attention back to the OPV campaign in India. Perhaps in the past it was believed that polio would be quickly eradicated and that the known harm resulting from the programme was not a major concern. Wild polio has, however, persisted beyond the expected date of eradication and has in some parts of the world, including India, been

prone to resurgence.<sup>5 7 18</sup> As a result, however, immunocompromised children continue to be harmed unnecessarily. Those with primary responsibility for the care of such children in India should express their concern and argue in the strongest terms, through the Indian Academy of Pediatrics (IAP), that it is time for the OPV programme to be modified to include IPV for children at increased risk of VAPP. The IAP can play an important part in representing the interests of their patients if they choose to do so. In fact, the IAP volunteered to join the national polio eradication programme. It has, however, not been included as a partner agency. This has meant that its role in the polio campaign has been limited. It is largely restricted to the fact that the convenor of the Polio Eradication Committee of the IAP is a member of the Indian Expert Advisory Group. The advisory group evaluates the progress of the polio programme and formulates recommendations for the Ministry of Health of India. Paediatricians have a primary responsibility for the children in their care. Given this, the relative lack of participation by the paediatricians from India in the polio eradication programme is surprising. Some organisation should seek to protect these children's interests, and no organisation is better able to do so than the IAP. We are convinced that the IAP, as an organisation, can do more than it has done so far to press for revision to the polio programme to benefit immunocompromised children.

In summary, it is the responsibility of the WHO (as the ultimate sponsor of the polio eradication programme) to clarify the respective roles of the different parties. The failure to provide IPV for immunocompromised children is a clear example of a foreseeable iatrogenic harm. The fact that IPV is recommended for such children strengthens the case for it to be automatically supplied for these children at risk in the internationally funded mass programme. As polio eradication is the WHO's programme, and they have formulated the worldwide eradication strategy, the WHO should accept ultimate responsibility for any foreseeable, but unnecessary, harm. The IAP, being a voluntary partner, has no say in policy decisions at such a level. On the other hand, the IAP has an obligation to safeguard the interests of all Indian children. As a result, although the IAP has a responsibility to do all it can to eradicate poliomyelitis, it also has a responsibility to ensure that no child is unnecessarily harmed as a result of the programme due to either vaccine failure (children should not develop polio after OPV) or the development of polio as a result of OPV itself (ie, VAPP). If nothing else, those at greatest risk of VAPP (ie, immunocompromised children) should be provided with IPV in the routine polio eradication programme.

## CONCLUSIONS

We are not suggesting that NGO-sponsored public health population-based interventions should be halted, nor are we calling for an end to the use of OPV in the strategy to eradicate poliomyelitis. We do, however, suggest the need for careful consideration of possible harms (as well as benefits) during the planning and implementation of such programmes and the need for action as soon as any problems are detected. Mass population-based programmes are an excellent way to benefit a population's health; it is vital that they are not undermined by the creation of unnecessary harm. Public trust in such programmes must be preserved.

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