

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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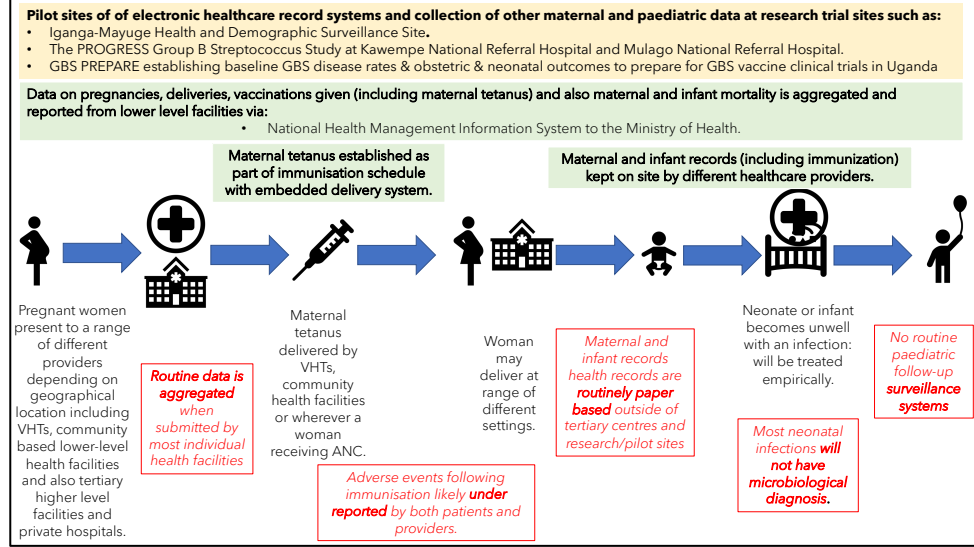
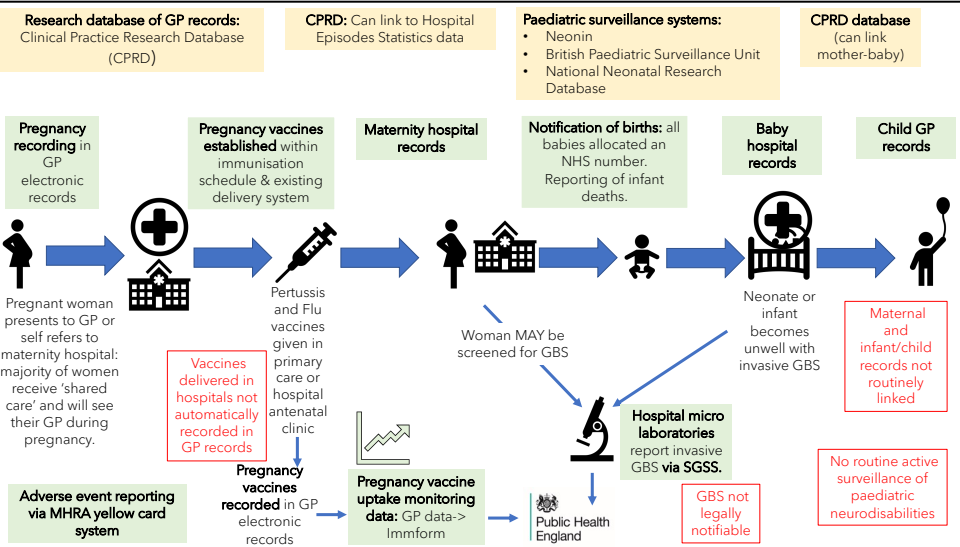
Background: A future Group B Streptococcal (GBS) vaccine for pregnant women to protect neonates is likely to be licensed based on serocorrelates of protection. Post-licensure effectiveness studies to evaluate the public health impact therefore need defining operationally. An expert stakeholder evaluation 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.

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.