The MAW Study

Biomarker Feedback to **M**otivate Tobacco Cessation in Pregnant **A**laska Native **W**omen Pilot Randomized Trial (Phase 3)

MAYO CLINIC

ALASKA NATIVE MEDICAL CENTER

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Abstract

Objective: There is some evidence for biomarker feedback when combined with cessation counseling for reducing smoking in pregnancy. This randomized controlled pilot study evaluated feasibility and potential efficacy of a social-cognitive theory (SCT)-based biomarker feedback intervention among pregnant Alaska Native (AN) smokers.

Methods: Participants were randomly assigned to receive three study calls (10–20 min each): (1) biomarker feedback intervention (n = 30) including personalized cotinine results and feedback on their baby's likely exposure to carcinogen metabolite NNAL, or (2) contact control usual care condition based on the 5As (n = 30). Assessments were conducted at baseline, post-treatment, and delivery.

Results: High rates of treatment compliance, study retention, and treatment acceptability were observed in both groups. 7-day point prevalence smoking abstinence rates at delivery verified with urinary cotinine were the same in both study groups (20% intent-to-treat analysis, 26% per-protocol). SCT-based measures did not change differentially from baseline by study group.

Conclusion: This trial supports the feasibility and acceptability of providing biomarker feedback within the clinical care delivery system, but the intervention did not promote increased smoking cessation during pregnancy compared to usual care.

Practice Implications: Efforts are needed to promote the usual care and to develop alternative biomarker feedback messaging for pregnant AN women.

Prenatal cigarette smoking among Alaskan women

Average percent of women who reported smoking in last 3 months of pregnancy, 2009-2017[1]		
Alaska Native Women	Alaska White Women	Other
28.4%	8.7%	6.7%

- Smoking prevalence significantly decreased among pregnant Alaska women in past decade, but not among AN women
  - **Continued disparity between AN and Alaska White women who smoke in pregnancy**[2]

- *Note:* During 2009 – 2012 prenatal smoking varied between 15.4% and 50.9% depending on region[2]

1. Alaska Department of Health and Social Services. Query results for Alaska's pregnancy risk assessment and monitoring survey (PRAMS) query module – Smoked during last 3 months of pregnancy. Accessed 05/08/2019. http://ibis.dhss.alaska.gov/query/builder/prams23/PRAMS/SmokeLast3MonthPreg.html
2. Alaska Department of Health and Social Services. Division of Public Health. Alaska Tobacco Facts 2018. http://dhss.alaska.gov/dph/Chronic/Documents/Tobacco/PDF/2018_AKTobaccoFacts.pdf

Risks of smoking in pregnancy to fetus and child include:[3,4]

- Preterm birth
- Stillbirth
- Low birth weight
- Exposure to carcinogens
- Sudden infant death syndrome
- Increase risk of tobacco dependence

3. Cnattingius, S. The epidemiology of smoking during pregnancy: Smoking prevalence, maternal characteristics, and pregnancy outcomes. *Nicotine Tob Res*, 2004; *6*(suppl 2):S125-140.
4. Buka SL, Shennassa ED, Niaura R. Elevated risk of tobacco dependence among offspring of mothers who smoked during pregnancy: a 30-year prospective study. *Am J Psychiatry*. 2003; *160*(11):1978-1984.

Previous tobacco cessation intervention with pregnant AN women[5]

- Only other intervention with AN pregnant women done in Bethel in 2010
- Intervention delivered to pregnant women at 1st prenatal care visit
- Treatment involved video, telephone counseling, and cessation guide
- To be eligible women had to plan to stop tobacco use in 30 days
- 35 enrolled:
  - Intervention = 17; Control = 18
  - 0% quit rate at the end of pregnancy for intervention vs. 6% for the control
- At end of study participants asked for “objective feedback” about harms of tobacco use to mother and baby to motivate tobacco cessation

5. Patten CA, Windsor RA, Renner CC, et al. Feasibility of a tobacco cessation intervention for pregnant Alaska Native women. *Nicotine Tob Res*, 2010; *12*(2):79-87.

Why the MAW Study?

- Other research demonstrated biomarker feedback interventions effective for tobacco cessation when combined with counseling
  - Research of this kind not done with pregnant AN women
- Based on suggestions from participants in previous intervention mentioned, and other research, proposed a 3-phase tobacco cessation intervention

MAW Study phase aims

- Phase 1 – Identify the 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.[6]

- Phase 2 – Develop the intervention to provide mothers with information about their unborn infant's exposure to cancer-causing agents.[7]

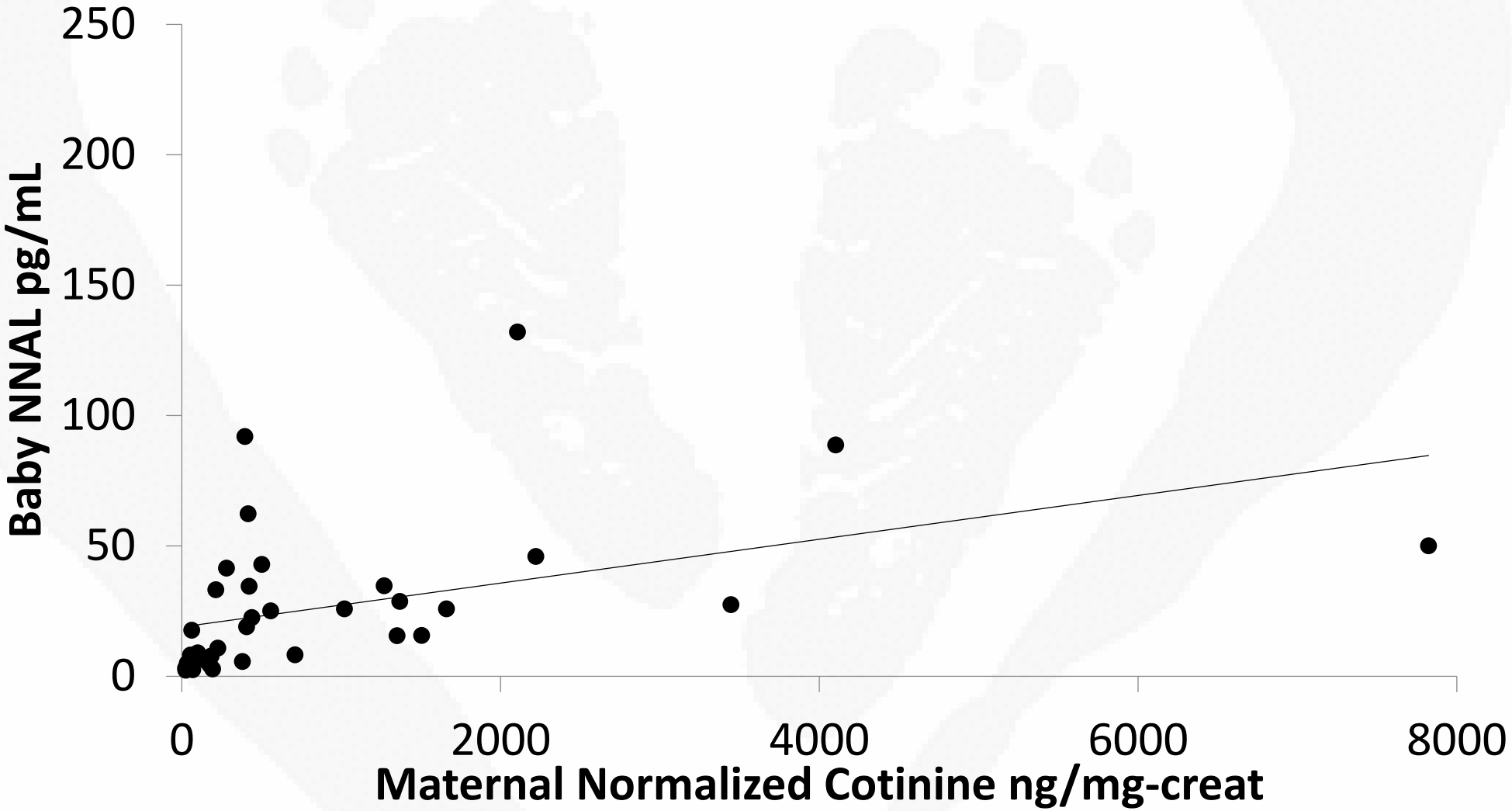
- Phase 3 – Pilot the intervention to determine if it is feasible and effective for helping pregnant women stop smoking tobacco.[8]

6. Flanagan CA, Koller, KR, Wolfe AW, et al. Fetal exposure to carcinogens with tobacco use in pregnancy: Phase 1 MAW Study findings. *Nicotine Tob Res,* 2016; doi:10.1093/ntr/ntw134
7. Koller KR, Flanagan CA, Day, GE et al. Developing a biomarker feedback intervention to motivate smoking cessation during pregnancy: Phase II MAW study. *Nicotine Tob Res*, 2016; doi:10.1093/ntr/ntw330
8. Patten CA, Koller KR, Flanagan CA, et al. Biomarker feedback intervention for smoking cessation among Alaska Native pregnancy women: Randomized pilot study. *Patient Ed and Counsel,* 2018; https://doi.org/10.1016/j.pec.2018.10.009

Phases 1 and 2 results

- Phase 1
  - Found moderate, positive correlation between maternal cotinine and infant NNAL levels in urine (see next slide)
- Phase 2
  - Biomarker feedback information presented to participants in brochure format during individual interviews
    - Based on results of interviews, information was perceived as acceptable and novel
  - Postpartum women felt motivated to quit smoking after learning personal results
  - Pregnant women thought generalized information potentially motivating for tobacco cessation

Correlation of maternal urine cotinine and infant urine NNAL levels among pregnant AN cigarette smokers



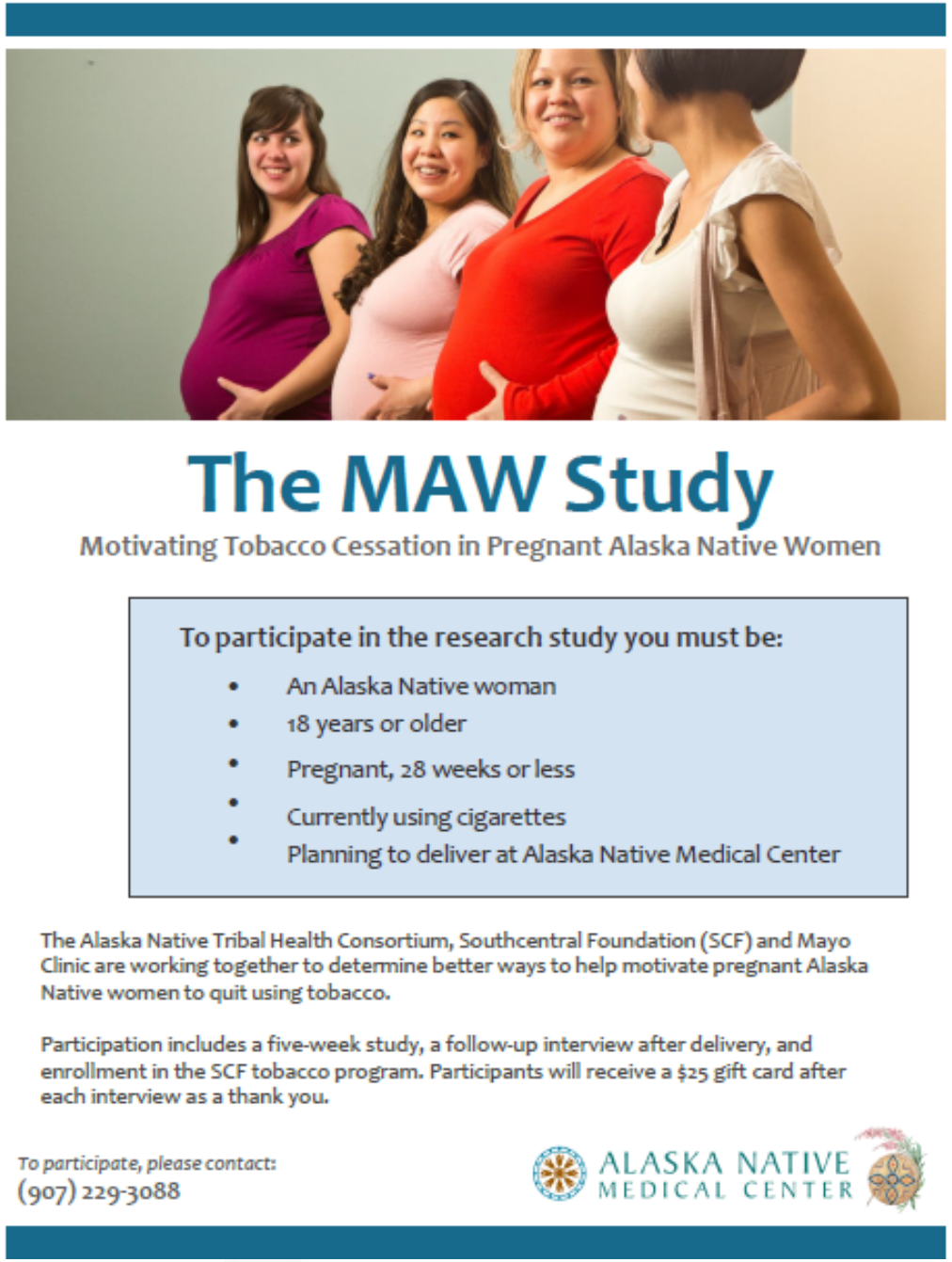
Phase 3 purpose and hypotheses

- Intervention piloted to determine if feasible and effective for helping pregnant AN women stop smoking tobacco
- Hypotheses:
  1. Intervention will be feasible and result in higher biochemically verified smoking abstinence rate at delivery compared to the control
  2. Self-efficacy and perceived cancer risk for self and baby will show differential changes from baseline for intervention compared to control condition

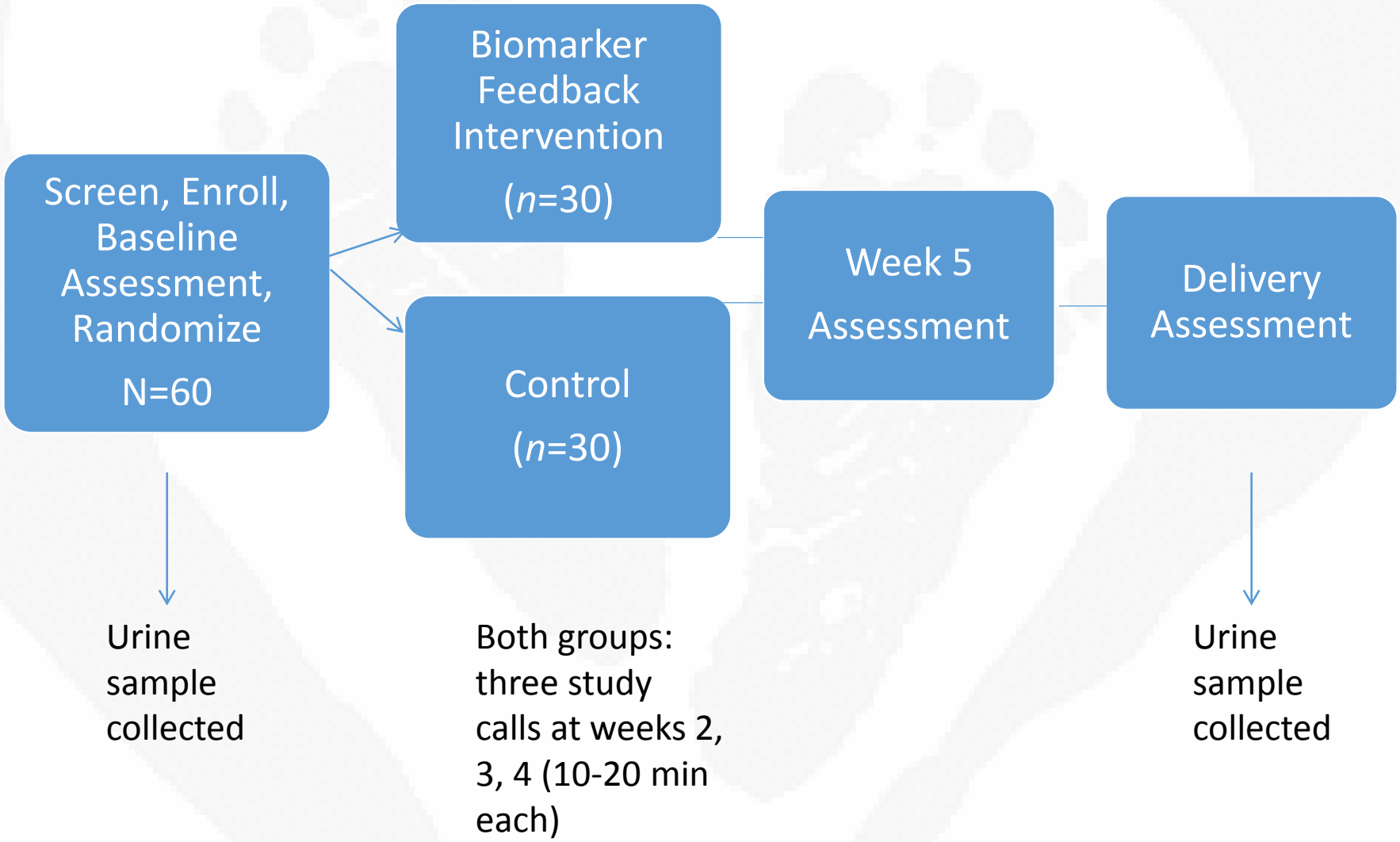
Study inclusion/exclusion criteria

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

- Willing to enroll in the SCF Quit Tobacco Program (QTP)



Study design



Control Condition

Standard QTP only:

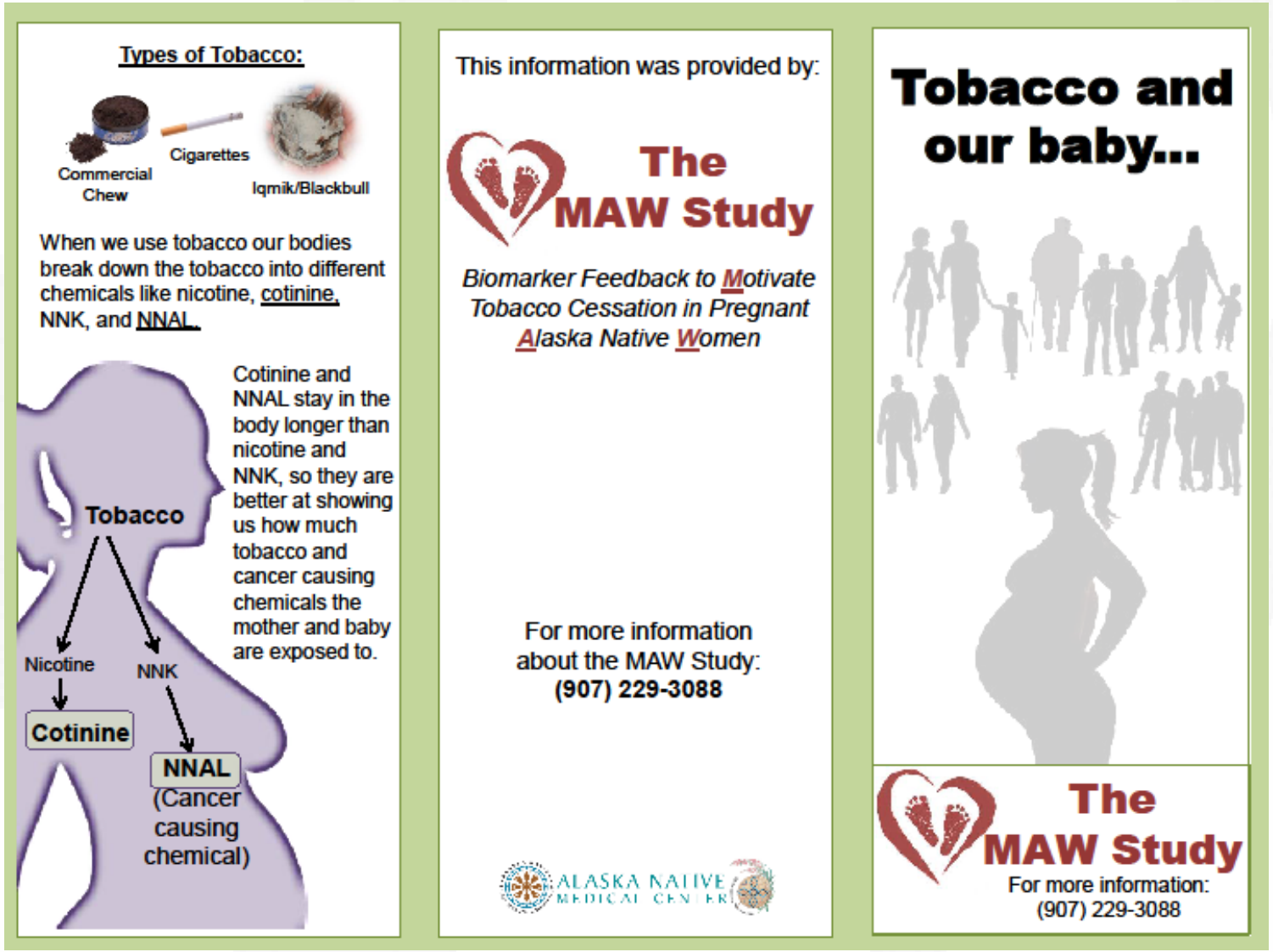
- Generic brochures about stopping smoking in pregnancy provided per standard of care
- Three standard of care counseling phone calls completed at weeks 2, 3, and 4 after enrollment

Intervention Condition

Standard QTP **plus biomarker feedback:**

- Study brochure describing cotinine and NNAL association to orient participants to biomarker feedback information
- Three counseling phone calls completed at weeks 2, 3, and 4 after enrollment, which included:
    1. Provided personal cotinine results to participants
    2. Reviewed risks of tobacco exposure to mother and baby
    3. Assessed participants thoughts, feelings, and reactions to biomarker information and perceived impact on their current cigarette use

Brochure used to describe biomarker feedback



Types of Tobacco:

Commercial Chew

Cigarettes

Iqmik/Blackbull

When we use tobacco our bodies break down the tobacco into different chemicals like nicotine, cotinine, NNK, and NNAL.

Tobacco

Nicotine

NNK

Cotinine

NNAL (Cancer causing chemical)

Cotinine and NNAL stay in the body longer than nicotine and NNK, so they are better at showing us how much tobacco and cancer causing chemicals the mother and baby are exposed to.

This information was provided by:

The MAW Study

Biomarker Feedback to Motivate Tobacco Cessation in Pregnant Alaska Native Women

For more information about the MAW Study:
(907) 229-3088

ALASKA NATIVE MEDICAL CENTER

Tobacco and our baby...

The MAW Study

For more information:
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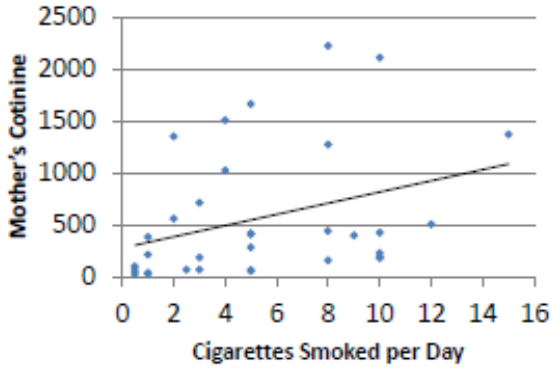
Brochure used to describe biomarker feedback

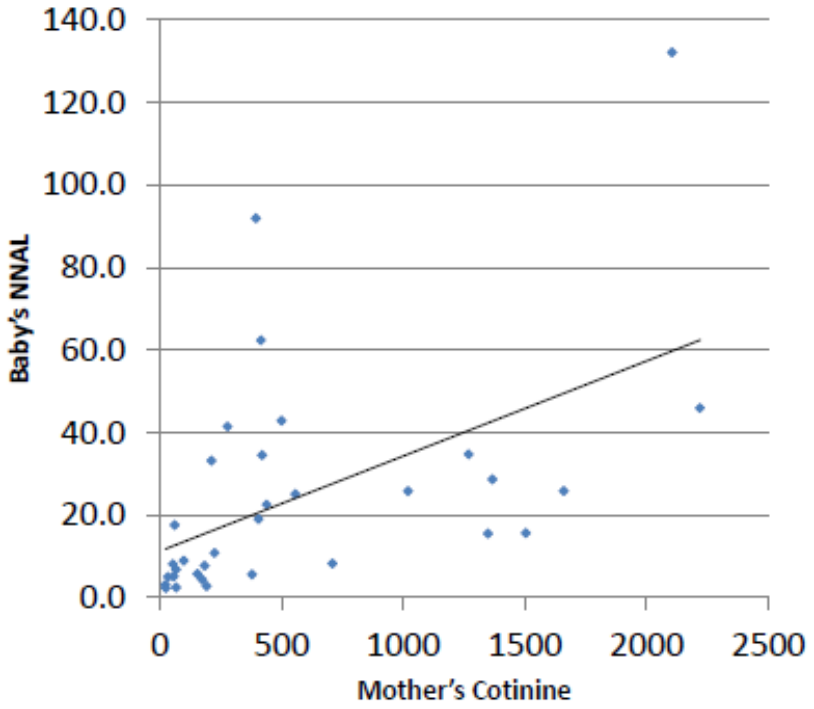
- Cotinine comes from nicotine in tobacco and can be measured in urine.
- The amount of cotinine in a pregnant woman's urine tells how much tobacco she used; the more tobacco she used, the higher her cotinine level in her urine.
- NNAL comes from NNK in tobacco and both chemicals can cause cancer. Like 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 more a person smokes the higher the cotinine level.

Baby's NNAL Increases as Mother's Cotinine Increases



The higher the cotinine in mother's urine, the higher the NNAL in the baby.

These are results from Alaska Native women.

Smoking abstinence results

Outcome	Week 5		Delivery	
	Intervention	Control	Intervention	Control
Self-report 7 day abstinence				
Per-protocol	17%	26%	26%	30%
ITT	13%	23%	20%	23%
Biochemically verified abstinence				
Per-protocol	--	--	26%	26%
ITT	--	--	20%	20%
Quit attempt since enrollment				
Per-protocol	61%	83%	65%	83%
ITT	60%	63%	63%	67%

-Per-protocol analysis included only those participants who followed the protocol they were assigned to.
-Intention To Treat (ITT) analysis included all participants according to arm they were assigned to.
-NRT use was 3% in both conditions at week 5 and delivery.

Conclusions

- Experienced high verified smoking abstinence rates compared to published literature
  - 10% psychosocial intervention vs. 20% for our study
- Intervention feasible to deliver as part of existing clinical care
- Study drew attention to:
  1. Need to update tobacco use history in electronic health record
  2. Ability to use NRT in pregnancy
  3. Need for placement of cessation counselor in Primary Care Center
- Study positively affected enrollment rate of pregnant women into QTP

Possible reasons for study findings

- Improved cessation rates may be outcome of programmatic changes influenced by the study, such as:
    1. More active outreach to pregnant women who smoked
    2. Placement of cessation counselor in accessible location
- Biomarker feedback may not be necessary if proactive outreach and resources easily accessed

Where to go from here?

Further investigation is needed to:

- Assess alternative messaging appeals and delivery channels for communicating risk information on fetal NNAL exposure
- Evaluate use of newborn's exposure to NNAL as approach for demonstrating secondhand smoke exposure and preventing smoking relapse after baby born
- Investigate risk factors for resumption of smoking and resiliency factors for those who stayed tobacco free

Thank you!

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