COVID-19 Vaccine Pharmacovigilance Data in Low and Middle-Income Countries: Addressing the Challenges Using a Community of Practice Approach

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Introduction: The ability to analyse local safety data is a critical enabler of locally-led pharmacovigilance research and policy implementation. Nevertheless, pharmacovigilance stakeholders in Low and Middle-Income Countries (LMICs) face a multitude of barriers to real-time data analysis, often in stark contrast to those in High-Income Countries (HICs). Fundamental pharmacovigilance challenges including nascent systems, low levels of data generation and limited access to training opportunities are compounded by a lack of publicly-accessible national/regional databases, weak regulatory requirements and data siloing by key stakeholders. The sensitization to pharmacovigilance practices, improved stakeholder collaboration and increase in data generation resulting from the global COVID-19 vaccine rollout offers a potential catalyst to strengthen safety data analysis activities in LMICs. This project seeks to harness the membership of an online pharmacovigilance platform, globalpharmacovigilance.org, to work together in a ‘Community of Practice’ (CoP) to address the barriers to COVID-19 vaccine safety data analysis in LMICs.

Aims: To identify the key barriers to the analysis of COVID-19 vaccine safety data in LMICs, to seek solutions to address these challenges, and to assess the value of a CoP approach in tackling these issues.

Methods: Taking a participatory action research approach, this project builds on the findings of The Global Health Network’s ongoing consensus-building research, seeking to identify the priorities for pharmacovigilance in LMICs during the COVID-19 pandemic. A novel international working group is working together as a CoP, to explore the overarching theme ‘The analysis of COVID-19 vaccine safety data’ and identify effective methods and interventions to address the current challenges in this area.

Results: Quantitative results will be presented in the form of descriptive analyses of working group membership, engagement with group activities, and where possible, the impact of group studies or interventions. Qualitative results will include analysis of group discussions, and feedback on group outcomes and the value of the CoP approach.

Conclusion: It is anticipated that findings will ascertain whether and how a CoP can successfully identify and address barriers to the analysis of COVID-19 vaccine safety data in LMICs, and that the CoP’s activities will have a positive impact on pharmacovigilance capabilities in this field.