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The cost-effectiveness of improving malaria home management: shopkeeper training in rural Kenya

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Home management is a very common approach to the treatment of illnesses such as malaria, acute respiratory infections, tuberculosis, diarrhoea and sexually transmitted infections, frequently through over-the-counter purchase of drugs from shops. Inappropriate drugs and doses are often obtained, but interventions to improve treatment quality are rare. An educational programme for general shopkeepers and communities in Kilifi District, rural Kenya was associated with major improvements in the use of over-the-counter anti-malarial drugs for childhood fevers. The two main components were workshop training for drug retailers and community information activities, with impact maintained through on-going refresher training, monitoring and community mobilization. This paper presents the cost and cost-effectiveness of the programme in terms of additional appropriately treated cases, evaluating both its measured cost-effectiveness in the first area of implementation (early implementation phase) and the estimated cost-effectiveness of the programme recommended for district-level implementation (recommended district programme).

The proportion of shop-treated childhood fevers receiving an adequate amount of a recommended antimalarial rose from 2% to 15% in the early implementation phase, at an economic cost of $4.00 per additional appropriately treated case (2000 US$). If the same impact were achieved through the recommended district programme, the economic cost per additional appropriately treated case would be $0.84, varying between $0.37 and $1.36 in the sensitivity analysis. As with most educational approaches, the programme carries a relatively high initial financial cost, of $11 477 ($0.02 per capita) for the development phase and $81 450 ($0.17 per capita) for the set up year, which would be particularly suitable for donor funding, while the annual costs of $18 129 ($0.04 per capita) thereafter could be contained within the budget of a typical District.

To reach the Abuja target of 60% of those suffering from malaria in sub-Saharan Africa having access to affordable and appropriate treatment within 24 hours, improvements in community-based malaria treatment are urgently required. From these results, policymakers can estimate costs for district-scale shopkeeper training programmes, and will be able to assess their relative cost-effectiveness as comparable evaluations become available from home management interventions in the future. Extrapolation of the results using a simple decision tree model to estimate the cost per DALY averted indicates that the intervention is likely to be considered highly cost-effective in comparison with standard benchmarks for interventions in low-income countries.

Key words: malaria, home management, costs, cost-effectiveness, drugs, shopkeepers, training

Introduction

Home management or self-medication is a very common approach to the treatment of potentially serious illnesses such as malaria, acute respiratory infections, tuberculosis, diarrhoea and sexually transmitted infections (Smith et al. 2001; McCombie 2002; Waters et al. 2003). In rural Africa, where qualified pharmacists are rare, home management most frequently takes place through the purchase of drugs from untrained retailers in general shops. Reasons for preferring shops include greater geographical accessibility, shorter waiting times, longer opening hours, more reliable drug stocks, greater confidentiality and lower costs (Brugha and Zwi 1998). However, many problems with the quality of such treatment have been documented, particularly concerning the failure to obtain appropriate medicines, excess use of inappropriate drugs and the frequency of sub-therapeutic doses. The risks from poor quality treatment may be very high; if not treated with an adequate dose of an effective antimalarial, uncomplicated malaria can proceed rapidly to severe disease and death, especially among young children who are yet to develop immunity (Greenwood et al. 1987). This has led to increasing calls for interventions to improve treatment obtained from shops. While there is growing interest in working with the retail sector, the evidence base remains very limited, and there are no comprehensive assessments of the cost-effectiveness of such interventions (Le Grand et al. 1999; Laing et al. 2001).

The Kenya Medical Research Institute (KEMRI)–Wellcome Trust Collaborative Research Programme and the Ministry of Health (MOH) developed an educational programme for drug retailers and communities on malaria home treatment. The intervention was associated with major sustained improvements in the use of over-the-counter (OTC) anti-malarial drugs for childhood fevers (Marsh et al. 2004), generating substantial interest. Key questions for policymakers are 'How much does shopkeeper training cost?' and 'Is it cost-effective?'. This paper uses prospective costing data collected during the Kenyan evaluation to address these issues.

The data are presented in two ways. The first is the measured cost-effectiveness of the programme in the first area of implementation (early implementation phase). The second is the estimated cost-effectiveness of the programme recommended for district-level implementation (recommended district programme).

The study received ethical approval from the Kenya national ethical committee. Informed consent was obtained for interviews conducted as part of the study.

Methods

Study setting

The early implementation phase was established in 1999 in the southern part of Bahari Division in Kilifi District, covering a population of 35 770. The programme was not extended to the northern part of the division until 2000, allowing the latter to act as a control area in 1999. The cost-effectiveness of the recommended district programme was estimated for all rural areas of Kilifi District (population 472 750).

Malaria transmission across the district is stable and endemic (Nevill et al. 1996). Bahari Division is dependent primarily on subsistence farming, with some cash income from the tourist, retail and industrial sectors of nearby towns. Formal health sector provision is through one government health centre, one dispensary, seven private clinics and six active community pharmacies. However, in 60% of childhood fevers, care is initially sought from general shops, which usually stock antimalarial and antipyretic drugs, as well as a wide range of other household commodities (Snow et al. 1992; Marsh et al. 1999). When the programme was introduced, chloroquine was the national first-line treatment for malaria and the only antimalarial available at most general stores.

Description of the intervention

The activities are summarized in Table 1 and described in detail in Marsh et al. (2004). The development phase took

Table 1. Intervention activities

Activities	Pre-implementation	Set up year	Continuation years
Development phase			
Knowledge, attitudes and practices survey	X		
District workshop to develop programme design	X		
Development and piloting of training programme	X		
Development of community mobilization materials	X		
Set up and continuation years			
Training			
Training of trainers supported by professional training advisor		X	X (refresher training)
On-the-job training for CWs		X	X (refresher training)
Training of shopkeepers		X	
Monitoring			
Monitoring of shopkeepers by CWs every 4–6 months		X	X
PHT and CW monthly monitoring and feedback meetings		X	X
Monitoring of CWs by PHTs in the field		X	X
Community mobilization			
Meetings with community groups		X	X
Meetings with health facility staff		X	
Printing and distribution of leaflets, flipcharts and posters		X	X
Certificate presentation ceremonies		X	
Performance of songs and plays		X	
Co-ordination and management			
Meetings with District Health Management Team		X	X
Mapping of shops		X	
Recruitment of trainers		X	X
Recruitment of shopkeepers		X	X
Planning of shopkeeper training workshops		X	X
General programme management		X	

CW = community health or development worker; PHT = public health technician.

place primarily between 1996 and 1998, with the set up and first continuation years of the early implementation phase in 1999 and 2000, respectively. The two main components were skill-based participatory workshop training for groups of drug retailers, and community information activities.

MOH public health technicians (PHTs) ran 4-day workshops for shopkeepers, assisted by community health or development workers (CWs). The training covered the cause and symptoms of malaria, appropriate treatment with antipyretic and antimalarial drugs, indications for referral to formal health services, and basic communication skills. Trained shopkeepers were given job aids, such as charts and rubber stamps, to reinforce messages on correct dosing. CWs visited each trained shopkeeper every 4 to 6 months to assess their skills in the workplace and to provide additional support. Shopkeepers were neither charged nor remunerated for their participation.

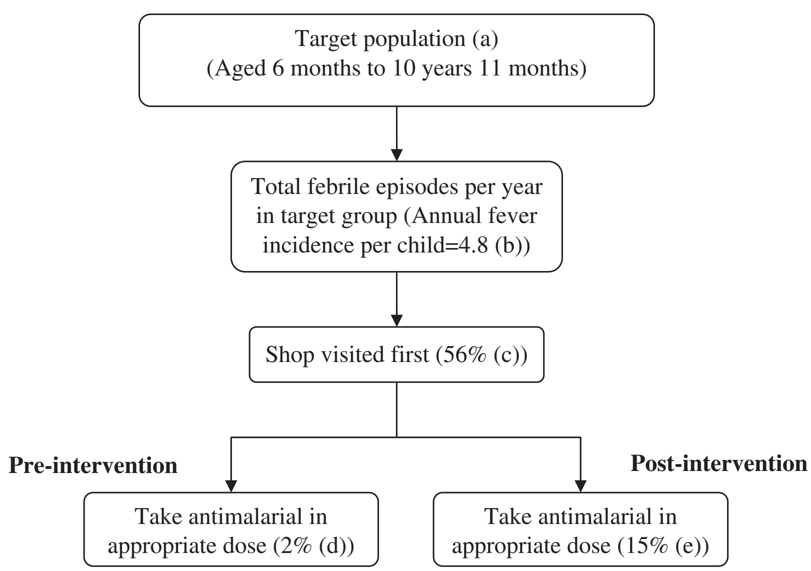
A key feature of the programme was that training was not considered a one-off activity. In continuation years, both trainers and shopkeepers attended refresher courses, and a limited number of introductory workshops were held to allow for turnover in shops and sales staff. Extensive community mobilization activities informed local residents about the programme and introduced key messages on appropriate treatment through community meetings, distribution of posters and leaflets, and public certificate presentation ceremonies.

Calculating effectiveness

The target population was children aged 6 months to 10 years 11 months treated for fever using shop-bought drugs as a first-line treatment. The key effectiveness indicator was the proportion of children receiving appropriate amounts of MOH-recommended antimalarial drugs. In line with national treatment guidelines, appropriate treatment with chloroquine was defined as 25–40 mg/kg over 3 days, based on locally derived weight-for-age charts.

Effectiveness was assessed through household surveys during the peak malaria transmission season (June to August) in randomized cluster samples of 2525 to 3685 households across Bahari Division in 1998 and 1999 (Marsh et al. 2004). Information was collected on childhood fevers occurring within the previous 2 weeks.

Effectiveness was calculated by multiplying the proportion of febrile cases appropriately treated before and after the introduction of the intervention in the early implementation area by the estimated number of febrile episodes first treated in shops in the target age group (Figure 1). The total number of febrile episodes was derived from a longitudinal cohort study of fever and



Sources:

(a) KEMRI 1995 census, scaled up to account for population growth.
(b) Longitudinal cohort study 1999–2000 in Ngerenya Location, Bahari Division (Mwangi 2003).
(c) Average from household surveys in southern Bahari Division in 1998 and 1999 (no significant change between the two years).
(d) Household survey in intervention area in 1998 (pre-intervention).
(e) Household survey in intervention area in 1999 (post-intervention).

Figure 1. Calculation of effectiveness: number of cases appropriately treated pre- and post-intervention

malaria between 1999 and 2001 within the study area (Mwangi 2003).

Measuring costs

The costs of the development phase were estimated retrospectively through discussion with programme staff. Development costs were estimated for replication, taking care to incorporate any inputs required to ensure effectiveness in another location, including technical assistance for background research, training and materials design. The costs of the implementation phase were collected prospectively in the early implementation area for the set up year and first continuation years through ongoing documentation of resource use and expenditure. Staff completed daily or weekly timesheets recording their contribution to the project, activity logs were maintained in each vehicle, and costing records were completed after each training and community mobilization activity.

To calculate a typical year's costs, annualized development costs and annualized set-up year costs were added to the costs of the continuation year, using a discount rate of 3% following standard practice (Gold et al. 1996) over an 8-year period, to reflect the minimum time over which the materials and approach were expected to remain relevant to the local retail market.[1]

A comprehensive economic costing of all programme activities was undertaken, including the overhead costs of general management at the District level, and the time of CWs and all programme and MOH staff, implicitly assuming a lack of spare capacity at baseline. Costs incurred above the District level were excluded, reflecting the decentralization of decision making, and levels of managerial input in practice. Care was taken to exclude resources related to research activities. In the analysis, costs were considered from a provider perspective. Economic implications for community members were considered separately by analysing average household drug expenditure per completed shop-treated fever episode, recorded during the household surveys for episodes starting at least 6 days before the interview. A separate qualitative assessment of shopkeepers' responses to the programme was used to assess financial and non-financial incentives for shopkeepers' participation.

Staff time per day was valued at full salary costs (including allowances) divided by the number of working days. The opportunity cost of CW time was valued at their daily allowance of \$2.62, which had been devised by asking village health committee members the amount required to attract CWs to the programme. Any donated goods and services, such as poster design and printing, were valued based on quotes from local suppliers, and the cost of office space and community buildings was proxied using local rents. All other recurrent costs were based on actual expenditure. Taxes were excluded from the economic costs, as they would be transfer payments between government departments and would not reflect resource consumption. Costs were converted to 2000 US\$, using the Kenyan shilling (KSH) consumer price index and the average 2000 exchange rate of US\$1 = KSH 76.28.

Capital costs were annualized using a discount rate of 3%, and an estimated useful life of 6 years for office equipment and bicycles. The capital costs of 4-wheel drive vehicles were based on the share of kilometres attributable to programme activities, replacement costs from the Kenyan Automobile Association, and a useful life of 8 years. KEMRI cost-recovery kilometre rates and insurance payments were used to estimate recurrent vehicle costs.

The cost-effectiveness ratio (CER) was calculated as the total economic cost of a typical year for the early implementation phase, divided by the incremental number of febrile episodes appropriately treated.

Estimating the cost-effectiveness of the recommended district programme

Cost data from the early implementation phase do not reflect large-scale implementation, the unit costs of MOH as opposed to KEMRI–Wellcome Trust resources, nor the programme design now proposed as best practice. Costs were therefore also estimated for a hypothetical district-scale programme for seven divisions, based on the currently recommended programme design.

The estimated costs of the recommended district programme incorporated four key changes in activities and resources:

- The number of shops targeted for recruitment was reduced to 60%, or a population coverage of around 350 per shop. This decision was made because aiming to recruit all shopkeepers selling drugs was found to be inefficient during the early implementation phase, due to high turnover among some shops and the cost of maintaining long-term support. The strategy has now been revised by using community groups to select 60% of shops on the basis of popularity, geographical access, stability and trustworthiness, which the implementation team believes to be more efficient.
- The duration of retailer training was reduced from 4 to 2 days as a subsequent evaluation by the research team demonstrated that retailers gained adequate skills with shorter training, while motivation to attend was greater.
- All programme management activities were allocated to existing MOH staff, comprising seven PHTs as Divisional Co-ordinators (DVCs), supervised by a District Co-ordinator (DSC). It was assumed that the DVCs would spend two-thirds of their time on the programme in the set up year and 20% in continuation years, and the DSC, 10% and 3% respectively.
- Motorbikes would replace 4-wheel drive vehicles as the main mode of transport, as would be typical in an

MOH programme. Their capital costs were estimated based on a useful life of 4 years, and the share of DVC time spent on programme activities.

In scaling up costs to district level, most resources were increased by total population, which determined both the target population for community mobilization and the number of retailers to be trained. Recurrent transport costs were adjusted according to average journey lengths, and capital transport costs and staff costs were scaled up by the number of divisions. Some activities and resources were not scaled up, as they would cover the whole district at their current cost. These included all Development Phase activities, the training of trainers, and office space, computing equipment and secretarial support.

The impact of the recommended district programme was estimated by applying the effectiveness data from the early implementation area to an estimated number of febrile episodes in the target age group treated through shops in all rural areas of Kilifi District. Sensitivity analysis was used to explore the potential impact of differences in implementation on cost-effectiveness.

Modelling the impact on final health outcomes

The use of cases appropriately treated as our outcome measure limits the potential to compare the cost-effectiveness of shopkeeper training with a broader range of interventions for malaria treatment and prevention and other health problems. This would require the use of final health outcome measures such as deaths or disability-adjusted life-years (DALYs) averted. However, empirical evaluation of the mortality impact would have required an evaluation on a much larger scale and been complicated by the potentially greater influence of confounding factors.

We therefore used a simple model to make rough estimates of the cost per DALY averted. The model is based on the decision tree in Figure 2, which calculates the probability of death for a child with fever for whom treatment is first sought from a shop, with and without the intervention. The mortality impact in practice will vary considerably depending on the drug used, resistance patterns and malaria transmission and immunity, so the model estimates can only be considered as tentative. The intervention changes P1, the probability that an appropriate antimalarial dose will be received. We assumed that 50% of fevers were caused by malaria (Mwangi 2003), and that the intervention would have no impact on outcomes for non-malarial fevers. Antimalarial efficacy was set at 90%; this is considerably higher than chloroquine efficacy at the time of the study, but in line with rates for combination therapies being introduced in East Africa (Adjuik et al. 2004). We assumed that not taking an antimalarial or taking an under-dose would lead to treatment failure, although in 95% of cases the illness would remain uncomplicated and the patient would recover. In 5% of treatment failures severe disease would develop (based on population surveillance and inpatient data from Kilifi, personal communication, Kevin Marsh). We assumed that 48% of severe cases would be admitted

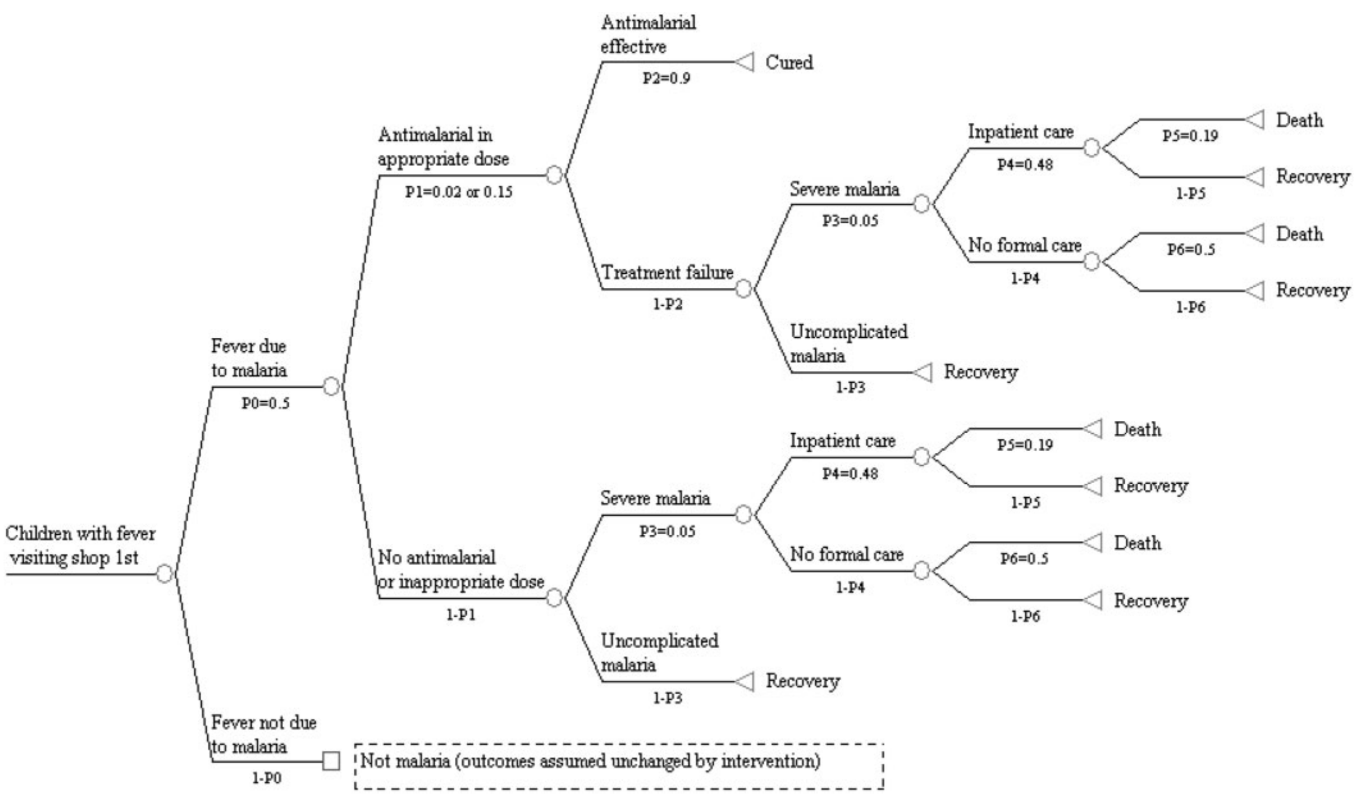


Figure 2. Decision tree model to estimate difference in probability of death with and without intervention

to hospital, where they would experience a 19% case fatality rate, in comparison with a 50% rate for untreated severe cases (Goodman et al. 2000). Each death was estimated to be equivalent to 27.5 discounted years of life lost (the mortality component of DALYs which accounts for the vast majority of the malaria disease burden), based on a life expectancy at death of 58 years, a discount rate of 3% and no age weighting.

The model was used to estimate the total deaths and DALYs averted by the early implementation phase and the recommended district programme, and the cost per death averted and per DALY averted was calculated in each case. The cost per DALY averted was compared with the suggested benchmarks that an intervention in a low-income country should be considered a 'highly attractive' use of resources if the cost per DALY averted falls below $25–30, and 'attractive' if it falls below $150 (WHO 1996).

Estimating the budgetary requirements of the recommended district programme

To assess affordability the financial budget requirements of the recommended district programme were also estimated. Budget requirements differed from full economic costs in two ways. Firstly, the full cost of capital items, such as motorbikes, was budgeted for in the year of purchase, rather than spread over their useful lives. Secondly, existing MOH resources were assumed to cover all staff time, office space and occasional 4-wheel drive use.

Results

Effectiveness

In 1999, 319 shopkeepers were trained from 187 shops out of a total of 199 shops selling drugs in the early implementation area. Ninety-five per cent of shopkeepers attending workshops gained certificates of satisfactory completion of training.

The household surveys showed a marked improvement in drug use (Marsh et al. 2004). The proportion of shop-treated childhood fevers receiving an adequate amount of a recommended antimalarial rose from 2% (95% CI 0.8–4%) to 15% (95% CI 10–19%) between 1998 and 1999 in the early implementation area, compared with an increase from 1% (95% CI 0.2–3%) to 4% (95% CI 2–6%) in the untrained area over the same period. As the change in the control area was statistically insignificant, the unadjusted increase in the intervention area was used to calculate effectiveness. Calculation of the incremental number of episodes appropriately treated is illustrated in Figure 1. For a population of 11 850 children in the target age group in the intervention area, it was estimated that there would be 31 546 fever episodes first treated in shops per year. The number of cases treated appropriately was estimated as 631 without the intervention and 4732 with the intervention, giving an incremental number of 4101 appropriate treatments.

Applying these effectiveness estimates to the target population in all rural Kilifi (156 614) gave an estimated number of fever episodes treated first in shops of 416 919, and 54 199 additional appropriate treatments for the recommended district programme.

Costs

The early implementation phase

The economic cost of the development activities for replication in a new area was estimated at $15 211 or $0.43 per capita (Table 2). Over a third of this total was accounted for by the cost of professional consultants to undertake the background research and advise

Table 2. Economic costs by activity for (a) early implementation phase and (b) recommended district programme (2000 US$)

Development phase			Implementation phase				
Activities	Total cost ($)	%	Activities	Set up year		Continuation year	
				Total cost ($)	%	Total cost ($)	%
(a) Measured cost of early implementation phase (population 35 770)							
Background research	7008	46	Training of trainers	11 531	30	1645	19
Workshop to develop programme design	3046	20	Shopkeeper training and job aids	10 933	29	1754	20
Development and piloting of training	4377	29	Monitoring	2945	8	885	10
Development of community mobilization	780	5	Community mobilization	2769	7	1593	18
			General management	9794	26	2969	34
Total cost	15 211	100		37 973	100	8847	100
Cost per capita	0.43			1.06		0.25	
(b) Estimated cost of recommended district programme (population 472 750)							
Background research	4542	54	Training of trainers	8036	9	193	1
Workshop to develop programme design	1273	15	Shopkeeper training and job aids	30 581	33	9495	30
Development and piloting of training	2202	26	Monitoring	15 702	17	3763	12
Development of community mobilization	394	5	Community mobilization	11 159	12	8394	27
			General management	25 938	28	9422	30
Total cost	8412	100		91 415	100	31 268	100
Cost per capita	0.018			0.19		0.07	

on training methods and materials design (Table 3). The total economic cost of the set up year was $37 973 ($1.06 per capita). Of this total, training of trainers accounted for 30%, training of shopkeepers 29%, monitoring 8%, community mobilization 7% and the remaining 26% was for general management activities. Continuation year costs were less than a quarter of those of the set up year, at $8847 ($0.25 per capita); costs were substantially lower than in the set up year for all activities, with only monitoring costs decreasing by less than 50%.

Adding the annualized costs of the development phase and set up year to the costs of the continuation year, gave a total economic cost of a typical year for the early implementation phase of $16 423, with the annualized costs making up just under half of this total (Table 4). The total economic cost was $87.82 per trained shop, $1.39 per child covered, $0.52 per initially shop-treated childhood febrile episode and $0.46 per capita.

The recommended district programme

For the recommended district programme, the costs were estimated at $8412 for the development phase, $91 415 for the set up year and $31 268 for the continuation year, giving a total annualized economic cost for a typical year of $45 489, or $0.10 per capita. This represented approximately a fifth of the cost per capita of the early implementation phase, due to the assumed changes in programme design and economies of scale at district level, particularly in spreading the costs of the development phase and the training-of-trainers over a wider area. This gave a total economic cost of a typical year of $18.41 per trained shop, $0.29 per child covered, $0.11 per initially shop-treated childhood febrile episode and $0.10 per capita.

Expenditure on OTC antimalarial and antipyretic drugs

The intervention led to very little change in expenditure by consumers on shop-bought drugs. Mean expenditure per completed episode in the early implementation phase was unchanged at $0.12 in 1998 and 1999, while median expenditure fell slightly from $0.11 to $0.10.

As full cost data were not collected for consumers, and the quantitative impact on shopkeepers was not monitored, the economic implications for these groups were not included in the cost-effectiveness analysis.

Table 3. Breakdown of economic costs by resource type

Resource type	Early implementation phase			Recommended district programme		
	Development phase	Set up year	Continuation year	Development phase	Set up year	Continuation year
Personnel costs						
Programme Management salaries	24%	19%	16%	3%	5%	5%
Other staff salaries	9%	8%	11%	11%	3%	6%
Allowances for attending training and field visits	3%	8%	24%	5%	20%	28%
Input of professional advisors	34%	12%	–	61%	4%	–
Facilitation course for project manager	–	2%	–	–	–	–
Supplies and services						
Posters	–	1%	1%	–	6%	4%
Rubber stamps and ink pads	–	9%	–	–	–	–
Accommodation and refreshments for training and meetings	4%	12%	14%	7%	16%	11%
Office space, equipment, supplies and utilities	3%	9%	15%	5%	23%	27%
Transport						
Capital	13%	9%	9%	3%	5%	6%
Recurrent	12%	10%	10%	5%	16%	13%
Total	100%	100%	100%	100%	100%	100%

Table 4. Calculation of cost-effectiveness (2000 US$)

	Early implementation phase	Recommended district programme
Annualized development costs*	$2167	$1198
Annualized set up year costs*	$5409	$13 023
Continuation year costs	$8847	$31 268
Total costs of typical year	$16 423	$45 489
Number of shops with at least one trained shopkeeper	187	2471
Cost per trained shopkeeper	$87.82	$18.41
Number of children in target age group covered	11 850	156 614
Cost per child covered	$1.39	$0.29
Number of additional episodes treated appropriately per year	4101	54 199
Cost per additional febrile episode treated appropriately	$4.00	$0.84

*Annualized over an 8-year period at a discount rate of 3%.

Table 5. Results of one-way sensitivity analysis on the cost per additional febrile episode treated appropriately (2000 US$)

Variation tested	Cost per additional febrile episode treated appropriately	
	Early implementation phase	Recommended district programme
Base case	$4.00	$0.84
Annualization of development and set up costs based on a useful life of (base case 8 years)		
5 years	$4.99	$0.98
10 years	$3.68	$0.79
15 years	$3.24	$0.73
Annual incidence of reported febrile episodes in target age group (base case 4.8 per child)		
10.8 per annum	$1.78	$0.37
Proportion treated appropriately with intervention (base case 15%)		
Lower 95% CI: 10%	$6.51	$1.36
Upper 95% CI: 19%	$3.06	$0.64
Reduction in effectiveness to explore potential impact of differences between early implementation phase and recommended district programme		
33% reduction in effectiveness		$1.36
50% reduction in effectiveness		$1.98

Cost-effectiveness

Combining the total economic costs of a typical year for the early implementation phase with the effectiveness results gave a cost per additional febrile episode appropriately treated, or CER, of $4.00 (Table 4). Combining the costs of the recommended district programme with the extrapolated effectiveness results for the district gave a CER of $0.84.

The sensitivity of the CERs to variation in key parameters was explored (Table 5). The useful life over which the development and set up year costs are annualized depends on unpredictable developments in the retail drugs market. Using a more conservative estimate of 5 years increased the CER of the recommended district programme to $0.98. Increasing the useful life to 10 or 15 years reduced the CER to $0.79 and $0.73, respectively. The annual incidence of reported childhood fevers varies geographically and from year to year, and the figure of 4.8 used in this analysis is relatively low compared with reports from other endemic settings in Africa (Snow et al. 2003), although this may partly reflect the younger age group commonly reported on (under 5 years). We would also expect higher incidence in areas of higher malaria transmission. Using an annual incidence of 10.8 reported for children aged between 6 months and 5 years in Busia District in Western Kenya in 2002 (Marsh et al. 2003) had a dramatic effect on the cost-effectiveness results, reducing the CER for the recommended district programme to $0.37.

Following the intervention, 15% of febrile episodes initially treated with shop-bought drugs were treated appropriately (Marsh et al. 2004). Varying this parameter between its upper and lower 95% CI of 10% and 19% varied the CER of the recommended district programme between $1.36 and $0.64.

The impact of the differences in programme design between the early implementation phase and the recommended district programme is not known, but to explore the potential for some fall in effectiveness, the CER of the district programme was estimated reducing effectiveness by a third and a half, leading to an increase in the CER to $1.36 and $1.98, respectively.

Estimated cost per death and per DALY averted

The model described in Figure 2 predicted that 32 deaths would have been averted per year for the population covered by the early implementation phase, and 429 for the recommended district programme, equivalent to 894 and 11 810 DALYs averted, respectively. This implied a predicted cost per death averted of $505.42 for the early implementation phase and $105.92 for the recommended district programme, and a cost per DALY averted of $18.38 and $3.85, respectively.

The results for both the early implementation phase and the recommended district programme remained under $30 per DALY averted for all variations explored in the sensitivity analysis in Table 5. We also tested the impact of varying individual model assumptions on the cost per DALY averted. Reducing antimalarial efficacy from 90% to 80% increased the cost per DALY averted for the early implementation phase from $18.38 to $20.68, and for the recommended district programme from $3.85 to $4.33. Reducing the proportion of treatment failures that become severe from 5% to 2% increased it to $45.95 for the early implementation phase, and to $9.63 for the recommended district programme. The model was most sensitive to the assumed case fatality rates. However, reducing the case fatality rates from 19% to 4% for inpatients, and from 50% to 10% for untreated cases, only increased the cost per DALY averted to $90.90 for the early implementation phase, and $19.05 for the recommended district programme.

Affordability

Table 6 shows the budgetary requirements of the recommended district programme, assuming existing resources cover all staff time and other resources listed in the last row. The incremental district budget is estimated as $11 477 for the development phase ($0.02 per capita), $81 450 for the set up year ($0.17 per capita), and $18 129 per year thereafter ($0.04 per capita).

Discussion

At the Abuja Summit, African heads of state agreed that by 2005 at least 60% of those suffering from malaria should have access to, and be able to use, affordable and appropriate treatment within 24 hours of the onset of symptoms (WHO 2000). Recent household surveys in 28 African countries have shown that on average only 42% of children under 5 years with fever were treated with an antimalarial drug (WHO/UNICEF 2003). Moreover, many will have received inappropriate doses (Marsh et al. 1999; McCombie 2002). Since up to 60% of fever treatments are purchased from retailers, shopkeepers have a potentially important role in the achievement of the Abuja target.

The Kilifi shopkeeper training programme has provided the first evidence that training private drug retailers can have a major impact on malaria home care practices, and the first comprehensive costing of such an intervention. There was a marked increase in the proportion of shop-treated childhood febrile episodes that were treated appropriately, at an economic cost of $4.00 per additional appropriately treated case. In the sensitivity analysis, the CER varied between $1.78 and $6.51, being most sensitive to annual fever incidence and the proportion of children treated appropriately. If the same impact were achieved through the recommended district programme, the economic cost per additional appropriately treated case was estimated at $0.84, varying between $0.37 and $1.36 in the sensitivity analysis.

Limitations

Study design

The effectiveness data should be interpreted carefully since the design does not include randomization or replication at the intervention level. However, Marsh et al. have argued that analysis of potential confounding factors and the maintenance of the improvements over time suggest that a causal association between implementation and the changes in OTC drug use is highly likely (Marsh et al. 2004).

Estimating the cost-effectiveness of the recommended district programme

Evaluating interventions at an early stage of implementation involves a number of challenges. Average costs are unlikely to be representative of a full-scale MOH programme because the programme is operating on a small scale, and programme design may evolve as experience leads to adaptations to improve effectiveness and efficiency (Over 1986; Coast et al. 2000). In this paper, we therefore present both the measured cost-effectiveness of the programme in the early implementation phase at sub-division level, and the predicted cost-effectiveness of a hypothetical recommended MOH programme at District scale.

The recommended district programme appeared more cost-effective than the early implementation phase because effectiveness was assumed to be the same, while the cost per capita was lower for the district programme for two reasons. First, there were economies of scale through spreading the costs of the development phase, training of trainers and central administration over a wider population. Secondly, changes in programme design were assumed, reflecting the research team's current recommendations to the MOH. As described above, these changes involved reducing the proportion of shopkeepers trained and the length of training, reducing managerial time, replacing KEMRI staff with MOH personnel and replacing 4-wheel drive vehicles with motorbikes. Two of these changes have since been adopted in Bahari Division (the selective recruitment of shops and the reduced length of the shopkeeper training), with no indication that they have compromised effectiveness. However, the impact of substituting MOH personnel for KEMRI staff, and substantially reducing the input of managerial time at divisional level, has not been tested. As with many novel interventions, the contribution to effectiveness of the highly qualified and motivated personnel involved in the initial programme is difficult to assess, but is likely to be important. To allow for a possible fall in efficiency and commitment, in the sensitivity analysis we explored the impact of major reductions in effectiveness.

Hidden benefits

The outcome used in the CER measures only the benefits of improved antimalarial use in the target age group. There were also improvements in the use of antipyretics, with a significant reduction in the use of multiple aspirin-based drugs, and an increase in the use of paracetamol, the recommended antipyretic for febrile children (Marsh 2001). The intervention may also have improved drug utilization outside the target age group, increased appropriate referral of children with danger signs to health facilities and reduced the number of failed home treatments leading to formal sector outpatient treatment with second-line antimalarial drugs. Improved home use of antimalarial drugs may also be associated with reduced pressure for the development of drug resistance. Other more generalized benefits may include an increase in

Table 6. Financial budget and Ministry of Health resources required for the recommended district programme (2000 US$)

Financial costs	Development phase		Set up year		Continuation year	
	Total cost ($)	%	Total cost ($)	%	Total cost ($)	%
Capital costs						
Motorbikes	3015	26	18 091	22	–	–
Computer/Printer	1470	13	–	–	–	–
Laminator	219	2	–	–	–	–
Bicycles	–	–	4471	5	–	–
Recurrent costs						
Allowances for attending training and field visits	401	3	18 635	23	8698	48
Input of professional advisors	5119	45	4023	5	–	–
Posters	–	–	5546	7	1110	6
Accommodation and refreshments for training and meetings	624	5	14 866	18	3311	18
Supplies and utilities	221	2	1043	1	1043	6
Recurrent transport costs	407	4	14 775	18	3968	22
Total financial costs	**11 477**	**100**	**81 450**	**100**	**18 129**	**100**
Financial cost per capita	**0.02**		**0.17**		**0.04**	
Other Ministry of Health resources	• 12 days for senior DHMT staff • 38 days for Public Health Officer • 70 days for PHTs • 10% of time for 1 secretary		• 30 days for senior DHMT staff • 10% of time of 1 DSC • 66% of time for 7 DVCs • 336 days for PHTs • 10% of time for 1 secretary • Office space at District level • Occasional use of 4-wheel drive vehicle and driver		• 6 days for senior DHMT staff • 3% of time of 1 DSC • 21% of time of 7 DVCs • 336 days for PHTs • 10% of time for 1 secretary • Office space at District level	

DHMT = District Health Management Team; PHT = public health technician; DSC = District Co-ordinator; DVC = Divisional Co-ordinator.

awareness of and commitment to health-related issues at the community level.

The implications for policy

Four key issues affecting the policy implications of these results are discussed below.

Are the effects sustainable?

Cost-effectiveness was evaluated by combining effectiveness results from the first year of implementation with a typical year's economic cost, implicitly assuming that the impact in the set up year would be sustained. However, in many training interventions targeted at both public and private sector staff, a sharp drop-off in effectiveness occurs after the initial year, as trainees forget some new knowledge and lose motivation (Ofori-Adjei and Arhinful 1996; Tuladhar et al. 1998). By contrast, household surveys in the second and third years of this intervention indicated a steady build-up and consolidation of effectiveness (Marsh et al. 2004). This was not unexpected, as the programme was designed to ensure sustainability, through refresher training for trainers and shopkeepers, further introductory workshops to allow for shopkeeper turnover, continuous monitoring of shopkeeper performance, and on-going community mobilization. Even with such activities, sustainability may be threatened if staff do not perceive economic benefits from participation. In this programme, the continued commitment of MOH and community staff was encouraged through the provision of allowances for training and field visits.

As shopkeepers were not remunerated by the programme, sustainability requires that they perceive a net benefit from participation in other ways. In the qualitative evaluation, the main perceived benefits were increases in personal knowledge, social status and trade. The main problems concerned the amount of time spent in training and in advising customers, particularly during busy periods (Nyamongo et al. 2002). Overall, the programme was popular, with a high recruitment rate, but there was also a high drop-out rate in the first year, with 30% of shops closing down, losing the trained seller or ceasing to sell drugs. To some degree this may reflect the general economic decline in Kenya over this period (Ministry of Finance and Planning 2000). In subsequent years, the remaining shops proved more stable, with losses of less than 5% per annum. Of interest, the improved OTC drug use observed was achieved despite this turnover, which may indicate that stable trained outlets attracted a disproportionate number of drug purchasers. However, improved methods are needed for identifying relatively permanent outlets and disseminating information to new staff within programme shops.

Are the results generalizable for other drugs?

The shopkeeper training could be used to support any antimalarial drug recommended for OTC sale. Due to increasing levels of chloroquine resistance in Kenya, a national policy change from chloroquine to the SP group took place at the end of 1999. The shopkeeper training programme was adapted in response, necessitating additional development costs for the modification of information, education and communication (IEC) materials, but no important changes in the methods or costs of implementation. There was some indication of increasing effectiveness in terms of appropriate treatment after the change to SP, probably due to the simpler dosing regime (single-dose compared with 3-day chloroquine regimen), as well as programme consolidation over time (Marsh et al. 2004). Moreover, the programme played an important role in facilitating the introduction of SP drugs in the intervention area by publicising the change with shopkeepers and customers.

Several East African countries, including Kenya, are now in the process of introducing combination antimalarial therapies, which have higher efficacy but are generally more expensive and have more complex regimens. Kenya's initial plans for distribution are limited to government and mission health facilities. If distribution is to be expanded to the retail sector at a later date, this type of carefully designed and tested educational programme will be critical to support good uptake and use. It is difficult to predict the effectiveness of shopkeeper training with these antimalarials, or with drugs for other health problems commonly treated over-the-counter. However, this evaluation provides information on the general feasibility of shopkeeper training and its unit costs which will be valuable in selecting and planning such interventions.

Is the programme affordable?

As with most educational approaches, the programme carries a relatively high initial cost, with fewer resources needed in continuation years, although these are critical for sustainability (Table 6). As an indication of affordability, the average budget allocation for five sentinel districts in Kenya (Kwale, Makueni, Bondo, Kisii Central and Gucha) was \$882 622 per district in 2003/4 (Isaac Ngugi and Bob Snow, personal communication). The costs of the set up and continuation years would represent 9% and 2% of this figure, respectively. We therefore suggest that set up costs may be particularly suitable for funding by donor organizations, with possible contributions from the pharmaceutical industry, while subsequent costs could be contained within the budget of a typical sub-Saharan African District.

The provider perspective used for the cost-effectiveness analysis does not incorporate the economic impact on households, which is important in assessing both sustainability and equity implications. There was no evidence of an increase in the financial burden of shop-bought drugs on households. Moreover, it is possible that more appropriate use of these medicines led to savings in expenditure on other treatment sources. It is therefore possible that if a full societal perspective had been used, the intervention would have looked more cost-effective, even including the time contributed by shopkeepers. These summary figures do not capture the distributional impact of the intervention. Work is urgently needed to assess which types of households benefit from interventions focused on the private sector, and whether the poorest groups can be reached effectively through this channel.

Is training shopkeepers cost-effective compared with other interventions?

Policy makers must finally consider whether this intervention is cost-effective in comparison with other strategies for improving malaria treatment, and with interventions for other health problems. To assess the former they require data on the costs and effects of a range of alternative and complementary strategies, including improving the quality of care in the formal health sector; training and resourcing other types of community-based drug distributors, such as community health workers; improving drug packaging and labelling; drug subsidies; and mass communication campaigns.

However, evidence from developing countries is extremely limited on the cost-effectiveness of interventions for improving compliance with treatment for any diseases (Cleemput et al. 2002). We identified only one study with comprehensive cost data and a comparable outcome indicator, which concerned the introduction of health worker training and patient treatment packs for sexually transmitted diseases in South Africa (Harrison et al. 2000). Recalculating their results to exclude drug costs, the incremental cost per patient correctly treated was $14.13, or $7.31 for replication elsewhere (2000 US$). No comprehensive cost-effectiveness studies were identified for interventions to improve compliance with shop-bought drugs. Tavrow et al. (2003) evaluated an intervention to improve malaria treatment obtained from antimalarial retailers through the provision of training and materials to their wholesalers in Bungoma District, Kenya. They estimated a cost of $9–11 per retail outlet reached, compared with figures from this study of $87.82 for the early implementation phase and $18.41 for the recommended district programme (all costs in 2000 US$). However, the Bungoma study costs exclude the time of district health personnel and outside technical advisors, and the impact on drug use was not evaluated.

In order to compare our results with a broader range of health care interventions, we used a simple model to make tentative estimates of the impact of the intervention on final health outcomes (assuming the use of an effective antimalarial). This led to an estimated cost per death averted of $505.42 for the early implementation phase and $105.92 for the recommended district programme, and a cost per DALY averted of $18.38 and $3.85, respectively. To set these estimates in context, an intervention in a low-income country has been argued to constitute a 'highly attractive' use of resources if the cost per DALY averted falls below $25–30, and 'attractive' if it falls below $150 (WHO 1996). The results for both the early implementation phase and the recommended district programme remained under $30 per DALY averted for all variations explored in the sensitivity analysis in Table 5. Moreover, the cost per DALY averted of the recommended district programme remained under $25 for reasonable variations in the model parameters, a robust indication that this programme is likely to be highly cost-effective where an effective antimalarial is used.

Conclusions

Home management is a very common approach in the treatment of potentially serious illnesses, but a much neglected area in terms of effective intervention. Considerable interest has rightly been captured by the potential for improvements demonstrated by this programme. However, financial and managerial resources are constrained, and policy decisions must be based on a consideration of the opportunity cost of these resources. The scope to conduct such an analysis is currently limited by the lack of comparable studies of alternative approaches to improving malaria treatment. However, these results can serve as a benchmark for future evaluations for malaria and other illnesses for which over-the-counter treatment is the norm. Moreover, our tentative estimates of the cost per DALY averted indicate that the intervention is likely to be highly cost-effective in comparison with standard benchmarks. Improving the evidence base for the full range of interventions that can contribute to improving malaria treatment should now be a key research priority.

Endnote

[1] In practice the first continuation year was atypical, because the national first-line antimalarial drug was changed from chloroquine to the sulfa-pyrimethamine (SP) group. Development costs related to the introduction of SP were not included in the costs of the continuation year.

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