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ISoP Africa Chapter Meeting

22nd - 24th July 2024 \rightarrow





Envisioning database networks for safety surveillance in Africa - opportunities and challenges



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The journey we will go on together

- The new status quo of vaccination in Africa
- The role of vaccine safety surveillance
- The state of vaccine safety infrastructure in Africa
- Existing vaccine safety data networks
- The GVDN "LMIC Model"
- Lessons learnt for future database networks



Accepting the new status quo

- The COVID-19 pandemic and the need for urgent mass vaccinations highlighted **an increasing problem with vaccine hesitancy**
- Recent data from WHO and UNICEF show that the uptake of routine childhood vaccinations has seen the most significant continuous drop in thirty years, with notable regressions throughout Africa¹
- This issue extends to adult vaccinations with some studies indicating safety concerns as a potential barrier to vaccines²
- Misinformation is a serious contributor to this³, and high-quality vaccine safety data is required to counter this, amongst other approaches



The role of safety surveillance

- Safety surveillance is crucial to the goal of providing vaccine safety data
- The challenge with that **is most serious vaccine adverse events are very rare** and require large amounts of people to be enrolled in post-licensure vaccine safety studies
- This can be done in a segmented approach by different researchers, but a more effective way to do this is to pool data and resources to form database networks that work to produce generalizable vaccine data



The state of vaccine safety infrastructure

- Most of the world lives in middle or low-income countries
- Most vaccine safety infrastructure has been centralized in high income countries.
- This was considered acceptable because most new vaccines were used in high income countries for a long time prior to use in low-income countries.
- This is no longer true.
 - With vaccines being developed for diseases endemic to Africa, there is need to build infrastructure to ensure their safety in local populations



Existing vaccine data networks

- One example of an existing data network is the Global Vaccine Data Network: a network of sites agreeing to conduct globally coordinated active surveillance and epidemiologic vaccine studies
- Its strength lies in numbers, with over 31 sites across 6 continents and 26 countries
 - Inclusion of multiple countries allows comparison of different vaccines and different schedules as well as providing increased statistical power.
- Their work has been in done in collaboration with various African sites, including South Africa





The GVDN "LMIC Model"

- The data collection model was initially developed for real time hospital data collection in South Africa.
- It was adapted for use in the ALIVE network of LIC countries in collaboration with GAVI
 - It was also adopted at three hospital sites in India.
- More than 60,000 hospitalizations were screened for possible adverse events of special interest following COVID-19 vaccination
- This **model is exportable to other countries** and sites for use in clinical trials as well as post introduction studies.









 Although the surveillance was a great stride forward in the inclusion of Africa in vaccine safety database networks, several

challenges are yet to addressed

- ✓ Data availability incl. that of patient medical records, vaccination history and previous treatment records
- ✓ Digitization of largely paper-based databases
- Privacy considerations when sharing data across multiple organisations
- ✓ Limited resources to investigate and confirm adverse events





References

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