

## Ethical dimensions of neglected tropical disease programming

David G. Addiss<sup>a,\*</sup>, Yvonne Kienast<sup>a,b</sup>, and James V. Lavery<sup>c</sup>

<sup>a</sup>Focus Area for Compassion and Ethics, Task Force for Global Health, Decatur, GA, USA; <sup>b</sup>Center for Ethics, Emory University, Atlanta, GA, USA; <sup>c</sup>Hubert Department of Global Health, Rollins School of Public Health, Emory University, Atlanta, GA, USA

\*Corresponding author: Tel: +1 269 873 7130; E-mail: [daddiss@taskforce.org](mailto:daddiss@taskforce.org).

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The global movement to control and eliminate neglected tropical diseases (NTDs) is grounded in an ethic of social justice, solidarity and health equity. NTD programmes deliver significant health benefits in socially complex environments characterized by poverty and economic disparity. We used two ethics frameworks—principlism and Upshur's public health framework—to examine ethical challenges faced by NTD programmes. They include management of serious adverse reactions associated with preventive chemotherapy, centralization of decision-making, 'opt-out' policies for school-based deworming, incomplete evidence for 'pro-poor' impact and persistent inequities in global partnerships. NTD programmes must actively address ethical challenges while pursuing global health goals.

**Keywords:** equity, ethics, justice, neglected tropical diseases, preventive chemotherapy

### Introduction

Neglected tropical diseases (NTDs) are diseases of poverty, primarily affecting people who lack access to adequate sanitation, hygiene, healthcare and economic stability. From its beginning, the global movement to control and eliminate NTDs has been grounded in an ethic of social justice and health equity. NTD programmes are 'pro-poor' in the sense that the diseases they address both result from and contribute to poverty and human suffering on multiple levels.<sup>1</sup> In practice, NTD programmes operate in complex social environments and within systems that do not always share a 'pro-poor' orientation. As a result, NTD programmes have tended to adopt disease-specific approaches that emphasize rapid scaling of health benefits through technical solutions. Although many individuals involved in NTD control are motivated by an ethic of social justice, the NTD scientific literature and meeting agendas concentrate on technical issues rather than ethical challenges that arise in NTD programmes.

Programmes for five NTDs—onchocerciasis, lymphatic filariasis, schistosomiasis, trachoma and soil-transmitted helminthiasis (STH)—rely on preventive chemotherapy (PC) as a major strategy. PC is the periodic (usually annual) presumptive treatment of at-risk populations with single doses of medicines, most of which are donated by research-based pharmaceutical companies. The 15 other NTDs, which are addressed in clinical settings through so-called innovative and intensified disease management (IDM), include Buruli ulcer, Chagas disease, leprosy

and snakebite envenoming, as well as several diseases that are considered 'neglected zoonotic diseases', such as taeniasis and cysticercosis, echinococcosis, leishmaniasis, rabies and human African trypanosomiasis. Additional control measures for many NTDs include vector control; water, sanitation and hygiene (WASH); and veterinary public health. NTDs in both PC and IDM categories are targeted for control and elimination.

NTDs contribute to a vicious cycle of poverty and poor health, as well as to the undermining of respect, agency and social association for affected persons.<sup>2</sup> These effects lead to persistent 'clusters of disadvantage' across the dimensions of well-being, as well as a range of ethical issues characterized by ongoing neglect, deprivation and health inequity. NTD-related stigma, disability and fear of contagion lead to further physical and mental suffering, particularly for persons affected by leprosy, filariasis and other NTDs that cause disfigurement.<sup>3</sup>

The social and environmental factors that enable NTDs to flourish also present ethical challenges to NTD programmes. For example, measures to control neglected zoonotic diseases may involve loss of livestock or wildlife, bereavement and financial ruin for farmers and herders. NTD programmes are broadly intended to contribute to health equity, economic well-being and social justice, but these aspirations remain elusive in the absence of broader social change.<sup>4,5</sup> Further, power imbalances among partners and insufficient stakeholder engagement result in ethical challenges that are structural in nature and difficult for NTD programmes to overcome.

## Principlism

The four main elements of principlism, a dominant framework in western bioethics,<sup>6</sup> offer a useful, if limited, starting point for considering the ethical dimensions of NTD programming. These four ethical principles include beneficence ('do good'), non-maleficence ('do no harm'), autonomy and justice. Using these principles as touchstones, we focus here briefly on the five NTDs addressed through PC and offer other examples from the IDM diseases.

### Beneficence

Evidence increasingly confirms that NTD programming yields massive health benefits to affected individuals as well as preventive benefits for at-risk populations through reduction and, in certain areas, elimination of transmission.<sup>7-9</sup> More than one billion persons now receive PC annually. PC is relatively inexpensive and cost effective and the donated drugs have proven to be pharmacologically safe.

Similarly, development of effective drugs for treatment of the IDM NTDs, such as human African trypanosomiasis and visceral leishmaniasis, has provided undeniable lifesaving benefits for individual patients, while complementary public health measures, including vector control, have accelerated efforts to achieve regional elimination of these diseases.<sup>10,11</sup> Increasingly, NTD programmes have also attended to the social and psychological dimensions of these diseases, particularly for leprosy; promoted self-care for persons with chronic filarial lymphedema; and mobilized surgical care for persons with trichiasis or filarial hydrocele. The interlinked twin 'pillars' of controlling or interrupting transmission and individual patient care distinguish several NTD programmes—notably for trachoma, lymphatic filariasis, leishmaniasis, Chagas disease and leprosy—from other disease elimination efforts, such as smallpox and polio, which have focused almost exclusively on interrupting transmission. As such, these NTD programmes combine population-level concerns, rooted in an ethic of social justice, with compassionate and beneficent responses to individual human suffering.

### Non-maleficence

Global health programmes have ethical obligations not only to provide benefit to populations, but also to minimize harm to individuals. The principle of 'do no harm' applies to global health as well as to medicine. For the PC diseases, which subject entire at-risk populations to mass drug treatment, the ethical requirement for non-maleficence is higher than for clinical medicine, since many—and typically most—people receiving PC are not infected with the organism(s) being targeted.

Two examples from the PC NTDs highlight challenges to the principle of non-maleficence. First, after studies documented the safety and extraordinary efficacy of ivermectin against *Onchocerca volvulus*, the parasite that causes human onchocerciasis, Merck donated the drug for PC for onchocerciasis control in 1987. PC with ivermectin began in 1989.<sup>12</sup> In addition to its effectiveness against *O. volvulus*, ivermectin offered significant collateral health benefits against other parasitic infections such as STH and scabies. Treatment resulted in only mild,

transient adverse reactions related to the death of the parasite. However, as PC began to scale up in central Africa, treatment-associated serious adverse events (SAEs) with neurologic complications were reported, including deaths. This radically shifted the calculus of benefit and harm. Five cases were reported between 1989 and 1993, followed by 13 in 1994, primarily from southern Cameroon.<sup>12</sup> By 1995, investigations had determined that affected persons had high levels of infection with another, co-endemic parasite, *Loa loa* (also known as African eye worm).<sup>12</sup> This realization prompted >30 y of international effort to understand the pathogenesis, improve clinical care for affected persons and implement risk-based strategies to maximize access to ivermectin for blindness prevention while minimizing the risk of encephalopathy.<sup>13</sup> These strategies include rapid mapping for loiasis using a simple questionnaire-based mapping tool, RAPLOA;<sup>14</sup> predictive models of *Loa*-related risk based on vector habitat and geographic features<sup>15</sup>; testing of alternative drug regimens;<sup>16</sup> and, most recently, development of the loascope, a field-friendly device that, with a drop of blood, can rapidly identify persons at risk and safely exclude them from PC.<sup>17</sup> Although significantly reduced, the risk of loiasis-associated SAEs persists and the aim of avoiding harm to those co-infected with *L. loa* during PC remains paramount for onchocerciasis elimination programmes.

A second example of unintended harm associated with NTD programming comes from STH. More than 188 million preschool-age children receive deworming medicine every year through PC.<sup>18</sup> A small number have fatally choked on the tablets. Four choking deaths were reported in Ethiopia by the World Health Organization (WHO) in 2007.<sup>19</sup> Anecdotal reports suggest that one or more cases occur every year.<sup>20</sup> Evidence indicates that forcing young children to take deworming tablets is the primary risk factor for choking.<sup>20,21</sup> Thus these tragic choking-related deaths are preventable through improved safety training for community drug distributors (CDDs) and other measures such as age-appropriate drug formulation, but they have not yet been eliminated, despite increased attention from the WHO,<sup>19,21</sup> non-governmental organizations<sup>22,23</sup> and national NTD programmes.

Inadvertent harm also results from toxicity of currently available drugs for some NTDs, such as visceral leishmaniasis. Administered in clinical settings to patients, the ethical calculation of benefit and harm is imbedded in the norms of medical practice. A more subtle, yet important, form of harm is perpetuated when NTD programmes and practitioners are not aware of or do not attend to the stigma associated with NTDs.<sup>3</sup> Effective advocacy by persons affected by leprosy, in particular, has begun to raise awareness of stigma-related harm, dismantle discriminatory legislation and insist on representation in NTD programme decision-making.

### Autonomy

The ethical principle of respect for persons—respect for the capacity of individuals to make informed, voluntary choices, free from undue influence and coercion—has been criticized for its limited applicability in non-Western societies.<sup>24</sup> Nonetheless, the early approach to PC adopted by the African Programme for Onchocerciasis Control involved considerable attention to autonomous, voluntary decision-making, primarily at the

community level. With this approach, known as community-directed treatment with ivermectin (CDTI), communities decided whether and when to participate; they selected who would distribute the drug and how they would be compensated.<sup>25</sup> PC for other NTDs, particularly lymphatic filariasis, was initially modelled on CDTI.<sup>26</sup> However, as NTD programme goals have increasingly shifted from national disease control to global elimination, planning has become more centralized. Top-down approaches to PC have been associated with reduced community participation and involvement of village chiefs.<sup>27</sup> Power imbalances between international donors, implementing partners and national programmes, which are a common feature in global health programmes, can limit the autonomy of national and local actors to respond to needs within their own context.<sup>28</sup>

In a second example, PC for control of STH and schistosomiasis is often administered at school by teachers, since the intensity of infection is often highest in school-age children.<sup>29</sup> Many programmes have an 'opt-out' consent policy in which all children are treated unless their parents or caregivers explicitly object. This policy avoids the logistical difficulties of written consent and presumably results in higher drug coverage. However, 'opt-in' programmes, in which written informed consent is required to treat children, afford parents greater autonomy and respects their authority. Data are lacking on the proportion of school-based PC programmes that use 'opt-in' policies.

## Justice

As noted earlier, social justice is a cornerstone of NTD programmes. Because NTDs are diseases of poverty and neglect, it is generally assumed that NTD programmes preferentially reach and benefit those 'who bear the heaviest burdens of pervasive disadvantage'.<sup>2</sup> However, program monitoring to document this is relatively uncommon. A recent analysis by Lo et al.,<sup>30</sup> using data from the Demographic and Health Surveys programme, found that in the vast majority of 50 STH-endemic countries studied, family income was positively associated with the likelihood of preschool-age children having received deworming medication during the previous 6 months (based on maternal recall). Further, this pattern of inequity was found in 30 of the 31 countries that reported achieving the national-level WHO drug coverage target of 75%. At a macro level, Stolk et al.<sup>31</sup> estimated changes in the burden of NTDs between 1999 and 2010 and found relative reductions of 6%, 17% and 56% for low, lower-middle and upper-middle income countries, respectively. These findings suggest that despite the intention of NTD programmes to 'rescue the bottom billion',<sup>32</sup> they may potentially increase NTD-related health disparities, at least in the short term. To better understand these inequities, data on gender, age, wealth and disability should be collected with routine monitoring of drug coverage, supplemented by qualitative research on underlying social and power dynamics.<sup>28</sup> Such information can be used to develop strategies that ensure access to underserved and marginalized groups.

## Principles for public health programmes

Although informative as a framework, principlism is less helpful for resolving or adjudicating ethical dilemmas that arise in

practical day-to-day programme operations. From an ethics perspective, how programmes are conducted may be more important than whether, in the end, they deliver benefits. Because public health interventions are authorized by governments and address the health of populations, Upshur<sup>33</sup> proposes four ethical principles to guide programmes on how they exercise their powers and authority. They include the harm principle, least restrictive means, reciprocity and transparency.

Criticism of NTD control efforts, particularly for the PC diseases, has focused not on the importance of controlling NTDs, which is well-accepted, but rather on how programmes are implemented with respect to least restrictive means, reciprocity and transparency. Critics express concern about the potential for coercion, suggest that consent to participate in PC may not be fully informed and question the degree to which PC exposes uninfected persons to antimicrobial drugs, potentially leading to antimicrobial drug resistance.<sup>34</sup> In response, NTD advocates have focused on NTD programme benefits and argue that it would be unethical to deny neglected populations these benefits, particularly when many of the drugs, both for PC and IDM NTDs, are donated free of charge.<sup>35</sup> They acknowledge the risk of antimicrobial resistance and the need for further attention, while highlighting that the WHO has developed recommendations and guidance for intensified monitoring of NTD drug efficacy and resistance.<sup>35-37</sup>

## Harm and least restrictive means

Upshur's principles recognize that public health interventions may, at times, inflict harm or restrict the liberty of individuals. The harm principle posits that such interventions and infringements on individual liberties can only be justified if the actions are undertaken to prevent harm to others. This sets up a chronic tension in which approaches that are restrictive, and even coercive, to individuals and groups, become entrenched as 'normal practice' because the ultimate aims of the programmes are to prevent harm more generally. For example, 'opt-out' consent policies for school-based deworming may be more common than 'opt-in' approaches, even though they are clearly more restrictive of individual liberties.

## Reciprocity

The reciprocity principle refers to a programme's ethical obligation or 'duty to care' for persons whose liberties are infringed by or are harmed through participation in public health interventions. Such persons deserve care because they have participated for the benefit of the community and, by doing so, accepted a certain level of risk to themselves. Twenty-five countries have national programmes to provide financial compensation to persons who are harmed by vaccine-associated injury or disability, based on clearly defined criteria.<sup>38,39</sup> Halabi and Omer have called for vaccine injury compensation programmes to be expanded to the global level.<sup>40</sup> In contrast, structures and policies to compensate for harm related to NTD interventions are generally lacking.

Several factors likely contribute to this, including limited programme funding, fear of litigation, the common perception that drugs used in PC are safer than vaccines, resistance to enacting the necessary legislation and a diffusion of responsibility for

providing assistance or compensation. National governments 'own' NTD programmes within their borders, but the goals, strategies and interventions are often developed at the global level, significantly influenced by partners in the global north, and authorized through resolutions at the World Health Assembly in Geneva. NTD programmes are also supported financially by a host of governmental and non-governmental organizations. Contractual agreements among these partners may not articulate specific responsibilities for redressing harms caused by program activities, actions or negligence.

## Transparency

Ethical dilemmas (and their resolution) arise not in the form of abstract principles, but in the practical day-to-day operations of programmes, in the structures and processes of institutions and in the interpersonal relationships that lie at the heart of all successful NTD initiatives. Upshur's final principle speaks to the need for transparency and trust at the global, institutional and interpersonal levels.

In response to a crescendo of calls to address persistent unfairness and inequity in global health, the Research Fairness Initiative (RFI) was recently launched.<sup>41</sup> The RFI guides participating research organizations through a detailed process of self-assessment related to fairness in their international partnerships and collaborations. Four major research institutions, three from the global north with a focus on tropical infectious diseases, have published their RFI self-assessment findings.<sup>41,42</sup> They highlight the need for conflict resolution guidelines, protocols for capacity building and systems of accountability for partnership practices. The honest reflection and dialogue that the RFI stimulates represents an initial, but important, step towards revealing ethical blind spots, addressing important gaps in ethics guidance for research and addressing long-standing structural inequities and power imbalances within international partnerships.<sup>43</sup> These advances could be beneficial for all organizations engaged in NTD programmes, especially for organizations in lower and lower-middle income countries with limited power and resources.

## Looking forward

NTD control and elimination programmes are deeply rooted in aspirational ethical commitments to address human suffering, reduce poverty and correct historical injustices. In practice, however, the ethical profile and effectiveness of NTD programmes are dependent on a range of factors, including political support, competent functioning of systems and organizations, complex motivations of leaders and practitioners and aligned interests of multiple stakeholders. The fact that NTDs primarily affect persons in resource-constrained environments, who have limited access to political power, highlights the need for NTD programmes to give greater, rather than less, attention to ethics. This requires ongoing vigilance, self-examination and openness to criticism.

We have identified ethical strengths as well as gaps in NTD programming. The NTD community's commitment to ethical programming is demonstrated by ongoing efforts to address these gaps. For example, a 'test-and-not treat strategy' using the loascope opens up the possibility of onchocerciasis elimination in

areas with intense transmission of loiasis.<sup>17</sup> Development of the loascope also highlights the important role of science and technology in overcoming specific ethical challenges and illustrates the need for ongoing attention to ethical as well as technological and logistical challenges to achieving WHO goals for NTD control and elimination. In addition, significant advances have been realized in addressing ethical challenges rooted in social dynamics. Decades of research on stigma has led to effective, comprehensive approaches that have been adapted for NTD programmes,<sup>44</sup> and qualitative research has provided guidance for more effective community engagement.<sup>28,45</sup>

Recent emphasis on PC safety provides another example of ongoing ethical awareness and concern, specifically with regard to non-maleficence. For example, to prevent choking, NTD guidelines increasingly address safe administration of tablets,<sup>22</sup> and the International Trachoma Initiative revised its dosing guidelines to provide Zithromax oral suspension, rather than tablets, to children up to 7 y of age or <120 cm in height.<sup>23</sup>

Finishing the job remains a crucial ethical issue for NTDs targeted for elimination. Historically, several disease elimination campaigns have faltered when success was declared prematurely and funding stopped. To a large extent, NTD programmes have been characterized to donors as 'quick wins', when in fact, sustained commitment and vigilance are needed to detect and respond to recrudescence of infection and develop the infrastructure, such as sanitation, vector control and primary health services, needed to sustain public health gains. Ambiguous use of the term 'elimination' to recruit donors has long-term ethical and programmatic implications,<sup>46</sup> as does the decision by donors to prematurely withdraw funding and support.

Through its focus on strengthening health systems and facilitating country ownership of NTD programmes, the WHO NTD road map for 2020–2031 addresses several ethical issues in NTD programming, including safety and adverse event management. It promotes cross-sectoral collaboration centred on the needs of people and communities and attends to issues of stigma and disability. The road map was developed through extensive stakeholder engagement, including regional and national workshops with NTD programme managers, input from NTD experts, donors and private partners and >300 responses to online consultations.<sup>47</sup> Thus, while it is primarily a strategic and technical document, the road map underscores the ethical foundations of NTD control and elimination and provides guidance for how these ethical values can be realized.

Although animated by an ethic of social justice and health equity, the day-to-day work of NTD programmes focuses largely on specific technical solutions. The ethical dimensions of this work tend to be implicit. As NTD programmes mature and evolve along the lines articulated by the road map, they will inevitably face new ethical challenges. Making explicit the ethical principles and values that undergird NTD control and elimination will be important for navigating these challenges and for enhancing the effectiveness of NTD programmes.

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