Clinical Investigation

Development and Validation of Weight, Height and Age Bands to Guide the Prescription of Fixed-Dose Dispersible Tablet Formulations

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OBJECTIVES: Conversion of pediatric essential drugs from syrup to dispersible tablet formulations would require fixed dose options guided by the weight band in which a child falls or a proxy for weight, such as height or age. The purpose of this study was to determine whether weight, height, or age bands can be created that would lead to greater than 95% of children receiving a therapeutic dose of 6 commonly prescribed essential drugs, including paracetamol, iron sulfate, amoxicillin, co-trimoxazole (i.e., trimethoprim/sulfamethoxazole), ciprofloxacin, and co-artemether (i.e., artemether/lumefantrine).

METHODS: Using World Health Organization growth standards, we created 4 weight bands and then matched them to height and age 50th percentile growth curves. The resulting weight, height, and age bands were then applied to Ugandan and Bangladeshi anthropometric data sets, and the percentage of children who would have received a correct therapeutic dose based upon weight, height, or age was determined. This percentage was interpreted as acceptable if >95%, marginal if 90% to 95% and unacceptable if <90%.

RESULTS: Applying the 4 weight bands to the 6 selected drugs, greater than 95% of children would have received an acceptable therapeutic dose across the 4 weight bands for each of the 6 drugs tested. None of the drugs tested would deliver an acceptable therapeutic dose across all bands based upon height or age among Ugandan children, and only co-trimoxazole would have been delivered at acceptable therapeutic levels based upon these bands in Bangladeshi children.

CONCLUSIONS: For the 6 drugs tested, dispersible tablets prescribed on the basis of a 4-dose regimen determined by weight bands would deliver an acceptable therapeutic dose greater than 95% of the time. Substituting weight for age or height bands would result in unacceptable levels of under- or overdosing.

INDEX TERMS: child health, dispersible tablets, essential drugs, IMCI, weight

J Pediatr Pharmacol Ther 2015;20(1):24–32

INTRODUCTION

In accordance with World Health Organization (WHO) and Integrated Management of Childhood Illness (IMCI) guidelines, doses of essential oral drugs in children younger than 5 years of age are based upon the child's weight or age and are then converted to milliliters of syrup.[1,2] Applying IMCI guidelines and flow charts, primary care health workers are provided with dose guidelines based upon a child's weight in milligrams per kilogram (mg/kg) or a specified dose base upon age ranges from 2 months to 5 years of age. Although there have been few studies examining the accuracy of drug dosing in low-income countries, there are several reasons to assume a large proportion of children are either over- or underdosed. In many settings, due to an absence of working scales, drug doses are calculated based on the estimated age of the child or a child's height. Sources of possible error include calculation errors, syrup measurement errors, incorrect age or height estimation, and widespread occurrence of malnutrition. A study in an urban Nigerian teaching hospital found that more than 50% of medication prescriptions were either underdosed or overdosed.[3] Within less supervised, rural settings it is reasonable to assume that inaccurate doses will be considerably more common. Even in well resourced, North American hospitals, studies have found that calculation errors are common in pediatric settings, leading to under- or overdosing.[4] This occurs among highly trained pediatricians armed with accurate weight scales and access to calculators.

Reducing error is absolutely critical to providing appropriate therapeutic drug doses and avoiding under- or overtreatment in young children. Overdosing may lead to toxicity, whereas underdosing can contribute to treatment failure and the emergence of antimicrobial resistance. In order to reduce provider or caretaker errors associated with syrups, consideration is being given to the feasibility of delivering essential oral drugs for children less than 5 years of age in dispersible tablet formulations.[5,6] By adding approximately 5 mL of water or breast milk, a dispersible tablet is converted to a syrup formulation. Dispersible tablets offer several advantages over syrups, including reduced cost, ease of transport and storage, ease of administration, and no need for calculations. Nevertheless, the transition from syrup to dispersible tablet formulations implies that drugs can be accurately and validly dispensed based upon fixed doses. For example, a 4-dose-tablet regimen would dispense dispersible tablets to be taken as follows; ½, 1, 1 ½, and 2 tablets based upon the weight band in which a child falls, or alternatively, a proxy band for weight such as a child's height or age.

A further concern with drug dosing is that in many rural health care centers in low-income countries, scales are often absent, uncalibrated, or not functioning. Because of this, despite universal recommendations to weigh the child and calculate drug doses based upon weight, in clinical practice, age is usually used as a de facto proxy. Weight-based and alternative proxy banding systems, therefore, need to be developed and tested for accuracy, validity, and feasibility. Feasibility will need to be assessed in the context of existing health systems and IMCI programs.

IMCI has been implemented in most low-income countries, but despite early successes, subsequent evaluation of effectiveness has not been encouraging.[7] Improving upon the effectiveness of IMCI could include introduction of fixed dose and color-coded bands to guide the administration of drugs and fluids. The aims of a fixed-dose banding system are to simplify decision making and drug administration, thus leading to an increased likelihood children will receive a correct therapeutic drug dose. The purpose of the present study was to determine whether weight, height, or age bands could be created with acceptable validity as a guide to essential drug dosages for children under 5 years of age. This initial assessment was limited to 6 of the most commonly prescribed oral pediatric medications for the following indications: paracetamol for fever, amoxicillin for pneumonia, co-trimoxazole (i.e., trimethoprim/sulfamethoxazole) for pneumonia, ciprofloxacin for diarrhea, co-artemether (i.e., artemether/lumefantrine) for malaria, and iron for anemia.

MATERIALS AND METHODS

Study Objectives

The first objective of this study was to create 4 band categories, weight, length/height, and age, based upon revised WHO/United Nations International Children's Emergency Fund (UNICEF) weight (3.0-22 kg) and height (45-120 cm) reference growth standards[9] matched to a child's age in months (1-59 months). The second objective was to obtain a best-fit dispersible tablet fixed dose for the 6 tested medications. The final objective involving use of anthropometric data sets derived from children under 5 years of age in Uganda and Bangladesh was to determine the validity of the weight, length/height, and age bands as defined by the proportion of children who would receive an appropriate essential drug dose and the proportion who were over- or underdosed. A priori, the bands' validity has been defined as "acceptable" if >95% of children younger than 5 years of age received a drug dose within the correct therapeutic range, "marginal" if children between 90% and 95% did, and "unacceptable" if <90% did.

Study Design

This was a cross-sectional study design analyzing data derived from existing anthropometric measurements obtained from national demographic and health surveys. Applying WHO standardized growth charts[8] and exist-

Table 1. Best Fit 4-Category Weight, Height, and Age Bands Selected

Band	Weight (kg)	Height (cm)	Age (mo)
[1]	3-5.9	45.0-59.9	1-3
[2]	6-9.9	60.1-80.0	4-15
[3]	10-14.9	80.1-100.00	16-42
[3]	15-21.9	100.1-120.0	43-59

ing anthropometric data sets from Uganda[9] and Bangladesh,[10] best-fit, 4-category weight, height, and age bands were created and then validated. Children under 5 years of age for which weight, height, and age were available in the Ugandan and Bangladeshi data sets were used to validate the bands. These data sets have no identifying information other than country of origin.

Weight, Height, and Age Bands

Based upon WHO standardized weight-for-height growth charts, 4 weight bands were arbitrarily selected and matched to height bands, as determined by the 50% weight-for-height growth curve. These bands represent a compromise between male and female growth standards. Weights were rounded off to the nearest 0.1 kg, and heights were rounded off to the nearest 0.1 cm.

Fixed Tablet Doses

For each of the selected essential drugs, a recommended dose plus upper and lower therapeutic range doses in mg/kg were identified. Ranges were based upon integrated IMCI treatment guidelines and further verified by a review of doses recommended by the US Food and Drug Administration. These doses were graphed, with weight on the x-axis and milligram of medication on the y-axis. A best-fit dispersible tablet dose was then selected that allowed for the maximum proportion of children within each weight band to receive a therapeutic dose. Applying the selected height and age bands to the Ugandan or Bangladeshi anthropometric data set, the validity of these bands as a proxy for weight was determined. These data sets recorded height to the nearest 0.1 cm and age in months. For each subject, the recorded height or age was assigned to a band and then linked to the child's weight to determine the mg/kg dose that would have been received. Validity was defined as the proportion of children receiving a correct therapeutic dose within each band and overall.

RESULTS

The selected 4-category weight bands and matching length/height and age bands are summarized in the Table 1. In order to maximize simplicity of application, sex-independent bands have been created that represent a compromise between male and female growth. Using ciprofloxacin as an example, the Figure shows the fitting of the selected weight bands to the optimal drug dose of a dispersible tablet. As the drug concentration of a tablet is increased, the mg/kg dose will increase, thus moving a weight band up the y-axis, with the band eventually crossing over the upper therapeutic threshold and resulting in an overdose. As the tablet concentration is decreased, the bands will move down the y-axis and eventually cross over the lower therapeutic threshold, leading to underdosing. We adjusted the fixed dose of the tablet to minimize or, when possible, eliminate under- or overdosing. This procedure was repeated for each of the 6 essential drugs tested. Table 2 lists the recommended target dose and therapeutic range for each drug for which the optimal tablet dose was eventually chosen. For each weight band, based upon these parameters, the proportions of children who would receive a therapeutic dose, an underdose, or an overdose are listed. For all 6 drugs, a fixed tablet dose was identified that would result in >95% of children receiving a correct therapeutic dose based upon their weight band assignments.

Table 3 summarizes the performance of the 4-category height bands among Ugandan and then Bangladeshi children for each drug tested. Among Bangladeshi children, only co-trimoxazole and amoxicillin had acceptable validity across all 4 height bands. Among Ugandan children, none of the drugs tested had acceptable levels of validity across all 4 height bands. Combining all height bands, an acceptable level of validity for the total sample (>95%) was not obtained for paracetamol, co-artemether, and ciprofloxacin in 1 or both countries. Similarly,

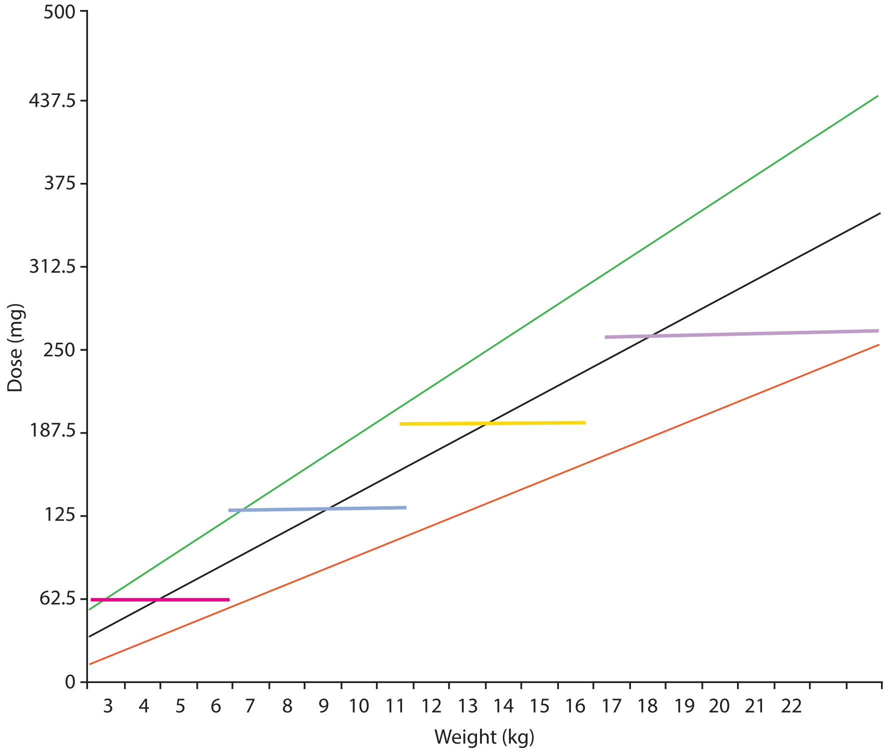

Figure. Results of fitting the weight bands to the optimal dose of a ciprofloxacin tablet. *Applying a 125-mg tablet, children in the 4 weight band categories, beginning with the lightest category, would receive 62.5, 125, 187.5, or 250 mg, respectively. The lowest-weight children within a weight band potentially may cross over the upper mg/kg threshold green line and thus be overdosed, whereas the highest-weight children in a band crossing the lower mg/kg threshold orange line would be underdosed.*

Table 4 summarizes the performance of age bands as a proxy for weight. Among Ugandan children, none of the drugs attained acceptable levels of validity across the 4 age bands. Only co-trimoxazole reached acceptable dose levels in Bangladeshi children based upon age. The observed trend for either height or age banding was a greater likelihood that the shortest or youngest children would be underdosed and to overdose children as they grew taller or older. The latter case would be consistent with populations younger than 5 years of age in whom low weight-for-height or for-age is highly prevalent.

DISCUSSION

This study has demonstrated that sex-independent, 4-category weight banding of children 1 to 59 months of age can result in greater than 95% of children within each of the weight bands receiving a therapeutic dose for the 6 commonly prescribed pediatric oral essential drugs tested (paracetamol, iron, co-artemether, co-trimoxazole, amoxicillin, and ciprofloxacin). This suggests that if these drugs were converted from syrup to fixed dose dispersible tablet formulations, each would perform at acceptable levels of therapeutic accuracy with a 4-dose regimen for children under 5 years of age and weighing less than 22 kg. This was the case for African (Uganda) and South Asian (Bangladesh) sample populations.

One can assume, given our attempt to find the best-fit weight band across the 6 drugs tested, that the best-fit weight bands would perform reasonably well. Whether height- or age-based bands can be substituted for weight in settings where weight scales are not available or are unreliable is an important question to address. In this study, these alternative bands resulted in inferior and largely unacceptable doses for children. None of the drugs tested would deliver acceptable therapeutic doses across all bands based upon height or age among Ugandan children, and only co-trimoxazole would have been delivered at acceptable therapeutic levels based upon these bands in Bangladeshi children. With the single exception of the highest weight band Ugandan children, none would receive an acceptable therapeutic dose of co-artemether based upon height or age, with the most being overdosed. For a drug with a wide therapeutic margin, such as co-trimoxazole, the performance of height and age bands was found to be acceptable. As would be expected in populations experiencing high levels of malnutrition in children younger than 5 years of age, older and taller children are more likely to be overdosed. Given that many primary health care clinics do

Table 2. Best Fit Tablet Dose (mg) and Proportion of Children Receiving the Correct Therapeutic Dose Based Upon Their Weight Band Assignment

Drug	Weight Band	Dose Received (mg)	Proportion in Therapeutic Range (% of Over- or Under-dose)
Paracetamol 100-mg tablet; target dose, 10 mg/kg (range: 5-15 mg/kg/dose)	[1]	50	97 (3% over)
	[2]	100	96 (4% over)
	[3]	150	100
	[4]	200	96 (4% under)
Iron 50-mg tablet (elemental iron); target dose, 6 mg/kg (range: 3-9 mg/kg/day)	[1]	25	100
	[2]	50	100
	[3]	75	100
	[4]	100	100
Co-arthemeter Co-arthemeter: 100-mg tablet; range: 8-15 mg/kg/day; Lumefantrine: target dose: 12 mg/kg (range: 8-15 mg/kg/day)	[1]	50	97 (3% over)
	[2]	100	95 (5% over)
	[3]	150	100
	[4]	200	100
Co-trimoxazole 40-mg tablet; target dose (trimethoprim): 6 mg/kg (range: 3-9 mg/kg every 12 hr)	[1]	20	100
	[2]	40	100
	[3]	60	100
	[4]	80	100
Amoxicillin 250-mg tablet; target dose: 25 mg/kg (range: 15-45 mg/kg every 8 hr)	[1]	125	100
	[2]	250	100
	[3]	375	100
	[4]	500	100
Ciprofloxacin 125-mg tablet; target dose: 15 mg/kg (range: 10-20 mg/kg every 12 hr)	[1]	62.5	99 (1% over)
	[2]	125	99 (1% over)
	[3]	187.5	100
	[4]	250	100

not have functioning scales and that health care workers use age as a de facto proxy, these findings suggest that currently, many children may be receiving inappropriate drug doses when doses are based on age.

Presently, dispersible tablet formulations exist for 5 of the 6 drugs tested, the exception being ciprofloxacin. These tablets may be dispersed in either water or milk. The potential advantages of dispersible tablet formulations over syrup include their light weight and ease of distribution, they are less costly to produce and eventually price, they are easily administered, they are not sunlight sensitive, and caregivers are able to easily keep track of the number of doses given.[6,11] Given these advantages, UNICEF has called upon pharmaceutical laboratories for the production of additional pediatric essential medicines in dispersible dosage forms.[6] The feasibility of a transition from syrups to tablets will rest upon the identification of weight (or proxy) bands that can be universally applied to these additional dispersible formulations.

Limitations to this study include the unavailability of weight scales in many primary care settings. The reality is that many primary care clinics across sub-Saharan Africa and South Asia will either not have a weight scale, or if they do, it will not be functional or will be poorly calibrated. This reality largely drives the substitution of age

Table 3. Validity of the 4-Category Height Band as a Guide to Essential Drug Dose Decision Making in Children <5 Years of Age

Drug	Height Band	Uganda				Bangladesh			
		No. of Subjects	% of Under-doses	% of Correct Doses*	% of Over-dosed	No. of Subjects	% of Under-dosed	% of Correct Doses*	% of Over-doses
Paracetamol	[1]	67	1.5	**97.0**	1.5	45	2.2	**95.6**	2.2
	[2]	814	25.6	66.5	7.9	688	5.3	80.7	14.0
	[3]	1190	18.2	77.8	4.0	1048	2.2	87.7	10.1
	[4]	229	6.1	90.0	3.9	116	0	94.8	5.2
	overall		19.2	75.6	5.5		3.2	85.8	11.0
Iron	[1]	75	18.7	81.3	0	45	28.9	71.1	0
	[2]	814	0.6	**98.2**	1.2	988	0	**97.7**	2.3
	[3]	1190	0.1	**98.7**	1.2	1048	0.1	**99.6**	0.3
	[4]	229	0	**99.6**	0.4	116	0	**100**	0
	overall		0.9	**98.0**	1.1		0.7	**98.3**	1.0
Co-artemether	[1]	75	46.7	53.3	0	45	11.1	86.7	2.2
	[2]	814	4.9	87.2	7.9	688	0.1	85.9	14.0
	[3]	1190	1.3	94.8	3.9	1048	0.1	89.8	10.1
	[4]	229	0	**95.6**	4.4	116	0	90.5	9.5
	overall		3.9	91.0	5.2		0.4	88.3	11.3
Co-trimoxazole	[1]	76	18.4	80.3	1.3	45	4.4	**95.6**	0
	[2]	815	0.7	**99.1**	0.2	688	0	**99.4**	0.6
	[3]	1191	0.2	**99.4**	0.4	1048	0.1	**99.4**	0.5
	[4]	230	0.4	**99.6**	0	116	0	**100**	0
	overall		1.0	**98.7**	0.3		0.2	**99.4**	0.4
Amoxicillin	[1]	76	18.4	80.3	1.3	45	4.4	**95.6**	0
	[2]	815	0.6	90.0	1.4	688	0	**97.7**	2.3
	[3]	1190	0.1	**98.6**	1.3	1063	0.3	**98.2**	1.5
	[4]	230	0.4	**99.2**	0.4	116	0	**100**	0
	overall		0.9	**97.9**	1.2		0.3	**98.0**	1.7
Ciprofloxacin	[1]	76	44.7	52.6	2.7	44	0	88.6	11.4
	[2]	814	5.0	89.6	5.4	687	0	91.3	8.7
	[3]	1190	1.4	**95.6**	3.0	1046	0	**97.3**	2.7
	[4]	229	0.4	**97.4**	2.2	116	0	**100**	0
	overall		3.9	92.3	3.8		0	**95.5**	4.5

** Boldface values indicate acceptable (<95%); green indicate marginal (90-95%); and red indicate unacceptable (<90%).*

as a proxy for weight. How well the suggested weight bands will perform in primary care clinical settings has yet to be tested. Furthermore, it needs to be confirmed whether health care providers will find weight banding or the eventual color coding of these bands acceptable. Finally, the therapeutic dose ranges used in this study were based on IMCI and US FDA dosage references; pharmacokinetic studies would provide a more accurate analysis but would be very costly.

Table 4. Validity of the 4-category Age Band as a Guide to Essential Drug Dose Decision Making in Children <5 Years of Age

Drug	Age Band	Uganda				Bangladesh			
		No. of Subjects	% of Under-doses	% of Correct Doses*	% of Over-doses	No. of Subjects	% of Under-doses	% of Correct Doses*	% of Over-doses
Paracetamol	[1]	39	5.1	92.3	2.6	23	0	**100**	0
	[2]	459	13.5	71.2	15.3	404	3.0	70.0	27.0
	[3]	1139	8.0	74.5	17.5	888	1.2	57.5	41.3
	[4]	685	3.6	74.9	21.5	582	0.2	41.9	57.9
	Overall		7.7	74.3	18.0		1.2	55.9	42.9
Iron	[1]	38	3.3	94.7	2.0	23	0	**100**	0
	[2]	459	0.7	**96.5**	2.8	404	0	93.3	6.7
	[3]	1057	0.3	**99.7**	0	888	0	88.1	11.9
	[4]	687	0	**95.8**	4.2	582	0	87.8	12.2
	Overall		0.3	**97.8**	1.9		0	89.2	10.8
Co-artemether	[1]	NA				NA			
	[2]	459	2.4	82.3	15.3	404	0.5	72.5	27.0
	[3]	1139	1.1	81.4	17.5	888	0	58.7	41.3
	[4]	685	0.1	77.0	22.9	582	0.2	38.5	61.3
	Overall		1.1	80.2	18.7		0.2	55.4	44.4
Co-trimoxazole	[1]	39	5.1	92.3	2.6	23	0	**100**	0
	[2]	460	0.9	98.7	0.4	404	0	**97.8**	2.2
	[3]	1144	0.8	96.8	2.4	888	0	**96.5**	3.5
	[4]	687	0	**99.4**	0.6	582	0	**97.6**	2.4
	Overall		0.6	**97.9**	1.5		0	**97.6**	1.5
Amoxicillin	[1]	39	5.1	92.3	2.6	23	0	**100**	0
	[2]	458	0.5	96.7	2.8	404	0	93.3	6.7
	[3]	1140	0.3	92.5	7.2	888	0	88.1	11.9
	[4]	687	0	**95.8**	4.2	582	0	89.5	10.5
	Overall		0.3	94.3	5.4		0	87.6	10.4
Ciprofloxacin	[1]	39	30.8	61.5	7.7	23	0	**100**	0
	[2]	458	2.6	86.1	11.3	402	0.3	81.8	17.9
	[3]	1144	1.5	83.7	14.8	887	0	71.8	28.2
	[4]	687	0.2	86.3	13.5	582	0	61.3	38.7
	Overall		1.8	84.6	13.6		0.1	71.0	28.9

*Boldface values indicate acceptable (<95%); green indicate marginal (90-95%); and red indicate unacceptable (<90%).
NA, not available.

Furthermore, the range of acceptable doses for some drugs varies. For example, in the United States, the recommended dose of acetaminophen (paracetamol) based upon their published weight bands ranges from 5 to 19 mg/kg/dose, whereas we applied a range of 5 to 15 mg/kg/dose. Dispersible tablets are subject to degradation under extreme temperatures and higher humidity conditions. This can be mitigated through aluminum or polyvinylchloride packaging but will require additional testing and longer term monitoring for stability.

This study's findings indicate that if the pediatric essential drugs tested were to be provided in tablet formulations, an acceptable drug dose could be prescribed based upon a child's weight. For this to occur would require that primary care facilities maintain a functioning, properly calibrated weight scale. Based on Ugandan and Bangladeshi anthropometric data sets, the substitution of weight with either a height measurement or the age of the child will not provide an acceptable guideline for fixed drug dose decision making. Where does this leave health providers working in facilities without a functioning weight scale, as is so often the case? Upward or downward adjustment in dose could depend upon the child's age and nutritional status as well as upon consideration of the potential risks associated with under- or overdosing, for example, underdosing antibiotics and overdosing iron.

CONCLUSIONS

Given the fact that the weight, height, and age bands tested performed similarly in sub-Saharan African and South Asian populations, it is concluded these results can be extrapolated to other low-income country populations. Alternative banding based upon long bone measurements, such as the tibia or ulnar length adjusted for nutritional status or mid-upper arm circumference may provide an acceptable substitute for weight, but these have yet to be validated. Weight estimates based upon a smart phone photographic application is another alternative to be considered.

Disclosure The authors declare no conflicts or financial interest in any product or service mentioned in the manuscript, including grants, equipment, medications, employment, gifts, and honoraria.

Abbreviations co-artemether, artemether/lumefantrine; co-trimoxazole, trimethoprim/sulfamethoxazole; IMCI, integrated management of childhood illness; UNICEF, United Nations Children's Fund; USFDA, United States Food and Drug Administration; WHO, World Health Organization.

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