TECHNICAL REPORT

Measurement and definition for smoking cessation intervention research: the Smoke-Free Families experience

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Abstract

The measures, definitions, and processes used in the Smoke-Free Families clinical trials to assure consistent measurement and reporting of various aspects of the trials are described. Definitions of current smokers at different points in the pregnancy, levels of addiction, biological verification, cessation, stages of change, and intervention approaches are presented along with the rationale underlying their adoption and development. (Tobacco Control 2000;9(Suppl III):iii87–iii90)

Keys: smoking cessation; pregnancy; clinical trials; addiction

The purpose of the Smoke Free Families (SFF) project is to identify innovative best practices for achieving smoking cessation before, during, and after pregnancy. Eleven clinical trials were undertaken with a wide variety of promising interventions. To assure consistency across all of the trials and to facilitate meta-analysis of the results from these trials, the Smoke Free Families National Program Office (NPO) and the Centers for Disease Control and Prevention (CDC) defined common measures and processes to be applied across all projects. This paper presents these measures and processes.

Methods

The literature on smoking cessation during pregnancy was reviewed to identify measures used for assessment of smoking status in the prenatal, preconceptional, and postpartum periods, biochemical verification of smoking status, determination of cessation, definition of the stages of pregnancy quitting, and documentation of the implementation of the intervention, including provider time. A working group met in September of 1995 to review the material and to achieve consensus on the most useful measures. The group was established by the CDC and SFF with membership from the American Cancer Society, the CDC, the Robert Wood Johnson Foundation, SFF NPO, SFF National Advisory Committee (NAC), SFF grantees, and invited experts. Comments from all SFF grantees were solicited and modifications to the measures were made as appropriate. Guidance for all SFF grantees was then distributed in advance of trial initiation.

Assessment of smoking status

Questions were chosen, adapted or developed to assess smoking status at two different points in time: (1) at the time of the first prenatal visit (prenatal screening), including questions about smoking before pregnancy (preconceptional); and (2) at some specified time following the end of pregnancy (postpartum screening). The questions listed in box 1 were used for prenatal assessments and, in box 2, for postpartum assessments.

PRENATAL SCREENING

The purpose of the prenatal screening questions is to identify pregnant smokers at the time they enter prenatal care. Accurate assessment of smoking status at the first prenatal visit identifies smokers for participation in the trial and establishes a baseline measure of smoking status for each enrolled participant and of smoking prevalence for the study population. Some studies also used these questions in subsequent assessments of smoking status, as specified by the trial protocol. All trials, at a minimum, were required to ask these questions at the first prenatal visit. A second assessment was required at or near the end of pregnancy to establish changes in smoking status during the pregnancy. The timing of the postpartum assessment varied with the study design. The suggested order of these questions was based on current knowledge of approaches to minimise non-disclosure of smoking status.1

MEASURES OF CURRENT SMOKING STATUS

At least two, and as many as four, questions about current smoking status were asked of the pregnant woman during her first prenatal visit (box 1).

Responses to questions 1, 2, and 3 allowed each woman to be categorised as a “smoker” or a “non-smoker”. Question 1 is designed to minimise non-disclosure of smoking status and to provide investigators more specific information about current smoking behaviour. Many pregnant women are reluctant to disclose their smoking status at the first prenatal visit. Deception rates as high as 23% among Medicare insured1 2 and 14% among privately
Box 1. Recommended questions for prenatal screening

1. Current smoking status
   Which statement best describes you now?
   a. I smoke regularly now—about the same amount as BEFORE I found out I was pregnant.
   b. I smoke regularly now, but more than BEFORE I found out I was pregnant.
   c. I smoke some now, but I have cut down SINCE I got pregnant.
   d. I stopped smoking AFTER I found out I was pregnant, and I am not smoking now.
   e. I stopped smoking BEFORE I found out I was pregnant, and I am not smoking now.
   f. I have NEVER smoked more than 100 cigarettes.

2. Current smoking status
   Have you had a cigarette, even a puff, within the last 30 days?
   a. Yes  b. No

3. Current smoking status
   Have you had a cigarette, even a puff, within the last 7 days?
   a. Yes  b. No

4. Current smoking quantity (optional)
   During the past 7 days, how many cigarettes or packs of cigarettes did you smoke on an average day? (A pack has 20 cigarettes)
   ___cigarettes or ___packs ( ) Less than 1 cig/day ( ) Didn’t smoke ( ) Don’t know

5. Addiction measure (optional)
   How soon after you wake up do you usually smoke your first cigarette?
   ___Immediately ___minutes (number) ___Hours (number) ___No usual time/time varies __Don’t know

6. Baseline biochemical measurements (optional)

7. Preconceptional smoking status
   In the past 3 months before you got pregnant, how many cigarettes or packs of cigarettes did you smoke on an average day? (A pack has 20 cigarettes)
   ___cigarettes or ___packs ( ) less than 1 cig/day ( ) Didn’t smoke ( ) Don’t know

Box 2. Recommended supplementary questions for postpartum screening

8. Current smoking status
   Did you smoke cigarettes at all during the 12 months before your delivery?
   ( )Yes—Go to next question ( )No

9. Smoking status during pregnancy
   In the 3 months after you got pregnant, how many cigarettes or packs of cigarettes did you smoke on an average day? (A pack has 20 cigarettes)
   ___cigarettes or ___packs ( ) less than 1 cig/day ( ) Didn’t smoke ( ) Don’t know

insured pregnant women have been biochemically confirmed. Non-disclosure can be reduced using a multiple choice question as compared to a simple “yes-no” question. The multiple choice question tested by Mullen was modified slightly by the working group and is used as the initial screening question (box 1, question 1). A woman was not classified as a smoker based on her response to question 1. She was also asked question 2 (box 1). If she indicated smoking, even a puff, within the previous 30 days, she was then asked question 3 to determine if she had smoked, even a puff, within the previous seven days. This question is frequently used to determine if a person is currently smoking. The answer of “yes” to question 3 and of “a”, “b” or “c” to question 1 resulted in the classification of the pregnant woman as a “smoker”. At this point, she was given an opportunity to enroll in the smoking cessation program. If she chose response “d”, “e” or “f” to question 1 and answered “no” to question 2, she was considered a “non-smoker” by self report.

Questions 4 and 5 were optional questions to be asked of pregnant smokers. They were used to measure the level of addiction based on the quantity of cigarettes smoked during a typical day and the timing of the first cigarette of the day. Question 5 may need to be adjusted for special populations such as teens who may not be in situations that let them behave as they would in unsupervised situations. For example, teens may postpone their first cigarette of the day in instances where they live at home and want to avoid smoking in front of their parents.

MEASURES OF PRECONCEPTIONAL SMOKING STATUS (OPTIONAL)

The preconceptional questions were used to obtain information about the pregnant...
Box 3. Staging pregnancy quitting

10. Have you smoked any cigarettes in the past 7 days, even a puff? 
   Yes—Go to next question No= Action 
11. If yes, are you seriously thinking about quitting completely during this pregnancy? 
   Yes—Go to next question No= Precontemplation 
12. If yes, are you planning to quit completely in the next 30 days? 
   Yes = Preparation No = Contemplation 

A thorough description of program components, methods and training. 

Documentation of the type, content and distribution schedule of self help materials provided to smokers. 

Descriptions of the pregnant smokers’ use and ratings of self help materials provided to them.
DOCUMENTATION OF PROVIDER TIME SPENT
IMPLEMENTING INTERVENTIONS

Given the significant time constraints faced by providers, it is important to document the time required to deliver interventions. A set of questions was developed by the working group to document: (1) how much of each type of provider’s time it actually took to implement a particular prenatal smoking cessation intervention; and (2) the sequencing of the intervention in relation to other activities occurring during the visit. Answers to these questions are important for purposes of quality assurance, clinic efficiency, and cost estimation as well as for future replication efforts.

Documentation of the following components was suggested but not required:

- Description of the particular component of the intervention being delivered by each provider
- Description of the content and method used in implementing each intervention component
- Documentation of the amount of time actually spent with the pregnant woman by each provider and the content of each interaction
- Description of the type of provider (for example, level of experience, training) implementing each component of the intervention
- Salary range for each type of provider

Conclusion

In the mid 1980s, a review of the literature on smoking cessation treatments for pregnant women resulted in a call for utilising scientific criteria for rigorous, valid research into ways to educate the pregnant smoker. When the SFF trials began in 1995, only a few approaches had been rigorously evaluated and did not, either collectively or individually, point the way for evidence-based practice for smoking cessation treatments for pregnant women. The SFF trials were designed, in part, to address this need for rigorous studies with clear implications for practice. They were also designed to be consistent in their definitions, measures, and processes. Definitions of current smokers at different points in the pregnancy and following it, levels of addiction, biological verification, cessation, stages of change, and intervention approaches created a template for the exchange of information and participation in subsequent meta-analyses. Rigorous and consistently applied processes and measures allowed the SFF investigators to meet the standards required for developing the most defensible evidence of intervention efficacy and for increasing the likelihood that findings from these trials would be useful in developing effective treatments for pregnant smokers.

With this information, it should be helpful to researchers in understanding and interpreting SFF findings, it may also serve as a useful construct for future work in this area. New approaches to some of the assessments used here are currently being explored. For example, new approaches to asking women about their smoking status were recently reported. As refinements and enhancements are made, they should be systematically incorporated into future efforts to evaluate the effectiveness of cessation treatments for pregnant women.

1 Windsor RA. Healthcare delivery issues and systems. Presentation at a consensus workshop on smoking cessation in pregnancy. Health Resources and Services Administration, Rockville, Maryland, 9-10 April 1998.
8 Centers for Disease Control and Prevention. PRAMS surveillance report. Atlanta, Georgia: Division of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, 1999.