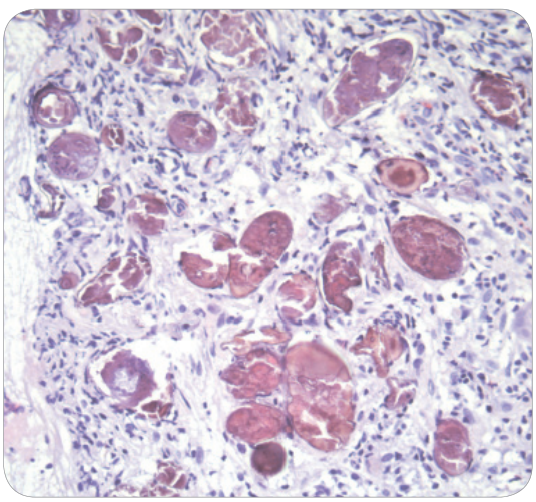
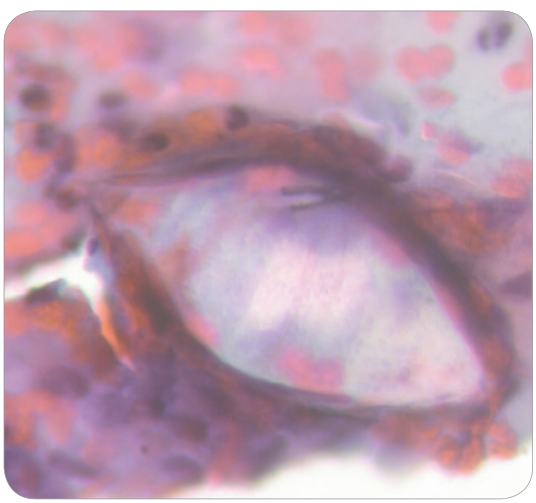
REPORT OF A MEETING TO REVIEW THE RESULTS OF STUDIES ON THE TREATMENT OF SCHISTOSOMIASIS IN PRESCHOOL-AGE CHILDREN

Geneva, Switzerland, 13–14 September 2010

World Health Organization





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WHO Library Cataloguing-in-Publication Data :

Report of a meeting to review the results of studies on the treatment of schistosomiasis in preschool-age children.

1.Schistosomiasis - drug therapy. 2.Praziquantel - administration and dosage. 3.Anthelmintics - administration and dosage. 4.Treatment outcome. 5.Child, Preschool. I.World Health Organization.

ISBN 978 92 4 150188 0 (NLM classification: WC 810)

Printed by the WHO Document Production Services, Geneva, Switzerland.

WHO/HTM/NTD/PCT/2011.7

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EXECUTIVE SUMMARY

Children aged under 4 years (or below 94 cm in height) have been excluded from mass treatment programmes for control of schistosomiasis because of the limited documentation on the safety of praziquantel in this age group. To address this information gap, the World Health Organization (WHO) convened a meeting at its headquarters in Geneva, Switzerland, on 13–14 September 2010 to review the results of studies on the treatment of schistosomiasis in preschool-age children.

To examine the treatment of schistosomiasis (attributable to *Schistosoma mansoni* and *S. haematobium* infections) in preschool-age children, WHO supported treatment trials in Mali, Sudan and Zimbabwe. Praziquantel, in tablet formulation or as a suspension, was assessed for its safety and efficacy in treating preschool-age children. In Sudan and Zimbabwe, the praziquantel suspension did not arrive on time for inclusion in the trials. Other groups independently assessed treatment in this age group in Niger and Uganda. As part of the schistosomiasis control programme in Egypt, praziquantel suspension was developed and used to treat young schoolchildren (aged 6–7 years) who had difficulties in swallowing the tablets. Data on efficacy and safety from this study that used both praziquantel tablets and suspension to treat school-age children were also presented during the meeting.

Preschool-age children are at high risk of schistosomiasis. In areas of Mali, Niger, Sudan, Uganda and Zimbabwe, prevalence of the infection ranged from 18% to 63%. Studies on the treatment of preschool-age children conducted in these five countries (n=3198) among children aged 1 month to 7 years showed that praziquantel in a tablet or suspension formulation was safe and effective against schistosomiasis, and acceptable. In all the studies, high cure rates

were observed, and significant reductions in mean egg counts occurred for both urogenital and intestinal schistosomiasis. The two studies in Mali and Uganda that compared suspension and tablets found no difference in cure rates between the two formulations. In Uganda, there was also no difference in rates of egg reduction between the two formulations.

The effectiveness of praziquantel suspension was also compared with that of the tablet formulation among 27 406 schoolchildren in Egypt. The data showed that cure rates were lower among schoolchildren treated with suspension than those treated with tablets. However, egg reduction rates were similar regardless of the formulation of praziquantel received. In the Uganda study, which also evaluated the use of the dose pole for determining dosage of praziquantel, it was concluded that height is not appropriate for determining the standard dose of praziquantel syrup.

Adverse events were reported from all the studies. Praziquantel, in tablet or syrup formulation, was well tolerated. Reported adverse events were mild and transient, and included fatigue, dizziness, drowsiness, headache, loss of appetite and stomach ache. Assessment of adverse events was not consistent among the studies; it was only in Uganda that questionnaires were administered to mothers before and after treatment to enable differentiation between existing symptoms and treatment-related events. Less than 1% of the treated school children in Egypt experienced adverse events.

Administration of praziquantel to preschool-age children was shown to be acceptable, safe and efficacious to individual children and in group settings. Preparation of the treatment dosages varied among studies: tablets and crushed tablets mixed with various fluids were used in the different studies. In Niger, doses of the suspension were measured using syringes, whereas in Mali spoons were used.

The studies reviewed in this report had some limitations of design and methodology. Systematic