Reinforcing participant and community-centred principles for vaccine clinical trials in Sub-Saharan Africa

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Participation in clinical research is based on an informed, autonomous, and voluntary decision-making. However, when conducting research in Sub-Saharan African settings, ensuring that the decision to participate complies with these ethical considerations is not a straightforward process and an issue of great concern. Multiple factors, including socio-cultural, socio-economic and historical, influence the interaction between researchers and communities, impacting on how information is understood and consequently consent given. Vaccine trials, moreover, have some particularities as they target health individuals and are framed in a previous understanding of vaccines and vaccination programs.

The objective of this work is to explore how the information and consent processes for vaccine trial participation in Sub-Saharan African can be reinforced by applying a community- and participant-centred approach that considers the needs, values and preferences of targeted communities and the wider context where research is conducted. Participation in clinical research is based on an informed, autonomous, and voluntary decision. To achieve these objectives, as a first step a literature review was conducted to identify practices and recommendations that could improve the quality of the information provision and consent processes. As a second step, a qualitative study was implemented to explore researchers' experiences in designing and implementing these processes.

The results of this work emphasize the importance of adapting information and consent processes to the specific context. In the Sub-Saharan African settings, a community and participant-centred approach would entail establishing an open dialogue between researchers, community representatives and potential volunteers in all stages of the vaccine trial. There is also a clear need to understand the context and the communities targeted by the trial. This could for instance avoid that local practices, such as involvement of influential people in the information process, do not threaten ethical standards and that consent remains an individual's informed voluntary decision.

The literature review can be accessed here:
https://journals.sagepub.com/doi/10.1177/17407745251346134