Current rotavirus clinical trials activity on the African Continent

<u>Lindi Mathebula</u>¹; Duduzile Ndwandwe¹; Charles S. Wiysonge^{1,2,3}

¹Cochrane South Africa, South African Medical Research Council, Tygerberg, South Africa, ²Division of Epidemiology and Biostatistics, Department of Global Health, Stellenbosch University, ³Division of Epidemiology and Biostatistics, School of Public Health and Family Medicine, University of Cape Town

Background

Rotavirus is a major infectious virus causing childhood diarrhea and is associated with significant mortality in children. Three African countries (Nigeria, Democratic Republic of Congo and Angola) are among the five countries that account for 50% of all diarrheal related deaths worldwide. The WHO International Clinical Trial Registry Platform (WHO-ICTRP) is a repository for primary registries reporting on clinical trials conduct globally. This study aimed to Identify and describe planned, ongoing and completed rotavirus trials conducted in Africa.

Methods

We searched WHO-ICTRP on 2 April 2019 and conducted a cross-sectional analysis of rotavirus studies listed in the database. Data extraction included trial location, intervention, participant age, and funders. We used registry identifiers to search PubMed for publications of the registered trials. Descriptive analysis was conducted in MS Excel™.

Results

We identified 30 African rotavirus trials registered from 2005 to April 2019. 18 studies were registered prospectively and 12 retrospectively. Most of the trials (83%) are studying children aged less than 5 years. The recruitment status for these trials are currently shown in the WHO-ICTRP as "not recruiting" for 21 trials, "recruiting" for 7 trials recruiting, and unknown for 2 trials. The trials have recruitment centres in 14 African countries. Funding sources include local research organisation (7 trials), pharmaceutical industry (8 trials), and international research organisations (15 trials). Most of the trials tested the effects of new rotavirus vaccines (90%) and the rest involved therapeutics. Only 7 of the registered trials have been published.

Conclusions

Mapping rotavirus clinical trial activity in WHO-ICTRP provides useful information on planned, ongoing or completed trials for researchers, funders, and healthcare decision makers. Despite the high rotavirus disease burden in Africa, there is minimal clinical trial activity on the continent related to the condition.