

Global Pharmacovigilance The Safety of COVID-19 Vaccination in Pregnancy in LMICs Working Group Meeting: Coordinator Introduction

Minutes of the above meeting held on **Tues 12th April**, 11.00am BST via Zoom.

Present

Ryan Walker, Joe Adu-Manuh, Nathaniel Omaru Rogers, Achu Takim, Abeer Noureldin, Abdourahamane Diallo, Yogesh Gajmal, Nousheen Aslam, Ruby Joy Alejado, Maya Khan, Sunaram Beshra

Note: All working-group registrants who had indicated an interest in a coordinating role within the group were invited to this introductory meeting.

Agenda

1 Background to Working Group

R. Walker (*Global Pharmacovigilance/The Global Health Network*) gave a presentation to provide a background to the working group.

The working group activities are part of a wider research project (R. Walker's PhD) '*Can building a community of Practice improve pharmacovigilance outcomes in low resource settings?*'. This project seeks to harness the knowledge and expertise of a 'pharmacovigilance community of practice' (the membership of [Global Pharmacovigilance](#)) to work together to address the current challenges facing pharmacovigilance in Low and Middle-Income Countries (LMICs). This research currently focuses on pharmacovigilance relating to COVID-19 vaccines in LMICs.

Previous Global Pharmacovigilance research activities (a survey and online workshop) have identified three priority areas of pharmacovigilance in LMICs during the COVID-19 pandemic:

- The safety of COVID-19 vaccination in pregnancy
- The safety of COVID-19 vaccination in children/adolescents
- Analysis of COVID-19 vaccination safety data

The intent is now to create working groups to explore and address the above priorities.

R. Walker presented demographic data describing the registrants of the proposed 'Safety of Covid-19 Vaccination in Pregnancy' working group (see below)

The Global Health Network's '[COVID Hub](#)' was provided as an example of The Network's previous experience in supporting research-based working groups.

2 Proposed Working Group Plans

- **Form a 'coordinating group'** of interested working group members to drive group activities, composed of the attendees of this meeting and extended to other interested members of the wider working group (see '4. Coordinator Role' below).
- **Determine an area for focus.** As the working group topic (the safety of COVID-19 vaccination in pregnancy) is very broad, it should be explored further to elucidate key areas of concern within the subject. The area(s) for focus are to be decided by the group.
- **Discuss potential group outputs.** This could include the development of a tool or learning resource, e.g. online workshop/webinar, research protocol, SOP, communication resources, position papers etc. The outputs are to be decided by the group.

3 Co-ordinator Role

It is envisaged that the role of a group coordinator will be voluntary. The exact roles and responsibilities will be determined (if deemed necessary) by the group. Similarly, no time commitments will be specified and each group coordinator is invited to offer as much or as little of their time as they wish.

Global Pharmacovigilance/The Global Health Network will look to play a supportive, but not a guiding, role in group activities. Supportive activities may include the development and provision of an online space for group activities (directed by the group), support in the development of tools and resources, and the facilitation of research activities. Ultimately, it is envisaged that all activities will be led by the group.

4 Discussion

Attendees introduced themselves and were invited to share their comments on the proposed working group plans.

A. Diallo shared his previous experience of working on the Ebola Vaccine Trials (EVT) and current experience of working in the Solidarity (COVID-19) Trial. It was noted that extremely high mortality rates were seen for pregnant women and children during Ebola outbreaks and yet these groups were initially excluded from EVTs. Alongside an appropriate risk-benefit analysis, this experience guided the decision to include pregnant women in the Solidarity trial. Dr. Diallo also shared his experience regarding the importance of effective communication of the risks and benefits of COVID-19 vaccination when vaccinating in the community.

N. Aslam highlighted that social media has facilitated the rapid spread of both accurate and inaccurate information. Many pregnant women are unsure as to whether or not they should receive the vaccination. Dr Aslam also suggested that any intervention in this area should not just be targeted to pregnant women, but also their surrounding family. In addition, any resources that are developed can be done so with the aim of repurposing them for other medical interventions (e.g. other vaccines) and other vulnerable groups.

It was agreed by the group that pregnant women represent a very vulnerable group in relation to COVID-19 infection. The importance of transparent, effective communication

regarding the safety and efficacy of the vaccine in pregnancy was identified as a key issue. The need to allow patients and trial participants the appropriate time to raise questions and discuss concerns regarding COVID-19 vaccination was also raised. Providing the information at an appropriate and understandable level was also discussed, so that patients 'feel comfortable and 'feel they can ask everything' from their healthcare provider. The value of healthcare providers sharing their vaccine-related communication experiences in writing was also noted.

It was agreed that 'communication' could be a good focus for this working group's activities. This could include the development of a training/education resource for healthcare providers regarding the effective communication of COVID-19 vaccination safety in pregnancy. It was suggested that these efforts form part of a larger study that includes a pre-training and post-training assessment of participants.

5 Set Action Points for Next Meeting

- Further explore the theme of communication in relation to COVID-19 vaccination safety in pregnancy in LMICs
- Identify potential interventions (training resources/tools etc.) to address this concern.
- Create an online space on Global Pharmacovigilance for group information
- R. Walker to disseminate meeting minutes to all working group members and welcome further involvement in the coordinating group.

6 Agree date and time of the next meeting

The next virtual meeting will be held in approximately one month's time (Mid-May 2022 exact date to be decided closer to the time).

The Safety of COVID-19 Vaccination in Pregnancy in LMICs Working Group: Demographics

Group Registrants: 196

Countries Represented: 61

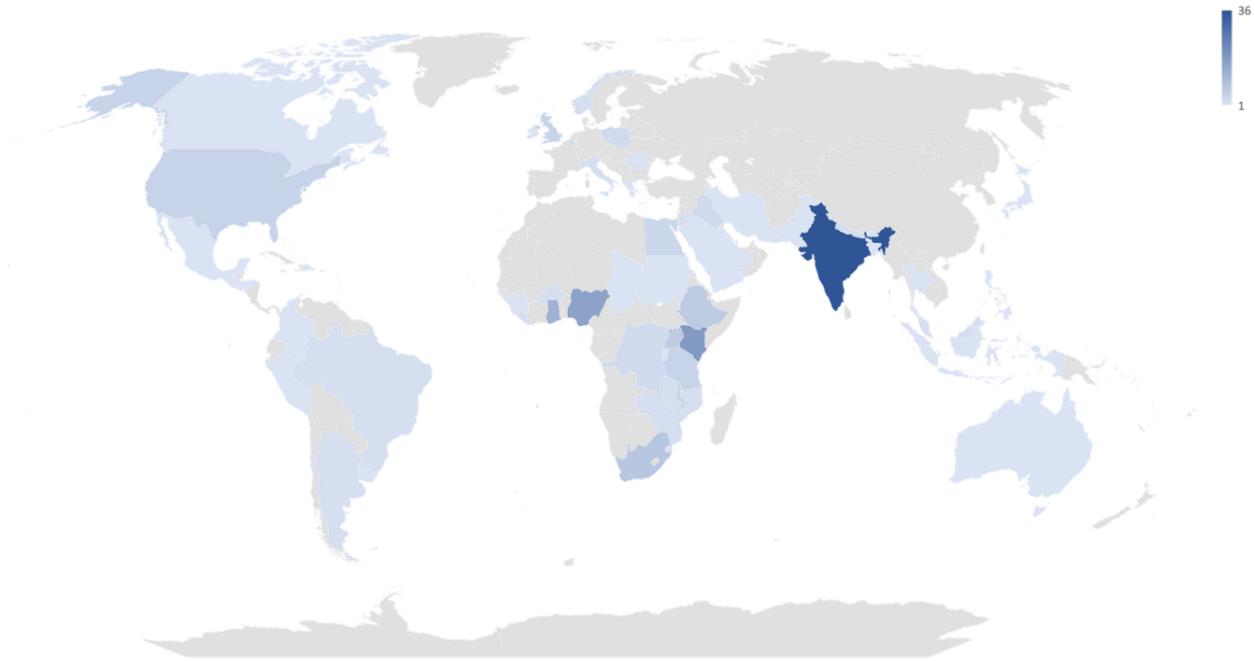


Fig 1: Working group registrants by country



Fig 2: The 10 most common job roles amongst working group registrants



Fig 3: The 10 most common institutions represented by working group registrants

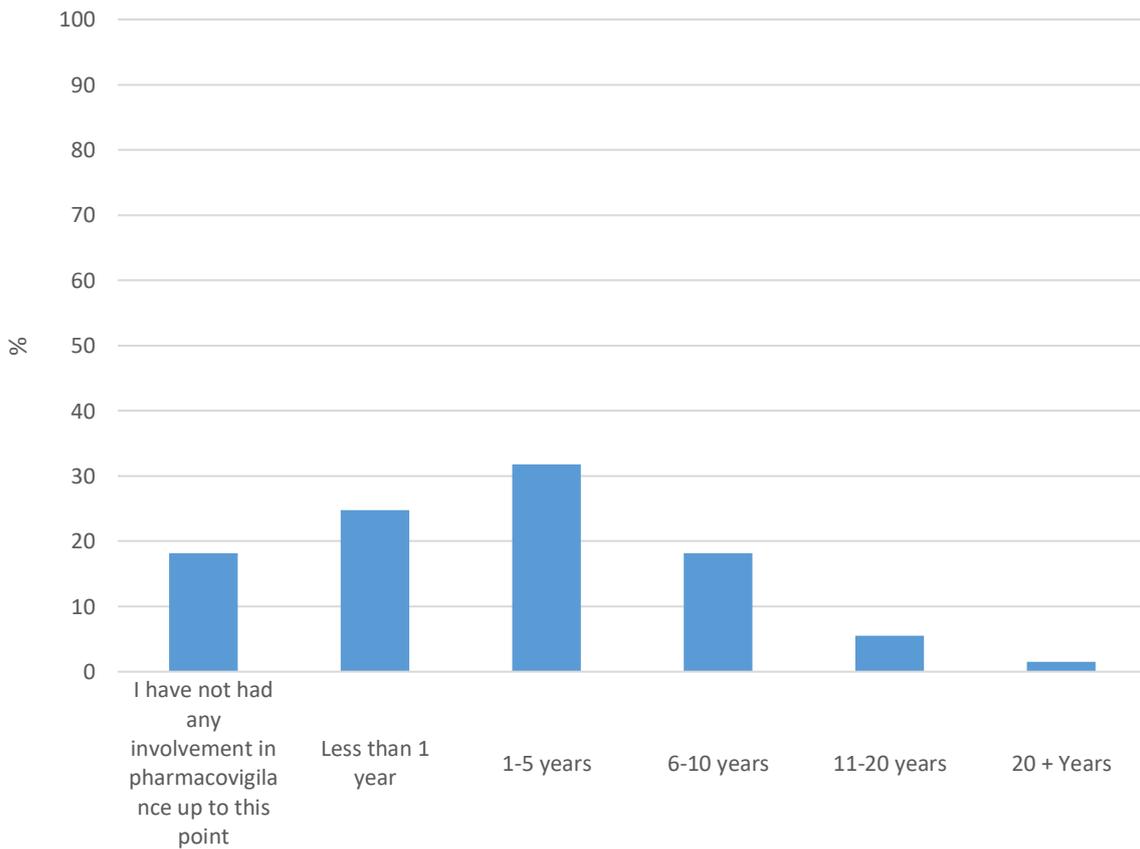


Fig 4: Years of involvement in pharmacovigilance of working group registrants. 'Involvement' may include paid or pro bono work, consultancy, research, post-graduate study etc.