Observational study to investigate vertically acquired passive immunity in babies of mothers vaccinated against HINIv during pregnancy

RL Puleston,[1]* G Bugg,[2] K Hoschler,[3] J Konje,[4] J Thornton,[2,5] I Stephenson,[6] P Myles,[1] J Enstone,[1] G Augustine,[1] Y Davis,[2] M Zambon,[3] KG Nicholson[6] and JS Nguyen-Van-Tam[1]

[1]Division of Epidemiology and Public Health, School of Community Health Sciences, University of Nottingham, Nottingham, UK
[2]Nottingham University Hospitals NHS Trust, Nottingham, UK
[3]Respiratory Virus Laboratory, Health Protection Agency, London, UK
[4]Clinical Division of Obstetrics and Gynaecology, Reproductive Sciences Section, University of Leicester and University Hospitals of Leicester NHS Trust, Leicester, UK
[5]School of Human Development, University of Nottingham, Nottingham, UK
[6]Infectious Diseases Unit, University Hospitals of Leicester NHS Trust and Department of Inflammation, Infection and Immunity, University of Leicester, Leicester, UK

*Corresponding author

Executive summary

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Executive summary

Background

The recent pandemic of 2009–10, although overall mild in impact, amply demonstrated that some individuals/groups are at increased risk of complications/death from influenza infection. Those at increased risk included pregnant women. Persuading patients to accept vaccination can be difficult, and in pregnancy there is rightly caution about providing any medical interventions unless the benefit outweighs the risk. This study was undertaken to determine if pregnant women vaccinated against A/H1N1v passed on humoral immunity to their unborn child and therefore would provide it with protection against acquiring influenza. Evidence that this was the case could be used by health policy-makers and clinicians to encourage women to accept protective vaccine in future pandemic influenza events, as well as seasonal influenza.

Methods

Across three hospital sites in the East Midlands (UK), 104 pregnant women who had [77 (74%)] or had not [27 (26%)] already been vaccinated against A/H1N1v (as part of the national immunisation programme) and were admitted for delivery (during winter 2009–10) were recruited to take part in this observational study. At parturition, venous cord blood samples were taken to determine if the baby had humoral immunity to A/H1N1v. Samples were analysed for haemagglutinin inhibition and microneutralisation titres in order to determine immune status.

The mothers were also asked to consent for long-term follow-up of the baby by means of an Office for National Statistics flag on the baby's records (for 5 years). Additionally, the babies in the study are being followed up to determine if the acquired humoral immunity provides clinical protection against acquisition of A/H1N1v. These two components of the study are not the subject of this paper and will be reported after their completion in the future.

Results

The results from this study demonstrate evidence of background humoral immunity in babies of unvaccinated mothers of 25%–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 (chi-squared test, $p < 0.001$).

Conclusions

This study provides evidence that maternal vaccination against monovalent A/H1N1v can provide humoral immunity to the unborn child, which may protect the baby against acquisition of the infection early in infancy when treatment options for infection are limited (because antiviral medications and immunisation are not licensed, have theoretical unwanted effects or may not be effective in this age group). The results will provide support to policy-makers and clinicians in advocating immunisation for pregnant women in future influenza epidemic and pandemic events, and will help pregnant women to make informed choices about vaccination under such circumstances.

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Publication

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The National Institute for Health Research

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This themed issue of the *Health Technology Assessment* journal series contains a collection of research commissioned by the NIHR as part of the Department of Health's (DH) response to the H1N1 swine flu pandemic. The NIHR through the NIHR Evaluation Trials and Studies Coordinating Centre (NETSCC) commissioned a number of research projects looking into the treatment and management of H1N1 influenza.

NETSCC managed the pandemic flu research over a very short timescale in two ways. Firstly, it responded to urgent national research priority areas identified by the Scientific Advisory Group in Emergencies (SAGE). Secondly, a call for research proposals to inform policy and patient care in the current influenza pandemic was issued in June 2009. All research proposals went through a process of academic peer review by clinicians and methodologists as well as being reviewed by a specially convened NIHR Flu Commissioning Board.

The final reports from these projects have been peer reviewed by a number of independent expert referees before publication in this journal series.

Criteria for inclusion in the HTA journal series

Reports are published in the HTA journal series if (1) they have resulted from work for the HTA programme or, in the case of this national priority, the NIHR, and (2) they are of a sufficiently high scientific quality as assessed by the referees and editors.

Reviews in *Health Technology Assessment* are termed 'systematic' when the account of the search, appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.

The research reports in this themed issue were funded through the Cochrane Collaboration; the Health Services Research programme (HSR); the Health Technology Assessment programme (HTA); the Policy Research Programme (PRP); the Public Health Research programme (PHR); and the Service Delivery and Organisation Programme (SDO).

The Cochrane Collaboration is an international not-for-profit and independent organisation, dedicated to making up-to-date, accurate information about the effects of health care readily available worldwide. It produces and disseminates systematic reviews of health-care interventions and promotes the search for evidence in the form of clinical trials and other studies of interventions. Cochrane reviews and the Cochrane Central Register of Controlled Trials are published and updated in *The Cochrane Library* (www.cochranelibrary.com).

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The HTA programme produces high-quality research information on the effectiveness, costs and broader impact of health technologies for those who use, manage and provide care in the NHS. 'Health technologies' are broadly defined as all interventions used to promote health, prevent and treat disease, and improve rehabilitation and long-term care.

The PRP provides the evidence base for policy development on public health and social care issues. It funds research in three main ways: 5-year programmes of research in 16 research units, a primary-care research centre, a public health research consortium, and a surveillance unit; programmes of interlinked studies on key policy initiatives; and single projects and literature reviews.

The PHR programme evaluates public health interventions, providing new knowledge on the benefits, costs, acceptability and wider impacts of non-NHS interventions intended to improve the health of the public and reduce inequalities in health. The scope of the programme is multi-disciplinary and broad, covering a range of interventions that improve public health.

The SDO programme commissions research evidence that improves practice in relation to the organisation and delivery of health care. It also builds research capability and capacity amongst those who manage, organise and deliver services – improving their understanding of the research literature and how to use research evidence.

The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' reports and would like to thank the referees for their constructive comments on the five draft documents. However, they do not accept liability for damages or losses arising from material published in this report. The views expressed in this publication are those of the authors and not necessarily those of the NIHR or the Department of Health.

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