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Evaluation of the Integrated Management of Childhood Illness guidelines for treatment of intestinal helminth infections among sick children aged 2–4 years in western Kenya*

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Abstract

Anthelmintic treatment of sick preschool-age children at health facilities is a potentially effective strategy for intestinal helminth control in this age-group. We conducted a study from July 1998 to February 1999 in western Kenya to determine whether the Integrated Management of Childhood Illness (IMCI) guidelines' clinical assessment can be used to identify helminth-infected children, and to evaluate the nutritional benefit of treating sick children without pallor with an anthelmintic (mebendazole is already part of IMCI treatment for sick children aged 2–4 years with palmar pallor in areas where hookworm and *Trichuris trichiura* infections are endemic). Sick children aged 2–4 years seen at 3 rural health facilities were clinically evaluated and tested for haemoglobin concentration, malaria parasites, and intestinal helminths. Children without pallor were randomly assigned to receive a single dose of 500 mg of mebendazole or a placebo and re-examined 6 months later. Among the 574 children enrolled, 11% had one or more intestinal helminths. Most infections were of light intensity. Selected clinical signs and symptoms available from the IMCI assessment, including palmar pallor and low weight-for-age, were not associated with helminth infection. Six months after enrolment, no differences in growth of children without pallor were observed between the mebendazole ($n = 166$) and placebo ($n = 181$) groups. However, there was a significantly greater mean increase in weight, height, and weight-for-age Z score among the helminth-infected children in the mebendazole group ($n = 22$) as compared with helminth-infected children in the placebo group ($n = 20$). We conclude that even lightly infected preschool-age children without palmar pallor benefit from anthelmintic treatment; however, in this study setting of low helminth prevalence and intensity, helminth-infected children could not be identified using the IMCI guidelines. Cost-effectiveness studies are needed to help define helminth prevalence thresholds for routine anthelmintic treatment of sick preschool-age children seen at first-level health facilities.

Keywords: Integrated Management of Childhood Illness, helminth infections, preschool children, nutritional status, palmar pallor, hookworm, *Trichuris trichiura*, *Ascaris lumbricoides*, chemotherapy, randomized trial, mebendazole, Kenya

Introduction

The soil-transmitted intestinal helminths *Ascaris lumbricoides*, *Trichuris trichiura*, and hookworm infect more than one billion people worldwide, and are an important cause of malnutrition among children (STEPHENSON, 1987). Several studies conducted in areas of high prevalence and intensity of helminth infection have found significant improvements in growth of school-age children after anthelmintic treatment (STEPHENSON *et al.*, 1989, 1993; ADAMS *et al.*, 1994; COOPER *et al.*, 1995; WATKINS & POLLITT, 1996; HADJU *et al.*, 1996, 1997). Recognizing the positive impact of deworming and the cost-effectiveness of school-based deworming programmes, the World Health Organization (WHO) recommends periodic mass treatment of children without prior screening (WHO, 1992) in areas where helminth prevalence exceeds 50%.

While intestinal helminth infections are also considered to be an important public health problem in preschool-age children (MARTIN *et al.*, 1983; OLSEN, 1998), similar guidelines for routine deworming of children in this age-group do not exist. Unlike school-age children, preschool-age children are not routinely brought together at a common location and are therefore more difficult to reach for mass treatment. The few studies measuring the nutritional impact of anthelmintic treatment in preschool-age children have been inconclusive; while some studies have demonstrated a significant impact from treatment (GUPTA *et al.*, 1977; WILLET & KIHAMIA, 1979), others have not (FREIJI *et al.*, 1979; GREENBERG *et al.*, 1981; GUPTA & URRUTIA, 1982; KLOETZEL *et al.*, 1982; ROUSHAM & TAYLOR, 1994).

The Integrated Management of Childhood Illness (IMCI) guidelines recently introduced by WHO (WHO & UNICEF, 1995) provide a means of delivering anthelmintics to sick preschool-age children. The IMCI guidelines provide a standard of care for children aged <5 years seen at first-level health facilities in developing countries: sick children are systematically assessed and treated for common childhood illnesses, such as malaria, diarrhoea, respiratory infections, measles, and malnutrition, which alone or in combination are responsible for more than 70% of childhood deaths (WHO, 1995). The guidelines use palmar pallor as the clinical indicator for anaemia and currently recommend that sick children aged 2–4 years with palmar pallor be treated with iron, an antimalarial in areas where the risk for malaria is high, and an anthelmintic where hookworm or *Trichuris* infections are endemic.

To understand better how the IMCI guidelines can be used for the control of intestinal helminth infections, we conducted a study in a malaria-endemic area, Bungoma District, western Kenya, to determine whether palmar pallor or other clinical signs and symptoms in IMCI are useful for identifying helminth-infected children, and to evaluate the nutritional benefit of treating sick children without palmar pallor (those not currently treated under IMCI), with an anthelmintic.

Methods

The protocol for the study was approved by the Centers for Disease Control and Prevention Institu-

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tional Review Board and the Kenya Medical Research Institute Ethics Committee. The study was conducted in Bungoma District in western Kenya, where IMCI guidelines have been implemented since 1997. Of the 20 first-level rural government health centres in Bungoma District, we selected the 3 busiest sites.

Cross-sectional study (Fig. 1)

To evaluate the predictive value of signs and symptoms in the IMCI clinical assessment for identifying children with intestinal helminth infections, we conducted a cross-sectional study of all sick children at the study sites presenting for the first consultation during their illness between 13 July and 12 August 1998. Children who had been dewormed in the previous 6 months, who were severely ill and required referral, or whose caretakers refused to give consent were excluded from the study. The study was explained to the caretaker of each child in the Luhya language and written consent was obtained. The caretakers were interviewed using a standardized questionnaire to obtain demographic and socio-economic data. Each child was assessed according to the IMCI guidelines and clinical findings were recorded using a standardized data collection instrument. Also, for all enrolled children, height and weight were measured, finger-stick blood samples were obtained to measure haemoglobin (Hb) concentration and prepare a thick smear for the examination of malaria parasites, and a stool specimen was examined for helminth ova. Each child's weight was measured to the nearest 0·1 kg with a digital scale (Seca Inc., Columbia, MD, USA). Height was measured to the nearest millimetre with a height board (Shorr Production Inc., Olney, MD, USA). Weight and height measurements were done 3 times for each child and the average of the readings was used for analysis. Children were considered to have 'low weight-for-age' (be underweight) and 'low height-for-age' (stunting) if the Z scores for these indices were <-2 SD below the National Center for Health Statistics growth reference medians (NCHS, 1977). Hb concentration was measured using the HemoCue photometer (HemoCue Inc., Mission Veijo, CA, USA). Anaemia was defined, using WHO criteria, as Hb concentration <11 g/dL (WHO, 2001). Thick smears were stained with Giemsa's stain and examined for malaria parasites.

Prospective randomized trial (Fig. 1)

To determine the nutritional impact of anthelmintic treatment of sick preschool children without palmar pallor, we conducted a prospective randomized study. All enrolled children were categorized into palmar pallor and no-palmar pallor groups. All children with palmar pallor were treated with the anthelmintic mebendazole, the antimalarial sulfadoxine–pyrimethamine, and iron, in accordance with the IMCI guidelines, and excluded from randomization and analysis. Using a computer-generated list of random numbers, children without palmar pallor were randomized to receive either a single oral dose of 500 mg mebendazole (Vermox*, Janssen Pharmaceutica, Inc., Beerse, Belgium) or a placebo (sucrose–starch capsule, Forrest Pharmaceuticals, Inc., St Louis, MO, USA). Treatment was provided under direct observation. Children in both groups received treatment for other conditions in accordance with the IMCI guidelines. Six months after enrolment, all children were re-assessed for weight, height, and Hb concentration. The nutritional outcome measures were differences between pre-treatment and 6-month post-treatment means for weight, height, and weight-for-age (WAZ), height-for-age (HAZ), weight-for-height (WHZ) scores in SD units, and Hb concentration.

Stool examination

A pre-treatment stool specimen was collected from each enrolled child and stored in 10% formalin. After enrolment was completed, all specimens were processed and quantitatively examined using the formol–ethyl acetate concentration method (BEACH *et al.*,

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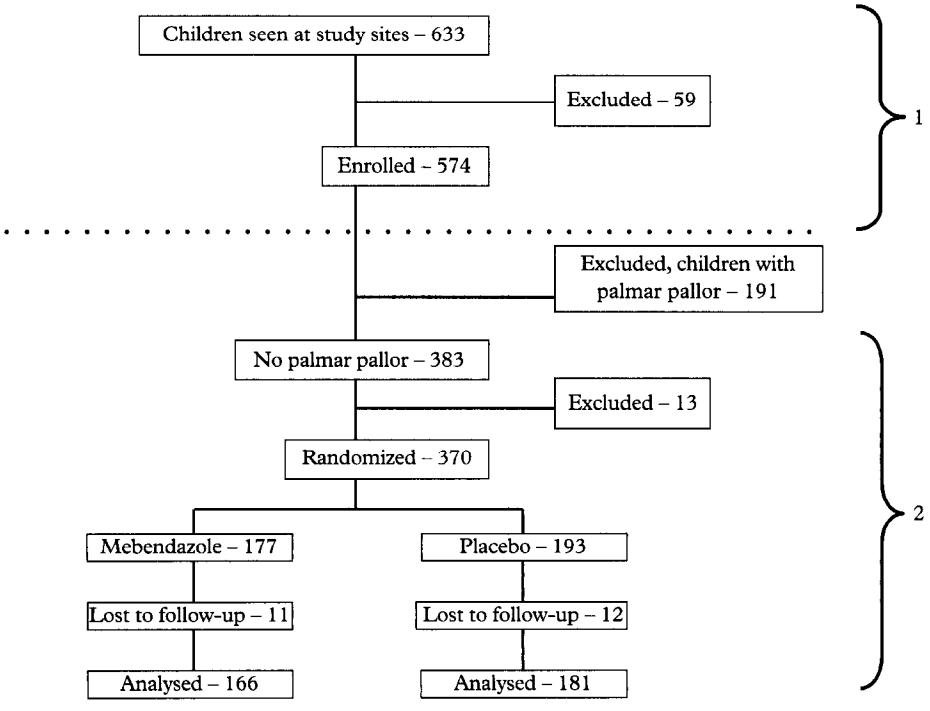

Fig. 1. Study design. (1) Cross-sectional study; (2) prospective randomized trial. Children, aged 2–4 years, sick but without palmar pallor were randomized to treatment with mebendazole or placebo and assessed for nutritional status 6 months later (western Kenya, 1998–99).

1999). The intensity of helminth infections was defined by egg count (eggs per gram of stool [epg]) (WHO, 1981, 1987) as follows. *Ascaris*: light, <5000 epg; moderate, 5000 to ≤50 000 epg; heavy, >50 000 epg. *Trichuris*: light, <1000 epg; moderate, 1000 to ≤10 000 epg; heavy, >10 000 epg. Hookworm: light, <2000 epg; moderate, 2000 to ≤7000 epg; heavy, >7000 epg.

Quality control

Several steps were taken to ensure the quality of field and laboratory work. The health workers participating in the study had been using IMCI guidelines since receiving training in 1997. Before the study, they received refresher IMCI training with an emphasis on assessment for palmar pallor. To train health workers to measure weight and height accurately, WHO-outlined standardization exercises were used (WHO, 1983). The accuracy of the HemoCue photometer was checked daily using the control cuvette provided by the manufacturer. To check quality of the examination of stool specimens, 10% of positive and 10% of negative stool specimens were selected randomly and re-examined at the Centers for Disease Control and Prevention (CDC) Reference Parasitology Laboratory. Because the mebendazole placebo is no longer manufactured, the trial was not double-blinded. However, during enrolment, the health workers did not open the drug packet containing mebendazole or placebo until after completing the clinical and anthropometric examination. The health workers were blinded to study group assignments at the time of the 6-month follow-up. The laboratory personnel analysing stool specimens were also blinded to group assignments.

Statistical analysis

Data were analysed using EpiInfo version 6.04 (CDC, Atlanta, GA, USA, July 1996) and Statistical Analysis Software (SAS Institute Inc., Cary, NC, USA). Student's *t* test was used to test pre- and post-treatment differences in means between the treatment and placebo groups.

Results

Cross-sectional study

Characteristics of the study population. During the enrolment period, 633 sick children were seen at the 3 study sites. In all, 34 children who had been dewormed in the previous 6 months, 13 who had a severe illness and 12 whose caretakers did not give consent, were excluded. Thus, 574 (91%) of all children seen at the study sites were enrolled (Fig. 1, cross-sectional study). The excluded children were similar to the enrolled children in regard to demographic and socio-economic characteristics (data not shown). The median age of the enrolled children was 37 months and 44% were girls (56% were boys). Ninety percent of the mothers and 93% of the fathers of enrolled children had at least a primary education (schooling through grade 5). Almost all children were from households that had access to a pit latrine. The average number of persons per household was 3·7.

Of the 574 enrolled children, 85% had fever or a history of fever and were treated for malaria in accordance with the IMCI guidelines. Seventy percent of the children had cough or difficulty breathing and 10% had diarrhoea. The prevalence of anaemia (Hb < 11 g/dL) was 61%, while 33% had palmar pallor. Most of the anaemic children had mild-to-moderate anaemia. Twenty-eight percent of the children were underweight and 39% were stunted.

The prevalence of malaria parasitaemia among enrolled children was 57%. In all, 32 (6%) were infected with *Ascaris*, 34 (6%) with hookworm, and 5 (1%) with *Trichuris*; 66 (11%) children had one or more intestinal helminths. Seventy-five percent of *Ascaris* infections, 97% of hookworm infections, and all *Trichuris* infections were of light intensity (only 3% of *Ascaris* infections and 3% of hookworm infections were of heavy intensity).

Socio-demographic predictors of helminth infections. The prevalence of helminth infection increased with age but this increase was not statistically significant. Similarly, differences in prevalence of helminth infection among boys and girls were not significant. In univariate analysis, mother's education less than grade 5 [prevalence ratio (PR) = 1·9, 95% confidence interval (CI) 1·1–3·3], and father's education less than grade 5 (PR = 2·0, 95% CI 1·1–3·7) were significantly associated with helminth infection. Also, children living in households with >5 persons had a higher prevalence of helminth infection compared with children living in households with <5 persons (PR = 2·3, 95% CI 1·5–3·7). Presence of a pit latrine in the household was not associated with helminth infection (PR = 1·8, 95% CI 0·3–10·0). In multivariate analysis, maternal education less than grade 5 and household size greater than 5 persons remained significantly associated with helminth infection.

Association between palmar pallor and anaemia. Children with palmar pallor were twice as likely to be anaemic compared with children without palmar pallor (PR = 2·0, 95% CI 1·8–2·3). Of the 191 children with palmar pallor, 176 (92%) had anaemia. Of the 351 children with anaemia, 175 (50%) had palmar pallor. Thus, overall, palmar pallor was a good predictor of anaemia but had a low sensitivity for diagnosing anaemia. The sensitivity of palmar pallor to identify children with anaemia increased to 72% among children with Hb < 9 g/dL, and to 100% among children with Hb < 7 g/dL.

Association between clinical signs and symptoms in IMCI guidelines and helminth infection. We found no association between selected clinical signs and symptoms in the IMCI guidelines and any helminth infection (Table 1). The PR describing this relationship for palmar pallor was 0·7 (95% CI 0·5–1·3). The sensitivity, specificity and positive predictive value of palmar pallor as a clinical indicator for helminth infection were 27%, 66%, and 9%, respectively. The PR for low weight-for-age was 1·2 (95% CI 0·7–1·9), and the sensitivity, specificity and positive predictive value were 32%, 72%, and 13%, respectively (the IMCI guidelines use only the weight-for-age classification 'very low weight' [*Z* score < −3 SD] but since only 36 (6%) children had this classification, we chose to use low weight-for-age).

Association between palmar pallor and hookworm or Trichuris *infection.* In the IMCI guidelines, anthelmintic treatment is given specifically for anaemia. In all, 38 children had an anaemia-causing helminth infection (hookworm or *Trichuris*). We found no significant association between palmar pallor and hookworm or *Trichuris* infection (PR = 0·9, 95% CI 0·5–1·8).

Prospective randomized trial

Of the 383 enrolled children without palmar pallor, 13 presented with a complaint of passing worms and were excluded after being treated with the anthelmintic mebendazole. The remaining 370 children without palmar pallor were randomly assigned to the mebendazole (177) and placebo (193) treatment groups (Fig. 1, prospective trial). The follow-up examination was completed for 94% of these children. Children in the mebendazole- and placebo-treatment groups were similar in age and gender. The prevalences of anaemia, malnutrition, malaria, and helminth infections were similar in each group (data not shown).

Mean differences in pre- and post-treatment measurements of weight, height, Hb, HAZ, WAZ, and WHZ between the mebendazole and placebo groups are shown in Table 2. Six months after anthelmintic treatment, no significant difference was noted in the

Table 1. Association between selected clinical assessment signs and symptoms in the IMCI guidelines and intestinal helminth infection among sick children aged 2–4 years, Bungoma District, Kenya, 1998

	Helminth infection		Prevalence ratio (95% CI)	Sensitivity (%)	Specificity (%)	Positive predictive value (%)
	Yes	No				
Palmar pallor						
Yes	18	173	0·7 (0·5–1·3)	27	66	9
No	48	335				
Weight-for-age *Z* score <−2 SD[a]						
Yes	21	140	1·2 (0·7–1·9)	32	72	13
No	45	368				
Height-for-age *Z* score <−2 SD						
Yes	21	203	0·7 (0·5–1·2)	32	60	9
No	45	305				
Diarrhoea						
Yes	4	51	0·6 (0·2–1·6)	6	90	7
No	62	457				
Fever						
Yes	56	429	1·0 (0·5–1·8)	85	16	12
No	10	79				
Cough/difficult breathing						
Yes	48	357	1·1 (0·7–1·9)	73	30	12
No	18	151				

IMCI, Integrated Management of Childhood Illness; 95% CI, 95% confidence interval; SD, standard deviation.
[a]Very low weight-for-age (<−3 SD) is used in the IMCI assessment, but low weight-for-age status can be determined using the information collected.

Table 2. Comparison of pre- and post-treatment nutritional status among all children in the mebendazole ($n = 166$) and placebo ($n = 181$) treatment groups, Bungoma District, Kenya, 1998–99

Nutritional indicator	Treatment group	Pre-treatment[a]	Post-treatment[a]	Difference[a]	*P* value[b]
Weight (kg)	Placebo	12·92 ± 0·19	14·11 ± 0·19	1·19 ± 0·05	0·79
	Mebendazole	13·13 ± 0·19	14·35 ± 0·20	1·21 ± 0·06	
Height (cm)	Placebo	90·55 ± 0·66	94·71 ± 0·64	4·17 ± 0·10	0·57
	Mebendazole	90·81 ± 0·65	95·06 ± 0·64	4·25 ± 0·11	
Haemoglobin (g/dL)	Placebo	11·26 ± 0·10	11·74 ± 0·10	0·48 ± 0·11	0·71
	Mebendazole	11·24 ± 0·11	11·78 ± 0·11	0·54 ± 0·11	
Weight-for-age[c]	Placebo	−1·24 ± 0·08	−1·03 ± 0·08	0·21 ± 0·03	0·87
	Mebendazole	−1·17 ± 0·09	−0·97 ± 0·08	0·20 ± 0·04	
Height-for-age[c]	Placebo	−1·48 ± 0·08	−1·36 ± 0·09	0·11 ± 0·03	0·54
	Mebendazole	−1·52 ± 0·10	−1·38 ± 0·09	0·14 ± 0·03	
Weight-for-height[c]	Placebo	−0·41 ± 0·07	−0·24 ± 0·07	0·17 ± 0·04	0·75
	Mebendazole	−0·30 ± 0·07	−0·14 ± 0·07	0·15 ± 0·04	

[a]Means ± SEM.
[b]*t* test for difference in means between the 2 treatment groups.
[c]*Z* score (SD units).

mean gain in any of the nutritional outcome measures between the mebendazole and placebo groups. However, when we compared helminth-infected children only, we observed a significantly greater mean increase in weight ($P = 0·04$), height ($P = 0·04$) and weight-for-age ($P = 0·02$) among those in the mebendazole group as compared with those in the placebo group (Table 3).

Discussion

Our findings show that, despite having light helminth infections, infected preschool-age children benefited from anthelmintic treatment. However, in our study setting, where the prevalence and intensity of helminth infection were low, clinical assessment signs in the IMCI guidelines were not useful in identifying helminth-infected children.

Previous studies showing a positive impact of treatment for helminth infection on nutritional status of children have been conducted primarily in populations of children who were almost universally parasitized and had high intensity of infections (STEPHENSON *et al.*, 1989, 1993; ADAMS *et al.*, 1994; COOPER *et al.*, 1995; WATKINS & POLLITT, 1996; HADJU *et al.*, 1996, 1997). Only one study among school-age children (BEACH *et al.*, 1999) and none among preschool-age children has reported a positive impact of anthelmintic treatment when infections are of light intensity. In a double-blind, randomized, controlled trial among Haitian school-age children aged 5–11 years, hookworm- and *Trichuris*-infected children benefited from anthelmintic treatment, even though most infections were light and the prevalence of malnutrition was low (BEACH *et al.*, 1999). The following factors may have contributed to the improvement in growth of infected children in our study, despite their having only light infections. Our study population was younger (2–4 years old), had a higher prevalence of malnutrition,

Table 3. Comparison of pre- and post-treatment nutritional status among helminth-infected children in the mebendazole ($n = 22$) and placebo ($n = 20$) treatment groups, Bungoma District, Kenya, 1998–99

Variable	Treatment group	Pre-treatment[a]	Post-treatment[a]	Difference[a]	*P* value[b]
Weight (kg)	Placebo	13·74 ± 0·63	14·82 ± 0·64	1·09 ± 0·15	0·04
	Mebendazole	13·24 ± 0·63	14·76 ± 0·64	1·53 ± 0·15	
Height (cm)	Placebo	92·88 ± 2·05	96·54 ± 2·03	3·66 ± 0·2	0·04
	Mebendazole	94·42 ± 2·10	98·85 ± 2·02	4·44 ± 0·26	
Haemoglobin (g/dL)	Placebo	11·34 ± 0·31	12·11 ± 0·33	0·77 ± 0·30	0·79
	Mebendazole	11·28 ± 0·30	11·91 ± 0·33	0·63 ± 0·30	
Weight-for-age[c]	Placebo	−1·01 ± 0·23	−0·88 ± 0·21	0·13 ± 0·08	0·02
	Mebendazole	−1·43 ± 0·26	−1·02 ± 0·26	0·41 ± 0·08	
Height-for-age[c]	Placebo	−1·34 ± 0·27	−1·34 ± 0·25	0·00 ± 0·08	0·07
	Mebendazole	−1·18 ± 0·29	−0·97 ± 0·26	0·22 ± 0·09	
Weight-for-height[c]	Placebo	−0·19 ± 0·16	−0·04 ± 0·16	0·15 ± 0·10	0·23
	Mebendazole	−0·89 ± 0·26	−0·57 ± 0·26	0·33 ± 0·10	

[a]Means ± SEM.
[b]*t* test for difference between the 2 treatment groups.
[c]*Z* score (SD units).

and was therefore likely to have a faster rate of growth. Also, with infection of similar intensity, young children have higher worm loads relative to their surface area than older children and adults. Improvement in appetite of helminth-infected children after treatment has been reported in previous studies (STEPHENSON *et al.*, 1993; ADAMS *et al.*, 1994). The follow-up period of our study corresponded with the harvest season in western Kenya, when food availability at the household level is good. Greater availability of food during the follow-up period may have enabled infected treated children to eat more when their appetites improved after treatment, thus facilitating 'catch-up' growth.

Although helminth-infected children benefited from treatment in our study, we found no impact of anthelmintic treatment on the entire group of treated children. The low prevalence of helminth infection limited the study's power to show an impact in all treated children. Previous studies in preschool-age children with adequate sample size, high prevalence of helminth infections, and adequate follow-up period have shown a positive impact of anthelmintic treatment (GUPTA *et al.*, 1977; WILLET & KIHAMIA, 1979). However, studies that failed to show a positive impact of anthelmintic treatment in preschool-age children have suffered from several limitations, such as small sample size, short period of follow-up (FREIJI *et al.*, 1979), and failure to cure helminth infection (GREENBERG *et al.*, 1981; GUPTA & URRUTIA, 1982).

Our study is the first to show that lightly infected, sick, preschool-age children benefit from anthelmintic treatment. The challenge is to identify such children. The cost and difficulties in performing stool examinations, and the absence of adequately sensitive and specific clinical signs that can be used to identify children with an intestinal helminth infection, point towards a presumptive-treatment strategy based on prevalence of helminth infections. In areas with low prevalence of helminth infections, using such a strategy to benefit the few infected children would result in treating mainly uninfected children. However, the safety of mebendazole, the anthelmintic drug recommended by IMCI, has been well-documented in children over 2 years of age (GOODMAN *et al.*, 1996), and the cost of mebendazole for treating a child aged 2–4 years is only €0.025 [*c.* US$ 0.025] (for a 500 mg tablet, not including transport) (INTERNATIONAL DISPENSARY ASSOCIATION, 2001). Cost-effectiveness studies should be conducted to help determine the prevalence of helminth infection at which sick preschool-age children at least 2 years old seen as outpatients should be treated routinely with an anthelmintic.

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