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Global Health

Supplementary appendix 3

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Supplement to: Max R, Toval-Ruiz C, Becker-Dreps S, et al. Neurodevelopment in preschool children exposed and unexposed to Zika virus in utero in Nicaragua: a prospective cohort study. *Lancet Glob Health* 2024; **12**: e1129–38.

Equitable Partnership Declaration

Researcher considerations

1. Please detail the involvement that researchers who are based in the region(s) of study had during a) study design; b) clinical study processes, such as processing blood samples, prescribing medication, or patient recruitment; c) data interpretation; and d) manuscript preparation, commenting on all aspects. If they were not involved in any of these aspects, please explain why.

This question is intended for international partnerships; if all your authors are based in the area of study, this question is not applicable.

This should include a thorough description of their leadership role(s) in the study. Are local researchers named in the author list or the acknowledgements, or are they not mentioned at all (and, if not, why)? Please also describe the involvement of early career researchers based in the location of the study. Some of this information might be repeated from the Contributors section in the manuscript. Note: we adhere to [ICMJE authorship criteria](#) when deciding who should be named on a paper.

a) Study design:
Filemon Bucardo was involved in the design of this study.
b) Clinical study processes:
Christian Toval-Ruiz, Evelin Martinez, Oscar Ortega, Damaris Collado, Omar Zepeda, Meylin Chavarria, Maria Jose Melendez, Juan Carlos Mercado, Angel Balmaseda, and Filemon Bucardo were involved in study processes such as patient enrolment, data collection and management, and participant assessments.
c) Data interpretation:
Filemon Bucardo, Oscar Ortega, Omar Zepeda, Evelin Martinez, and Christian Toval-Ruiz were both involved in the interpretation of study data.
d) Manuscript preparation:
Filemon Bucardo, Oscar Ortega, Omar Zepeda, Evelin Martinez, and Christian Toval-Ruiz were all involved in the preparation of the manuscript.

2. Were the data used in your study collected by authors named on the paper, or have they been extracted from a source such as a national survey? ie, is this a secondary analysis of data that were not collected by the authors of this paper. If the authors of this paper were not involved in data collection, how were data interpreted with sufficient contextual knowledge?

The Lancet Global Health *believe contextual understanding is crucial for informed data analysis and interpretation.*

The data used in this study were collected, generated, and interpreted by all of the Nicaragua-based authors named on the paper, including Christian Toval-Ruiz, Evelin Martinez, Oscar Ortega, Damaris Collado, Omar Zepeda, Meylin Chavarria, Maria Jose Melendez, Juan Carlos Mercado, Angel Balmaseda, and Filemon Bucardo. Their contextual knowledge of the study setting were indispensable in the design of the study, collection of data, and interpretation of that data.

3. How was funding used to remunerate and enhance the skills of researchers and institutions based in the area(s) of study? And how was funding used to improve research infrastructure in the area of study?

Potentially effective investments into long-term skills and opportunities within institutions could include training or mentorship in analytical techniques and manuscript writing, opportunities to lead all or specific aspects of the study, financial remuneration rather than requiring volunteers, and other professional development and educational opportunities.

Improvements to research infrastructure could be funding of extended trial designs (such as platform trials) and use of master protocols to enable these designs, establishment of long-term contracts for research staff, building research facilities, and local control of funding allocation.

Skills:

Psychologists from Leon and Managua were trained by senior neuropsychologist (Dr. Boivin, Dr. Familiar, Dr. Goldman, and Dr. Ortiz-Pujols) using videoconferences on a weekly basis for 3 months, in addition to virtual sessions and in-person training or in-person workshop. In person training was carried out periodically throughout the year and videos of the testers administering the MSEL were evaluated by the senior neuropsychologist collaborating on this study. During this research program, the field team learned scientific writing, as well as key points on how to seek external funding. Omar Zepeda travelled to Emory University for 1 month to obtain additional lab training and then present the Serology analysis in an international conference (Keystone symposia). Additionally, data from this research was used by three masters level students for their own research in pursuit of their PhDs. The funding also supported SS and YY to attend international conferences to present their research. Evelin Martinez acquires writing skill that she used to publish as first author.

Research infrastructure:

In Leon, a clinic in the psychology department was renovated to be child friendly which was used to perform the MSEL and KABC to train Psychologist students. Laptops, laboratory reagents, consumables and a research vehicle were purchased as well.

4. How did you safeguard the researchers who implemented the study?

Please describe how you guaranteed safe working conditions for study staff, including provision of appropriate personal protective equipment, protection from violence, and prevention of overworking.

All staff in Leon and Managua dedicated 8 hours per day to the study, which is according to the national labour laws and received appropriate time off for national holidays as well as vacation time. Personnel protective equipment were provided and the staff followed good clinical and laboratory practices.

Benefits to the communities and regions of study

5. How does the study address the research and policy priorities of its location?

How were the local priorities determined and then used to inform the research question? Who decided which priorities to take forward? Which elements of the study address those priorities?

In 2016, the Pan American Health Organization and WHO declared the Zika epidemic a public health emergency. Nicaragua, like many Central and South American countries, was not spared. At the time of the Zika epidemic, Drs Balmaseda and Bucardo were already actively engaging in robust Dengue testing within their respective laboratories. Leveraging their existing lab capacity, they seamlessly transitioned to conducting Zika testing, directly tackling the emerging health challenge. A natural extension of the laboratory testing for Zika was determining pregnancy outcomes and long-term neurodevelopmental outcomes of infants exposed to Zika in utero and the current study was championed by Dr. Bucardo and Dr. Balmaseda.

Their endorsement and involvement in the study further underscored its alignment with regional research and policy priorities and enabled the study to address many different dimensions of the Zika epidemic including laboratory diagnostics, pregnancy outcomes, and infant health, effectively contributing to the advancement of knowledge and the formulation of evidence-based policies.

6. How will research products be shared in the community of study?

For instance, will you be providing written or oral layperson summaries for non-academic information sharing? Will study data be made available to institutions in the region(s) of study? The Lancet Global Health encourages authors to translate the summary (abstract) into relevant languages after paper editing; do you intend to translate your summary?

The preliminary result from this study have been presented in scientific meetings at the local in Nicaragua. We plan on providing a written summary in Spanish for sharing and data will be made available to local institutions upon request. All publication involving the Ministry of health are deposited in the Ministry of Health library and can be access for any employee.

7. How were individuals, communities, and environments protected from harm?

Any sample remaining and laboratory waste was handled by following safety procedures established in the microbiology lab, including sterilization by autoclaving.

a) *How did you ensure that sensitive patient data was handled safely and respectfully? Was there any potential for stigma or discrimination against participants arising from any of the procedures or outcomes of the study?*

Data was collected, stored, and transferred securely with participant privacy ensured in each step. Participation in the study was not contingent on any social or medical characteristics other than pregnancy, and participants were recruited from prenatal health visits. We do not believe there was potential for stigma or discrimination resulting from participation in this study.

b) *Might any of the tests be experienced as invasive or culturally insensitive?*

The only test involved apart from patient questionnaires and anthropometry at participant follow up visits was the Mullen Scales of Early Learning assessment, which was reviewed and adapted to the study context with the help of local researchers.

- c) *How did you determine that work was sensitive to traditions, restrictions, and considerations of all cultural and religious groups in the study population?*

All study staff were extensively trained to administer the neurodevelopmental assessments in the local language and during the initial training as well as ongoing refreshers sensitivity to local traditions and cultures was addressed.

- d) *Were biowaste and radioactive waste disposed of in accordance with local laws?*

Not applicable.

- e) *Were any structures built that would have impacted members of the community or the environment (such as handwashing facilities in a public space)? If so, how did you ensure that you had appropriate community buy-in?*

Not applicable.

- f) *How might the study have impacted existing health-care resources (such as staff workloads, use of equipment that is typically employed elsewhere, or reallocation of public funds)?*

Study staff were hired specifically for the study and thus did not use existing health care workers. Assessments were conducted either in specific study rooms or in the participant homes. We do not believe that our study procedures had a significant impact on existing health-care resources in León or Managua.

8. Finally, please provide the title (eg, Dr/Prof, Mr/Mrs/Ms/Mx), name, and email address of an author who can be contacted about this statement. This can be the corresponding author.

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