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The Gambian National Impregnated Bed Net Programme: evaluation of effectiveness by means of case–control studies

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Abstract

Two case–control studies, one on mortality and the other on malaria morbidity, were carried out in order to evaluate the impact of the Gambian National Insecticide Bed Net Programme during the second year of intervention and to explore the feasibility of such a study for the evaluation of programme effectiveness. For the mortality study, children 1–9 years old who died during the 1993 rainy season were matched by age and sex with 2 healthy controls from the same village. For the morbidity study, children 1–9 years old attending Fatoto or Jahalia Health Centres in The Gambia and who had fever and parasitaemia ≥5000/μL were matched by age with a child attending the health centres without fever or parasitaemia. An additional healthy control was recruited from the case's village. No impact of insecticide-treated bed nets on mortality was detected and this was in keeping with the results obtained by prospective surveillance. A protective effect of insecticide-treated nets on malaria morbidity was detected when cases were compared with controls recruited at the health centres. However, this disappeared when cases were compared with controls recruited from the cases' villages. The mortality case–control study suggested that reducing the time between onset of disease and treatment may have an important impact on childhood mortality. In order to calculate programme cost-effectiveness, important for informed resource allocations to be made by health managers, it is essential to obtain evidence of effectiveness. This can be done by means of case–control studies, which are easier to carry out and require fewer resources than prospective surveillance. Nevertheless, it is necessary to be conscious of their pitfalls, particularly of the bias involved in the choice of cases and controls. The measurement of insecticide on the nets of the cases or controls is essential for such studies.

Keywords: malaria, *Plasmodium falciparum*, prevention, bed nets, permethrin, The Gambia

Introduction

On the basis of the results of several preliminary trials (SNOW *et al.*, 1987; ALONSO *et al.*, 1991), the government of The Gambia initiated, in 1992, a national impregnated bed net programme (NIBP) which had the initial objective of introducing insecticide-treated bed nets into all large villages over a period of 2–3 years using an established primary health care (PHC) system. The UK Medical Research Council (MRC) laboratories were asked to evaluate the impact of this programme on childhood mortality and malaria morbidity. The results of the first year of implementation, when the insecticide was provided free of charge to half of the PHC villages throughout the country, have been described elsewhere. Briefly, a 25% reduction in all-causes mortality in children 1–9 years old and a decrease in malariometric indices in children aged 1–4 years were detected (D'ALESSANDRO *et al.*, 1995a, 1995b), as well as an improvement in the outcome of pregnancy in primigravidae (D'ALESSANDRO *et al.*, 1996). During the second year of intervention, insecticide was offered to all PHC villages, including those which had been in the control group the previous year, but charges were introduced in the villages that had previously received free insecticide. Unfortunately, the introduction of a fee brought about a substantial decrease in coverage (CHAM *et al.*, in press). During the second year it was not possible to compare treated and untreated villages as all villages received insecticide and a proper control group no longer existed.

Case–control studies have been identified as important tools for the evaluation of interventions against tropical diseases (SMITH, 1987; SELBY, 1994), as they avoid many of the ethical issues inherent in longitudinal and intervention studies (RODRIGUES & KIRKWOOD, 1990) and are easier to organize. Therefore, 2 case–control studies, one on child mortality and another on malaria morbidity, were carried out, in order to evaluate the individual protective efficacy of insecticide-treated bed nets and look at other risk factors, and to compare the results, which are reported here, with those obtained using a population surveillance system.

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Subjects and Methods

Study area

Five areas of The Gambia were chosen at the beginning of 1991 as sentinel sites for the evaluation of the NIBP. Within these areas, 104 PHC villages were identified and allocated at random to one of 2 groups. In one group of villages the programme, which involved the treatment of existing bed nets with 20% permethrin, was implemented in June–July 1992, and in the other group nets were treated for the first time in June–July 1993. Details of the implementation of the NIBP and of its impact on mortality and malaria morbidity during the first year of the intervention have been described elsewhere (D'ALESSANDRO *et al.*, 1995a, 1995b). During the second year of intervention, information on deaths was collected by means of the established surveillance system, which was discontinued in March 1994. In addition, 2 case–control studies, one on mortality and the other on malaria morbidity, were carried out. Their objective was to explore a different method of evaluating such a programme and to continue monitoring its impact on child mortality and malaria morbidity.

Case–control study on mortality

Children aged 1–9 years, who died between August and December 1993, who had been resident in one of the 5 surveillance areas, and who were identified through an established mortality surveillance system (D'ALESSANDRO *et al.*, 1995a), were taken as cases. They were matched by sex, age (±6 months) and village of residence with 2 healthy control children chosen randomly from the census file. A questionnaire on bed net use, socioeconomic variables and treatment-seeking behaviour (Table 1) was administered to the mother or

Table 1. Potential risk factors for death or for malaria morbidity investigated

Ethnic origin of parents
Mother's marital status
Occupation of parents
Educational level of parents
Total number of people sleeping with the index child
Mosquito avoidance behaviour of the family, including bed net usage and treatment with insecticide
Chloroquine availability
Treatment of the last serious illness
Mother's understanding of fever, its causation and treatment
Mother's understanding of convulsions, their causation and treatment
Distance of the compound from the nearest source of water
Structure of the house and of the compound
Ownership of animals, bicycle, motorcycle and radio

guardian of each child by senior field assistants. Case questionnaires were administered within one month of death while control questionnaires were administered within 2 weeks after the case questionnaire.

Case–control study on morbidity

Two health centres, one in surveillance area 3 (Jahali) in the Central Region of The Gambia and one in surveillance area 5 (Fatoto) in the Eastern Region, were identified and a small laboratory where blood slides could be examined was set up in each of them. An MRC laboratory technician and 3 field assistants were stationed at each health centre for the duration of the 1993 rainy season. Every day, a field assistant recorded the body temperature of all children aged 1–9 years old who attended the health centre and their names and addresses. The laboratory technician collected 2 blood slides from all children; one was stained with Field's stain and examined immediately, the other was stained with Giemsa's stain and examined the following morning. Parasite densities were computed assuming that one parasite per high power field (HPF) indicated a density of 500 parasites/μL (GREENWOOD & ARMSTRONG, 1991). Haemoglobin (Hb) was determined immediately after blood collection using a portable β-haemoglobin photometer (Hemocue®). Cases were defined as children with a body temperature of 37·5°C and a *Plasmodium falciparum* parasitaemia of 5000/μL or more. These were matched by age with 2 controls—a 'sick' control and a healthy control. Sick controls were recruited at the health centre within 2 weeks of presentation of a case and were defined as children who presented to the health centre with a recent illness but who had a body temperature of less than 37·5°C and a negative malaria blood slide. Thus, at the health centre 6 categories of children were identified: children with or without fever, each group being subdivided into those with parasitaemia of ≥5000/μL, those with a parasitaemia lower than 5000/μL, and those with no parasite seen. Those with no parasite and without fever were considered as 'potential controls' and those with fever and a parasitaemia ≥5000 μL as 'potential cases'. They became 'real cases' or 'real controls' on the condition that a suitable child of the opposite category was found within 2 weeks after their identification.

The second healthy control was chosen by field assistants from among children of the same age as the case, resident in the index child's village. From the house of the index child, the field assistant chose a direction by spinning a pen and then selected the tenth compound in that direction and the subsequent compound until he found a suitable control. A questionnaire, similar to that used for the mortality study, was administered to the mother or guardian of the control child.

Statistical methods

For the mortality study, comparisons were made between all cases and all controls. For the morbidity study, cases of malaria were compared separately with controls recruited at the health centre and with the healthy con-

Table 2. Estimated odds ratio for mortality risk factors (deaths vs. healthy controls)

Potential risk factors	Cases	Controls	Crude odds ratio[a]	P[b]	Adjusted odds ratio[a]	P[c]
Persons whom mother consulted first for treatment before last/serious illness						
Village health worker	19(11·4%)	105(31·4%)	1·00		1·00	
Health centre	114(68·3%)	200(59·9%)	4·40(2·31,8·40)	<0·001	4·43(2·13,9·20)	<0·001
Traditional healer/nobody	34(20·4%)	29(8·7%)	9·19(4·12,20·5)	<0·001	12·62(4·94,32·1)	<0·001
Any treatment before consulting						
None	98(59·4%)	168(50·6%)	1·00		1·00	
Tablets/wet cloth	30(18·2%)	110(33·1%)	0·46(0·29,0·75)	0·002	0·32(0·17,0·58)	<0·001
Other	37(22·4%)	54(16·3%)	1·37(0·80,2·35)	0·24	1·36(0·70,2·60)	0·35
Mother's view of cause of fever						
Malaria	14(8·4%)	49(14·7%)	1·00		1·00	
Other	153(91·6%)	285(85·3%)	2·00(1·03,3·85)	0·03	1·83(0·80,4·16)	0·14
Chloroquine in the household						
Yes	2(1·2%)	23(7·0%)	1·00		1·00	
No	163(98·8%)	305(93·0%)	5·00(1·16,21·3)	0·03	4·46(0·95,20·8)	0·05
Mother usually treated fever first with						
Wet cloth	24(14·5%)	73(21·9%)	1·00		1·00	
Tablets	88(53·3%)	155(46·4%)	2·00(1·08,3·72)	0·02	1·59(0·76,3·28)	0·21
Other(traditional treatment)	5(3·0%)	24(7·2%)	0·81(0·25,2·60)	0·73	0·38(0·10,1·46)	0·16
Health centre visit	48(29·1%)	82(24·6%)	1·73(0·75,3·99)	0·19	1·39(0·58,3·35)	0·45
Mother's view of cause of fits						
Malaria/high fever	15(9·0%)	62(18·6%)	1·00		1·00	
Other	152(91·0%)	272(81·4%)	2·60(1·36,4·96)	0·004	2·07(0·97,4·43)	0·05
Mother has a job apart from house-keeping						
Yes	36(21·8%)	105(31·4%)	1·00		1·00	
No	129(78·2%)	229(68·6%)	1·97(1·17,3·30)	0·01	1·80(0·94,3·46)	0·07
Number of buildings in the compound						
≤10	114(68·3%)	250(75·5%)	1·00		1·00	
>10	53(31·7%)	81(24·5%)	1·49(0·95,2·32)	0·08	1·78(1·03,3·09)	0·03

[a]95% confidence intervals in parentheses.
[b]Probability value for crude odds ratio.
[c]Probability value for adjusted odds ratio.

Table 3. Estimated odds ratio for malaria morbidity risk factors (clinical malaria cases vs. sick children without malaria)

Potential risk factors	Cases	Controls	Crude odds ratio[a]	P[b]	Adjusted odds ratio[a]	P[c]
Time to bed						
Before last prayer (21:00)	23(20·9%)	37(33·9%)	1·00		1·00	
After last prayer	87(79·1%)	72(66·1%)	3·00(1·09,8·25)	0·03	2·86(0·95,8·59)	0·06
Bed net use						
No net/untreated net	113(79·0%)	103(72·0%)	1·00		1·00	
Insecticide-treated net	30(21·0%)	40(28·0%)	0·64(0·35,1·16)	0·14	0·41(0·18,0·92)	0·03
Mother used insecticide spray						
Yes	14(11·3%)	28(22·0%)	1·00		1·00	
No	110(88·7%)	99(78·0%)	2·20(1·04,4·64)	0·03	1·96(0·68,5·62)	0·20
Father had a job other than farming						
Yes	72(50·3%)	86(50·1%)	1·00		1·00	
No	71(49·7%)	57(39·9%)	1·51(0·93,2·43)	0·09	1·96(0·97,4·00)	0·06

[a]95% confidence intervals in parenthesis.
[b]Probability value for crude odds ratio.
[c]Probability value for adjusted odds ratio.

trols recruited in the index child's village. Continuous variables were tested by the paired sample t test. Matched univariate analysis, using the statistical package EGRET™, was performed to produce estimates of the odds ratios (OR) associated with each factor and their 95% confidence intervals (95% CI). Multivariate analysis of factors significant in the univariate analysis was performed by conditional logistic regression to construct a parsimonious model that included only those factors that remained statistically significant in the presence of other factors (KORAM *et al.*, 1995a).

Results

Mortality

Between 1 August 1993 and 31 December 1993, 167 deaths of children aged 1–9 years were detected in the study area and were matched by age, sex and village of residence with 334 suitable controls. Sleeping under an insecticide-treated bed net was not associated with child survival (cases 43·1% vs. controls 41·6%; OR 1·10, 95% CI 0·68–1·77; P=0·68). Some other risk factors were significantly associated with mortality, in particular those related to socioeconomic status and health-seeking behaviour (Table 2). Children whose mothers first consulted a village health worker (VHW) during their last/serious illness were less likely to die compared to those who were referred to a health centre or to a traditional healer. Having chloroquine tablets available in the house and the prompt treatment of the sick child with tablets (probably paracetamol or chloroquine) or with sponging was also associated with a decreased risk of dying, as was the mother's awareness that the main cause of fever or convulsions was malaria. Other risk factors associated with death were crowding (compounds with more than 10 buildings) and the mother having a job other than family farming. All these factors were included in a model and multivariate analysis was performed by conditional logistic regression. Factors related to health-seeking behaviour were still significantly associated with risk of death, as was crowding and the mother's awareness of malaria being the main cause of fits.

Malaria morbidity

Nine hundred and eighty-two children 1–9 years old attended Fatoto (n=527) and Jahali (n=455) health centres between August and December 1993. Overall, 63·5% (624/982) of the children had *Plasmodium* infections, most of which were *P. falciparum*. However, 3 infections with *P. ovale* (all mixed with *P. falciparum*) and 11 infections with *P. malariae* (9 of which were mixed with *P. falciparum*) were detected also. In the following analysis, only *P. falciparum* infections were considered. Parasitaemia, high parasitaemia, and clinical malaria, defined as body temperature of 37·5°C or more associated with a parasite density of 5000/μL or more, occurred most frequently in October.

One hundred and forty-six cases of malaria were matched by age with children without fever and without peripheral parasitaemia who attended Fatoto or Jahali health centres. A suitable control could not be found for several cases, particularly during the month of October when almost 80% of the children who attended the clinic had a positive blood slide. Therefore, more than half of the cases and sick controls (56·2%) were recruited during the months of August and September, while only 31·3% of the 357 healthy controls matched with cases were recruited during these months. The mean Hb level was significantly lower among cases than among controls (8·05 g/dL vs. 9·67 g/dL; mean difference −1·6 g/dL, 95% CI −2·12 to −1·12: P<0·0001).

Some potential risk factors were associated significantly with protection against clinical malaria. These were going to bed before 21:00, use of insecticide spray, and the father having a job other than working on the family farm (Table 3). Multivariate analysis showed that going to bed early, father not working on the farm, and the use of insecticide-treated bed nets were significantly associated with protection against clinical malaria, while the association with the use of insecticide sprays disappeared.

A healthy control child matched for age was recruited from the village of the index child and an identical questionnaire was administered to the parents; 357 controls were recruited in this way. No association was found between use of insecticide-treated bed nets and protection against malaria (OR 1·17, 95% CI 0·77 to 1·79; P=0·45), and no other variable was associated with significant protection against malaria in this analysis (data not shown).

Discussion

Using a case–control analysis, we did not find a significant effect of insecticide-treated bed nets on mortality; the odds ratio was very similar to the rate ratio measured with the normal surveillance system at the same time (insecticide charged vs. free insecticide) (CHAM *et al.*, in press). This was to be expected as the odds ratio, under fairly general circumstances, is interpretable as the ratio of incidence rates for disease among exposed versus unexposed members of the population (THOMPSON, 1994). Furthermore, because death is a relatively rare event, the 3 measures of incidence (relative risk/relative rate/odds ratio) must be numerically equal. Even taking into account the coverage of the programme (77%) and

applying the formula suggested by LENGELER & SNOW (1996), the result was very similar to the rate ratio (measured by intention-to-treat analysis) reported by CHAM *et al.* (in press).

In this study, information on bed net usage relied upon that given by the family of children who had died or presented at the clinic with malaria, or who were recruited as controls. Because the bed net programme was accompanied by substantial publicity on the radio, and through posters and leaflets, on the potential benefits of sleeping under insecticide-treated nets, mothers of children who had died or who had developed malaria may have felt guilty if their child had not slept under a treated net and thus have given an incorrect response to a question on net usage and insecticide treatment. If this effect was substantial, it would have reduced any apparent beneficial effect from sleeping under a treated net. This problem could be overcome if nets of cases and controls were tested for the presence of insecticide. Subsequently we have devised a simple, semi-quantitative assay (MULLER *et al.*, 1994) which would be useful in this kind of situation. If case–control approaches are to be used to evaluate further large-scale bed net programmes, it is important that these incorporate insecticide measurements on study nets. This would be especially important if the bed net programme were accompanied by extensive publicity on the benefits of treated nets.

Children who used insecticide-treated bed nets were less likely to have clinical malaria when cases were compared with children recruited at the health centres. However, no protective effect of insecticide-treated bed nets was found when cases were compared with healthy controls. This apparently contradictory result may be explained by the time of recruitment of cases and controls: more than half of the cases and sick controls were recruited within the first 2 months of the intervention, while the healthy controls and the corresponding cases were recruited throughout the whole rainy season, from August to December, and the efficacy of treated nets may have begun to decline by the end of the year. The introduction of a cost-recovery system led to a dramatic drop in coverage: only 14% of beds were found to have an insecticide-treated net in villages where a fee had to be paid for the insecticide, while in the other group of villages, where the insecticide was offered free, most of the bed nets were treated (77%) (CHAM *et al.*, in press). It could be expected that, because of the important difference in coverage, child mortality rates would increase in villages that had to pay for the insecticide and decrease in those that had received it free. However, this did not happen and child mortality rates at the end of the observation period were very similar in the 2 groups of villages. Nevertheless, an inversion of mortality rates relative to the previous year and between the 2 groups of villages was observed during the first 2 months after the intervention (data not shown). This may indicate that the efficacy of the insecticide did not last for the whole malaria season. Permethrin almost certainly spread from free-insecticide to charged-insecticide villages and some of it was even sold in local markets (H. Pickering, personal communication). As the amount of permethrin given to a village was calculated on the number of bed nets in that village, and any amount of insecticide left after the dipping was collected by the regional health teams and checked with the number of nets treated, overdilution was the easiest way of getting some insecticide out of the system in order to sell or distribute it among friends or relatives. This could explain the discrepancy of results between the analysis of cases vs. sick controls and cases vs. healthy controls, as more than half of the cases and sick controls were recruited during August and September, a time when the insecticide may still have been effective.

A smaller proportion of mothers of dead children had consulted the VHW for treatment, had treated the child before consulting, or had chloroquine readily available in the household than mothers of control children. This suggests that reducing the time between onset of disease and treatment, in particular antimalarial treatment, might have an important impact on childhood mortality. Malaria was probably an important cause of death among cases. It has been suggested that it might be possible to prevent some cases of malaria progressing to severe disease and death if mothers were educated about the importance of taking children with symptoms of malaria to a health centre for treatment (KORAM *et al.*, 1995b). Educating mothers to give the correct antimalarial treatment, and the right dosage might be an important additional factor for reducing childhood mortality. The finding that children whose mothers knew that the major causes of fits are malaria and high fever were less likely to die supported the idea that prompt treatment, at the health centre or by the mother, is important in preventing death.

Mortality was also associated with the size of the compound and with the mother's job. This may reflect an association between death and low socioeconomic status, the former factors being proxies for the latter. A compound with more than 10 buildings may reflect crowding, a factor which has already been associated with mortality in Gambian children (DE FRANCISCO *et al.*, 1993), while a job for the mother other than housekeeping indicates more readily available cash. However, collection of data on a large number of socioeconomic or other factors increases the likelihood of observing associations by chance alone, and the positive associations found in this study must be treated with some caution.

Negative findings included the absence of any association between death and maternal or paternal education, household wealth and the use of personal protective measures against malaria other than bed nets (coils, insecticide spray, etc.), confirming the result of similar studies carried out previously in The Gambia (DE FRANCISCO *et al.*, 1993; KORAM *et al.*, 1995b).

This was the first study on insecticide-treated bed nets to measure their effectiveness instead of their efficacy (D'ALESSANDRO *et al.*, 1995a). The amount of resources required to do this for a population of over 100 000 makes this technique difficult to apply to other public health interventions. However, in order to calculate cost-effectiveness, important for informed resource allocation by health managers, it is essential to document programme effectiveness (LENGELER & SNOW, 1996). This can be done by means of case–control studies, which are easier to carry out and involve fewer resources than large prospective community-based studies. Nevertheless, one should be conscious of their pitfalls, particularly of the bias involved in the choice of cases and controls (LENGELER & SNOW, 1996). Measurement of insecticide on the nets of the cases or controls is important if reliable data are to be obtained.

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Announcements

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The appeal for funds to establish fellowships in memory of the late Professor P. C. C. Garnham, FRS, is progressing well. A Garnham Fellowship will enable a young physician or scientist to carry out a short term field project in parasitology or medical entomology in a tropical country of their choice and will be a fitting memorial to Cyril Garnham, who believed passionately in the importance of field work. The appeal has already received generous sponsorship from the Garnham family and the London School of Hygiene and Tropical Medicine. Glaxo Wellcome plc has made a generous donation on the understanding that the Society raises an equivalent amount. Fellows who have not yet contributed but would like to do so are asked to send a donation by cheque (in pounds sterling or Canadian or US dollars) or credit card (stating the number and expiry date) to the Honorary Treasurer, Royal Society of Tropical Medicine and Hygiene, Manson House, 26 Portland Place, London, W1N 4EY, UK; fax +44 (0)171 436 1389, e-mail mail@rstmh.org