A public–private partnership for malaria control: lessons from the Malarone Donation Programme

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Abstract In 1996, Glaxo Wellcome offered to donate up to a million treatment courses annually of Malarone, a new antimalarial, with a view to reducing the global burden of malaria. The Malarone Donation Programme (MDP) was established the following year. Eight pilot sites were selected in Kenya and Uganda to develop and evaluate an effective, locally sustainable donation strategy that ensured controlled and appropriate use of Malarone. The pilot programme targeted individuals who had acute uncomplicated *Plasmodium falciparum* malaria that had not responded to first-line treatments with chloroquine or sulfadoxine–pyrimethamine. Of the 161 079 patients clinically diagnosed at the pilot sites as having malaria, 1101 (0.68%) met all the conditions for participation and received directly observed treatment with Malarone. MDP had a positive effect at the pilot sites by improving the diagnosis and management of malaria. However, the provision of Malarone as a second-line drug at the district hospital level was not an efficient and effective use of resources. The number of deaths among children and adults ineligible for MDP at the pilot sites suggested that high priority should be given to meeting the challenges of malaria treatment at the community level.

Keywords Chloroguanide/supply and distribution/pharmacology; Naphthoquinones/supply and distribution/pharmacology; Antimalarials/supply and distribution; Malaria, Falciparum/drug therapy; Drug industry; Public sector; Private sector; Intersectoral cooperation; Pilot projects; Program evaluation; Kenya; Uganda (*source: MeSH, NLM*).

Mots clés Proguanil/ressources et distribution/pharmacologie; Naphtoquinones/ressources et distribution/pharmacologie; Antipaludique/ressources et distribution; Paludisme Plasmodium falciparum/chimiothérapie; Industrie pharmaceutique; Secteur public; Secteur privé; Coopération intersectorielle; Projet pilote; Evaluation programme; Kenya; Ouganda (*source: MeSH, INSERM*).

Palabras clave Cloroguanida/provisión y distribución/farmacología; Naftoquinonas/provisión y distribución/farmacología; Antimaláricos/provisión y distribución; Paludismo falciparum/quimioterapia; Industria farmacéutica; Sector público; Sector privado; Cooperación intersectorial; Proyectos piloto; Evaluación de programas; Kenya; Uganda (*fuente: DeCS, BIREME*).

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Introduction

In November 1996, Glaxo Wellcome offered to donate up to a million treatment courses per year of Malarone, a new antimalarial drug, to help reduce the global burden of malaria. Malarone, a synergistic combination of atovaquone and proguanil hydrochloride, is well tolerated and highly effective against acute uncomplicated *Plasmodium falciparum* malaria, including multidrug-resistant strains (*1*). However, the complex production process makes the drug expensive to manufacture and its price is beyond the reach of most individuals and health care providers in countries where malaria is endemic. The reasons for donating Malarone were as follows: it was one of a small number of new, effective and potentially life-saving drugs; the people in greatest need would benefit from it only if it was free; and the potential risk of parasite resistance meant that a structured system was required in order to ensure the appropriate use of the drug (*2*).

The Malarone Donation Programme (MDP) was initiated as a pilot project in April 1999 and ended in September 2001. In this paper we describe the origins of MDP, present the results of the pilot phase, discuss the issues surrounding the programme, and identify the lessons learnt from this exploratory public–private partnership.

Development of the Malarone Donation Programme

The concept of donating Malarone arose within Wellcome plc, the pharmaceutical company that developed the drug in 1994.

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Further support came in 1995 when Glaxo and Wellcome merged. The foundations of MDP were shaped through consultations involving Glaxo Wellcome, international malaria experts, and various institutions, including WHO and the United Kingdom Department for International Development (DFID). In late summer 1996, Glaxo Wellcome asked the Task Force for Child Survival and Development to assist with implementing the programme.

The overall MDP framework and operating principles grew out of the recommendations of a Glaxo Wellcome working group convened in February 1997. An overriding objective was to avoid premature widespread and inappropriate use of Malarone so as to minimize the development of resistance that might make the drug ineffective for future malaria control. An MDP Advisory Committee was formed and met for the first time in London in December 1997. It recommended that MDP should involve other partners, assist in strengthening the national malaria control programmes of collaborating countries, and initially limit pilot sites to countries with a resource and management structure dedicated to a national malaria control programme. The MDP objectives were as follows: to donate up to a million treatment courses of Malarone globally per year for patients with uncomplicated malaria who failed first-line treatment and lived in areas of highly endemic malaria and known resistance to standard and first-line therapy; to examine the most effective and responsible method of introducing a new antimalarial that was being donated for use in countries of endemicity; and to explore public–private partnerships that could be developed to improve the health of those at risk of tropical diseases.

Glaxo Wellcome undertook not to encourage or commercially promote the therapeutic use of Malarone in areas of endemicity outside the donation programme and not to sell the drug at a discounted price in countries where the disease was endemic, since its high price was considered a major barrier to inappropriate use.

It was decided that the pilot phase should be conducted in sub-Saharan Africa, where 85% of the global malaria burden and 90% of malaria deaths occur and where socioeconomic conditions deny many patients access to effective medicines. East Africa was selected because of reported high levels of malarial parasite resistance to first-line chloroquine therapy and increasing resistance to sulfadoxine–pyrimethamine (SP), the replacement first-line drug, in coastal areas and on the shores of Lake Victoria.

Malarone was approved and registered in Kenya in March 1998 for unrestricted use in the treatment of *P. falciparum* malaria. Concerns expressed by advisers to the Kenyan Ministry of Health delayed the initiation of the programme until January 1999, when MDP was approved for one pilot site. Four more sites were added subsequently. In March 1999, Uganda approved Malarone for exclusive use by MDP at two pilot sites, one of which was later replaced by a third site. The first Ugandan and Kenyan patients were treated with Malarone in April and May 1999, respectively.

Programme implementation strategy

Pilots were established in Uganda at the following sites in March, April, and September 1999, respectively: Kawolo Hospital, Lugazi; Jinja District Hospital, Jinja; and Old Mulago Hospital, Kampala. The Jinja site was discontinued in October 1999 because there were too few patients that qualified for Malarone. Sites were established in Kenya at Siaya District Hospital in April 1999; Kimbimbi Sub-District Hospital in April 2000; and Bondo District Hospital, Kirinyaga District Hospital, Kerugoya, and Nandi District Hospital, Kapsabet in May 2000. All MDP pilot sites in Kenya also served as sentinel sites for the East African Network for Monitoring Antimalarial Treatment. Laboratory staff of the Department of Vector-Borne Diseases, Kenyan Ministry of Health, performed microscopic examinations for both MDP and the East African Network for Monitoring Antimalarial Treatment, which overlapped in time.

Implementation protocols for the pilot sites were developed in collaboration with national malaria control programme staff in both countries. They were reviewed by the MDP advisory committee and approved by the health ministries. The manager of the malaria control unit in each Ministry of Health provided overall supervision and direction of the pilot sites in partnership with MDP. Staff members were trained at all pilot sites and laboratory equipment was provided where necessary. At each site the district medical officer worked in close liaison with the director of MDP, Africa and was responsible for daily programme administration, drug- and patient-tracking, and coordination of clinical activities.

The individuals included in the programme were of either sex, weighed at least 11 kg, and had acute uncomplicated *P. falciparum* malaria that had not responded to treatment with SP. They had a convincing oral or written history of SP use 3–14 days before their current illness. Evidence of current parasitaemia was confirmed by means of positive blood smears for *P. falciparum*, and the patients agreed to attend a clinic for directly observed treatment and to return for follow-up.

Individuals excluded from participation included those with infection or concurrent infection with malaria parasites other than *P. falciparum*, pregnant and lactating women, children weighing less than 11 kg, and those with severe vomiting or concomitant severe malaria. Also excluded were persons with haemoglobin levels $\leqslant 5$ g/dl and children aged <5 years who had blood glucose levels $\leqslant 40$ g/dl. The inclusion and exclusion criteria were consistent with the approved package labelling for Malarone.

Each patient qualifying for MDP was registered, and all dosing and major medical events were documented on a patient evaluation form. A blood specimen was collected from each patient for haemoglobin determination and thick and thin blood smears, and a filter-paper sample of blood was taken for parasite DNA analysis and sequencing (*3*). All adverse events were noted and reported.

Malarone was given in standard doses ranging from one to four tablets, depending on body weight, for three consecutive days. If clinical improvement was evident when the third and final dose was given the patient was provided with funds for transportation and asked to return to the clinic for follow-up on day 28, or earlier if fever or any other symptoms were experienced. Follow-up evaluation included the collection of blood from patients returning to the clinic 3–28 days after starting treatment, regardless of whether they were symptomatic. This made it possible to test for the presence of *P. falciparum* in smears. Patients with smears that were positive for asexual parasites were treated with quinine and continued to receive the customary medical care. Moreover, filter-paper specimens of blood were paired with those collected on day 0 and were sent for parasite DNA analysis (*4*).

MDP staff evaluated the programme operations through regular visits, monitored the stocks and clinical use of Malarone, evaluated evidence of drug resistance, and documented and reported suspected adverse drug reactions. An independent expert provided laboratory quality assurance by re-examining all blood smears.

Results

Evaluation checklists completed by staff at the pilot sites were reviewed at quarterly meetings. Experience at the sites from inception to 31 August 2001 is summarized in Table 1. Of the 161 079 clinical diagnoses of malaria recorded at the pilot sites, 2792 (1.7%) were presumed clinically to have failed to respond to SP. Blood smears from these presumed failures were examined, and 1347 (0.8% of the total number screened) were confirmed parasitologically.

A further 246 were excluded from treatment because they did not meet the treatment criteria. The most common reasons for this were infection with *Plasmodium malariae*, weight <11 kg, and pregnancy/lactation. Of the clinical cases, 1101 (0.68%) received directly observed treatment with Malarone, 1063 of them as outpatients. Patient compliance with follow-up exceeded 80%. Four patients reported stomach cramps, nausea and vomiting, all of which are non-serious adverse events listed in the manufacturer's product information.

Genetic fingerprint and sequence analysis of recurrent falciparum isolates failed to demonstrate molecular evidence of Malarone treatment failures, despite a high prevalence of dihydrofolate reductase gene mutations in the isolates (K.C. Kain, personal communication, 2001).

At the first quarterly review in 1999 it emerged that a substantial number of deaths attributable to malaria had occurred among children and adults who were ineligible for MDP. Of the 777 cases diagnosed as severe malaria, 116 (15%) were fatal. An informal review of records of fatal cases at the district hospitals and of opinions of the attending staff convinced the MDP Advisory Committee that earlier treatment at the community level could greatly reduce the number of deaths. The Committee therefore recommended that MDP assist the health ministries to improve the coordination of malarial management activities in the community. In March 2000 the Siaya District Malaria Initiative was established by the Kenya Ministry of Health in partnership with MDP, the Siaya District Hospital, CARE (Siaya), and 12 local nongovernmental organizations.

Discussion

Glaxo Wellcome and the Advisory Committee viewed MDP as a corporate humanitarian response to emerging multidrug-resistant malaria in economically disadvantaged communities. However, some international advisors in Kenya and malaria experts considered MDP to be irresponsible. Primary concerns revolved around the perceived potential for inappropriate Malarone use leading to early development of resistance, diversion of Ministry of Health resources away from routine health care duties, inequity of drug distribution, diversion of donated drug stocks for sale in local markets, and programme sustainability (*5–11*).

Drug resistance

The MDP protocol required parasitological confirmation of eligible cases and directly observed treatment to reduce the risk of selecting resistant parasite strains that might render Malarone ineffective in the future (*5*, *6*). No molecular evidence was found for in vivo Malarone resistance; however, the numbers of patients treated and tests performed may not have been sufficient to rule out this possibility in an extended programme.

Diversion of Ministry of Health resources

The additional effort of recording patient histories, completing forms, tracking Malarone usage, and collecting data were perceived by hospital staff as good medical practice, more than recompensed by the value received. Hospital staff remarked that MDP had provided a safe and effective back-up drug, enhanced laboratory performance, and motivated staff to raise the standard of clinical practice and provide patients with improved information about malaria. However, the participating staff at each site also benefited personally by attending MDP quarterly meetings and receiving per diem payments. Scaling up MDP nationwide would have required significant additional public or private resources for supervision, staff training, laboratory quality assurance and supplies, controlled drug monitoring, and national programme oversight.

Equity of access to the donated drug

In the public sector, MDP sought to achieve equity within the constraints of package labelling by making Malarone available to all Ministry of Health medical facilities in Kenya and Uganda that had laboratory capabilities for malaria diagnosis and the capacity to administer directly observed treatment to all eligible patients. The unintended consequences of this policy was the exclusion of patients in mission facilities that provide medical care for about 40% of the Kenyan population, patients attending Ministry of Health facilities not qualified for MDP, and patients lacking access to MDP sites because of poverty or the absence of transport (*8*).

The MDP policy in Kenya also excluded patients in the private sector. In October 1999 the Advisory Committee responded to complaints from the private medical community by recommending that Malarone be made available in a controlled manner, where legally and ethically possible, for dispensing against prescriptions through selected pharmacies in the private sector. This raised further concerns that Malarone would assume a dual monetary value by being provided at no cost in the public sector and priced highly within the private sector, thus increasing rewards for leakage from MDP (*8*). Inappropriate drug use might have become an issue if MDP had expanded, but no evidence of leakage from the programme or of increased demand was evident during the year the policy was in place.

Programme sustainability

The debate on the programme's sustainability focused primarily on the Glaxo Wellcome offer to donate up to a million adult treatment courses annually. Glaxo Wellcome had assumed this to be a reasonable base from which to begin. MDP drug demand estimates for Kenya, made in collaboration with the Kenya Medical Research Institute/Wellcome Trust Unit, revealed that one-third of the global offer would have been used for the treatment of patients in government hospitals had the programme been expanded in Kenya (R. W. Snow, personal communication, 2000).

Table 1. **Experience at Malarone Donation Programme pilot sites up to 31 August 2001**

Country/Site	Start date	Total patients with clinical diagnoses of malaria	No. of patients failing first- and second-line treatments[a]			
			Presumed clinically	Confirmed parasitologically	Treated with Malarone	Adverse events
Uganda						
Kawolo	27 Mar 99	16 485	287	210	124	0
Jinja[b]	19 Apr 99	2 550	64	3	3	0
Mulago	1 Sep 99	44 346[c]	242	89	86	3
Kenya						
Siaya	2 Apr 99	22 092	1 025	424	318	0
Bondo	1 May 00	16 423	261	134	122	0
Nandi	2 May 00	16 654	350	147	142	1
Kerugoya	17 May 00	28 656	158	66	66	0
Kimbimbi	26 Apr 00	13 873	405	274	240	0
Total		**161 079**	**2 792**	**1 347**	**1 101**	**4[d]**

[a] Sulfadoxine–pyrimethamine.
[b] Jinja site was discontinued in October 1999.
[c] 28 October 1999 to 31 August 2001 only.
[d] Adverse events were non-serious and listed in the manufacturer's product information.

Issues of programme sustainability arose in all exploratory discussions, including those in Kenya and Uganda. Two candidate African and South American countries with multidrug resistant malaria declined to participate in MDP, citing doubts about its sustainability: if the manufacturer stopped donating the drug, the countries would either have had to purchase it (which they could not afford) or discontinue its use after it had become part of the national malaria control strategy.

Lost in the debate over the manufacturer's long-term commitment was the capacity of the recipient countries to sustain a programme for the management of multidrug-resistant malaria with a reserved therapy. MDP provided microscopes, slides, stains, training and quality assurance for all pilot sites. These basic elements of good medical practice cannot be assumed in developing countries with competing health needs. Thus, the larger issue of MDP sustainability in Kenya and Uganda in the absence of outside resources was not considered, because neither country considered the programme to be a future component of its national malaria control programme.

Ancillary issues

It is difficult to determine whether the best strategy would have been for Glaxo Wellcome to announce the donation goal and determine later how to achieve it, or to have gained extensive experience before the goal was announced. Not stating a donation limit was also likely to have been criticized as unrealistic. Whether Glaxo Wellcome could have avoided initial criticism of MDP through better communications is also open to question. MDP established a web site at an early stage and periodically published and widely distributed a newsletter.

It was suggested during the final Advisory Committee meeting that future donation programmes should consider inviting bids from national malaria control programmes in order to encourage innovation and allow issues to be resolved separately in each country. Although there is merit in this, it is worth noting that the countries with the largest needs for a donated drug are also likely to have the greatest requirement for international support for programme management and drug distribution.

Conclusions

Global public–private partnerships have been the subject of numerous debates (*12*, *13*) and have been depicted as social experiments attempting to solve intractable health problems (*14*). For donors, the basic question is how to ensure that the greatest possible good is obtained from its humanitarian contributions. The larger societal issues raised by MDP, concerning drug equity and programme sustainability, remain unresolved. There are no simple answers, but whatever the programme, collaborating partners and local stakeholders must have a common goal (*15*).

MDP was discontinued on completion of the pilot phase because the Advisory Committee and GlaxoSmithKline (formed in 2000 by the merger of Glaxo Wellcome and SmithKline Beecham) concluded that the programme would not be an efficient or effective use of malaria resources. Less than 1% of malaria patients presenting at outpatient departments met the prescribed criteria for second-line treatment with Malarone. Furthermore, the patients who received treatment were those least likely to die from malaria.

MDP was founded on the assumption that the most efficient method for preventing malaria morbidity and mortality is presumptive treatment of fevers with first-line drugs at the community level and second-line treatment of non-responders at a facility with functioning microscopy. The number of deaths among children and adults ineligible for MDP at the pilot sites starkly demonstrated the need to give high priority to malaria treatment at the community level. ■

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Conflicts of interest: none declared.

Résumé

Partenariat public-privé pour la lutte antipaludique : les leçons du Malarone Donation Programme

En 1996, Glaxo Wellcome a offert de faire don chaque année d'un million de traitements par le Malarone, un nouvel antipaludique, dans le but de réduire la charge mondiale du paludisme. L'année suivante a été créé le Malarone Donation Programme (MDP). Huit sites pilotes ont été choisis au Kenya et en Ouganda pour élaborer et évaluer une stratégie de don efficace et localement viable, afin d'assurer une utilisation contrôlée et adaptée du Malarone. Le programme pilote visait les personnes atteintes de paludisme aigu à *Plasmodium falciparum* sans complications, n'ayant pas répondu à un traitement de première intention par la chloroquine ou la sulfadoxine-pyriméthamine. Parmi les 161 079 patients ayant fait l'objet d'un diagnostic clinique de paludisme sur les sites pilotes, 1101 (0,68 %) remplissaient toutes les conditions de participation au programme et ont reçu un traitement par le Malarone sous surveillance directe. Au niveau des sites pilotes, le MDP a eu un effet positif en améliorant le diagnostic et la prise en charge du paludisme. En revanche, la fourniture de Malarone comme médicament de deuxième intention au niveau de l'hôpital de district ne constituait pas une utilisation efficace et efficiente des ressources. Au vu du nombre de décès parmi les enfants et les adultes qui ne répondaient pas aux critères de participation au programme dans les sites pilotes, il faudrait répondre en priorité aux problèmes posés par le traitement du paludisme au niveau de la communauté.

Resumen

Alianza publicoprivada contra el paludismo: lecciones del Programa de Donación de Malarone

En 1996, Glaxo Wellcome se ofreció a donar hasta un millón de tratamientos anuales con Malarone, un nuevo antipalúdico, a fin de contribuir a reducir la carga mundial de paludismo. Al año siguiente se estableció el Programa de Donación de Malarone (PDM). En Kenya y Uganda se seleccionaron ocho sitios piloto para desarrollar y evaluar una estrategia eficaz de donación localmente sostenible que asegurase un uso controlado y apropiado del Malarone. El programa piloto se dirigió selectivamente a los individuos que sufrían paludismo agudo sin complicaciones por *Plasmodium falciparum* y no habían respondido a los tratamientos de primera línea con cloroquina o sulfadoxina–pirimetamina. De los 161 079 pacientes con diagnóstico clínico de paludismo en los sitios piloto, 1101 (0,68%) reunían todas las condiciones para participar en la iniciativa y recibieron Malarone bajo observación directa. El PDM tuvo un efecto positivo en los sitios piloto pues mejoró el diagnóstico y tratamiento del paludismo. Sin embargo, el suministro de Malarone como medicamento de segunda línea a nivel del hospital de distrito no resultó una alternativa eficiente y eficaz de uso de los recursos. El número de defunciones registradas entre los niños y los adultos no elegibles para el PDM en los sitios piloto lleva a pensar que hay que otorgar alta prioridad a la solución de los retos que plantea el tratamiento del paludismo a nivel comunitario.

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