The MAW Study

Biomarker Feedback to Motivate Tobacco Cessation in Pregnant Alaska Native Women Pilot Randomized Trial (Phase 3)
Prenatal tobacco use among Alaska women

Data Source: Alaska Bureau of Vital Statistics
Smoking during pregnancy increases risk for:

- Preterm birth
- Stillbirth
- Low birth weight
- Miscarriage
- Placental complications (e.g., abruption or previa)
- Premature rupture of membranes
- Sudden & Unexpected Infant Death Syndrome
Tobacco cessation intervention pilot in Bethel

- Culturally targeted, evidence-based intervention based on 5As

- 35 enrolled
  - Intervention = 17; Control = 18
  - 0% quit rate at end of pregnancy for intervention

- Intervention delivered by research staff and not integrated within clinical care

- Women suggested specific information about fetal exposure to tobacco
MAW Study Phases

- Phase 1 – Identify level of tobacco exposure (by testing cotinine and NNAL) in mother’s and their babies and demonstrate an association between maternal cotinine and infant NNAL levels

- Phase 2 – Develop intervention to provide mothers with information about their unborn infant’s exposure to cancer causing agents

- Phase 3 – Pilot intervention to determine if feasible and effective for helping pregnant women stop smoking tobacco
Phase 1: Correlation for maternal urine cotinine and infant urine NNAL levels among smokers and chewers\(^4\)
Brochure used to describe biomarker feedback
Brochure used to describe biomarker feedback

- **Cotinine** comes from nicotine in tobacco and can be measured in urine.
- The amount of cotinine in a pregnant woman's urine tells how much tobacco she used; the more tobacco she used, the higher her cotinine level in her urine.
- **NNAL** comes from N-Nitrosamines in tobacco and both chemicals can cause cancer. Like cotinine, NNAL levels can be measured in urine.
- The more tobacco a pregnant woman uses, the more cotinine and NNAL she exposes herself and her unborn baby to.

**Cotinine Levels Increase as Number of Cigarettes Smoked Increases**

- The higher the cotinine in mother's urine, the higher the NNAL in the baby.
- These are results from Alaska Native women.
Study eligibility

• No use of Nicotine Replacement Therapy (NRT), medications for cessation or enrolled in tobacco cessation program in past 30 days

• Willing to enroll in SCF Quit Tobacco Program (QTP)
Study design

- Screen, Enroll, Baseline Assessment, Randomize (N=60)
- Biomarker Feedback Intervention (n=30)
- Control (n=30)
- Week 5 Assessment
- Delivery Assessment

Both groups: three study calls at weeks 2, 3, 4 (10-20 min each)

Urine sample collected
Integration of study into SCF QTP

• Counseling
  • Delivered by certified tobacco treatment specialists (TTS)
  • Based on 5A’s clinical practice guidelines (Fiore et al., 2008)
  • Written educational materials on risks of tobacco use in pregnancy and benefits of quitting

• Not required to set a quit date

• Call schedule
  • Weeks 2, 3, and 4 after enrollment (10-20 minutes each)

• NRT
  • Gum, lozenge, patch
Counselor training

• All counselors:
  • Received refresher training for motivational interviewing
  • Updates on tobacco use risk in pregnancy
  • Updates on NRT use in pregnancy

• Two intervention counselors trained to deliver biomarker feedback results

• One counselor trained to deliver control

• Counselor placed in Primary Care Center (PCC) to help with enrollment
<table>
<thead>
<tr>
<th>Conditions</th>
<th></th>
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<tbody>
<tr>
<td><strong>Control</strong></td>
<td><strong>Intervention</strong></td>
</tr>
<tr>
<td>Modified QTP</td>
<td>Modified QTP + biomarker feedback results</td>
</tr>
<tr>
<td>Generic brochure</td>
<td>Brochure describing cotinine and NNAL association</td>
</tr>
</tbody>
</table>
| 3 study counseling phone calls:  
  • Standard of care  
  • No additional treatment | 3 study counseling phone calls:  
  • Cotinine results and emphasized risks of tobacco exposure to mother and baby  
  • Assessed participants thoughts, feelings, and reactions to information |
## Baseline characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Intervention</th>
<th>Control</th>
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<tbody>
<tr>
<td>Age mean ± SD</td>
<td>25.1 ± 5.0</td>
<td>27.8 ± 4.9</td>
</tr>
<tr>
<td>Married/partner</td>
<td>17%</td>
<td>41%*</td>
</tr>
<tr>
<td>Spouse/partner smokes</td>
<td>80%</td>
<td>83%</td>
</tr>
<tr>
<td>Weeks gestation</td>
<td>14.3 ± 6.1</td>
<td>15.2 ± 7.1</td>
</tr>
<tr>
<td>≥1 biological children</td>
<td>83%</td>
<td>79%</td>
</tr>
<tr>
<td>Readiness to quit score</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low (0-3)</td>
<td>7.4 ±1.5</td>
<td>6.9 ± 2.0</td>
</tr>
<tr>
<td>Medium (4-6)</td>
<td>23%</td>
<td>48%</td>
</tr>
<tr>
<td>High (7-10)</td>
<td>77%</td>
<td>52%</td>
</tr>
<tr>
<td>Cigarettes per day</td>
<td>4.6 ± 2.9</td>
<td>4.9 ± 3.0</td>
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* p<0.05
Smoking abstinence – Per protocol

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Week 5</th>
<th>Delivery</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Intervention</td>
<td>Control</td>
</tr>
<tr>
<td>Self-report 7 day abstinence</td>
<td>17%</td>
<td>26%</td>
</tr>
<tr>
<td>Biochemically verified abstinence</td>
<td>--</td>
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- Per protocol analysis included women who completed week five of intervention and delivery assessments.
- NRT was used by 3% of the sample at week 5 and delivery.
Conclusions

• Feasible to deliver the intervention as part of existing clinical care

• Study drew attention to:
  • Need to update tobacco use history in EHR
  • NRT provision in pregnancy
  • Placement of TTS in PCC

• Study positively affected enrollment rate of pregnant women into QTP

• Further formative work needed to determine how best to communicate biomarker feedback to encourage more women to quit smoking in pregnancy
Future directions

• Explore potential impact of biomarker feedback information on smoking abstinence postpartum in MAW participants
  • MAW Phase 4 underway

• Efforts needed to promote standard of care for smoking cessation among pregnant AN smokers
  • Proximity of TTS to patients is important
  • Increase program reach for those who are low-readiness to quit
  • Promote provider dissemination of Phase 1 results
    • Creating infographic to use in clinics
Thank you!

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ALASKA NATIVE TRIBAL HEALTH CONSORTIUM
References


