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Supplementary appendix 2

This Equitable Partnership Declaration (EPD) was submitted by the authors, and we reproduce it as supplied. It has not been peer reviewed. *The Lancet*'s editorial processes have not been applied to the EPD.

Supplement to: Nakabembe E, Greenland M, Amaral K, et al. Safety and immunogenicity of an acellular pertussis vaccine containing genetically detoxified pertussis toxin administered to pregnant women living with and without HIV and their newborns (WoMANPOWER): a randomised controlled trial in Uganda. *Lancet Glob Health* 2025; **13:** e81–97.

Equitable Partnership Declaration questions

This Equitable Partnership Declaration is a statement being published online alongside papers at *The Lancet Global Health*, as a separate appendix, to allow researchers to describe how their work engages with researchers, communities, and environments in the countries of study. This is part of our broader goal to decolonise global health, handing control and leadership of research to academics and clinicians who are based in the regions of study, and to affected communities.

Please answer all questions with as much detail as possible, noting that all included information will be published open-access and it will be freely available online to all who wish to read it. If a question does not apply to your study, please state "Not applicable".

The format of and questions in this statement are currently in a pilot phase. Please email Dr Liam Messin (Liam.Messin@lancet.com; deputy editor) and Dr Kate McIntosh (Kate.McIntosh@lancet.com; senior editor) with any feedback, particularly if you find any questions unclear.

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: Our study was co-designed by a team of academic researchers and clinicians including paediatricians, obstetricians and laboratory scientists from St George's University of London (SGUL), London; Makerere University College of Health Sciences (MakCHS), School of Medicine, Kampala, Uganda and Vaccine Evaluation Centre-University of British Columbia (UBC), Vancouver, Canada. The trial principal investigator was EN from MakCHS and the chief investigators were KLD from SGUL and MS from UBC
b) Clinical study processes: Screening the target population of pregnant women, obtaining informed verbal and written consent and enrolment of those who consented and met the study inclusion criteria for a low risk singleton pregnancy was done by in country study team. All clinical care and study procedures including delivery of the pregnant women and follow up of mothers and infants up to one-year post delivery

was supervised by the principal investigator from MakCHS, assisted by in country clinical research teams based at Makerere University-Johns Hopkins University Research Collaboration (MU-JHU), Kawempe National Referral Hospital and Kisenyi Health Centre IV in Kampala, Uganda.
Laboratory work was done at different laboratories including Medical Research Centre/Uganda Virus Research Institute, SGUL-KLD research laboratory-Vaccine Evaluation Centre and Pubic Health England-UK Health Security Agency (UKHSA), Porton, Salisbury, United Kingdom. The study PI from MakCHS participated in the laboratory analysis at the various institutions.

c) Data interpretation:
All data was collected in REDCap, query generation, resolution and verification were done by a dedicated data team at MU-JHU. Statistical analysis was as per a drawn statistical analysis plan led by Oxford Vaccine Group, NIHR Oxford Biomedical Research Centre, University of Oxford, Oxford, UK.
Technical and scientific oversight in the interpretation of data was led by the chief investigator from SGUL, the principal and senior investigators from MakCHS, UBC, Oxford and UKHSA.

d) Manuscript preparation:
The manuscript preparation was led by the principal investigator from MakCHS with investigators from Oxford and UBC, the chief investigators supervised the manuscript preparation. All authors participated in drafting and reviewing the primary manuscript and they approved the final version prior to submission for publication.

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.*

All data used in our study was collected by authors named on the paper and has not been extracted from a national survey.

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: The principal investigator, a Ugandan senior obstetrician and faculty at MakCHS was trained for a doctorate in maternal vaccinology and immunology at SGUL. Her training involved setting up and running maternal vaccine clinical trials, vaccinology and immunology including laboratory analysis from UBC, SGUL and UKHSA. The research team in Uganda (MU-JHU; WoMANPOWER study team) which included doctors, nurses, statisticians and data teams were supervised and mentored in conducting maternal vaccine early phase clinical trials. Our study was the first maternal vaccine early phase clinical trial (phase IIb) in Uganda. Seven of the authors including the first author are Ugandans i.e. three obstetricians, one paediatrician, two medical officers and one statistician. Four of the seven authors are working with a public university which is a great opportunity for long-term skills transfer.
Research infrastructure: The clinical trial was conducted within existent research infrastructure in Makerere University-Johns Hopkins University research collaboration. Funding was obtained for other clinical trials and observational studies in line with maternal vaccines, these studies are currently ongoing with the help of newly established maternal vaccine research platform.

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.

The research was led and implemented by in-country research teams at MU-JHU and MakCHS, working conditions adhered to the established research policies and procedures for well-being and safety of all the staff involved.

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?

The university and country have a health research agenda; reducing neonatal mortality and improving care for the HIV-exposed uninfected infants are among the public health priorities.

Research questions were agreed upon with academic researchers from MakCHS, MU-JHU, SGUL and UBC.

Assessing vaccine safety and immunogenicity among pregnant women living with HIV and their infants was the priority area of research focused on. In consultation with the country Ministry of Health, academic institutions, the National Immunisation Technical Advisory Group of Experts (NITAG) and ethical regulatory authorities, the area of vaccine safety was prioritized.

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?*

There is an established community engagement platform within MU-JHU within which community members were brought on board through the life time course of the study at screening, enrolment, follow up and results shared in community dialogue meetings. An independent social science team exploring vaccine confidence, hesitancy and consenting processes to participate in clinical trials was established. The social science team has worked closely with the clinical trial team to translate and share results with the community using translated local language materials. Other forums like radio and the arts have been used to communicate key messages regarding maternal vaccines trials.

Our data will be made available to institutions in the region of study and our summary will be translated to the local language for community sharing.

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

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?*

All data was de-identified, coded and stored on secured servers. The trial strictly adhered to ICH and GCP guidelines. There was no potential stigma or discrimination against participants arising from study procedures or outcomes.

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

There were no tests experienced as invasive or culturally insensitive

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

Multi-faceted community representation and discussion of all aspects of the trial including appropriate consenting process was done prior to starting the trial. There has been ongoing community engagement with key opinion, religious and cultural leaders to ensure that community norms were respected.

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

All biowaste waste was disposed off in accordance with Uganda's policies and procedures

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?*

No structures were built that would impact on members of the community or environment

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)?*

The study worked majorly within existent health care system, additional study staff were employed for study specific procedures including working on the additional documentation required. All required laboratory and imaging investigations were paid for using study funds and there was no reallocation of public funds.

8. Finally, please provide the title (e.g., 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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