

BRIEF COMMUNICATION

Obstetrics

Considerations for post-licensure group B streptococcus vaccine effectiveness studies

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KEYWORDS

group B streptococcal disease, pregnancy, vaccines

A Group B Streptococcal (GBS) vaccine for pregnant women is likely to be licensed based on a correlate of protection.¹ However, post-licensure effectiveness studies will then be needed to evaluate the vaccine's impact on prevention of GBS disease among pregnant women and babies. Therefore, a priority now is to understand the preparedness of different health systems to deliver a GBS vaccine and undertake suitable post-licensure surveillance studies.²

A stakeholder evaluation in Uganda and the United Kingdom (UK) involving maternal and child-health practitioners, researchers and regulators aimed to describe operational strengths and gaps relevant to post-licensure GBS vaccine studies. Convenience sampling was undertaken from IMPRINT's (Immunizing-PRegnant-Immunizing-women-and-infants-NeTwork) professional network with clinical, academic, and regulatory stakeholders approached by email and interviewed with their informed consent. In November and December 2020, nineteen interviews were conducted with midwifery (2), general-practice (1), community-health (1), pediatric (6), obstetric (2), microbiology (2) and public-health regulatory (5)

stakeholders: (10 from the UK and 9 from Uganda). The interviews focused on three areas relevant to post-licensure vaccine studies; (i) existing data-systems for the surveillance of pregnancy, birth, and maternal and infant outcomes; (ii) health-system preparedness for delivering an additional pregnancy vaccine and (iii) wider stakeholder engagement for a GBS vaccine.

Stakeholders confirmed that in both the UK and Uganda established systems for offering vaccines to pregnant women existed which would facilitate the addition of a GBS vaccine. Awareness of GBS disease in Uganda was perceived to be much lower compared to the UK, but stakeholders in both countries felt that improved education and engagement about GBS disease was important for both pregnant women and healthcare workers prior to any vaccine introduction.³

The UK's strong existing data systems meant stakeholders considered it well placed for hosting post-licensure GBS vaccine studies though enhancement of current mother and baby data-linkage systems maybe required. In Uganda the lack of electronic health

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Pilot sites of electronic healthcare record systems and collection of other maternal and paediatric data at research trial sites such as:

- Iganga-Mayuge Health and Demographic Surveillance Site.
- The PROGRESS Group B Streptococcus Study at Kawempe National Referral Hospital and Mulago National Referral Hospital.
- GBS PREPARE establishing baseline GBS disease rates & obstetric & neonatal outcomes to prepare for GBS vaccine clinical trials in Uganda

Data on pregnancies, deliveries, vaccinations given (including maternal tetanus) and also maternal and infant mortality is aggregated and reported from lower level facilities via:

- National Health Management Information System to the Ministry of Health.

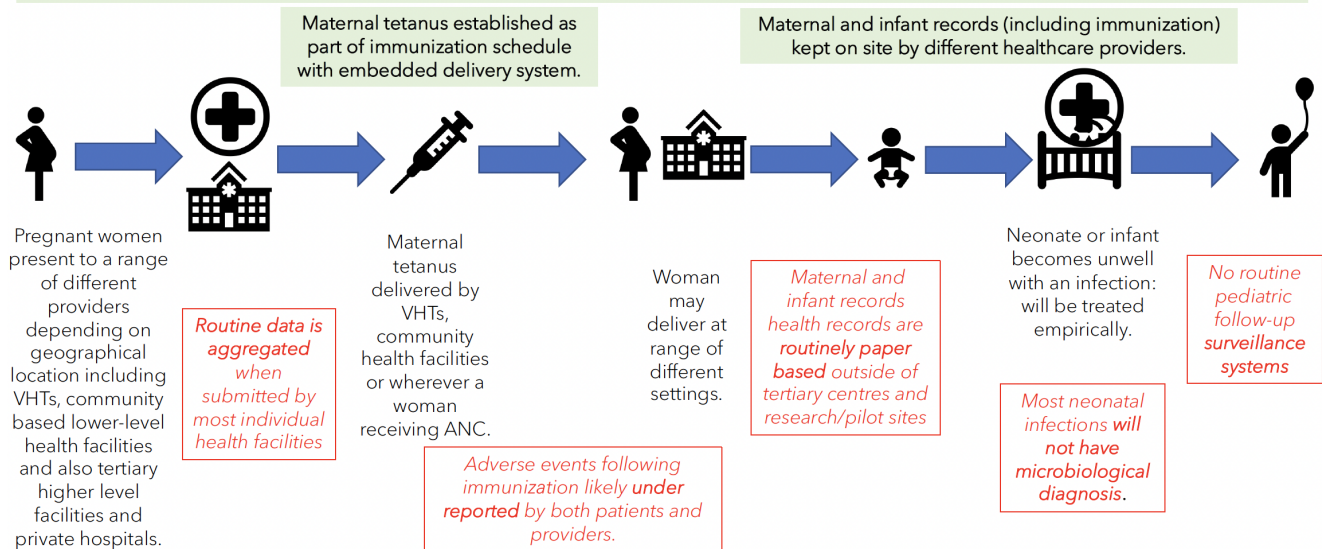


FIGURE 1 Existing data systems and healthcare system pathways for pregnant women and neonates in Uganda, indicating potential operational gaps. ANC, Antenatal Care; VHT, Village Health Teams.

records outside of tertiary or research settings was seen as a major barrier to post-licensure GBS studies (see Figure 1). This is likely to be reflective of other Low-and-Middle-Income-Countries situations. However, stakeholders also felt that further investment into existing research databases in Uganda (e.g. the Iganga-Mayuge Health and Demographic Surveillance Site or PREPARE study sites) could result in suitable systems.⁴

In planning post-licensure GBS effectiveness studies, each country's readiness needs careful consideration. To evaluate the impact of a future vaccine on GBS disease, timely investment is essential in low-and-middle-income countries' electronic health systems.²

AUTHOR CONTRIBUTIONS

HS contributed to design and carrying out the study, data curation, data analysis, writing original article draft and reviewing and editing. DK contributed to design and carrying out the study, and reviewing and editing article draft. KLD contributed to research design and carrying out the study, and reviewing and editing article draft. TC contributed to data analysis and reviewing and editing original article draft. BK conceptualized the idea for the study, contributed to design, analysis and carrying out the study, and reviewing and editing original article draft.

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CONFLICT OF INTEREST STATEMENT

HS has undertaken a 6 month IMPRINT network funded fellowship during which time she was employed by Imperial College London (home institution) as a Clinical Research Fellow. This IMPRINT

fellowship has involved HS undertaking shadowing at Pfizer UK vaccines trials team, however this has excluded any GBS or Covid-19 vaccine trials shadowing. HS has not and will not, receive any money, stock options, payment in kind, travel expenses, food expenses, conference fees or any reimbursement from Pfizer or any associated companies. HS training agreement between the IMPRINT network, Imperial College London and Pfizer states that: 'it is expressly understood and agreed that this Agreement does not intend and shall not be construed to create the relationship of agent, servant, employee, partnership, joint venture or association between the Home Institution or IMPRINT or its Fellows and Pfizer'.

DATA AVAILABILITY STATEMENT

Research data are not shared.

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