A Randomized Controlled Trial of an Educational Intervention to Promote Influenza Vaccine Uptake Among Pregnant Women

Valerie W. Y. Wong RN MPH
Daniel Y. T. Fong PhD
Marie Tarrant RN MPH PhD
School of Nursing, University of Hong Kong
Background

- Pregnant women at greater risk for increased morbidity and mortality from influenza infection during pregnancy.

- Compared with non-pregnant women, risk of influenza-related hospital admission:
  - ~50% higher from weeks 14-20
  - ~5-fold higher in weeks 37-42
Background

- Risk is ≥ than for persons 65-69 years with chronic diseases or those at high-risk or.
- Pregnant women susceptible to influenza during pregnancy because of physiological and immunological changes.
Background

• Physiological changes:
  – Alterations in the chest shape and dimensions and elevation of the diaphragm
  – ↑ dyspnea, ↑ $O_2$ consumption & tidal volume, ↓ functional residual capacity
  – ↑ susceptibility to respiratory pathogens

• Immunological changes:
  – Maternal immune system suppresses cell-mediated immunity to tolerate fetal antigens during pregnancy.
  – ↑ susceptibility to intracellular pathogens such as viruses and bacteria
Background

- HK infants ≤6 months have ↑ hospital admission rates for influenza.
- Infants ≤6 months have ↑ influenza-associated mortality.
- Infants ≤6 months of age cannot receive influenza vaccine – maternal vaccination can provide protection for first 6 months.
Background

Benefits of Vaccination:

- ↓ respiratory illnesses among pregnant women by 36%.

- 15% to 20% ↓ in LBW, ↓ SGA, ↓ preterm birth, and stillbirth in vaccinated mothers.

- Maternal influenza vaccine can ↓ hospitalization from influenza infection in infants ≤6 months of age by >90%.
Background

• Despite the benefits, vaccine rate is low – around 20-40% in most countries.

• HK studies show rates are low in pregnant women:
  – In 2005-06 rate was 3.9%.
  – In 2009-10 rates of H1N1 vaccination was 6.2%.
  – In 2010-11 rate was 1.7%.
Research Aims

• Designed a RCT to evaluate the effectiveness of a brief education intervention on maternal influenza vaccine uptake

• Primary outcome:
  – influenza vaccination rate during pregnancy

• Secondary outcome:
  – proportion of participants seeking out influenza vaccine
Methods

- Recruited pregnant women from 4 public antenatal clinics
- Inclusion criteria were:
  - Singleton pregnancy
  - 18 years of age
  - ≥ 2nd trimester
  - Cantonese speaking
  - Hong Kong resident
  - No serious medical or obstetrical complications
  - Has not received the influenza vaccine this pregnancy
  - Staying in Hong Kong for 2 weeks after birth
- Followed up by telephone at 2 weeks postpartum
Methods

- Randomized to receive:
  - Standard antenatal care
    - Routine maternal and foetal health checks + health education to promote a healthy pregnancy
    - Printed pamphlet on benefits of influenza vaccine widely available in antenatal clinics
  - Standard care + one-to-one brief (10 mins) education session
    - Overview of the safety and benefits of the vaccine to pregnant women, the foetus, and the newborn baby

- Randomized at 1:1 ratio w/ block randomization
  - random block sizes of two to eight
Methods

- Intervention focused on four key recommendations from US preventative task force:
  - inform pregnant women of vaccination recommendations
  - encourage discussion with their healthcare practitioners
  - increase accessibility of vaccine by making referral to clinics where vaccine can be obtained
  - provide credible information from the government official website
Assessed for eligibility (n=489)

Excluded (n=168)
- Did not meet inclusion criteria (n=28)
- Declined to participate (n=140)

Randomized participants (n=321)

Standard care (n=160)

Brief Education (n=161)

Lost to follow-up (n=6)

Lost to follow-up (n=10)

Intention-to-Treat (n=160)
Per Protocol (n=154)

Intention-to-Treat (n=161)
Per Protocol (n=151)
<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Standard Care</th>
<th>Brief Education</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maternal age, years M(SD)</td>
<td>33.8 ± 4.3</td>
<td>33.2 ± 4.0</td>
<td>.21</td>
</tr>
<tr>
<td>Maternal education</td>
<td></td>
<td></td>
<td>.26</td>
</tr>
<tr>
<td>Compulsory secondary</td>
<td>64 (40.0)</td>
<td>64 (42.2)</td>
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<tr>
<td>Upper secondary</td>
<td>22 (13.8)</td>
<td>31 (19.3)</td>
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</tr>
<tr>
<td>University degree or above</td>
<td>74 (46.3)</td>
<td>62 (38.5)</td>
<td></td>
</tr>
<tr>
<td>Parity</td>
<td></td>
<td></td>
<td>.69</td>
</tr>
<tr>
<td>0</td>
<td>99 (61.9)</td>
<td>92 (57.1)</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>53 (33.1)</td>
<td>60 (37.3)</td>
<td></td>
</tr>
<tr>
<td>≥2</td>
<td>8 (5.0)</td>
<td>9 (5.6)</td>
<td></td>
</tr>
<tr>
<td>Family income</td>
<td></td>
<td></td>
<td>.56</td>
</tr>
<tr>
<td>Below median</td>
<td>44 (27.5)</td>
<td>49 (30.4)</td>
<td></td>
</tr>
<tr>
<td>Above median</td>
<td>116 (72.5)</td>
<td>112 (69.6)</td>
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<tr>
<td>Pre-existing chronic disease</td>
<td></td>
<td></td>
<td>.006</td>
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<tr>
<td>No</td>
<td>149 (93.1)</td>
<td>134 (83.2)</td>
<td></td>
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<tr>
<td>Yes</td>
<td>11 (6.9)</td>
<td>27 (16.8)</td>
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<tr>
<td>Medical condition during pregnancy</td>
<td></td>
<td></td>
<td>.99</td>
</tr>
<tr>
<td>No</td>
<td>125 (78.1)</td>
<td>126 (78.3)</td>
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<tr>
<td>Yes</td>
<td>35 (21.9)</td>
<td>35 (21.7)</td>
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<tr>
<td>Advised by HCP to receive vaccine</td>
<td></td>
<td></td>
<td>.66</td>
</tr>
<tr>
<td>No</td>
<td>151 (94.4)</td>
<td>150 (93.2)</td>
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</tr>
<tr>
<td>Yes</td>
<td>9 (5.6)</td>
<td>11 (6.8)</td>
<td></td>
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</tbody>
</table>
Results

• 11.8% had a pre-existing chronic disease ➞ high-risk for influenza infection.

• 21.8% had pregnancy-related health problem.

• Only 6.2% were advised by HCP to receive the vaccine.
Influenza Vaccination Rate

**Per Protocol Analysis**

- **Standard Care**: 10.4%
- **Brief Education**: 22.5%

**ITT Analysis**

- **Standard Care**: 10%
- **Brief Education**: 20.4%

*Adjusted OR: 2.45; 95% CI 1.28, 4.68*

*Adjusted OR: 2.52; 95% CI 1.32, 4.82*
Results

- Among non-vaccinated participants, 17% (n=45) reported asking HCP about the vaccine.
- Intervention group participants more likely to attempt to get vaccinated (33.0% vs. 5.9%; p<0.001)
- 47% (n=21) were given anti-vaccination advice by HCP.
Expected Influenza Vaccination Rate

**Per Protocol Analysis**

- Standard Care: 15.6%
- Brief Education: 31.1%

\[ P = .001 \]

**ITT Analysis**

- Standard Care: 15%
- Brief Education: 29.2%

\[ P < .01 \]
Discussion

- Intervention significantly improved vaccine uptake, but the overall impact was not substantial.

- Vaccination rates remain suboptimal.

- However, vaccination rates in standard care group (~10%) higher than previously reported in this population.
Discussion

• A positive recommendation by obstetric HCP is strong predictor of vaccination.

• Failure of obstetric HCPs to recommend vaccination to pregnant women is main contributor to low uptake.
  – <10% of pregnant women had received a vaccine recommendation

• Not uncommon that HCPs give anti-vaccination advice to pregnant women.
Discussion

- Multicomponent approaches should be evaluated to ↑ maternal influenza vaccination:
  - Brief maternal education
  - + HCP vaccination recommendations
  - On-site vaccination

- Education programs should target both pregnant women and HCPs
Strengths and Limitations

**Strengths**
- RCT with adequate study power
- Followed CONSORT guidelines
- Measured actual uptake of vaccination and not intention
- 100% intervention fidelity
- Low loss to follow-up (<5%)

**Limitations**
- Generalizability of public hospital patients to larger population.
- Participants may have been more receptive to message → higher uptake in standard care group.
- Vaccination status assessed by self-report data → potential for recall bias.
Acknowledgements

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**Clinical Trial Registration:**
- www.clinicaltrials.gov: NCT01772901

**Ethical Approval by:**
- HKU/HKW Cluster IRB & REC at all study sites
Publications


References


References


