



# A Pilot Study Of Intermittent Preventive Treatment And Home Based Management Of Malaria In A Rural Area Of The Gambia.



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# Objectives



- Aim: To determine whether IPTc adds significant benefit to HMM.
- Objective: To determine the degree to which morbidity from malaria can be prevented in children who receive intermittent preventive treatment with SP plus amodiaquine and home based management of malaria with Coartem during one malaria transmission season.



# Methods (1)



- Individually randomised, placebo controlled, community intervention study.
- Required sample size = 600 children aged 3-59 months per arm.
- Sample recruited from a group of 42 villages and hamlets near Farafenni which form part of the rural demographic surveillance area.
- All children were randomised to receive either IPT with SP + AQ, or placebo from a VHW at monthly intervals on three occasions during the months of September, October and November. The first dose was supervised.



# Methods (2)



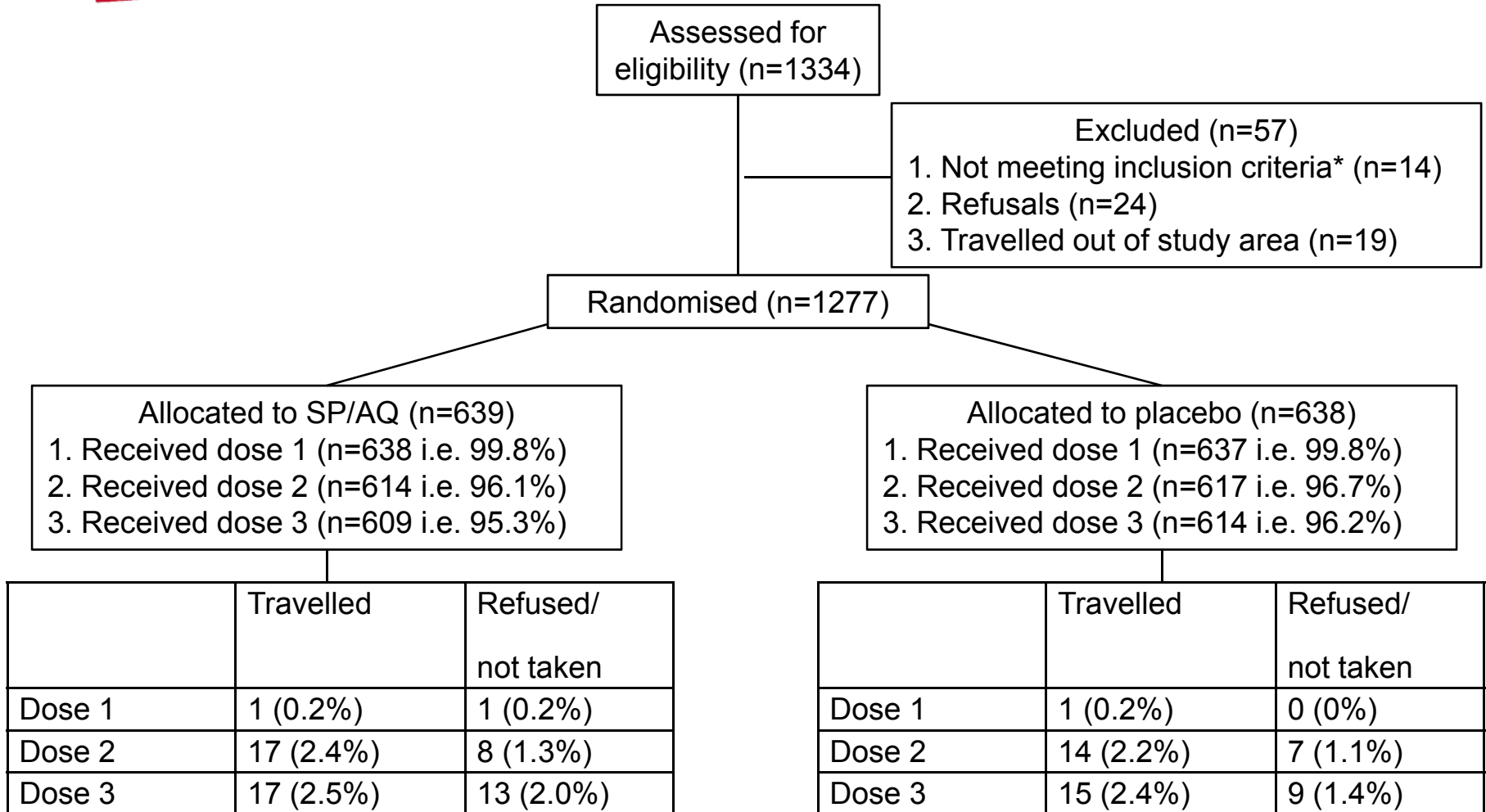
- A baseline cross-sectional survey was done involving all children at the beginning of the malaria season.
- Passive surveillance for malaria was maintained throughout the transmission season at various HCs.
- An cross-sectional survey was done involving all children at the end of the malaria transmission season.
- VHWs were trained to administer HMM with Coartem® after a RDT was done.
- Study patients with severe illness were admitted in a nearby hospital for management.



# Baseline characteristics

Variable	Intervention group	
	Placebo (n=638)	SP/AQ (n=639)
Age (months) (mean, SE)	29.9 (16.5)	30.1 (17.3)
Sex (% male)	323 (51.4%)	309 (49.6%)
Sleep nightly under impregnated bednet	596 (93.3%)	596 (93.3%)
Mean Haemoglobin g/dl	10.2 (1.4)	10.1 (1.5)
Splenomegaly	16 (3.0%)	18 (3.4%)
Malaria parasitaemia present	3 (0.5%)	3 (0.5%)
Parasite count (geometric mean)	31.4	92.1

# Trial Flow



\* **Chronic illness=6, Over-age=5, Severe malnutrition=1, Under-age=1, Severe anaemia=1.**



# Incidence of Malaria

Outcome	Placebo			SP/AQ			Protective efficacy (95% CI)	P value
	Events	Person months at risk	Incidence rate /1000 person months	Event	Person months at risk	Incidence Rate/1000 person months		
Clinical malaria, diagnosed at OPD	2	2279	0.88	1	2248	0.44	49% (-46.8%, 95%)	0.59
Clinical malaria, diagnosed at OPD or by VHW	3	2279	1.32	1	2248	0.44	66% (-22.8%, 96%)	0.35

**Note, no multiple malaria episodes within any child**



# All-cause morbidity from Health Centres

Outcome	Placebo (person months at risk = 2279)		SP/AQ (person months at risk = 2248)	
	Events	Incidence rate/100 person months	Events	Incidence rate/100 person months
Total outpatient visits	142	6.2	155	6.9
Anaemia (Hb<11g/dL)	71	3.1	70	3.1
Moderate anaemia (Hb<9g/dL)	14	0.6	13	0.6
Fever (temp $\geq 37.5^{\circ}\text{C}$ )	33	1.4	28	1.2
Upper respiratory tract infection	48	2.1	49	2.2
Skin/soft tissue infection	25	1.1	21	0.9
Gastroenteritis	42	1.8	39	1.7



# VHW consultations

Outcome*	Placebo (person months at risk, 2279)		SP/AQ (person months at risk, 2248)	
	Events	Incidence rate/100 person months	Events	Incidence rate/100 person months
Total visits to VHW	30	1.3	29	1.3
Anaemia (Hb<11g/dL)	24	1.1	20	0.9
Moderate anaemia (Hb<9g/dL)	4	0.2	1	0.04



# Admissions



- 16 admissions in total during surveillance period.
- 12 cases were due to severe pneumonia.
- 1 mortality (post-discharge) due to complication from severe pneumonia.
- No admissions due to severe malaria.
- No admissions due to severe anaemia.
- No admissions due to severe adverse events.



# End-of-season survey

End-of season survey	Placebo (n=533)	SP/AQ (n=513)	P
<i>P.falciparum</i> parasitaemia (any density) %	5 (0.9%)	3 (0.6%)	0.73*
Geometric mean density (IQR) of positive blood films	212 (46, 686)	347 (22, 1685)	0.72
Splenomegaly ( %)	16 (3.0%)	10 (2.0%)	0.28

\* *P-value calculated using Fisher's exact test.*



# Adverse Events



Self-reported adverse events	Placebo (n=533)	SP/AQ (n=513)	P
Lethargy/fatigue	8 (1.5%)	15 (2.9%)	0.12
Diarrhoea	38 (7.1%)	30 (5.8%)	0.40
Drowsiness	5 (0.9%)	10 (1.9%)	0.17
Vomiting	24 (4.5%)	81 (15.8%)	<0.001



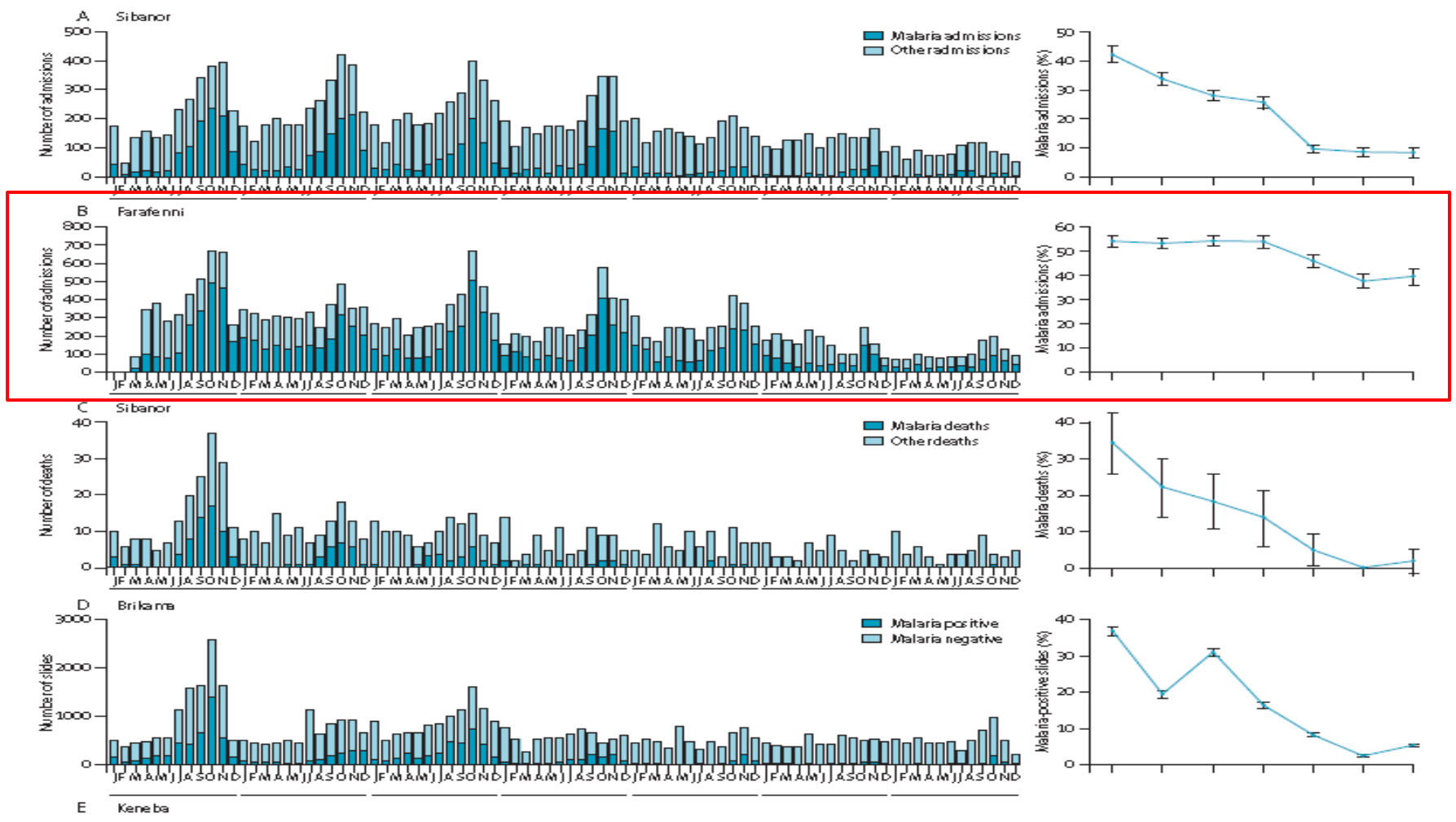
# Discussion & Conclusions



- Significant IPTc coverage can be achieved at community level using VHWs.
- IPTc did not appear to add significant benefit to HMM in children aged 3-59 months in our setting.
- The effect could have been affected by the high prevalence of ITN use in the study area (approx. 93% in both arms) and decrease in malaria transmission.
- Indirect effects of intervention because of individually randomised design?
- Conclusion: There is no evidence of supplementary benefit of IPTc with SP/AQ in addition to HMM in this study.



# Changes in malaria indices in The Gambia





# Future perspectives



- More studies need to be done in higher transmission settings. Maybe a cluster-randomised design?
- As malaria transmission decreases in some regions, do we need to re-evaluate some of the possible intervention strategies?
- Are we on the verge of eliminating malaria in The Gambia?

Thank you for listening!!!

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