

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.

Helen Skirrow¹, Dan Kajungu², Kirsty Le Doare^{3,4}, Tracey Chantler⁵ & Beate Kampmann^{6, 7}.

1. Department of Primary Care and Public Health, School of Public Health, Imperial College London, UK. **2.** Makerere University Centre for Health and Population Research, Uganda. **3.** St. George's, University of London, UK. **4.** MRC/UVRI @ London School of Hygiene & Tropical Medicine (LSHTM) Uganda Research Unit, Uganda. **5.** Department of Global Health & Development, Faculty of Public Health & Policy, LSHTM, UK. **6.** The Vaccine Centre, Faculty of Infectious and Tropical Diseases, LSHTM, UK **7.** Vaccines and Immunity Theme, MRC Unit The Gambia at LSHTM, The Gambia.

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.

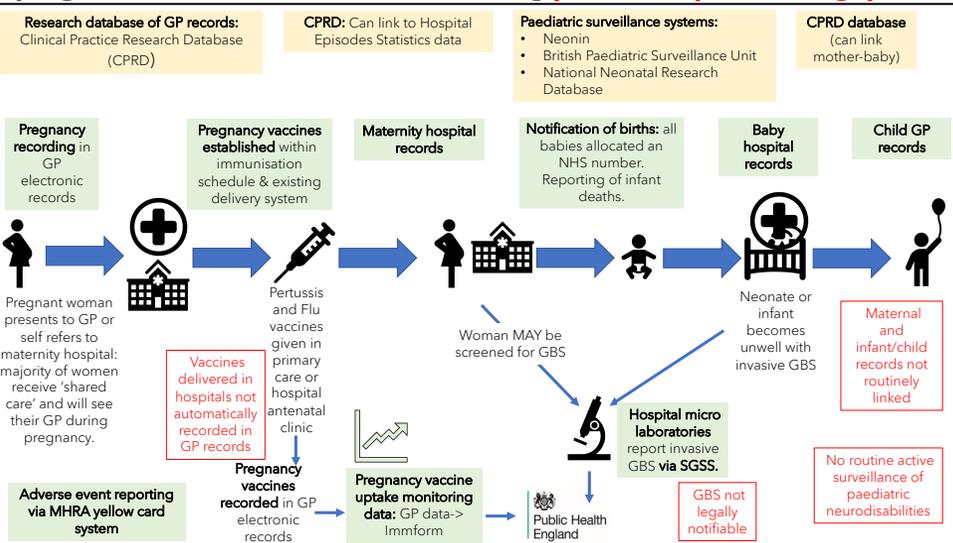
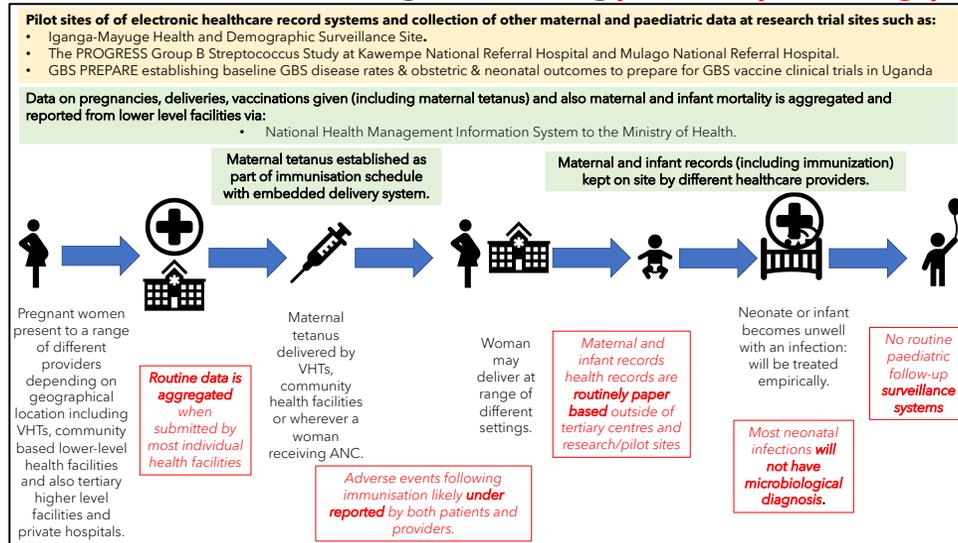


Fig. 2: Existing data systems and healthcare system pathways for pregnant women and neonates in the Uganda including potential operational gaps.



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.

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.