MACEPA PATH
Malaria Control and Elimination Partnership in Africa

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Government of the Republic of Zambia

Adverse event reporting from malaria mass drug administration (MDA) rounds conducted in Southern Province, Zambia

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Background

- The National Malaria Elimination Centre of the Ministry of Health of Zambia conducted a large-scale mass drug administration (MDA) community randomized controlled trial to evaluate the effectiveness of different MDA distribution strategies on reducing malaria parasitemia.
- The trial involved two MDA strategies: MDA, where all eligible individuals were treated with DHAp, and focal MDA (fMDA), where all eligible individuals residing in a household with at least one RDT-positive member were treated with dihydroartemisinin-piperaquine (DHAp).
- This provides an opportunity to document the extent to which potential safety issues are reported or adverse events occur given the level of exposure to treatments.

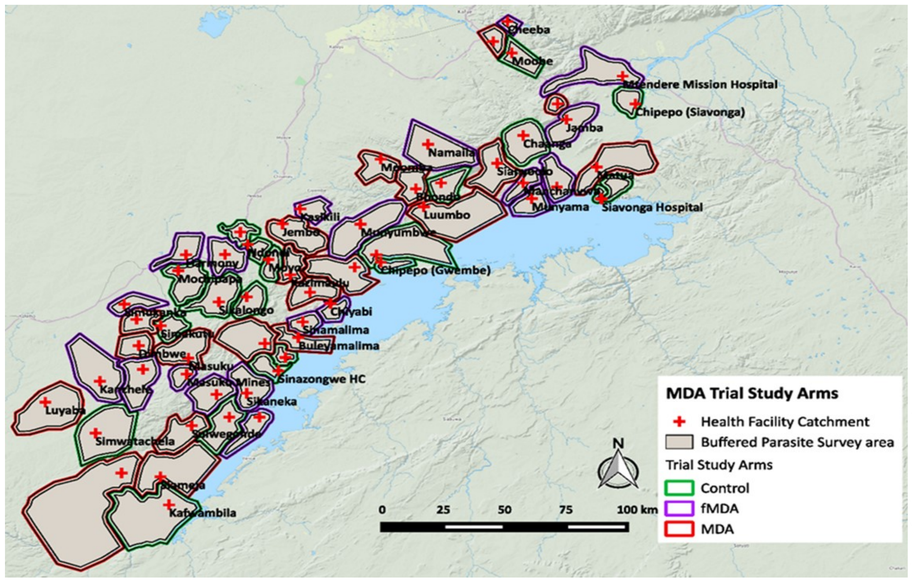
Methods

- Field teams comprised of community health workers, enumerators, and adherence monitors, and supervised by facility-based staff, received standardized training on the treatment campaign procedures, use of DHAp for eligible participants, adverse event monitoring, grading of events, and emergency and event handling procedures by grading.
- Adverse events were recorded on standard forms and in line with recommendations from national pharmacovigilance network recommendations.
- The principle aim of this data collection activity was to document and follow up on all adverse events (AEs) and serious adverse events (SAEs) occurring during the course of implementing the MDA trial for individuals taking DHAp.

Results

- Four rounds of MDA were conducted over two years. During the first two intervention rounds, 280,638 participants were tested and 159,696 were treated with DHAp in 40 health catchment areas. During the second two intervention rounds, 261,814 participants took part. Across all four rounds, 336,821 courses of DHAp were given.

Figure 1. MDA study trial area



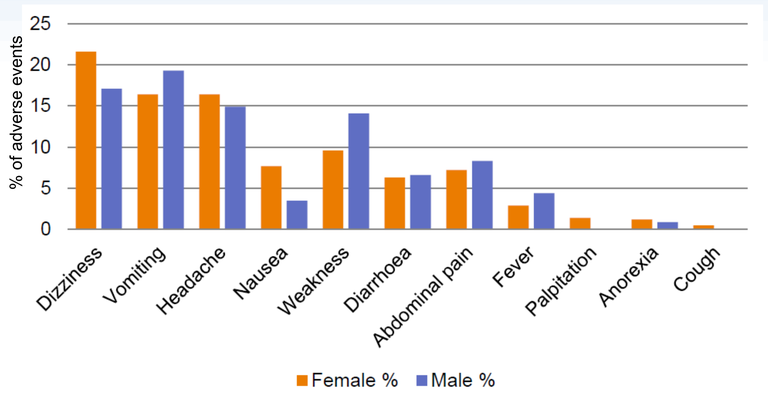
- A total of 687 AEs (0.13% of participants and 0.24% of treatments) were reported; four were initially reported as serious adverse events—choking (1), vomiting (2), and fainting (1). And three were identified as not related to drug ingestion.
- The most common AE reported was gastrointestinal disturbances (diarrhea, vomiting, abdominal pain, and nausea) at 48.6%; dizziness 19.8%; headache 16.0%, and general body weakness at 11.4%.
- Among those reporting AEs, the mean age was 23.1 and the median was 20.0 years (see Table 1 for more detail).

Table 1. Reported adverse event symptoms (n= 687 adverse events), by children under five, adolescents, and adults

Adverse event	Under 5 (n=66), %	Adolescents (n=249), %	Adults (n=353), %
Vomiting	36.4	16.9	13.0
Diarrhoea	16.7	6.4	4.8
Headache	9.1	15.3	17.9
Dizziness	10.6	20.5	21.0
Abdominal pain	3.0	9.2	7.1
Weakness	3.0	8.8	15.0
Nausea	3.0	5.6	7.7
Fever	9.1	3.2	2.6
Palpitations	-	0.8	1.4
Other	9.1	13.3	9.5
Total	100.0	100.0	100.0

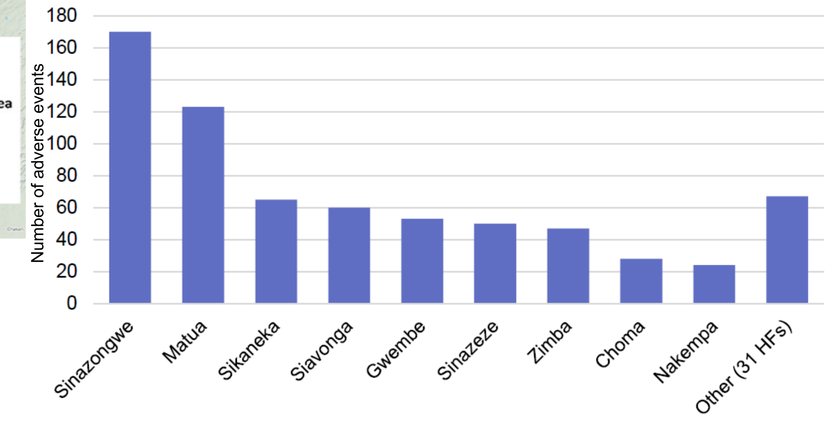
Results continued

Figure 2. Proportion of all adverse events by symptom among males and females (n = 687 adverse events)



Prominence of adverse events was generally similar by gender with nausea and weakness being the only notable difference.

Figure 3. Number of adverse events reported by health facilities



Reporting rates for adverse events by health facilities were low, with the majority of the reported adverse events coming from only 9 of 40 health facilities.

Conclusions

During this large MDA trial, the use of DHAp for malaria treatment was generally safe and well tolerated. Phamacovigilance is important for the early detection of new adverse reactions which were not previously known or recognized, however there was notably poor reporting in most facilities.

All adverse drug events should be assessed, managed, and reported to the Zambia Medicines Regulatory Authority.