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Defining operational strengths and gaps relevant to post licensure Group B Streptococcus vaccine effectiveness studies: an expert stakeholder evaluation of the United Kingdom and Uganda.

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Background: A future Group B Streptococcal (GBS) vaccine for pregnant women to protect neonates is likely to be licensed based on serocorrelates of protection. Post-licensure effectiveness studies to evaluate the public health impact therefore need defining operationally. An expert stakeholder evaluation was undertaken aimed at describing the operational strengths and gaps relevant to post-licensure GBS vaccine studies in the UK and Uganda.

Methods: The stakeholder evaluation was undertaken using semi-structured interviews with expert practitioners and researchers purposively sampled from Uganda and the United Kingdom (UK). Interviews focused on three areas: existing data-systems, healthcare-systems and wider health practitioners and policymakers engagement. Thematic analysis of transcripts was then undertaken to identify strengths and limitations.

Fig. 1: Existing UK data systems and healthcare system pathways for pregnant women and neonates including potential operational gaps.

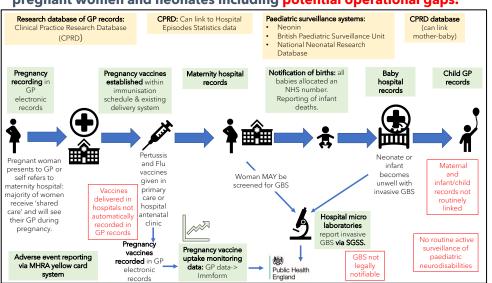


Fig. 2: Existing data systems and healthcare system pathways for pregnant women and neonates in the Uganda including potential operational gaps.

Pilot sites of 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 · National Health Management Information System to the Ministry of Health Maternal tetanus established as Maternal and infant records (including immunization) part of immunisation schedule with embedded delivery syster resent to a range becomes unwell tetanus No routine Maternal and of different with an infection: delivered by infant records will be treated providers VHTs. follow-up deliver at ealth records are depending on empirically. community surveillance geographical range of routinely paper health facilities systems different cation including ertiary centres and /HTs community Most neonatal research/pilot sites pased lower-leve infections will ealth facilitie health facilities not have Adverse events followina and also tertiary microbiologica immunisation likely under hiaher level reported by both patients and facilities and

Conclusion: In Uganda, existing databases need development, likely to be reflective of other Low-and-Middle-Income-Countries situations. However, with investment there is potential for post-licensure studies in established research settings. The UK's strong existing operational systems makes it well placed to host post-licensure GBS vaccine studies.

Results: In November and December 2020, nineteen interviews were conducted with midwifery, general practice, community health, paediatric, obstetric and public health regulatory experts (10 from UK, 9 from Uganda). In both settings existing healthcare systems used for delivering current maternal vaccines were identified as a strength. Improved education and engagement of pregnant women and healthcare workers about GBS was considered necessary, though more so in Uganda. UK data systems were identified as a strength though linking public health databases needed for effectiveness studies. In Uganda inconsistencies in electronic health. record availability outside of tertiary and research settings was identified as a weakness. See figures 1 and 2.

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