

# TitleObservational Study to Investigate Vertically Acquired Passive Immunity<br/>in Babies of Mothers Vaccinated Against H1N1v During PregnancyAgencyNETSCC, HTA, NIHR Evaluation and Trials Coordinating Centre<br/>Alpha House, University of Southampton Science Park, Southampton, SO16 7NS, United Kingdom;<br/>Tel: +44 2380 595 586, Fax: +44 2380 595 639; hta@soton.ac.uk, www.hta.ac.ukReferenceVol. 14.55(or). ISSN 1366-5278.<br/>www.netscc.ac.uk/supporting\_research/flu\_project\_portfolio/0984136.asp

# Aim

To determine the proportion of babies who acquired passive immunity to A/H1N1v, born to mothers who accepted vaccination as part of the national vaccination program while pregnant (during the second and/or third trimesters) against the novel A/H1N1v influenza virus (exposed group) compared with unvaccinated (unexposed) mothers.

#### Conclusions and results

The primary endpoint in the study was the serological results of the cord blood samples for immunity to A/ H1N1v. The results from this study demonstrate evidence of background humoral immunity in babies of unvaccinated mothers of 25% to 30%. Humoral immunity in babies of vaccinated mothers was present in 80% of the group. The difference in positive immunity between the babies of unvaccinated and vaccinated mothers was statistically significant (X2, p <0.001).

This study provides evidence that maternal vaccination against monovalent A/H1N1v can provide humoral immunity to the unborn child that may protect the baby against acquiring the infection early in infancy when treatment options for infection are limited (because antiviral medications and immunization are not licensed, have theoretical unwanted effects, or might not be effective in this age group). The study findings reveal a highly significant difference in HI titers between babies born to mothers vaccinated with pandemic-specific vaccine against A/H1N1v during the 2009 to 2010 pandemic period. The results will provide support to policy makers and clinicians in advocating immunization for pregnant women in future influenza epidemic and pandemic events and will help pregnant women make informed choices about vaccination under such circumstances.

# Recommendations

Continued circulation of 2009 A/H1N1-like viruses is uncertain, but is possible as seasonal influenza in years to come. It is possible that future seasonal waves may display increased virulence. Given the adverse outcomes experienced for a small proportion of pregnant women during the influenza pandemic of 2009 to 2010, this study provides useful evidence to support vaccination in pregnancy to protect both the mother and baby.

# Methods

See Executive Summary www.netscc.ac.uk/supporting\_research/flu\_project\_portfolio/0984136.asp.

# Further research/reviews required

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