Effectiveness and treatment adherence to artemether-lumefantrine colour coded unit dosed blister-packs versus standard blister-packs in the treatment of uncomplicated malaria in Ugandan children: a randomised controlled equivalence trial

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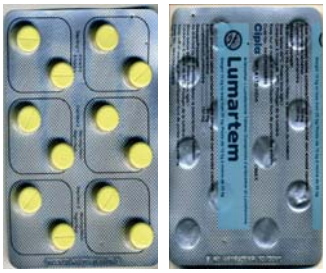
Key messages

- Risk of treatment failure (parasitological and clinical failure) and treatment adherence was not different between children who receive colour coded unit dosed blister-packs to those who receive standard packs.
- Standard blister-packs could serve as alternatives to colour coded unit dosed blister-packs in management of uncomplicated malaria without compromising effectiveness and adherence in Uganda.



Lumartem colour coded blue for children aged 3-8 years

Lumartem standard blister-pack

Introduction

Pre-packing drugs for treatment of uncomplicated malaria into colour coded unit doses has been shown to improve adherence and therefore effectiveness of treatment. However, it restricts access to those within the specific age or weight category and since each unit dosed blister-pack is a separate commodity, this creates challenges regarding procurement and administration. In addition, stock outs of unit dosed blister-packs may lead to either use of non-recommended therapies or the combination of smaller dose packs to make larger doses and cutting from larger dose packs to make smaller doses, resulting in over or under-dosing. This study investigated whether effectiveness and treatment adherence to standard blister-packs would be equivalent to unit dosed blister-packs.

Methods

An open-label individually randomised trial was conducted in 846 children aged six to 59 months and living in a high malaria transmission setting in Uganda. Children were randomised to receive colour coded unit dosed blister-packs or standard blister-packs, and followed up for 28 days. The primary outcome was treatment adherence. Secondary outcomes included risk of treatment failure, cure rates, change in mean haemoglobin, gametocytemia, and adherence.

Results

Table 1: Baseline characteristics of the study participants by study group

Variable	Colour coded unit dosed packs	Standard blister packs
Number of children	366	480
Mean age (SD, months)	24.2 (16.2)	25.2 (16.1)
Sex (Female, n %)	198 (54.1)	249 (51.9)
Mean weight (SD, kg)	10.7 (3.2)	10.7 (3.0)
Mean Hb (SD, g/dl)	8.9 (1.7)	9.1 (1.7)
Mean parasite density (SD)	14,647	12,830
P. Falciparum (n, %)	366 (100)	478 (99.6)
P. Ovale	0	1
P. Vivax	0	1
Gametocyte present (n, %)	42 (11.5)	61 (12.7)

Table 2: Adherence by treatment group

Outcome	Colour coded unit dosed packs n/N (%)	Standard blister-packs n/N (%)	P-value
Used labels as reminders for adherence	1/257 (0.3)	3/472 (0.6)	0.532
Reported missing some pills	11/346 (3.2)	14/458 (3.1)	0.935
Did not follow dosing schedules	26/357 (7.3)	30/475 (6.3)	0.568
Gave medicine without food	96/357 (26.9)	134/475 (28.2)	0.678
Still had tablets in the pack	66/358 (18.4)	89/472 (18.9)	0.855

Figure 1: Cumulative risk of clinical failure over the 28 days of follow up unadjusted by genotyping

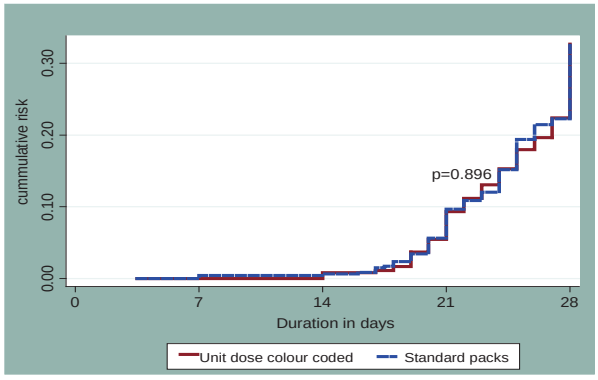
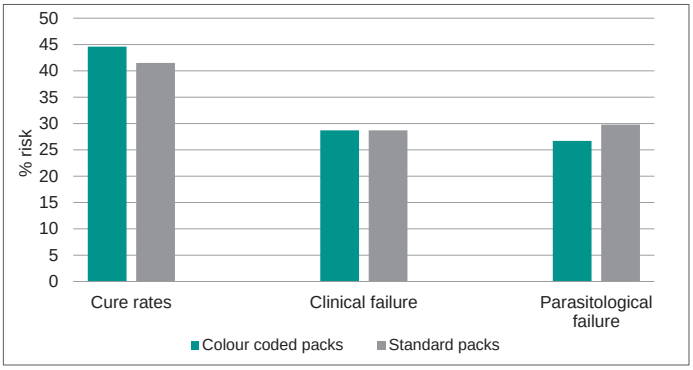


Figure 2: Overall risk of adequate outcome, clinical failure and parasitological failure by study group



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