

BRIEF REPORT

A new tool for malaria prevention?: Results of a trial of permethrin-impregnated bedsheets (*shukas*) in an area of unstable transmission

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Background Despite gains in malaria control through impregnated treated nets (ITN), malaria remains a major concern. Netting is expensive and impractical for many communities. Here we present the findings of a community-based trial of impregnated bedsheets (*shukas*) in Kenya.

Methods A total of 472 individuals were enrolled in a randomized community trial where the unit of randomization was the hamlet (*manyatta*). Baseline data included socio-demographic data, parasite prevalence data from thick and thin blood smears, and clinical measures of malaria. The intervention involved the dipping of *shukas* owned by the experimental group in permethrin.

Findings The prevalence of malaria in the study population (based on laboratory results) was considerably lower than that used for the power calculation based on clinical estimates (2.2% versus 20%). For those aged 6 or over, the rate of malaria cases (events per 10 000 person-days at risk) was 1.41 in the experimental group versus 7.49 in the control group (incidence rate ratio 0.187, 95% CI: 0.046–0.770). For children ≤ 5 years of age results were imprecise with no clear benefit of the intervention.

Conclusions These results suggest that permethrin-impregnated bedsheets may be protective against malaria prevention but further studies with greater power are required to confirm this.

Keywords Malaria control, malaria prevention, impregnated treated materials, personal protection

Malaria is an important public health problem in Africa.^{1–4} The International Campaign to Roll Back Malaria promotes use of insecticide-treated materials, emphasizing bednets and curtains in particular.^{2,5} However, the cost of bednets and regular insecticide re-impregnation is prohibitive for some

communities,^{6,7} and for some groups nets or curtains are not compatible with local housing construction or lifestyles. Although other materials and repellent combinations have been experimented with,^{8,9} the need remains for innovative interventions that make use of effective prevention methods to decrease cost and overcome acceptability barriers to the poorest, most marginalized sectors of society.

This study reports results of a trial to evaluate whether treating personal clothing/sheets worn by nomads is protective against malaria infection. The aim was to test the efficacy of an inexpensive, non-toxic, and locally appropriate strategy. The intervention employed insecticide-impregnated bedsheets, or *shukas*. A *shuka* is a 6' by 4' sheet (smaller for children) of varying

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material that doubles as a wrap during the day and a sheet at night. Nearly all Samburu own at least one *shuka*.

The impetus for this study occurred during a malaria epidemic in 1997–1998 in Samburu district, north Kenya, following *El Nino* rains.¹⁰ During the epidemic communities dipped their *shukas* in permethrin. This approach to malaria prevention cleverly adapted two well-known protection techniques: bednet and clothing impregnation. The effectiveness of insecticide-treated bednets has been demonstrated in a variety of settings.^{11–14} The use of insecticide-impregnated uniforms by military personnel dates back to at least World War II.¹⁵ We were interested to see whether impregnated *shukas* were effective in malaria prevention.

Data and Methods

The study was conducted in the village of Ngilai located in Samburu District, northern Kenya. The Samburu people who inhabit the area are livestock-herding pastoralists who live in *manyattas*, a collection of huts built of mud, sticks and animal hides. As nomadic pastoralists, Samburu men and adolescent boys migrate to bring animals to grazing pastures. More recently, Samburu women and children have become increasingly sedentary,¹⁶ settling around water points, schools, and health services. Samburu Aid for Africa (SAIDIA), a Kenyan non-governmental organization, operates the only clinic in the area. The nearest hospital is 30 km away.¹⁷

Study design

Permethrin was selected for this intervention, because it has been extensively tested, is used by military personnel throughout the world¹⁸ and is 'considered the insecticide of choice for clothing treatment'.¹⁹ Also, permethrin-based creams for child and neonate scabies and lice are widely used.^{20–22}

A community randomized study design was used to test the efficacy of the intervention. Randomization was at the level of the *manyatta* and approval to carry out the study was received from community elders. The sampling frame was constructed using the sole criterion that eligible *manyattas* be located within a 2-hour walk of the Ngilai health clinic. This represents the clinic's proximate catchment area and totalled 84 *manyattas*. Village records suggested the average *manyatta* size was 13 people. A minimum sample size of 440 (220 experimental and 220 control participants) was calculated using a confidence level of 95%, power of 80%, an estimate of 20% malaria parasitaemia in the control group, and a least extreme detectable difference of 10% among experimental group members. The estimated prevalence of malaria parasitaemia was based upon clinic reports that suggested a prevalence of 50% during the rainy season. Since this estimate was not based on blood samples we used a more conservative estimate of 20% to calculate the sample size. Of the 84 *manyattas*, 36 were randomly selected and allocated to the control or experimental groups so that each arm of the study contained 18. Of the original 36 *manyattas* selected, one elder refused (on behalf of his whole *manyatta*) to be involved in the study. A substitute *manyatta* was randomly selected. Informed consent was obtained from all adults and parental consent for all children in the study. A total of 472 people were enrolled: 234 and 238 in the experimental and control arms, respectively.

Appropriate doses of sulphadoxine-pyrimethamine (Fansidar) were given to all members of the study at baseline. *Shukas* were dipped at baseline and an attempt was made to impregnate all *shukas* owned by the experimental group. Active case detection to measure parasitaemia took place at 2-week intervals over 4 months. Blood smears were collected, analysed in the field according to standard, quality-controlled procedures, and slides then taken to Nairobi for verification by KEMRI technicians. The lab technicians were blinded to the identity of the blood slides. A malaria case was defined as presence of asexual *Plasmodium falciparum* parasitaemia at any density.

Efficacy was assessed by comparing the incidence density rates (IDR) of the experimental and control groups while controlling for the clustering effect of *manyatta* randomization (analysis done using Stata 7.0). An incident case was defined as an individual's first episode of parasitaemia.

Results

Table 1 shows selected demographic characteristics of the study population. Members of the control and experimental groups were similar in terms of numbers of households, age and sex distribution, and *shuka* ownership. About 58% of the study population was female and slightly more than 20% were ≤ 5 years.

Table 2 shows the incidence of malaria in the experimental and control groups and the incidence rate ratio for the intervention. The intervention showed a protective effect among the older children, adolescents, and adults in the experimental group versus the control group (IDR = 1.41 versus 7.49, experimental and control groups, respectively; $P = 0.02$). Among children ≤ 5 years, however, there was no effect.

Discussion

These results suggest that impregnated bedsheets are protective against malaria in older children and adults; in younger children and infants the results show no benefit. Our study is limited by its low statistical power with estimates in both age groups

Table 1 Social and demographic characteristics of the study population

Population characteristics	Control (n = 238)		Experimental (n = 234)	
	n	%	n	%
No. households:	64		60	
Sex				
Female	141	59.2	131	56.0
Male	97	40.8	103	44.0
Age: mean (sd)	20.2 (18.2)		20.6 (17.8)	
	n	%	n	%
≤ 5	47	19.7	50	21.4
6–10	44	18.5	41	17.5
11–19	58	24.4	48	20.5
20–29	28	11.8	31	13.2
30–39	24	10.1	23	9.8
40+	37	15.5	41	17.5
Shuka ownership: mean	1.9		1.7	

Table 2 Incidence density rates and ratios of control and experimental groups, by age

Age group	Control group		Experimental group		Incidence rate ratio		
	No. cases	IDR ^a	No. cases	IDR ^a	IRR ^b	(95% CI) ^c	P
≤5 (n = 97)	2	5.35	4	10.03	1.874	(0.311–11.299)	0.49
>5 (n = 375)	11	7.49	2	1.41	0.187	(0.046–0.770)	0.02

^a Incidence density rate per 10 000 person days at risk.

^b Incidence rate ratio.

^c Standard errors adjusted for clustering.

being imprecise. Clinic reports implied that 35% of all patients were seen for malaria, and the clinicians’ predicted prevalence of parasitaemia was even higher (50%). Although a more conservative 20% was used to calculate sample size, the 2.2% parasitaemia observed at baseline clearly reduced the statistical power of the study. This highlights the unreliability of malaria reports based on clinical diagnoses, reflecting the problems faced by clinic personnel without microscopy and the consequent difficulties for researchers in this area.

An attempt was made to impregnate all *shukas* of the experimental group. However, some children refused to have their *shukas* dipped in the cold early morning hours as it was their only clothing. Other children, one-third of the 5 and unders in both groups owned no *shuka*. The researchers had been aware of this prior to the study but had felt that this should not affect results since preliminary research indicated that children without *shukas* slept under their mother’s *shuka* at night. Of the four cases that occurred in the intervention group, three did not own their own *shuka* and the fourth owned a *shuka* that was not impregnated.

In summary, this study has some interesting and potentially exciting results. These findings justify further research in this area.

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KEY MESSAGES

- Permethrin-impregnated bedsheets may provide an alternative to impregnated bednets in communities where bednets are unaffordable or incompatible with the population’s lifestyle.
- The results of this small trial suggest that impregnated bedsheets may be protective against malaria infection.
- Further large trials are required to assess the efficacy and effectiveness of impregnated bedsheets.

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Samburu family, Ngilai, Kenya (Source: S. Sosler)