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Public–private partnerships in blindness prevention: reaching beyond the eye

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Abstract

The control of river blindness (onchocerciasis) has been one of the major public health achievements of recent decades. Initially, vector control was used to stop transmission of the parasite *Onchocerca volvulus* by blackflies (*Simulium*) but the introduction of ivermectin (Mectizan) as a means of morbidity control enabled new strategies of distribution to be developed based on community directed treatment. The donation of Mectizan by Merck & Co. Inc. for onchocerciasis control in 1987 'as long as needed' was a public health landmark to be followed by a donation from GlaxoSmithKline of albendazole in 1997 for lymphatic filariasis to which Merck also responded by agreeing to extend their donation to include the coadministration of Mectizan and albendazole. Both the drugs, however, have wider impacts than those specific to filarial parasites and are effective against a range of intestinal parasites, whilst ivermectin has an important effect on ectoparasites. The wider benefits of the annual public health intervention-collateral benefits—therefore include deworming, improved nutritional status, increased growth, improved school performance and attendance, and improved haemoglobin status as a result of the impact of albendazole on hookworm, a major cause of anaemia. More recently, studies suggest that worm-free children have a significantly reduced frequency of malaria specific episodes of fever and *Ascaris*-infected children have a two-fold higher frequency of cerebral or severe malaria than those without *Ascaris*. These findings suggest that programmes based on annual interventions to control river blindness and lymphatic filariasis can contribute disproportionately more to a range of public health problems than has been hitherto recognized, thereby assisting in attaining the millennium development goal targets.
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Introduction

Several reviews have been published in recent years, which have summarised the specific issues relating to the partnerships based around onchocerciasis (river blindness) control as well as overviews about such partnerships in the broader area of international health.[1–5] More recent analyses have been published on various aspects of the onchocerciasis control programmes (OCP).[1,6,7] These publications provide not only excellent summaries of the body of knowledge to date and serve as an entry point into the literature, but also cover the scientific and strategic evolution of these programmes. Publications on current mass drug chemotherapy,[8] on progress of the APOC programme[9] the delivery of ivermectin,[10] and the role of NonGovernmental Development Organisations (NGDOs) in onchocerciasis control[11] have been summarised recently.

This paper is intended to avoid duplication of content of these publications and to discuss the opportunities that onchocerciasis programmes have and should continue to provide to enhance the benefits of the structures, strategies, capacity building, health systems, impact assessment as well as the intervention itself on the health of populations, in addition to the impact of ivermectin (Mectizan®) on the morbidity and mortality[12] associated with river blindness.

The concept of maximising opportunity from onchocerciasis control raises the following issues:

1. *The impact of ivermectin on infectious agents other than* Onchocerca

The value of ivermectin has been recently highlighted in a study carried out in north-east Brazil.[13] Heukelbach *et al*[13] studied the effect of treatment with a generic ivermectin (Revectina) on helminths and ectoparasites in a highly endemic community. The population under study was around 600 individuals and assessment took place at 1 month and 9 months after treatment. Declines in hookworm from an initial prevalence of 28.5 to 7.7% after 9 months were recorded; *Ascaris* declined from 17.1 to 7.2%; *Trichuris* from 16.5 to 9.4%; *Strongyloides* from 11 to 0.7%. Similar reductions in prevalence were observed in headlice, (*Pediculus capitis*), scabies (*Sarcoptes scabiei*), cutaneous larva migrans and tungiasis (*Tunga penetrans*). Heukelbach *et al*[13] conclude, 'ivermectin was an effective safe means of reducing the prevalence of most of the parasitic diseases prevalent in a poor community'. These studies confirm the published benefits described by earlier studies on Mectizan summarised by Ottesen *et al*,[14] later summarised in a table by Molyneux and Nantulya.[15] The deworming benefits of ivermectin are often cited as the principal perceived benefit by communities.[16]

2. *The benefits the programme has brought to health systems themselves after facilitating wider disease control issues*

Onchocerciasis programmes have been suggested to facilitate improvement in the health system itself. The OCP contributed significantly to human resource development through the provision of fellowships, over a period of 28 years, which included a major contribution to strengthening national research capacities in participating countries, to strengthening evaluation, monitoring, and surveillance systems, strengthening links between the health facilities and communities through community-based approaches, encouraging community engagement in health delivery, engaging local as well as international NGDOs, and improving all aspects of drug management, delivery, and distribution (see Figure 1).

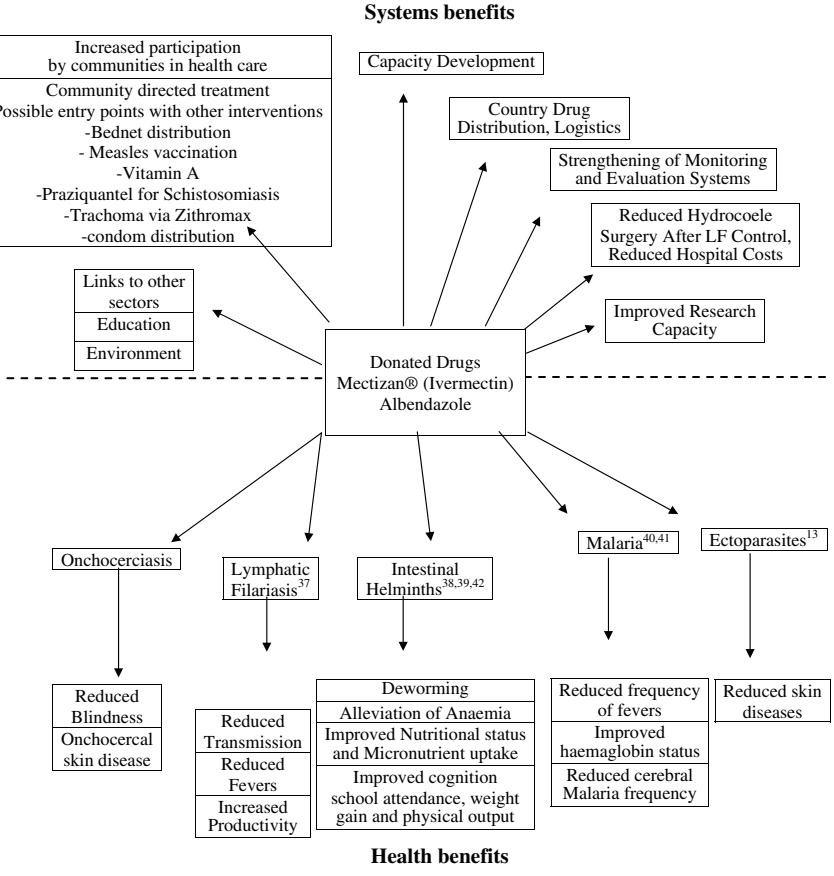

Figure 1 Summary of benefits of donated drugs to disease-specific conditions and to the health system.

3. *The opportunities provided by the concept of community directed treatment using ivermectin (CDTI)—the chosen method of drug delivery in engaging communities in health-care issues*

The concept of utilising the CDTI approach to achieve sustained delivery of Mectizan as the most viable approach to achieving mass drug distribution at the coverage required has been well documented. Such an approach also provides the prospect of long-term sustained annual distribution when support from central APOC funds terminates.[17] Amazigo *et al*[18] identify the challenges as management, technical, and socio-political. To sustain distribution systems, these authors identify the major challenges as timely drug collection, integrating CDTI with existing primary health-care services, strengthening local health care infrastructure, maintaining optimum treatment coverage, ensuring community self-monitoring, implementing locally relevant operational research, ensuring performance of community distributors, increasing involvement of local nongovernmental groups, ensuring financial sustainability, implementing equitable cost recovery systems, and ensuring effective advocacy. These issues are significant challenges, but the concept of CDTI suggests that additional opportunities exist to utilise the concept and framework to expand public health interventions via such a community directed approach.[18] Homeida *et al*[19] summarise the activities of community directed distributors (CDDs) in other health-care activities and emphasise the value of the approach as a pro-poor strategy, which embodies the principles of primary health care (see Tables 4 and 5 in Homeida *et al*[19]). The pattern of involvement of CDDs in other activities varies with the country and the setting but some 20 additional activities in four different countries were identified as health assignments undertaken by CDDs.[19] The focus at present for implementation in areas of Africa where onchocerciasis is endemic is the use of CDDs for expanding vitamin A distribution, for their involvement in LF programmes and in distribution of condoms as part of family planning services, and potentially, HIV/AIDS prevention. Clearly, there is a danger that such volunteerism could be exploited by the health service providers, given that CDDs have traditionally not been remunerated. However, given the philosophy of the intervention, it is the responsibility of the communities to devise appropriate reward systems to compensate those entrusted and empowered with the responsibility of CDTI.

4. *Mectizan donation as a public health landmark*

There is no doubt that the groundbreaking donation of Mectizan has been a stimulus for other donation programmes.[20–22] This donation, it can be argued, was instrumental in maintaining donor commitment to a programme based on a 'vertical' intervention of vector control that could not readily be devolved to country programmes or their health services and which required a centralised management system and technical expertise of a highly specialised nature. Mectizan as a product combined the ideal qualities of being an efficacious drug reducing microfilaria density in the skin, preventing advancement of anterior segment eye lesions but also, as has been subsequently demonstrated, reducing the onchocercal pruritus and skin disease, a feature of onchocerciasis morbidity that previously had been less well studied.[23] However, the donation of Mectizan 'for as long as needed' for the control of onchocerciasis as a public health problem provided an important opportunity to effectively engage national health services of the participating countries in the OCP in a more meaningful way in the process of devising what had been called 'devolution'—the greater involvement of country health systems in planning the future positioning of post-OCP onchocerciasis activities.[24] Mectizan donation was also the framework for the development of APOC.[24]

However, Mectizan is registered for human use for the treatment of onchocerciasis alone. It is not donated for any other purpose even though its origins and chemical structure and that of its analogues are recognised to be among the most efficacious of all antihelminthics. Ivermectins have proved their value in many areas of animal health.[25] These well-known benefits translate to its efficacy in humans on a wide range of human macroparasites, the 'beyond' onchocerciasis benefits, benefits that are well appreciated by communities.[13,14]

The donation of Mectizan was a signal to other potential pharmaceutical donors to view products that were either out of patent or uniquely valuable as public health tools to be made available (see Table in Lucas[21] where some donors and donations are listed) for lymphatic filariasis, trachoma, leprosy, and sleeping sickness. These donations have been one of the major public health milestones of the past decade but have inevitably attracted criticism as the motives of pharmaceutical companies are constantly questioned and analysed.

5. *The onchocerciasis–lymphatic filariasis coendemicity interface*

We have recently emphasised the importance of linking health programmes, in particular in Sub-Saharan Africa, to maximise opportunity for synergy.[15] The donation of Mectizan provides a unique opportunity, particularly when combined with albendazole, in the areas of

codistribution of *Onchocerca volvulus* and *Wuchereria bancrofti* to extend the benefits of the Mectizan donation to (1) populations who are coinfected but who are outside the area of hyper-and meso-endemic onchocerciasis (2) protect the gains achieved to date through distribution of Mectizan and albendazole in areas where onchocerciasis was previously a public health problem but where lymphatic filariasis has high prevalence (eg south-west Burkina Faso).[26–28]

Mectizan itself has been used extensively for onchocerciasis control since the late 1980's on a vast scale (currently annual treatments are around 50 million for onchocerciasis in Africa). Initially, it was used in the OCP, where it demonstrably reduced the duration of vector control in areas of the Western Extension (Guinea, Senegal, and Mali) and also in areas where there was a low initial level of community microfilarial load (CMFL). Mectizan was also used to supplement ground larviciding in the Black Volta (Mouhoun) area of Burkina Faso since the 1988's, where a previously undetected *Simulium* breeding site revealed a focus of onchocerciasis within the core area of the OCP. This focus was treated from 1988 to 2002 with Mectizan.[27] The public health problem of onchocerciasis has been eliminated and in a recent study no *W. bancrofti* was detected in treated villages; adjacent untreated villages demonstrated a *W. bancrofti* prevalence of 3% (Molyneux *et al*[8]). Kyelem *et al*[27] demonstrated that in the Bourgouriba valley, where villages that suffered a resurgence of onchocerciasis due to the re-creation of *Simulium* breeding sites that were not incorporated in the weekly larviciding by OCP and treated at a coverage of around 65%, showed a marked reduction in *W. bancrofti* prevalence and intensity.[27]

These results suggest that in areas currently under Mectizan treatment for onchocerciasis there will be an impact over time on *W. bancrofti* prevalence and intensity; much of this impact is not currently being monitored, particularly in areas of Guinea, Senegal, and Western Mali where earlier studies indicate there was endemicity of *W. bancrofti* with a prevalence, as determined by night blood examination, of around 5–20%.[29] The impact of Mectizan on other human parasites besides *O. volvulus* and *W. bancrofti* was recently assessed by Heukelbach *et al*,[13] who used a Brazilian manufactured ivermectin for human use in a study in north-east Brazil; important public health impacts of the ivermectin were observed on scabies, *Strongyloides*, and hookworm in particular. The focus of evaluations of Mectizan has always been on the impact on parasitological, opthalmological, and entomological parameters within the OCP programme. The extensive use of Mectizan in some 500 plus villages in the Gambia river basin in Senegal, throughout the Rio Corubal and Rio Geba in Guinea Bissau, and the Niger basin in Guinea will complicate assessment of the distribution and prevalence of *W. bancrofti*. The sustained use of Mectizan alone for periods beyond the 5–8-year initial support from APOC will not only reduce the public health problem of onchocerciasis but will in parallel probably reduce transmission of *W. bancrofti*.[30]

6. Loa loa *and onchocerciasis*

The serious adverse events associated with treatment with Mectizan of individuals infected with *Loa loa* following mass treatment has created significant problems for APOC, particularly in Cameroon.[31] The majority of such events have been restricted to a relatively small area of central Cameroon. The analysis of data from patients suggest that the risk of *Loa loa* encephalopathy is dependent on the existence of a microfilaraemia of >3000 mf/ml. The need of APOC was to predict the areas with the highest risk of high prevalence of *Loa loa*. This would be extremely difficult and expensive to acquire on the basis of survey data based on blood film examination. Over the past 4 years two different but compatible approaches to obtaining data to predict areas of risk have been developed. The first was based on the development and subsequent refinement of remote sensing technologies combined with geographical information systems to predict areas of overlap of onchocerciasis hyper- and meso-endemicity with a high risk of *Loa loa* prevalence. Initial studies relied on forest vegetation maps to define areas where the vector *Chrysops* would be found.[32] This approach was then refined to incorporate the concept of probability of risk to provide maps for programme management to define the probability of a prevalence to be above a particular level.[33] In parallel, a rapid assessment of *Loa loa* prevalence was developed to define the predicted *Loa loa* prevalence based on questionnaires of the restricted definition of eye worm within a population.[34] The two approaches provided remarkably compatible results and have provided management tools to assist the programme in decision making. The use of remote sensing and spatial statistics in disease mapping and prediction have expanded significantly in recent years but the practical application of such approaches has been limited. The development of such an approach in APOC to assist the resolution of the *Loa loa* problem has been a notable exception. The development of RAPLOA as a technique for the rapid assessment of prevalence and hence the risk of SAEs derives in part from the rapid assessment tool of rapid epidemiological mapping (REMO) and rapid epidemiological assessment (REA) as a basis for decision making in the APOC programme. REMO maps based on REA have provided a basis for the

decision making in APOC projects when communities are assessed on the basis of nodule prevalence initially developed by Taylor *et al*[35] but refined further by Ngoumou *et al*.[36] Only by using such rapid techniques can large-scale mapping of communities be undertaken, avoiding invasive techniques. The concept of rapid assessment as a programmatic tool developed by onchocerciasis programmes has been a conceptual leap that has extended not only to the linked problem of *Loa loa* but to other disease control programmes such as schistosomiasis.

7. The worm–malaria interaction—a new public health dimension?

A recurrent theme in some recent papers has been the potential crosslinkages between programmes, which could be achieved by developing opportunities for synergy.[15,37] A document 'extending the benefits' of the use of the Mectizan and albendazole combination produced by the Lymphatic Filariasis Support Centre at Emory University draws together the evidence base by building on the supplement published by Parasitology.[38]

The opportunities for strengthening health systems and providing additional public health and educational benefits[38,39] are summarised in Figure 1. However, particular interest in extending benefit relates to malaria because of the following reasons:

- Worm-free children appear to have significantly less malaria fevers than children with intestinal helminth infections; indeed, worm-free status suggests that the level of protection derived is of the same level as provided by the sick cell trait.[40]
- Children with *Ascaris* have a significantly greater chance of developing severe or cerebral malaria than those without *Ascaris*.[41]
- Incorporation of albendazole also provides an added benefit as, in contrast to Mectizan, albendazole has an important impact on hookworm and the anaemia caused by hookworm.[42]

The use of ivermectin alone or in combination with albendazole could clearly make a significant difference in malaria morbidity and mortality, as pointed out by Molyneux and Nantulya.[15] Indeed, given that the maximum protective efficacy obtained by the use of impregnated bed nets in trials when compared with no nets was 50%, the use of antihelminthics to reduce malaria fevers (as well as anaemia due to hookworm) could be a significant contribution to malaria control.[15] There is no doubt that the studies initiated on the relationship between worm status and malaria need to be extended to scale and evaluated in a way that would provide unqualified evidence of a public health impact on malaria morbidity. There is, however, an apparent reluctance on the part of the malaria community to embrace such an approach to reducing morbidity and mortality in malaria.

In conclusion, the programmes that were initiated to control a disease that is a principal cause of blindness in Sub-Saharan Africa have not only had a massive public health benefit and socio-economic impact but have also contributed to improving several aspects of health systems; increased NGDO commitment to blindness programmes; induced additional massive drug donations; spawned new public–private partnership models; and as a result, further enhanced the collateral and synergistic benefits of Mectizan and albendazole, affording the benefits to millions of eligible individuals—perhaps their only access to any health care. However, there are other contexts through which these programmes have contributed—they have emphasised the value of disease mapping and rapid assessment methodologies, developed CDTI as a new approach to health care delivery, thereby opening up linkages to other compatible interventions. These interventions, which are overtly pro-poor, can impact proportionately more towards the achievement of the millennium development goals (MDGs). Indeed, if recent studies on worms and malaria are validated on a larger scale, strategies based on antihelminthic drugs may provide a cost-effective approach to reducing the burden of malaria in Sub-Saharan Africa. The opportunity through a drug initially donated to control blinding onchocerciasis has many more potential spin-offs and when combined with albendazole poses the question of why health policy makers do not see the benefits of delivering two free, safe, efficacious drugs once a year, which not only control blindness and skin disease associated with onchocerciasis but also lymphatic filariasis, intestinal helminthes, and other skin diseases at an annual cost of delivery in the range of 5–15 US cents. The greater benefit in the long term may stem from the impact on malaria through improved haemoglobin status and reduced frequency on malaria-specific fevers, which could have a dramatic impact on malaria morbidity and mortality, and with significant cost benefits, given the contribution of malaria to the burden of health expenditure among poorest households.

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