

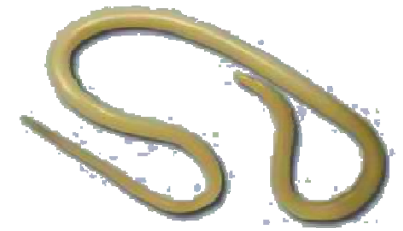
**SAFETY AND FEASIBILITY
OF SCHOOL-BASED
COMBINED MASS DRUG ADMINISTRATION
FOR SOIL-TRANSMITTED HELMINTHIASIS
AND SCHISTOSOMIASIS
AMONG SCHOOL-AGE CHILDREN**

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Introduction

- ❑ Neglected tropical diseases (NTDs) are a group of chronic and disabling conditions which are mostly infectious diseases of poverty (WHO, 2012)
- ❑ Co-endemicity of selected NTDs, consider co-administration of anthelmintics through integrated mass drug administration (MDA) (WHO, 2006)
- ❑ Soil-transmitted helminthiasis (STH) and schistosomiasis (SCH) are most common
- ❑ Children are most vulnerable to infections



Introduction

- STH and schistosomiasis may cause the following morbidities:
 - Anemia
 - Growth stunting (malnutrition)
 - Poor mental and physical development affecting school performance
- Schistosomiasis causes chronic liver disease and is potentially fatal



Nodular liver due to chronic schistosomiasis

Rationale

- ❑ In the Philippines, the Department of Health (DOH) has different national programs for control of selected NTDs with separate MDA implementation
- ❑ Co-administration of albendazole and praziquantel safe based on several studies conducted in Africa and Asia
(Adoubryn *et al.*, 2012; Anto *et al.*, 2012; and Olds *et al.*, 1999)

DOH Programs and MDA Implementation



	Integrated Helminth Control Program	Schistosomiasis Control Program
Targeted Helminth Infection	STH infections	Schistosomiasis
Drugs	Albendazole (ALB) 400 mg	Praziquantel (PZQ) 40 mg/kg
Target Population	School-age children (6-12 years old)	5-65 years old
Mode of Implementation	School-based	Community-based
Implementing Agency	Department of Education (DepEd)	Local Health Unit (LHU)
MDA Schedule	January & July	July

Objectives of the Study

- **General Objective**

To demonstrate safety and feasibility of school-based combined MDA using albendazole and praziquantel in selected co-endemic areas for STH infections and schistosomiasis in the Philippines

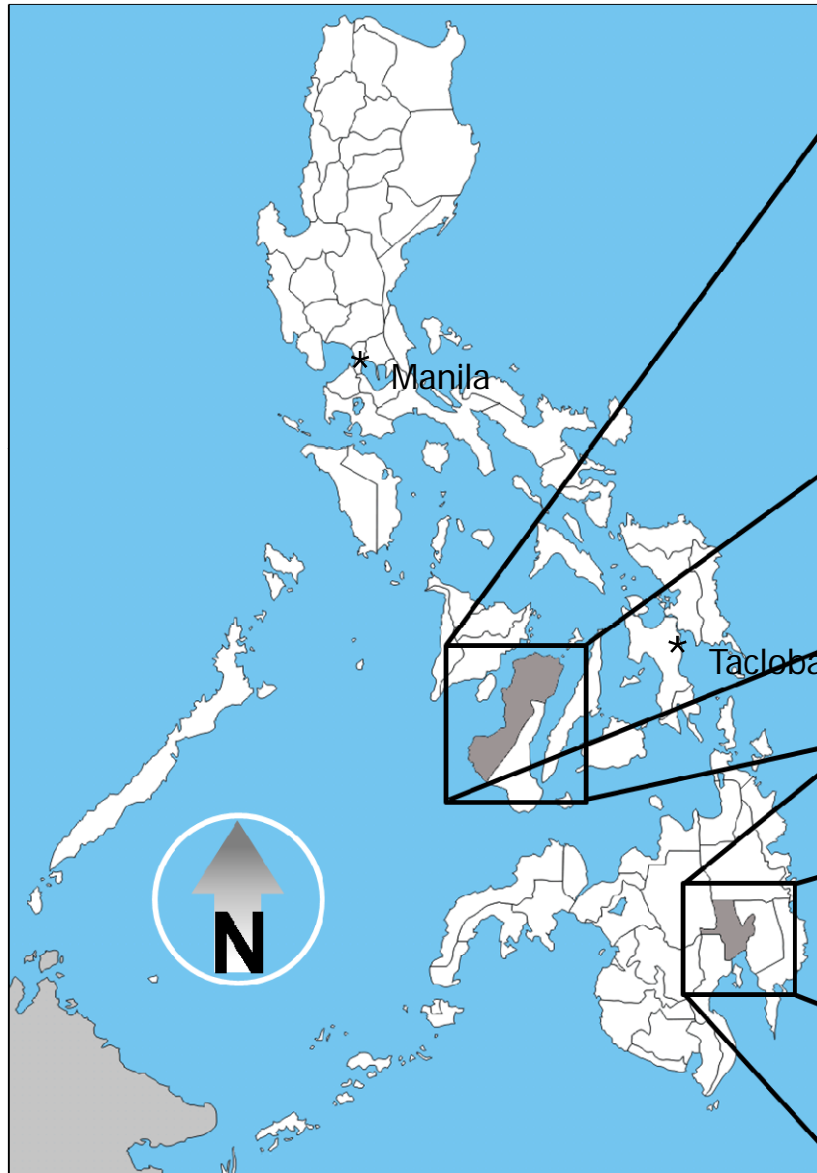
- **Specific Objectives**

1. To describe incidence, severity, and causality of adverse events (AEs) following combined MDA in selected co-endemic areas in the Philippines
2. To describe combined MDA coverage in selected co-endemic areas in the Philippines

Methodology

- Phase I: Pilot assessment of safety and feasibility of school-based combined MDA
 - Study Sites: two public elementary schools in Calatrava, Negros Occidental
 - Participants: Grades 4 to 6 students
- Phase II: Larger-scale assessment of safety and feasibility of school-based combined MDA
 - Study Sites: 8 public elementary and 2 high schools in Santo Tomas and Carmen, Davao del Norte
 - Participants: Students in all grade- and year levels

Study Sites



Methodology

School-Based Combined MDA

Phase I	Phase II
ALB administered by trained DepEd nurses in a classroom setting	ALB and PZQ co-administered by trained class teachers with the presence of health workers from DepEd or LHU
PZQ administered by LHU nurses with assistance from village health workers in a treatment station in school premises	



Trained health workers administering PZQ tablets to students on school premises in Calatrava, Negros Occidental



Trained class teacher co-administering ALB and PZQ tablets to students in the classroom in the presence of a health worker

Methodology

Assessment and Management of AEs

Phase I	Phase II
AEs assessed and monitored up to 4 hours	
Project physicians assessed and monitored all AEs	Initial assessment of AEs and management of mild AEs by trained local nurses or midwives
	AEs of at least moderate severity were referred to project physicians
Severity and causality assessed according to the WHO toxicity grading scale and standard operating procedures for clinical investigators (DMID-NIAD, 2003; Karbwang and Pattou, 1999)	



Trained project team medical doctor performing initial assessment of AEs



Trained DepEd nurse performing initial assessment of AEs

Results

- Phase I (done in one half day)
 - ▣ Combined MDA coverage: **80.1%** (71.2 - 94.4%) (n=408)
 - ▣ AEs in **5.2%** (0.0 - 14.7%) (n=327)
- Phase II (done in two half days)
 - ▣ Combined MDA coverage: **75.5%** (70.0 - 87.5%) (n=3,192)
 - ▣ AEs in **5.4%** (2.6 - 11.1%) (n=2,410)



Class Teacher co-administering PZQ and ALB to a student in Davao Del Norte



Assessment of AE by Project Physician in Anibongan High School, Davao del Norte

National STH MDA Coverage Rate for School-Age Children in 2012: **19.7%**
National Schistosomiasis MDA Coverage Rate for School-Age Children in 2012: **20.4%**

Rate of students assessed to have AEs following treatment are lower than other reported rates reaching as high as **35%** (Olds *et. al.*, 1999)

Results: Phase I

Assessment and Management of AEs

Incidence, severity, and causality of AEs in Calatrava, Negros Occidental

Clinical signs/ symptoms	Incidence (n=327) No. (%)	Severity		Causality			
		Mild No. (%)	Moderate No. (%)	Unlikely No. (%)	Possible No. (%)	Probable No. (%)	Most Probable No. (%)
Dizziness	10 (3.1)	10 (100)	0 (0.0)	0 (0.0)	7 (70.0)	2 (20.0)	1 (10.0)
Headache	8 (2.4)	7 (87.5)	1 (12.5)	0 (0.0)	3 (37.5)	2 (25.0)	3 (37.5)
Nausea	7 (0.4)	6 (85.7)	1 (14.3)	0 (0.0)	2 (28.6)	2 (28.6)	3 (42.9)
Vomiting	5 (0.3)	4 (80.0)	1 (20.0)	0 (0.0)	2 (40.0)	1 (20.0)	2 (40.0)
Abdominal pain	4 (0.2)	4 (100)	0 (0.0)	0 (0.0)	4 (100)	0 (0.0)	0 (0.0)
Others ^a	1 (0.1)	1 (100)	0 (0.0)	0 (0.0)	1 (100)	0 (0.0)	0 (0.0)

^aSleepiness

Results: Phase II

Assessment and Management of AEs

Incidence, severity, and causality of AEs in Davao del Norte

Clinical signs/symptoms	Incidence	Severity		Causality			
	(n=2,410)	Mild	Moderate	Unlikely	Possible	Probable	Most Probable
	No. (%)	No. (%)	No. (%)	No. (%)	No. (%)	No. (%)	No. (%)
Headache	79 (3.3)	74 (93.7)	5 (6.3)	28 (35.4)	30 (38.0)	21 (26.6)	0 (0.0)
Dizziness	49 (2.0)	47 (95.9)	2 (4.1)	11 (22.4)	19 (38.8)	19 (38.8)	0 (0.0)
Abdominal Pain	30 (1.2)	27 (90.0)	3 (10.0)	5 (16.7)	10 (33.3)	15 (50.0)	0 (0.0)
Vomiting	29 (1.2)	27 (93.1)	2 (6.9)	5 (17.2)	8 (27.6)	16 (55.2)	0 (0.0)
Nausea	21 (0.9)	21 (100)	0 (0.0)	2 (9.5)	8 (38.1)	11 (52.4)	0 (0.0)
Fever	3 (0.1)	2 (66.7)	1 (33.3)	1 (33.3)	1 (33.3)	1 (33.3)	0 (0.0)
Allergic Reaction ^a	1 (0.04)	1 (100)	0 (0.0)	0 (0.0)	1 (100)	0 (0.0)	0 (0.0)
Others ^b	1 (0.04)	1 (100)	0 (0.0)	1 (100)	0 (0.0)	0 (0.0)	0 (0.0)

^a Erythematous pruritic wheals, without difficulty of breathing or facial swelling

^b Chest pain

Summary

- School-based combined MDA was generally safe
 - ▣ 5% of students assessed to have AEs
 - ▣ Most AEs observed were mild and transient
 - ▣ All resolved in schools
 - ▣ None were severe requiring referral to hospitals
- Scheme for AE assessment and management
 - ▣ Initial assessment can be done by local health workers, *i.e.*, nurses or midwives
 - ▣ Establish referral system linking schools to local health units and referral hospitals

Summary

- Combined MDA was feasible
 - ▣ Coverage rates met the WHO target of 75%
 - ▣ Utilization of existing infrastructures, *i.e.*, schools, for MDA to access more school children
 - ▣ Utilization of existing manpower (*e.g.*, nurses, midwives, school teachers, and village health workers) for treatment as well as assessment and management of AEs
 - Teachers can administer both drugs to students with supervision from local health workers
- Importance of multisectoral collaboration among key stakeholders (DOH, DepEd, and local government units)

Recommendations

- Scaling-up of school-based, teacher-assisted combined MDA in all co-endemic areas in Calatrava, Negros Occidental and Davao del Norte
 - ▣ Serving as model for implementation in other co-endemic areas in the Philippines and elsewhere
 - ▣ Basis for formulation of national policy and practice guidelines
 - ▣ Subject of capacity building activities among local health officials and health workers
 - ▣ Social mobilization activities to help increase parental consent and MDA coverage

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- Department of Education Regions VI and XI
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Thank you

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