

Improving malaria home treatment by training drug retailers in rural Kenya

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Summary

Recent global malaria control initiatives highlight the potential role of drug retailers to improve access to early effective malaria treatment. We report on the findings and discuss the implications of an educational programme for rural drug retailers and communities in Kenya between 1998 and 2001 in a study population of 70 000. Impact was evaluated through annual household surveys of over-the-counter (OTC) drug use and simulated retail client surveys in an early (1999) and a late (2000) implementation area. The programme achieved major improvements in drug selling practices. The proportion of OTC anti-malarial drug users receiving an adequate dose rose from 8% ($n = 98$) to 33% ($n = 121$) between 1998 and 1999 in the early implementation area. By 2001, and with the introduction of sulphadoxine pyrimethamine group drugs in accordance with national policy, this proportion rose to 64% ($n = 441$) across the early and late implementation areas. Overall, the proportion of shop-treated childhood fevers receiving an adequate dose of a recommended anti-malarial drug within 24 h rose from 1% ($n = 681$) to 28% ($n = 919$) by 2001. These findings strongly support the inclusion of private drug retailers in control strategies aiming to improve prompt effective treatment of malaria.

keywords malaria, malaria home care, over-the-counter drugs, drug retailers, shopkeepers, training

Introduction

The major burden imposed by malaria on populations in sub-Saharan Africa (SSA) is well recognized. Of an estimated 300–500 million malaria episodes worldwide per annum, 90% occur in SSA, mainly affecting young children and leading to around 750 000 deaths in this age group each year (Snow *et al.* 1999; WHO 2000a). In recent years, increased efforts have been made to raise political commitment and coordinate donor and development agency activities for malaria control (WHO 2000a,b). Current national malaria control strategies in SSA have been developed around targets agreed at the Africa Head of States meeting in Abuja in 1998, coordinated by the Roll Back Malaria initiative (RBM), including strategies to improve access to prompt effective treatment and home care for malaria (WHO 2000a). A major theme for RBM has been to maximize effective use of existing resources and develop efficient strategies and tools for malaria control (Alnwick 2000; WHO 2000b). The development of public–private linkages to support over-stretched public health sector resources has received much attention (World

Bank 1993; Giusti *et al.* 1997; Alnwick 2000; WHO 2001a). The value of building such linkages is emphasized by estimates that over 50% of all anti-malarial drugs are distributed through the informal private sector (Foster 1991).

The rationale for encouraging effective home use of anti-malarial drugs as a strategy for malaria control is based on a number of well-reported phenomena. In many SSA countries, the earliest action taken for fever in a majority of episodes is to use drugs bought over-the-counter (OTC) from untrained retailers (Deming *et al.* 1989; Slutsker *et al.* 1994; Ruebush *et al.* 1995; McCombie 2002). In part, this arises through poor geographic access to facilities with a trained health worker, but the popularity of self-treatment is strengthened by the frequent drug shortages, long waiting times and user fees common in public health facilities (McCombie 1996). In all areas where self-treatment practices have been studied, they have been typified by the use of inappropriate drugs and dosages. In many settings, childhood fevers are treated with antipyretic drugs only, with a common preference for aspirin-based drugs (McCombie 1996). Both antipyretic and anti-malarial

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drugs are used in inappropriate ways, often including aspirin over-dosage and anti-malarial under-dosage (McCombie 1996; English *et al.* 1996; Marsh *et al.* 1999). In the case of childhood malaria, the ineffectiveness of these early practices represents a major problem, since many malaria deaths occur within the first 48 h of illness (Greenwood *et al.* 1987). This need for rapid treatment, alongside the lack of resources to make a parasitological diagnosis of malaria at community level, has led to guidelines for all childhood fevers to be treated rapidly and presumptively as malaria in endemic areas in sub Saharan Africa (WHO 1997b).

Since private retailers are often the primary source of drugs used in the home, the potential role of this group as partners for malaria control has been recognized (Van Der Geest 1987; Snow *et al.* 1992; Kafle *et al.* 1996; WHO 1997a; Marsh *et al.* 1999; Laing *et al.* 2001). Whilst concerns exist about regulation of activities in the private retail sector, the pragmatic approach of channelling information on OTC drugs through their suppliers has clear potential to improve the early treatment of childhood fevers. Since a retailer intervention would be developed around an existing drug distribution system, there may also be economic advantages for the Ministry of Health in setting up and sustaining retailer programmes to improve access to early effective treatment over alternative *de novo* community based delivery systems, such as community pharmacies.

Against this background, the Kilifi shopkeeper training programme was set up to explore the benefits and problems of training drug retailers. We aimed to describe the willingness and ability of drug retailers to take on an advisory role and the impact of training drug retailers on patterns of OTC drug use in the community. The main aim of the programme was to increase the proportion of childhood fevers treated promptly with a recommended anti-malarial drug in an adequate amount for age. Further aims were to increase recognition and appropriate treatment seeking for complicated malaria, to support recognition of good quality anti-malarial drugs and to promote appropriate use of OTC antipyretic drugs. The operational components were developed and managed collaboratively with the Ministry of Health to strengthen sustainability, generalizability and efficient use of district health resources. In this context, further aims of this programme were to describe a programme infrastructure and training modalities required for sustainable change, to assess the factors promoting and hindering changes in behaviour and to estimate the financial and economic costs associated with the operational components. This paper reports on the quantitative findings on changes in retailers' and purchasers' practices between 1998 and 2001. The results

of the qualitative and economic assessments will be published separately.

Methods

The study area

The Kilifi Shopkeeper Training Programme is an educational intervention, targeting drug retailers in general shops and the community in a rural area within Kilifi District, Kenya. In this district, 39% of the population live more than 5 km from a formal health provider and small general shops selling anti-malarial and antipyretic drugs alongside household commodities provide first-line care for 60% of childhood fevers (Snow *et al.* 1992; Marsh *et al.* 1999). Such outlets fall under the supervision of both the district public health office and the local council, through annual health clearance from the former and trade licensing by the latter. Drugs are primarily sourced through wholesale shops in nearby towns. A few mobile distributors operate infrequently in the area. Wholesale shops are supplied by larger wholesalers in major towns or directly by drug manufacturers.

Approximately 70 000 people live within the rural area chosen for the programme. The programme was implemented in two phases across this study area, with an early implementation phase in the south in 1999 and a late implementation phase in the north in 2000. Active sources of pharmaceuticals within this area are two government dispensaries, seven private clinics, six community pharmacies and 316 small general shops selling drugs alongside household goods. The district general hospital is situated in the town of Kilifi, 40 km from the furthest point of the study area. The Mijikenda ethnic group predominates in this area, working primarily as subsistence farmers, with some cash income from the tourist, retail and industrial sectors of nearby towns. The pattern of malaria transmission is stable and endemic, with two seasons of intense transmission annually. Descriptions of the geography, demography, anthropology and epidemiology of malaria in this area have been published by Nevill *et al.* (1996) and Snow *et al.* (1993).

The programme

The programme was developed collaboratively by the Kenya Medical Research Institute (KEMRI)-Wellcome Trust Research Programme with the Kilifi District Health Management Team (DHMT) and the Division of Malaria Control (DoMC) in the Ministry of Health (MOH). Methods were based on existing MOH primary health care personnel and resources, as far as possible, to strengthen

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potential impact and sustainability, and build district capacity for information, education and communication (IEC). The two main components of the programme were workshop training for groups of drug retailers and community information activities. Anti-malarial drug distribution systems remained unchanged. Trainers were drawn from two existing groups in the community. The first were MOH public health technicians (PHT), a cadre of health workers with 2 years of tertiary level training, normally responsible for control of communicable diseases at community level, including inspection of retail premises. The second were community health or development workers (CW), with 8–12 years of formal education, and chosen by local leaders and programme managers on the basis of experience in community development work. All trainers were remunerated for time spent in programme activities, in accordance with government or village health committee recommendations.

Training used participatory skill-based methods for groups of 15–20 people, including role-play demonstration and practising, and small group discussions and exercises. One or two retailers attended from each outlet, depending on size. In the set-up years, training was given over 4 days; all programme shops were invited to attend annual 1-day refresher workshops in subsequent years. The content of the training is given in Figure 1. In 1999, we trained on the use of chloroquine (CQ) drugs in the early implementation phase, in accordance with MOH recommendations. In 2000, sulphadoxine pyrimethamine (SP) group drugs replaced CQ drugs as the recommended first-line OTC anti-malarial drugs in Kenya. Training in all areas thereafter addressed SP drug use, and discussed the reasons for change. Table 1 gives the SP and paracetamol dosage chart used by trained retailers, based on government recommendations. Retailers were visited in their normal workplace after the training, and were evaluated through role-play demonstration of the skills taught in the workshop, including advising on drug dosages and making appropriate referrals. This evaluation was conducted by trainers using fixed scenarios

- The cause of malaria
- Signs of malaria and their relation to severity of illness
- Types of OTC antimalarial and antipyretic drugs according to age, using drug charts for reference
- Drug resistance and the link to under dosing
- Drug stock purchase, storage and quality
- Indicators for referral, including treatment failure and danger signs (breathing difficulty, severe weakness, convulsions and severe diarrhoea or vomiting)
- Basic communication skills

Figure 1 The main content of the shopkeeper training.

Table 1 SP and paracetamol drug dosage chart

SP tablets; take once only	Age of user	Paracetamol tablets; take up to four times per day
½	2–11 months	¼
1	1–4 years	½
1½	5–8 years	½
2	9–14 years	1
3	15+ years	2

and a role-play checklist. Successful sellers were awarded certificates of satisfactory completion of training, and posters were displayed outside their shops providing accreditation to the MOH. After training, CWs visited shops twice annually to monitor activities, reporting back to the programme manager at monthly meetings.

The programme outlet recruitment policy was changed during the second round of training. In the early implementation phase, all retailers selling anti-malarial or antipyretic drugs were eligible to be included in the training. About 94% of all shops ($n = 199$) participated in the training, but 34% either closed down or lost the trained seller within 12 months of training. To address this problem, we selected shops for training in the late implementation area in 2000. Selection was based on the advice of community groups, using criteria of popularity, geographic access and the perceived stability of outlets and trustworthiness of the owners and their employees. On this basis, 60% ($n = 117$) of all drug retail outlets were selected for training in the late implementation area, and 93% of targeted shops were successfully recruited to the programme.

Through the public information activities, we aimed to create awareness of the programme, identify trained retailers and give information on the importance of early effective treatment for malaria in children, changes in anti-malarial drug policy and situations when a trained health worker should be consulted. Trainers attended planned meetings or arranged specific meetings in the community to provide programme information and opportunities for discussion. In 2000, they attended 55 general public, 13 women's group and 16 school or parent teacher association meetings across the study area. At these gatherings, they used flip charts to systematically present consistent messages about the programme. A total of 373 posters, providing information about the programme, and showing the logo that would identify a trained outlet, were displayed in widely used places, such as piped water sources and transport centres. Senior administrative leaders presented certificates to trained sellers in four public ceremonies, with wide inter-sectoral support. On these occasions,

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local dance and drama groups were used to attract crowds and convey programme messages through entertainment. A full description of the operational components of the programme is available from the authors as a manual.

Study design

The two-phase implementation of the programme allowed contemporaneous comparisons of OTC drug use patterns in trained and untrained areas at baseline (1998) and after the first round of training (1999). OTC drug use patterns were followed across both areas in 2000 and 2001. The evaluation was based on annual household surveys assessing specific behavioural indicators.

This design was chosen for compatibility with MOH operational resources, based on the requirement to develop and test a sustainable programme using existing administrative structures and personnel. Although a lack of randomization and replication at the intervention level limits the interpretation of the findings, the design allows us to assess an operational approach that is readily generalizable within Kenya and many other parts of SSA. A causal relationship between programme implementation and any changes seen would be highly plausible since the indicators used are specific to the programme approach. We also assessed potential confounding factors, including the cost of OTC drugs and the existence of other educational programmes in the study area. The merits and disadvantages of this type of plausibility assessment, as opposed to a randomized controlled design, have been discussed by Habicht *et al.* (1999).

Study methods*Household surveys on OTC drug use*

A population-based impact was examined through annual household surveys assessing treatment seeking behaviour for recent childhood fevers, including OTC drug use, amongst children under 10 years. The surveys were conducted across the study area during the peak malaria transmission seasons between 1998 and 2001. In 1998–2000, households were selected for interview by drawing random index households from an existing demographic database, and identifying a cluster of the 50 nearest households for each index household. In 2001, households were selected randomly without clustering. Where overlapping fevers were encountered in siblings, the first child to become unwell was recruited to the study. A second field worker validated 30% of all OTC anti-malarial drug use histories within 24 h. Data were collected on the types and timing of treatment seeking behaviour, and the types and pattern of administration of OTC drugs used. Dosages of anti-malarial drugs were assessed for

adequacy by comparison with national standard treatment guidelines (Kenya Ministry of Health 1998).

Shopkeepers' skills

A 'simulated client' survey was conducted in 1999 and 2000 by local mothers, trained to assess retailers' skills when buying drugs for a standardized illness scenario (Madden *et al.* 1997). These assessments were made outside their normal areas of residence, using simple checklists and avoiding repeat visits by the same person. Simulated clients visited all shops in both the early and late implementation areas in 1999 and 2000, and requested OTC drugs for a child with fever. Where questioned about the illness, they described a 2-year-old child with signs compatible with mild malaria. The majority of shops were visited three times and data collected from all outlets selling drugs at the time of the visit.

Data management and analysis

Household and simulated client survey data were checked daily for inaccuracies and inconsistencies, before double entry and verification using FOXPRO version 6. We present the estimated proportions and their 95% confidence intervals for each area and year separately. In 1998, 1999 and 2000, the 95% confidence intervals for the estimated proportions were calculated using robust standard errors that adjust for within-cluster correlation (Williams 2000). The analysis was performed using STATA version 7 (StataCorp, Texas, USA).

Results**Retailers' willingness and ability to participate**

Retailers were generally both willing to participate in the programme and able to learn the skills needed for active participation. In the first round of training during 1999, retailers from 187/199 (94%) shops selling anti-malarial or antipyretic drugs in the southern area attended training. In 2000, 72/117 (62%) shops were selected and all retailers recruited for training. Over the course of the programme, more retailers from 23 shops were trained to replace closed outlets in strategic positions. In both areas, 95% of shopkeepers attending workshops later demonstrated adequate skills for advising on anti-malarial drugs during evaluation in their own shops.

Table 2 summarizes the data from all simulated client visits to shops in 1999 and 2000. Results are provided from trained and untrained shops in the early and late implementation areas, respectively, in 1999, and trained shops across both areas in 2000. The data in Table 2 were

Table 2 Simulated client survey results (1999–2000)

Questions asked or advice given to simulated clients	Early implementation area		Late implementation area	
	1999, after CQ training	2000, after SP training	1999, no training	2000, after SP training
Asked about previous treatment/all visits	66/295 (22%)	72/220 (33%)	0/224	64/183 (35%)
Asked about 1+ danger signs/all visits	78/299 (26%)	70/220 (32%)	0/224	76/183 (42%)
Advised to buy an AM/all visits	119*/299 (40%)	99†/220 (45%)	2‡/224 (<1%)	99§/183 (54%)
Gave appropriate advice on AM/OTC AM buyers¶	102/119 (86%)	96/97 (99%)	0/2	96/98 (98%)

Types of AM drugs recommended: * AQ = 1, others CQ; † CQ = 4, others SP;

‡ All CQ; § All SP.

¶ Appropriate advice defined as advised to buy the MOH recommended AM drug (CQ in 1999, SP in 2000) and to give in an appropriate dose and regime according to age.

collected across three visits made to all shops, and represents retailer practices in those that were both open and selling drugs when visited. This accounts for between 65% and 75% of all attempted visits, the remainder being accounted for by outlets that were temporarily closed or not selling drugs. In the untrained shops, the vast majority (>99%) of simulated clients were not sold anti-malarial drugs. They were generally sold antipyretic drugs, and were not asked questions or provided with information on drug usage. In the trained outlets, retailers advised on the use of anti-malarial drugs in around half of visits. As shown in Table 2, the anti-malarial advised was the MOH recommended anti-malarial and the sale was accompanied by accurate dosage advice in the vast majority of sales. However, trained retailers were less consistent in asking about danger signs.

Community drug use

In 1998, there were 5677 households in the study area, of which 3437 were in the early implementation and 2240 in the late implementation area. Table 3 presents a summary of the main findings of the household surveys. OTC drug use in the table includes only those fever episodes where the first action taken was to visit a drug retailer. We have excluded a small number of episodes where OTC drugs were used following a health facility visit or where OTC drugs were taken from supplies kept in the home.

Presumptive treatment of fever with recommended OTC anti-malarial drugs

There was an increase in the proportion of fevers first treated through retail outlets that were given an anti-malarial drug,

as opposed to an antipyretic drug, coinciding with the introduction of training in both the early and late implementation areas, shown in Table 3. Overall, 26% ($n = 697$) fever treatments included an anti-malarial drug prior to programme implementation in 1998, and 48% ($n = 919$) by 2001. There was generally a steady increase over time, with the exception of a small drop in 2001 in the late implementation area.

Prior to 2000, no sales of SP anti-malarial drugs were recorded ($n = 291$). After introduction of SP into the programme in 2000, there was a rapid uptake of SP drugs in the study area with 72% ($n = 301$) and 90% ($n = 441$) of all OTC anti-malarial brands used belonging to the SP group in 2000 and 2001, respectively.

Adherence to recommended drug dosages and timeliness of treatment

There was a marked increase in the proportion of those buying anti-malarial drugs that reported appropriate use in the early implementation area between 1998 and 1999, from 8% to 33%, as shown in Figure 2. At this time, the same proportion rose in the untrained late implementation area from 6% to 12%. After the introduction of SP drugs in both areas in 2000, appropriate use of anti-malarial drugs was reported in 64% of OTC-treated fevers by 2001, with a steady increase over time. By 2001, 71% ($n = 396$) of fevers treated with OTC SP were given a dosage appropriate for age. Overall, the proportion receiving an adequate amount of a recommended anti-malarial drug rose from 2% ($n = 677$) to 31% ($n = 923$) in 2001, as shown in Figure 3. There was a steady increase over time in each part of the study area following introduction of training, and the pattern was similar for both CQ and SP.

Table 3 Households visited, fever episodes and characteristics of OTC drug use for childhood fevers

	Early implementation area				Late implementation area			
	1998, untrained	1999, trained (CQ)	2000, trained (SP)	2001, trained (SP)	1998, untrained	1999, untrained	2000, trained (SP)	2001, trained (SP)
Households visited	2035	1462	1705	1506	1650	1693	1690	1019
Recent fever episodes	655	521	504	1188	513	589	453	662
% fevers treated through shops	375/655 57% (53–62%)*	281/521 54% (50–59%)	296/504 59% (55–62%)	568/1188 48% (45–51%)	322/513 63% (56–70%)	395/589 67% (63–71%)	289/453 64% (58–69%)	355/662 54% (50–58%)
% fevers treated through shops where AM used	111/375 30% (24–35%)	129/281 46% (40–52%)	135/296 46% (40–51%)	264/564 47% (43–51%)	69/322 21% (17–26%)	123/395 31% (26–36%)	167/289 58% (51–64%)	177/355 50% (45–55%)
% OTC AM users taking adequate dose†	8/98 ^a 8% (3–13%)	40/121 ^a 33% (24–42%)	66/130 ^b 51% (40–61%)	171/264 ^c 65% (59–71%)	4/62 ^a 6% (1–14%)	14/116 ^d 12% (5–19%)	94/165 ^c 57% (48–66%)	112/177 ^c 63% (56–70%)
% shop treated fevers receiving adequate dose of recommended AM	8/362 2% (0.8–4%)	40/273 15% (10–19%)	66/291 23% (16–29%)	171/568 30% (23–37%)	4/315 1% (0.2–3%)	14/388 4% (2–6%)	94/287 33% (27–39%)	112/355 32% (27–37%)
% shop treated fevers receiving adequate dose of recommended AM within 24 h onset illness	7/366 2% (0.6–3%)	37/273 14% (9–18%)	55/291 19% (14–24%)	151/568 27% (23–30%)	3/315 1% (0.1–2%)	13/388 3% (1–5%)	78/287 27% (22–32%)	106/355 30% (25–35%)

AM, anti-malarial drug; AQ, amodiaquine; CQ, chloroquine; OTC, over-the-counter; SP, sulphadoxine pyrimethamine group drug.

* Figures given in brackets throughout are 95% CIs.

† This represents use of all anti-malarial drugs. For CQ, adequate dose is defined as between 25 and 40 mg/kg over 3 days, using locally derived weight for age charts to estimate weight. Adequate SP is defined in accordance with national recommendations (see Table 2). Over dosage (not indicated in national recommendations) is taken as more than double the recommended dose. Amongst AM drugs coded adequate: ^a All AM = CQ, ^b SP = 61, CQ = 4, amodiaquine (AQ) = 1, ^c All AM = SP, ^d CQ = 13, AQ = 1, ^e SP = 90, CQ = 2, AQ = 2.

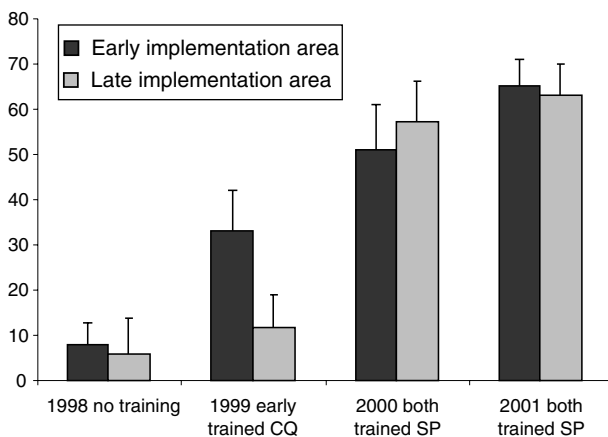


Figure 2 Percentage of OTC AM users taking an adequate dose. Error bars are upper 95% CIs.

Discussion

Death due to malaria in children typically occurs rapidly. In Africa, the majority of episodes are first treated at home using OTC drugs, but such treatments usually involve

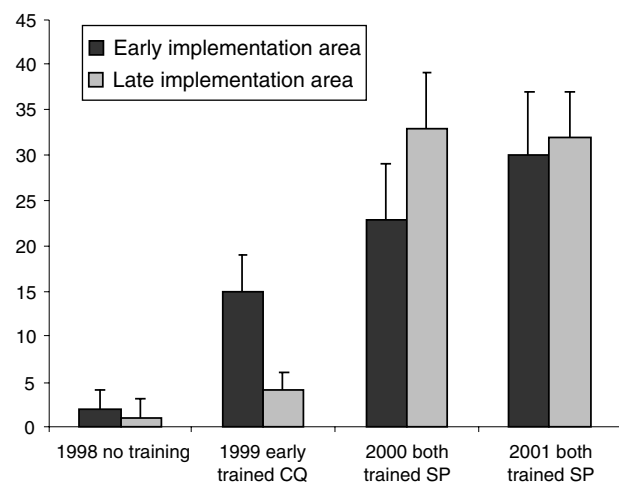


Figure 3 Percentage of OTC treated fevers with adequate dose of a recommended AM drug. Error bars are upper 95% CIs.

inappropriate types and amounts of drugs. Improving the home use of shop-bought anti-malarial drugs therefore potentially offers a major opportunity for reducing malaria

deaths in endemic areas. Such initiatives require carefully designed educational interventions, yet there is little evidence to guide development and implementation of such approaches (Kafle *et al.* 1992; Oshiname *et al.* 1992; Ross-Degnan *et al.* 1996; Sia & Valerin 1997; Tavrow *et al.* 2003). We report on the findings of an educational programme, developed and implemented collaboratively by the MOH and the KEMRI-Wellcome Trust Research Programme, targeting malaria home care practices through training drug retailers and public information activities. The findings indicate that drug retailers in a typical rural area were willing and able to offer advice on the drugs sold through their shops. Further, the study provides strong evidence that the programme led to major improvements in community OTC drug use. Introduction of the programme coincided with a fourfold increase in the proportion of anti-malarial drug users taking an adequate amount in the first year of implementation, compared to the moderate increase seen in untrained areas at the same time. Overall, the proportion of children accessing effective anti-malarial treatment within the first 24 h of a fever rose from 1% to 28% between 1998 and 2001. Although the lack of long-term control data limits interpretation of these results, we believe that the findings strongly support the inclusion of private drug retailers in malaria control strategies, and emphasize the importance of such programmes in reaching targets set by the Abuja declaration (WHO 2000c).

The change from CQ to SP

The retailer programme provided support for the national drug policy change from CQ to SP in two broad ways; the first was to promote uptake of the new drug by purchasers and the second to improve adherence to recommended dosage. Effecting a drug policy change at user level is difficult, both from supply and demand perspectives. The main supply issues for the Kilifi retailers were the inadequacy of existing distribution systems for SP drugs, leftover from its earlier 'prescription-only medicine' status, the economic disincentive to adopt changes that lead to unsold stock and the lack of familiarity with this type of drug. From a demand perspective, uptake of SP drugs was handicapped by widely held beliefs within the community that CQ drugs were effective, lack of familiarity with SP drugs, beliefs that SP drugs were 'too strong' for children, the increased cost in comparison to frequently used 'underdoses' of CQ and the slow reduction of symptoms typical of SP products. This was counterbalanced by ease of administration provided by a single dose regimen. In this programme, SP drugs were taken up by the communities very rapidly after training (72% of OTC anti-malarials bought were SP drugs within 6 months of beginning

training, and 90% within 18 months), and we believe that this was strongly influenced by the programme. National information programmes to support the policy change did not begin until late 2000. These have been of limited effectiveness, demonstrated by surveys of OTC drug use in four other districts in Kenya indicating that, by 2002, only 31% of childhood fevers treated with retail anti-malarial drugs were given SP brands (Amin AA, Marsh V, Noor AM, Ochola SA & Snow RW, submitted).

After introduction of the programme, we also observed a high rate of adherence with recommended regimens for administration of SP drugs. However, interpretation of our findings on adherence is complicated by the lack of data on SP usage from non-programme areas, or prior to programme implementation. We can make this comparison for CQ drugs, where a marked improvement in adherence was seen in programme areas in contrast to both historical and contemporaneous controls. It is reasonable to assume that adherence to a single dose SP drugs would be easier to achieve, but it is unlikely that widespread appropriate use of a new drug would occur in rural African settings with no input over and above that instituted by the manufacturer. Holtz *et al.* (2003) note that only 42% of children with fever treated with SP drugs at home in Malawi received the recommended dose. A MOH survey in Busia district in Kenya records the same phenomenon in 46% children less than 5 years (Marsh *et al.* 2003). Furthermore, it is likely that emerging drug resistance will lead to SP drugs being replaced by a new generation of anti-malarial treatments in the near future. All the potential candidates to replace SP drugs will require multi-dose administration (WHO 2001b). Given the effectiveness of this type of training approach in improving the home use of CQ drugs, even over a relatively short period of time, we suggest that skill-based educational programmes for retailers and communities will provide good support for new multi-dose drugs introduced in the future.

Promoting presumptive treatment of childhood fevers as malaria

The most difficult communication task that drug retailers were faced with through this programme, and reflected in Table 1, was to persuade purchasers who intended to buy an antipyretic drug for a child with fever to buy an anti-malarial drug either instead (for CQ), or in addition (in the case of SP). OTC antipyretic drugs are widely used as a first-line treatment for children with fever at home. Important barriers to change included the cost of the drugs, the deeply rooted nature of these practices and the inability of some purchasers to influence choice of drug. A common example of the latter situation occurred where

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young children were sent to buy drugs on behalf of a parent. Over the period of the evaluation, the proportion of shop-treated childhood fevers receiving an anti-malarial drug increased from around a quarter to approximately a half immediately after training, but did not continue to rise. In part, this may be an influence of selective training, since, in 2001, twice as many treatments through trained outlets (61%, $n = 566$) involved an anti-malarial drug than through untrained outlets (29%, $n = 332$). It is clearly important for this message to continue to be emphasized in retailer refresher training activities, but we believe that choice of type of drug cannot be effectively addressed through retailers alone. The important change agents are decision makers at household level. This type of health communication is therefore an important part of public information activities, particularly when retail outlets are selectively recruited. There may also be important contextual differences that influence the usefulness of messages about the presumptive treatment of childhood fevers as malaria, particularly in different transmission settings. In epidemic areas, for example, promotion of anti-malarial drugs for fevers might be associated with particular seasons, and not restricted to young children.

Limitations of this study

We have discussed that this study lacks replication and randomization at the intervention level. However, the data show a highly plausible relationship between the introduction of a specific training intervention and changes in behaviour indicators closely related to content of the intervention. The magnitude of the changes seen and the consistency of patterns emerging over time and place provide evidence of an impact of the intervention. To support the plausibility of the relationship, we assessed the presence of potential confounding factors for the intervention. No other local or national sources of information on anti-malarial drug use were available in the study area over this period, other than those provided routinely through manufacturers. We monitored the price of retail drugs over the period of the intervention, and no changes in the price of anti-malarial drugs occurred between 1998 and 2001 to account for changes presented in Table 3. In addition, the programme evaluation has coincided with a period of rising national poverty indicators in a district with the fifth highest absolute poverty rate in Kenya (Kenya Ministry of Finance and Planning 2000).

The reported drug histories used to assess adherence are subject to recall and reporting bias, recording errors and present difficulties in validation (Nwanyanwu *et al.* 1996). We minimized these potential effects through training of

interviewers, focusing on improving communication skills and minimizing inter-observer variation. Interviews were intermittently monitored throughout the study period, with 95% concordance between first and repeat interviews in a random one-in-three sample of anti-malarial drug use reports. Further, the survey method used was developed in a pilot study of 1996, where the caretaker's reported use of chloroquine was validated through HPLC measurement of blood chloroquine levels (Marsh *et al.* 1999). Finally, there is consistency between the findings of the simulated client survey, the household survey and the qualitative assessment.

Recommendations for programme development and implementation

An important finding of this study is that public information is critical to the success of the training programme by providing trained drug retailers with credibility, promoting the use of trained shops, targeting specific messages for caretakers, facilitating change amongst purchasers and encouraging retailers to maintain good standards of practice. Involving the community in selecting trainers and shops for inclusion in the training programme increases the awareness and support of the community, while strengthening the sense of social responsibility and motivation of trained retailers.

We selected outlets in the late implementation area to try to reduce the high rate of outlet loss to the programme and to streamline monitoring activities. Whilst this was only partially successful in the first year of the programme, losses to the programme in subsequent years were very low (less than 5%). However, selection remains a compromise between maximizing programme effectiveness and minimizing resource input. The drawback of selection is the possibility that many fevers will continue to be treated inadequately through untrained outlets. In part, this can be counteracted by promotion of trained outlets in the community. In the late implementation area, where 60% of outlets had been selected for training, approximately 80% of all OTC treated childhood fevers were treated with drugs bought from a trained retailer in 2000. In addition, we noted improvements in anti-malarial drug dosages for OTC drugs bought from untrained outlets over time, likely to reflect information spread within the community and facilitated by the simple regime for SP drugs.

There is potential for extending the scope of this programme. The services offered at trained shops could include other malaria-related products, such as bed nets and insecticide, as well as non-malaria commodities, such as oral rehydration salts and condoms. This is likely to be most successful for products for which there is already

demand and serve the individual rather than the public good (Smith *et al.* 2001). In some settings, however, the scope may also be limited by the legal framework for OTC drug sales. National drug regulatory authorities should be partners in planning, and changes in existing drug policy may be considered a potential way forward. Extending the programme to types of drug retailers outside the rural, fixed outlets described in this programme will require further development and testing. In rural Kilifi, drug retailers have shown a clear sense of social responsibility to the communities they serve. This may be lacking in urban areas with high employee turnover rates, or with highly itinerant drug retailers.

However, we believe that there is sufficient evidence of the usefulness of this approach to malaria control to encourage further development and implementation of training and education strategies for drug retailers and purchasers. An important challenge is to tie programme implementation to continuing research on impact, and gain a better understanding of generalizability and operational effectiveness. In addition, there are concerns that increasing the peripheral distribution of anti-malarial drugs without parasitological diagnosis will promote the development of anti-malarial drug resistance. Although there are similar concerns that the current widespread inappropriate use of anti-malarial drugs is achieving the same result, more information is needed on drug resistance as with all programmes aiming to improve home care of malaria. Finally, a better understanding of the way that this strategy can be incorporated into malaria control activities at district level is critical to programme delivery. This research needs careful planning and coordination by policy makers, health managers and multi-disciplinary research teams to strengthen our understanding of the important contribution that private sector drug retailers can make to malaria control, while gaining health and economic benefits for malaria endemic communities.

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