

Effectiveness & Process Evaluation Results for the RFTS-SCRIPT Dissemination Project: 2006-2010 *

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- The information and data contained in this presentation is currently under review for publication in Public Health Reports.

What is the Problem?

West Virginia Pregnant Medicaid Smokers:

1. Highest Smoking Prevalence Rate
 - 40%-45%
 - Highest in the U.S.
 - **Non-Disclosure Rate = 25%**
2. Unchanged since 1995
3. Smoking Attributable Risk-LBW Rate
 - 15.0 vs 7.0 among Non-smokers
4. WV LBW rate increased 35.0%
 - 6.8% in 1992 to 9.2% in 2007

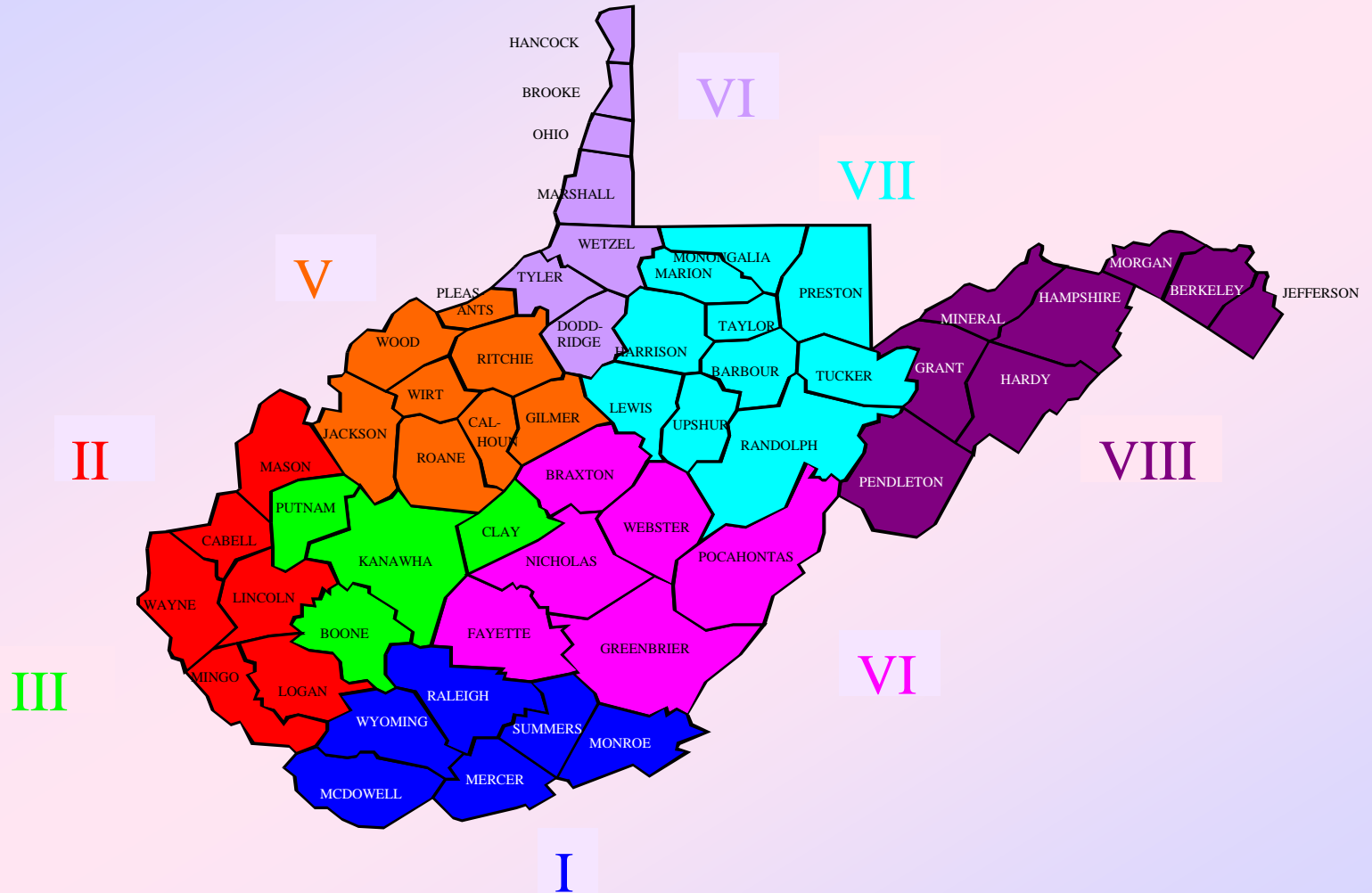
Right From The Start (RFTS)

- **ACOG Recommends Home Visitation Prenatal Health/Social Services**
- **8 Regions each lead by a Regional Care Coordinator (RCC)**
 - **120+ Designated Care Coordinator (DCC)**
- **Serve 2000+ Pregnant Medicaid Clients per year**
 - **800+ Smokers**

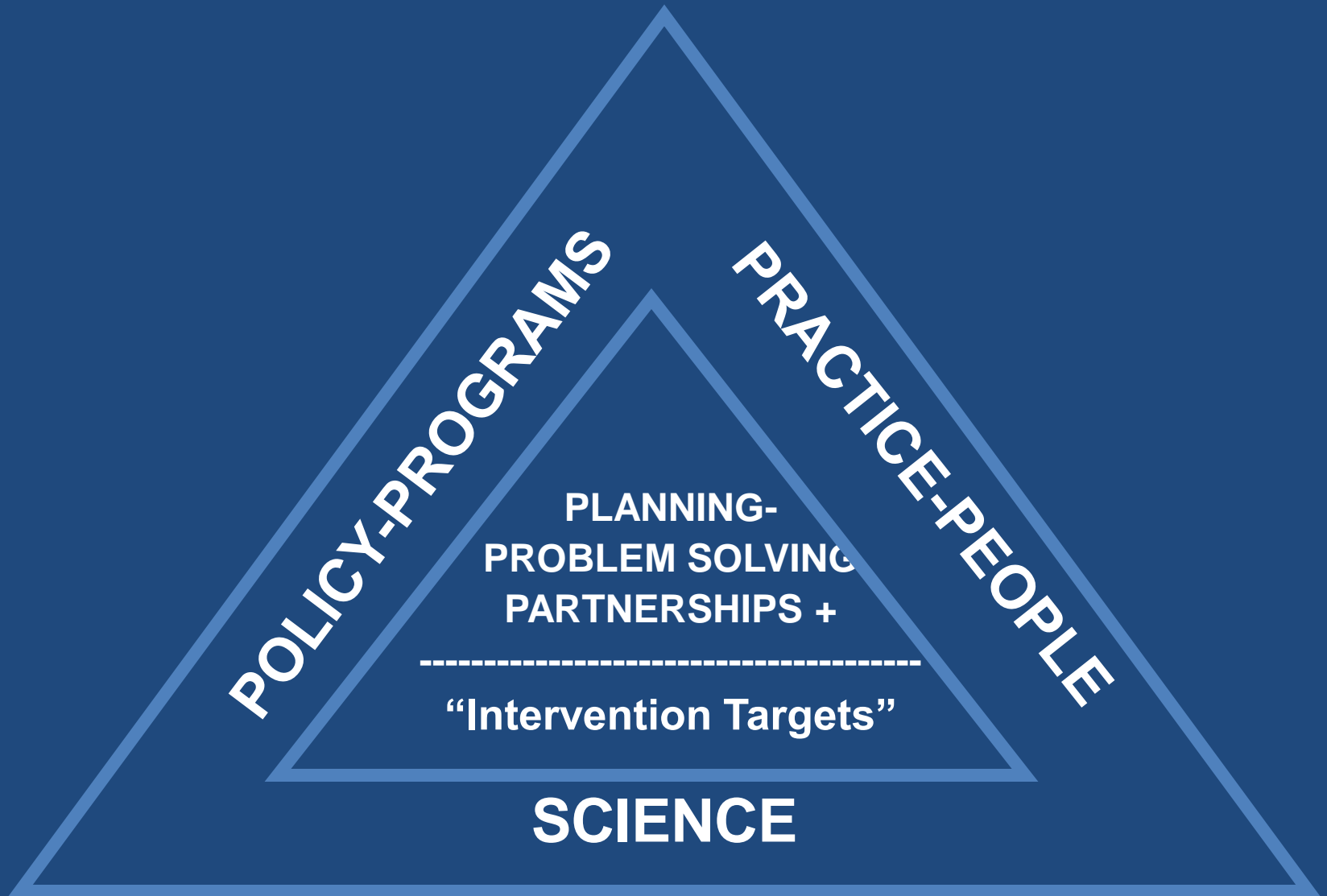
Right From The Start (RFTS)

- **Visits are based on Risk:**
 - **Low Risk = 3 visits**
 - **Moderate Risk = 5 visits**
 - **High Risk = 7 visits**
- **Tobacco Screening + Counseling a Regular Component**
- **DCC visits = 30-60 minutes/per session**

RFTS Program Regions



Primary Partners-Stakeholders to Plan-Evaluate Dissemination and Adoption of a New Treatment



Evaluation PHASES: Producing the Intervention Process-Impact Evidence for Populations at Risk

PHASE I	PHASE II	PHASE III	PHASE IV
EVALUATION RESEARCH (Theory Based)		PROGRAM EVALUATION (Practice Based)	
FORMATIVE EVALUATION	EFFICACY EVALUATION	EFFECTIVENESS EVALUATION	DISSEMINATION- ADOPTION EVALUATION
INTERNAL VALIDITY		INTERNAL AND EXTERNAL VALIDITY	
META + QUALITATIVE + PROCESS + COST EVALUATIONS & ANALYSES (Systematic Reviews of Primary Results of Treatment Program)			

Windsor, Clark, Boyd, & Goodman, "Evaluation of Health Promotion-Disease Prevention Programs", Chapter 1, 3rd Ed., McGraw-Hill Publisher, 2004

RFTS-SCRIPT Dissemination Committee

- **Regional Care Coordinators:** Brenda Johnson, Dee Meadows, Bev Kitchen, Sandra Ellard, Mary Christian, Joan Dayoub, Charlita Atha, Patsy Parker
WV RFTS Staff: Jeannie Clark, Stephanie Thorn
- **GWU Research Staff:** Dr. Richard Windsor, Dr. Sean Cleary, Amanda Davis, John Wedeles

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RFTS-SCRIPT Dissemination Program Aims

- **Aim #1:** To conduct an Effectiveness Evaluation to document the cessation and significant reduction (SR) rates attributable to SCRIPT delivered by DCCs to annual RFTS cohorts of pregnant smokers in 2006-07 and 2009-10.
- **Aim #2:** To conduct a Process Evaluation to document the level of fidelity of SCRIPT procedures delivered by DCCs to RFTS clients who smoked, and to confirm the RFTS-SCRIPT Project Adoption Rate in 2009-10.

SCRIPT Evidence-Base

- **Meta-Analyses of Literature + Tobacco Treatment Guidelines for Pregnant Smokers: AHRQ, 2000 + 2008**
- **Synthesis of 3 RCT's: > 2400 Medicaid patients directed by the PI (Windsor) and his evaluation team (1982-2007): SCRIPT Trial I – II - III**
- **Synopsis of 5 independent SCRIPT evaluations.**
- **NCI Peer Review and Funding: 2007-12**

Examples: Effective Interventions--Pregnant Patients

<p>Ershoff, et al (1989)</p>	<p>Brief health educator discussion of risks (3-5 minutes); advised of a free cessation class; and pregnancy-specific self-help materials mailed weekly for 7 weeks.</p>
<p>Walsh, et al (1997)</p>	<p>MD advice (2-3 min.); video on risks, barriers, and quitting tips;+ one 10-minute session by CNM + self-help manual + follow up letters.</p>
<p>Windsor, et al (1986) PHASE I - <u>AJPH</u></p>	<p>Pregnancy-specific self-help materials (Pregnant Woman's Guide To Quit Smoking) and one 10 min counseling session with a health educator.</p>
<p>Windsor, et al (1993) PHASE II - <u>AJPH</u></p>	<p>15-minute counseling session--how to use the Guide (Windsor et al., 1986) + MD letter; social support + buddy letter, contract, + tip sheet.</p>
<p>Windsor, et al (2000) PHASE III-<u>AJOb/yn</u></p>	<p>SCRIPT Methods: Guide & Commit to Quit Video (10 min.) & Patient Counseling (5 min.) NOTE: Published 2000 Meta-Analysis/Guidelines</p>

SCRIPT Evaluations: E vs C Group Quit Rates

Evaluation Study P.I. Location	Measure	E Group		C Group		Diff. (E vs C)
		N	%	N	%	
Windsor, WV, 2011 (Trial IV)	CO	259	13.9%	259	4.6%	+ 9.3%
Windsor, Al, 2000 (Trial III)	S-COT	126	17.3%	139	8.8%	+ 8.5%
Gebauer, Ohio,1998	S-COT	84	15.5%	94	0.0%	+15.5%
Hartmann, NC,1996	CO	107	20.0%	100	10.0%	+10.0%
Valbo(Norway),1994-1996	CO	107	27.0%	105	11.4%	+15.7%
Windsor,AL,1993 (Trial II)	S-COT	400	14.2%	414	8.4%	+ 5.8%
O'Connor, (Canada),1992	U-COT	90	13.3%	84	6.0%	+ 7.3%
Hjalmarson, (Sweden),1991	SCN	444	12.6%	209	8.6%	+4.0%
Windsor, Al,1985 (Trial I)	SCN	102	14.2%	104	2.0%	+11.8%
US Studies (N = 2176)		Total = 15.0%		6.5%		+ 8.5%
Non-US Studies (N=1039)		Total = 15.0%		8.8%		+ 6.2%
(Total N = 2697)		Total = 15.2%		7.5%		+7.7%

The Core SCRIPT Procedures

- **Component #1: Commit to Quit Smoking During & After Pregnancy Video (10 Min.)**
- **Component #2: A Pregnant Women's Guide to Quit Smoking (5th-6th grade level)**
- **Component #3: Patient-centered counseling session (10-15 Minutes)**

SCRIPT Procedures for DCC Practice

ASK < 1 minute

- 1.Document smoking status + cigarettes per day (cpd) + CO Sample
 - A. Never smoker or quit before pregnant
 - B. Quit since pregnant
 - C. Smoker: reduced cpd
 - D. Smoker: same cpd

Response A and B: Congratulate her on success and stop home & social ETS

Response C and D: ASSESS--ADVISE--ASSIST--ARRANGE

ASSESS <1 minute

- 2.Document readiness to quit

ADVISE <1 minute

- 3.Provide clear, strong messages about risks of smoking to mother/fetus
- 4.Provide clear, strong and personal advice to quit and stay quit

ASSIST >10 minutes

- 5.Review cessation skills in Video-Guide & sign an agreement to use Guide
- 6.Express confidence that use of the Guide and methods will help them to quit
- 7.Encourage patient to seek family & social support to quit
- 8.Advise patient to stop ETS exposure at home, car and social
- 9.Remind patient of next visit and put "smoker" label in notes

ARRANGE < 1 minute

- 10.Schedule next visit for patient & Call Patient on Quit Date (Optional)

A Pregnant Woman's



5th
EDITION!

Guide To Quit Smoking

The RFTS-SCRIPT Impact Evaluation

RFTS-SCRIPT Evaluation Design

- **Matched Historical Comparison Group Design**
 - **Experimental E Group: clients from 2009-2010 who provided a CO at screening, indicated a desire to quit to their DCC, and received SCRIPT home visit (n = 259)**
 - **Comparison (C) group: clients from 2006-2007 who received the same CO assessment methods as the – E - Group (n = 259)**

RFTS-SCRIPT Program Evaluation Methods

- The E Group and (C) Group clients were stratified by baseline CO into 10 strata (CO predicts behavior)
- The (C) Group clients were also stratified and an equal number were randomly selected within each of these 10 CO strata from the 688 clients (295 - 2006 + 393 – 2007), who received the same CO assessment methods at the E group

Results of Analysis of Selection Bias

- Cohort 1: self-reported smokers
- Cohort 2: self-reported smokers who agreed to a CO assessment at screening
- Cohort 3: self-reported smokers who agreed to a CO measurement, had the opportunity to receive SCRIPT, and received a tobacco follow-up 30-60 days after screening
- **Comparable for most major baseline variables, except cigarettes per day (CPD)**

RFTS-SCRIPT Effectiveness Results

RFTS-SCRIPT Cohort comparisons: 2006-2010

Variable	Cohort 1	Cohort 2	Cohort 3	p-values
	n = 3311	n = 2725	n = 1894	
Baseline CO	12.4	12.4	12.4	0.98
EGA at Screening (weeks)	18.2	18.1	18.0	0.58
% smokers in house	78.0	78.2	77.7	0.79
Mean Maternal Age (years)	23.9	23.9	24.0	0.96
Mean CPD +	10.0	11.9	9.9	0.01
Confidence level	4.7	4.8	5.0	0.24
Perceived harm to self	8.5	8.6	8.7	0.19
Perceived harm to baby	9.2	9.3	9.3	0.26

+ CPD vs CO value: $r = 0.31$

RFTS-SCRIPT Effectiveness Results

RFTS-SCRIPT Matched (C) vs. E Groups by CO

Time Period	2006 - 2007	2009 - 2010	<u>p-values</u>
Group Size	(C) Group = 259	(E) Group = 259	
Baseline CO	13.1	13.6	0.60
EGA at Screening (weeks)	18.0	17.2	0.17
% smokers in house	81%	78%	0.27
Mean Maternal Age (years)	23.8	24.3	0.17
Mean CPD	9.7	8.8	0.13
Perceived harm of smoking to self	8.7	8.9	0.22
Perceived harm of smoking to baby	9.4	9.5	0.30

+40% missing data in 2006

RFTS-SCRIPT Effectiveness Results

Behavioral Impact Rates by (C) and (E) Groups

Time Period	2006-2007	2009-2010	% change	p-values
Group Size	(C) Group = 259	(E) Group = 259		
% Smoke-Free Homes	30.0%	34.0%	> 4.0%	0.30
MD/RN advice to quit	67.0%	76.0%	> 9.0%	0.01
CO Confirmed Cessation	4.6%	13.9%	> 9.3%	0.01
CO Confirmed Sig. Red. *	6.9%	11.2%	> 4.3%	0.05

* $\geq 50\%$ reduction; ≥ 10 ppm at screening.....CO-20 ppm ≥ 200 Saliva Cot

RFTS-SCRIPT Effectiveness Results

E and (C) Group CO values at baseline and follow-up

Behavior	E Group			(C) Group		
	Baseline	Follow-up	% change	Baseline	Follow-up	% change
Cessation	7.2	0.6	< 92%	9.0	1.3	< 86%
Significant Red.	25.8	9.2	< 64%	21.9	6.3	< 86%
No Sig. Change	12.4	15.6	< 23%	13.4	15.3	> 14%

Excess Smoking Attributable Health Care Cost for Mother and Baby

Miller, et al, Birth and 1st Year Costs for
Mothers and Infants Attributable to Maternal Smoking, Nicotine and
Tobacco Research, 2001, 25-25.

SAR > Cost Range = \$1142-\$1358 for 1996... >>> 2002 (?)
Adjusted for BLS-CPI Medical Inflation Index >>> \$2000

Li, Windsor, Lowe, et al, Evaluation of the Impact of Dissemination of
Smoking Cessation Methods on Low- Birth Weight Rates and Health
Care Costs in the U.S.: Achieving the year 2000 Objectives,
American J. of Preventive Medicine, 1992, 171-77

Richard Windsor, MS, PhD, MPH,
**“Smoking Cessation and Reduction in Pregnancy
Treatment (SCRIPT) Methods: A Meta-Evaluation
of the (Economic) Impact of Dissemination”,
American J. of Medical Science, 2003, 216-22**

Return on Investment (ROI):

Smokerlyzer® MaternityCO Chart

COppm

%FCO_{Hb}



> 20 5.66

19 5.38

18 5.09

17 4.81

16 4.53

15 4.25

14 3.96

13 3.68

12 3.40

11 3.11

10 2.83

9 2.55

8 2.26

7 1.98

6 1.70

5 1.42

4 1.13

3 0.85

2 0.57

1 0.28

0 0.00

Table 1: Average Dose of Selected Chemicals in Cigarettes: 5-10-20 CPD and Per Pregnancy *

CHEMICALS	Dose/ cigarette	(A) 5 CPD	(B) 10 CPD	(C) 20 CPD	(D) 5 CPD/ Pregnancy	(E) 10 CPD/ Pregnancy	(F) 10 CPD/ Pregnancy
CO	10-23 mg	83	165	330	22275	44550	89100
Nicotine	01-03 mg	10	20	40	2700	5400	10800
Hydrogen cyanide	400-500 mg	2250	4500	9000	607500	1215000	2430000
Aniline	360-655 mg	3438	5050	10150	928125	363500	2740500
Catechol	200-400 mg	1500	3000	6000	405000	810000	1620000
Nitrogen oxide	100-600 mg	1750	3500	7000	472500	945000	1890000
Methanol	100-250 mg	875	1750	3500	236250	472500	945000
Phenol	80-160 mg	600	1200	2400	162000	324000	648000
Acrolein	60-140 mg	500	1000	2000	135000	270000	540000
Pyridine	16-40 mg	140	280	560	37800	75600	151200
Ammonia	10-130 mg	350	700	1400	94500	189000	378000
Hydrogen sulfide	10-90 mg	250	500	1000	67500	135000	270000
Arsenic	40-120 mg	400	800	1600	108000	216000	432000
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Hexavalent chromium	4-70 ng	185	370	740	49950	99900	199800
Cadmium	4-70 ng	185	370	740	49950	99900	199800
Nickel	0-600 ng	1500	3000	6000	405000	810000	1620000
Lead	34-85 ng	298	595	1530	80325	160650	413100

Source: Hoffmann & Wynder, 1998 CPD= Cigarettes Per Day

* Estimated by Windsor = 270 days ✕ A-B-C Averages/DAY... D-E-F Averages/PREGNANCY

Table 2: Average Dose of Selected Carcinogens in Cigarettes: 5-10-20 CPD and Per Pregnancy*

CARCINOGENS	Dose/ cigarette	(A) 5 CPD	(B) 10 CPD	(C) 20 CPD	(D) 5 CPD/ Pregnancy	(E) 10 CPD/ Pregnancy	(F) 20 CPD/ Pregnancy
Polynuc.Aromatic Hydroc. Heterocyclic compounds	60-190 ng 3-14 ng	625 43	1250 85	2500 520	168750 11475	337500 22950	675000 140400
N-Nitrosamines	200-4900 ng	12750	25500	51000	3442500	6885000	13770000
Aromatic amines	30-670 ng	1750	3500	7000	472500	945000	1890000
N-heterocyclic Amines	40-300 ng	850	1700	3400	229500	459000	918000
Aldehydes	570-1,500 ng	5190	10350	20700	1401300	2794500	5589000
Volatile Hydrocarbons	500-1,500 ng	4125	8250	16500	1113750	2227500	4455000

Source: Hoffmann & Wynder (1998)

CPD= Cigarettes Per Day

* Estimated by Windsor= 270 days ×A-B-C Averages/Day...D-E-F Averages/Pregnancy

PROCESS EVALUATION

Major problem documented by all Meta-Evaluations: Did the staff deliver all Intervention Procedures to all patients?

PROCESS > BEHAVIORAL IMPACT



RIGHT FROM THE START PROJECT (RFTS) TS002 TOBACCO FOLLOW-UP FORM

CO VALUE

PPM

 Refused Equipment Problem Explanation in Progress Notes

- Prenatal
 Postpartum

Follow-up #

Date of Birth:

Date:

Name:

Last Name

MI

First Name

County:

Region:

DCC ID#

DCC Name:

Agency:

1. Have you smoked a cigarette, even one puff, within the last 7 days? (choose only one)

 Yes No Never Smoked

2. Since you started maternity care with the Right From The Start Project (RFTS) has the smoking pattern changed where you live? (choose all that apply)

 No change. No one smokes where I live - they smoke outside. I have started/increased smoking since pregnant. People may smoke anywhere I live. People may smoke in certain rooms.**If Never Smoked - STOP HERE**

3. Since your first RFTS home visit, which statements best describes your cigarette smoking? (choose all that apply)

 I smoke about the same number. Number of cigarettes smoked each day: I smoke, but I have cut down on the number of cigarettes. Number of cigarettes smoked each day: I have started/increased smoking. Number of cigarettes smoked each day: I dip, chew, or use smokeless tobacco. I have quit!

4. If you are a smoker, how many times since your first RFTS visit have you made a serious attempt to stop smoking (went without a cigarette for at least 24 hours). (choose only one)

 0 1 2 3 I have quit!

5. How soon after you wake up do you usually smoke your first cigarette or use other tobacco? (choose only one)

 5 minutes or less 6 to 30 minutes 31-59 minutes 1 to 2 hours Greater than 2 hours I am not smoking!

6. Since you started RFTS, has your DCC provided the following: (choose only those methods provided)

 I received no information. My Right From The Start worker counseled me to quit. I was given A Pregnant Woman's Guide To Quit Smoking. I watched the "Commit To Quit" video. I was advised to call the WV Quitline. My DCC called me on my quit date.

7. a. My doctor advised me to quit.

 Yes No

b. My doctor advised me to call the WV Quitline.

 Yes No

c. I called the WV Quitline.

 Yes No

d. The WV Quitline called me.

 Yes No

8. I found the SCRIPT Program helpful? (choose only one).

Low

 1 2 3 4 5 6 7 8 9 10

High

9. During this pregnancy, has anyone who is living with you:

a. Tried to quit smoking.

 Yes No

b. Successfully quit smoking.

 Yes No

The DCC PII/Quit Rate Connection

- In 2010: 62 DCCs with ≥ 4 clients who self-reported as smokers (**Fewer Clients < PII and Behavior Change**)
 - 16 DCCs had a PII of $\geq 90\%$: CO-confirmed quit rate = 9.1%
 - The average PII for the Video was only 33%: 22 DCCs did not show the Video at all
- 7 of the 16 DCCs ≥ 10 clients who self-reported as smokers.
 - CO-confirmed quit rate = 18.9%

Other Findings/Conclusions

- The study produced insight about the challenges to conducting SCRIPT and an Evaluation:
 - $\geq 20\%$ of the DCC's were not implementing SCRIPT with fidelity
 - PII were $\leq 50\%$ in 2009-2010
 - 19% of the RFTS clients who wanted the SCRIPT did not have it delivered by a DCC

RFTS-SCRIPT Effectiveness

- Other findings/conclusions
 - Because RFTS enrollment is voluntary, lag time between RFTS contact and screening visit by a DCC was typically three months.
 - The typical RFTS client received SCRIPT three months later than a clinic-based smoker: 2nd - 3rd trimester.
 - Smokers who remained were the most addicted, had the highest ETS rates in their home, and had the lowest levels of psycho-social support and motivation to quit.

RFTS-SCRIPT Effectiveness: Final Comments

- Institutionalization of SCRIPT into the RFTS Program has been achieved: The NIH Objective.
- Study results provide valid, empirical evidence that an additional proportion of women, **even very late in pregnancy**, can be helped by trained nurses and social workers to change their smoking behavior.
- Appreciation of **life challenges for RFTS clients** and **implementation challenges for DCC's- Primary Care**