

## CHILDHOOD CANCER SURVIVOR STUDY

ANALYSIS CONCEPT PROPOSAL, April 10, 2006

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**1. Title:** Long-Term Smoking Cessation Outcomes Among Childhood Cancer Survivors in Partnership for Health (a follow-up to the PFH study outcomes paper, published in *Journal of Clinical Oncology*, 2005 September 23(27);6516-6523).

**2. Investigators:** This proposed publication will be written by the investigators who were involved in the original study and their research team. Other interested investigators may join the writing team. Proposed investigators include:

|                     |  |        |
|---------------------|--|--------|
| Karen Emmons (lead) | <a href="mailto:Karen_m_emmons@dfci.harvard.edu">Karen_m_emmons@dfci.harvard.edu</a> | DFCI   |
| Ann Mertens         | <a href="mailto:mertens@epi.umn.edu">mertens@epi.umn.edu</a>                         | U Minn |
| Elaine Puleo        | <a href="mailto:epuleo@schoolph.umass.edu">epuleo@schoolph.umass.edu</a>             | U MASS |
| Fred Li             | <a href="mailto:Fred_li@dfci.harvard.edu">Fred_li@dfci.harvard.edu</a>               | DFCI   |

### 3. Background and Rationale:

Partnership for Health (PFH) was a randomized control trial, with follow-up at 8- and 12-months, that involved smokers (n=796) enrolled in the CCSS cohort. This study was funded as a separate RO1, but used participants in the CCSS cohort. Smokers who were identified through the CCSS baseline questionnaire were invited to participate in PFH. Eligibility criteria for PFH included: (a) age of at least 18; (b) not currently in treatment for cancer; (c) mentally able to provide informed consent; (d) reading and speaking English; and (e) being a current smoker. 22 CCSS institutions participated in PFH; each received IRB approval before patients were invited to participate in PFH.

Participants were randomly assigned to either self-help control or a peer-counseling intervention that included up to 6 telephone calls from a trained childhood cancer survivor, tailored and targeted materials, and free nicotine replacement therapy. The intervention was delivered by telephone and mail.

The quit rate was significantly higher in the counseling group compared with self-help at both the 8-month (16.8% vs. 8.5%;  $p < .01$ ) and 12-month follow-ups (15% vs. 9%;  $p \leq .01$ ) (Emmons, et al, 2005). The intervention group was twice as likely to quit smoking, compared to the self-help group. This was the first large-scale smoking cessation intervention with this population, and the effects were strong compared to other population-based interventions (e.g. those that targeted all smokers, not just those interested in quitting) in the general population. However, we were only able to include an 8-month post-baseline follow-up in the original study. It is increasingly

recommended that long-term follow-ups be conducted in order to determine maintenance of intervention effects (Ockene, et al., 2000).

We were very fortunate to be able to include items on the Follow-up #2 survey that allow for the evaluation of long-term outcomes among CCSS participants who participated in PFH. The proposed analysis is to examine these long-term outcomes, which will supplement the 8-month post-baseline outcomes already analyzed and published. This paper will add significantly to the literature, as it will provide long-term follow-up data for the largest randomized smoking cessation trial conducted to date with childhood cancer survivors.

*Specific Aims:*

1. *What is long-term smoking status among PFH participants in the intervention vs. self-help group?* We hypothesize that there will be a higher rate of smoking in the self-help control group vs. the intervention group.
2. *Among those who continue to smoking, are there differences in quit attempts among the two study conditions?* We hypothesize that there will be more quit attempts among continued smokers who were in the intervention group, vs. the self-help control group.
3. *Which demographic, health-related, and smoking-related variables predict continued cessation, by group?* We hypothesize that lower income/education, depression, nicotine dependence and not using NRT will predict poorer smoking cessation outcomes.

*Analysis Framework*

(a) Outcomes: smoking status, quit attempts

(b) Subject Population: 796 CCSS participants who also participated in PFH.

(c) Data Sets: PFH baseline (BL), PFH 8-month follow-up (PFH FUP), CCSS Follow-up #2 (CCSS FUP)

(d) Predictor Variables:

Race (BL)

Age (BL)

Gender (BL)

Education (CCSS FUP)

Household income (CCSS FUP)

Marital status (CCSS FUP)

Age at cancer diagnosis (BL)

Cancer type (BL)

Cancer treatment (BL)

Subsequent cancer diagnoses (CCSS FUP)

Smoking status (BL, PFH FUP; CCSS FUP):

Current smokers -- smoked at least 100 cigarettes in their lifetime and smoked at each survey point on a regular basis.

Former smokers—smoked 100+ cigarettes in their lifetime but did not smoke at a given survey point.

Age of smoking onset (CCSS FUP)

Average number of cigarettes smoked (PFH FUP; CCSS FUP)

Total number of years smoked (PFH FUP; CCSS FUP)

Depression/mood and intrusive thoughts questions (CCSS FUP) (need to decide which of sections F, G, K to use)

Nicotine Dependence (PFH BL)

Use of NRT (PFH FUP)

**6. Special Consideration:** As noted above, the CCSS steering committee was generous in allowing smoking cessation outcomes to be included in follow-up #2, so that we could examine the long-term outcomes of PFH participants. This reflects a substantial economy of the scale provided by CCSS, and also provides an unprecedented opportunity to capture long-term outcomes of a smoking cessation intervention designed specifically for childhood cancer survivors.

## Sample Tables

### Long-Term Smoking Outcomes by Study Condition

| <i>Smoking Status</i>  | <i>Intervention</i> | <i>Self-Help</i> |
|--|---------------------|------------------|
| Quit by 8-months<br>(as measured on PFH FUP),<br>Relapsed by follow-up |                     |                  |
| Continued Quitter  |                     |                  |
| Relapser   |                     |                  |

Multivariable Logistic Regression Models of Smoking Cessation Outcomes {Note these are sample variables—for illustrative purposes }

| <b>Variable</b>            | <b>Odds Ratio</b> | <b>95% Confidence Limits</b> |
|----------------------------|-------------------|------------------------------|
| <b>Age group</b>           |                   |                              |
| 18 – 25 vs. 36+            |                   |                              |
| 26-30 vs. 36+              |                   |                              |
| 31-35 vs. 36+              |                   |                              |
| <b>Gender</b>              |                   |                              |
| f vs. m                    |                   |                              |
| <b>Nicotine Dependence</b> |                   |                              |
| 1=yes vs 0= no             |                   |                              |
| <b>Intervention</b>        |                   |                              |
| 1=yes vs 0=no              |                   |                              |
| <b>Depressive symptoms</b> |                   |                              |

## References

Ockene JK, Emmons KM, Mermelstein RJ, Perkins KA, Bonollo DS, Voorhees CC, Hollis JF Relapse and maintenance issues for smoking cessation. Health Psychol. 2000 Jan;19(1 Suppl):17-31.

Emmons KM, Puleo E, Park E, Mertens A, Gritz E, Butterfield R, Li F. Peer-delivered smoking counseling for childhood cancer survivors increases rate of cessation: The Partnership for Health Study. *Journal of Clinical Oncology*, 2005 September 23(27);6516-6523.