FSFW HEALTH, SCIENCE, AND TECHNOLOGY WAVE 2 REQUESTS FOR PROPOSALS

TOPIC 2: OUTCOMES RESEARCH

OUTCOMES RESEARCH: INTRODUCTION

Cohort studies provide the best scientific evidence of all observational research designs, with several notable benefits. Prospective cohort studies can establish a time sequence or temporality, an essential factor in determining causality. They can determine incidence as opposed to prevalence, and provide more information about the natural history of disease and direct estimates of relative risk. Subjects in cohorts can be matched over the course of the study, limiting the influence of confounding variables. Cohort studies are able to examine multiple outcomes, an advantage in certain fields of study.

Cohort studies played a critical role in establishing the cause of many of the public health concerns of the 20th century among men and women. For instance, the Nurses' Health Study firmly established the link between women's health and various lifestyle factors, including smoking, physical activity, weight, oral contraceptive use, etc. The Framingham Heart study determined that cigarette smoking, elevated cholesterol and high blood pressure each increase the risk for heart disease.

Cohort studies have provided the basis for many pivotal findings around the effects of smoking. The British Doctors' Study and the Hammond-Horn Study solidified the link between smoking and such diseases as lung cancer and heart disease. The landmark 1964 U.S. Surgeon General's Report on Smoking and Health relied strongly on cohort study data when evaluating the link between smoking and disease. Cohort studies also established a dose-response relationship between smoking and disease, showing a positive relationship between the number of cigarettes smoked daily and the likelihood of developing disease. Cohort studies have also demonstrated the benefits of smoking cessation, even after many years of smoking, for both men and women.[1,2]

Cohort studies also have drawbacks. They are expensive and can be slow to yield results. Many of the major studies took place in high-income countries, and the findings may not be relevant to low- or middle-income countries. There are challenges to following large groups of people over time, and the studies can be susceptible to selection or recall biases. Tobacco-related studies present additional challenges. Product use patterns change over time and will do so even more

[1] Doll R, Peto R, Boreham J, Sutherland I. Mortality in relation to smoking: 50 years' observations on male British doctors. BMJ 2004; 328:1519-1533

[2] Pirie K, Peto R, Reeves GK, Green J, Veral V. The 21st century hazards of smoking and benefits of stopping: a prospective study of one million women in the UK. Lancet 2013 Jan 12; 381(9861):133-141

quickly as more reduced-risk products come to market. Self-reporting of smoking and nicotine use can occasionally be unreliable.

There are opportunities to innovate the ways cohort studies are undertaken to address these drawbacks. Technology is fundamentally reshaping traditional study methods, from the quality and pace of data collection to more rigorous analysis of large datasets. Validated surrogate outcomes can be evaluated while waiting for ultimate outcomes to appear, reducing the lag time to results. Additionally, studies such as the Millennium Cohort Study are looking at exposures beyond typical 'clinical' exposures, such as economic circumstances, parenting, relationships and family life.

It is worth noting that the recently developed ANDS have not yet been evaluated in any long-term cohort studies. Similar studies are required to assess the benefits of switching for smokers, as well as any increased risks for non-smokers who take up ANDS.

In this context, the Foundation is looking to explore the best way to undertake cohort studies in the 21st century in men and women, providing better, faster, more gender-inclusive, and cheaper insights. We are also looking for a comprehensive fact base around the benefits of quitting or switching in high-risk populations. This will help us understand what (if any) future cohort studies and clinical trials will be needed. We also welcome expressions of interest from organizations interested in leading or participating in such studies.

REQUEST FOR PROPOSAL 2A: DEFINING A 21ST CENTURY COHORT STUDY

Issue date:	January 18, 2019
Question window ends:	March 18, 2019
Closing date:	April 18, 2019
Closing time:	5pm US Eastern Standard Time
Contact information:	support@smokefreeworld.org
Submit questions to:	support@smokefreeworld.org
Submit proposals to:	See submission instructions in RFP
Financing instrument:	Scoping grant (2 grants available)
Financing amount:	Up to US$ 150,000
Financing duration:	Up to 3 months

(Please review the Topic 2 Introduction document as well for further background)

FOUNDATION FOR A SMOKE-FREE WORLD

SCOPING RESEARCH QUESTION

How can we design cohort studies for the 21st century cohort, delivering insights better, faster, in a more gender-inclusive way, and cheaper?

The main challenges of cohort studies were described in the introduction to this section: high cost, long timeframe, follow-up challenges, data quality issues, and changing product use patterns over time.

Technological advancements suggest that cohort studies can be undertaken better, faster, in amore gender-inclusive way, and cheaper in the 21st century:

Better: Advances in areas such as mobile and wearable sensing devices can allow researchers to collect and process data in greater detail, in more natural settings, over longer periods of time, with lower participant burden than ever before. Self-reporting issues can be addressed by technology solutions that measure people's behaviors more objectively, such as video cameras and devices with in-built sensors that detect usage frequency, and by the use of objective biomarkers. There are also a growing number of online tools to help researchers share and validate research more openly. These solutions and tools bring with them data privacy risks, which must be recognized and minimized.

Faster: Recruiting for cohort studies can be accelerated through the use of social networks and public databases, and online screening for inclusion and exclusion criteria. Study data can be collected almost immediately as ubiquitous mobile networks enable rapid transmission of cohort data to the researcher. The use of advanced analytics and data visualization can provide more insights faster. Measuring validated surrogate outcomes while waiting for ultimate outcomes themselves may also substantially reduce the lag time.

More gender-inclusive: Technology solutions for data collection and online recruitment channels can be designed to be equitably accessible and sensitive to existing cultural and social norms. The potential for unintended consequences (in particular gender bias) must be recognized and minimized.

Cheaper: Mobile and wearable devices are expected to significantly lower the cost of collecting data, compared with paper-based or interview-based techniques. More accurate and objective measures of data should also make it possible to use smaller cohorts without sacrificing the statistical power of the study.

Some of these technologies have already been incorporated into recent cohort studies. For example, the UCL CLOSER study has had participants use wearable accelerometers to measure physical activity. Participants in the Millennium Cohort Study complete their diaries via a smartphone app or online. The California Teachers' Study (CTS), studying risk factors for breast cancer and other diseases, is using mobile devices and cloud-based technology to dramatically cut the time and cost of managing the huge amounts of data that are the cornerstone of epidemiological studies.

Deliverables

- A report on how cohort studies can be done better, faster, in a more gender-inclusive way, and cheaper. Such a report should build on existing scientific literature, tools and techniques being used in ongoing cohort studies, and interviews with leading practitioners and experts in cohort study design. It should cover each step of a cohort study, including:
  - Study design, e.g., sample size, inclusion and exclusion criteria, control groups, study locations
  - Cohort recruitment (gender-appropriate)
  - Data gathering (gender-specfiic exposures and outcomes) and follow-up over time

Data analysis

- 1-2 symposia with leading experts to debate the report findings and define 2-3 designs for "cohort studies of the future," combining the elements above and comparing quality, speed and cost with a "traditional" cohort study.

Qualifications

Applicants should be academic institutions with expertise in cohort study design and strong epidemiology expertise, who also bring expertise in relevant technologies (whether through the institution itself or through a partnership).

Geographic focus

Global

Estimated budget and duration

Up to $150k and up to three months
(We may issue two grants in parallel.)

Submission Instructions

Applications should be submitted through our online portal which can be accessed here. This link will always start a new application form.

You may save a started application at any time by using the 'Save & Finish Later' button at the end of each page. If you do so please use this link to return to the log-in screen to access the saved form.

A list of application portal FAQs can be found here.

For all access inquiries, please contact us at support@smokefreeworld.org.

REQUEST FOR PROPOSAL 2B: BENEFITS OF QUITTING OR SWITCHING IN HIGH-RISK POPULATIONS

Issue date:	January 18, 2019
Question window ends:	March 18, 2019
Closing date:	April 18, 2019
Closing time:	5pm US Eastern Standard Time
Contact information:	support@smokefreeworld.org
Submit questions to:	support@smokefreeworld.org
Submit proposals to:	See submission instructions in RFP
Financing instrument:	Scoping grant (potentially multiple grants to cover different population segments)
Financing amount:	Up to US$ 100,000
Financing duration:	Up to 3 months

(Please review the Topic 2 Introduction document as well for further background)

FOUNDATION FOR A SMOKE-FREE WORLD

RESEARCH QUESTION

What is the current fact base on the benefits of quitting and switching for high-risk smoker populations?

Certain segments of the smoker population are at higher risk from the harms of smoking. These include smokers with chronic health conditions (e.g., cardiovascular disease, chronic obstructive pulmonary disease, diabetes, multiple morbidities), HIV/AIDS and tuberculosis, and schizophrenia and other serious mental health conditions.

Smoking in women is of growing concern. Prevalence of smoking among women is declining at a slower rate than that among men and is even increasing in some parts of the world.[1] Furthermore, the boy: girl smoking prevalence ratio is narrower than the men: women ratio in many countries, with some reversals.[2] The consequences of this trend in 20-25 years for women's health will be significant. Smoking during pregnancy also continues to be an issue in many countries.

Certain population segments have a very high prevalence of smoking, in particular, indigenous populations (including pregnant women) and military veterans.

We are also interested in the benefits of quitting or switching for healthy smokers aged over 50.

To help these smokers quit or switch to ANDS, they, their physicians and other healthcare providers, and payors all need to understand better the benefits of doing so. As a first step, we seek to establish a fact base on what is already known about the benefits of quitting or switching in these population segments. This will help us identify knowledge gaps to be closed through further research.

Three sources will need to be reviewed:

Peer-reviewed literature: A thorough review of existing literature to understand what we already know about the benefits of quitting or switching in high-risk populations. We recognize that there is likely to be more data on quitting than on switching. For example, complete smoking cessation appears to be beneficial in smokers with mild, moderate and likely even advanced COPD.[3,4]

Existing datasets: Datasets that could be mined to provide further insights, by population and country, including public and industry datasets.

Ongoing cohort studies: Existing cohort studies (including industry studies) that could be used to inform the fact base, by population and country (e.g., US FDA's PATH study, Singapore Chinese Health Study).

Deliverables

A fact base on existing knowledge, datasets and studies that can inform the benefits of quitting or switching in high-risk populations.

1. Systematic review of the existing literature for quitting, and separately for switching, by population segment and disagreggated by sex:

[1] GBD 2015 Tobacco Collaborators. Smoking prevalence and attributable disease burden in 195 countries and territories, 1990–2015: a systematic analysis from the Global Burden of Disease Study 2015. Lancet 2017; 389: 1885–906.

[2] Warren CW, Lea V, Lee J, Jones NR, Asma S, and McKenna M. Changes in tobacco use among 13-15 year olds between 1990 and 2008: Findings from the Global Youth Tobacco Survey. Glob Health Promot. 2009; 16:38-90

[3] Pride NB. Smoking cessation: effects on symptoms, spirometry and future trends in COPD. Thorax 2001; 56: Suppl. 2, ii7–10

[4] J. Zielinski, M. Bednarek, D. Gorecka. Complete smoking cessation is beneficial in older and more advanced COPD patients. European Respiratory Journal 2010 36: 216-217

a. Smokers with chronic health conditions (e.g., cardiovascular disease, chronic obstructive pulmonary disease, diabetes, multiple morbidities)
b. Smokers with HIV/AIDS and tuberculosis
c. Smokers with schizophrenia and other serious mental health conditions
d. Smokers in at-risk populations (e.g., indigenous populations, veterans)
e. Healthy smokers aged over 50

2. List of existing datasets with relevant information on smoking and nicotine-use behaviors and health outcomes, by population segment and by country
3. List of relevant ongoing cohort studies stating
    a. Population
    b. Countries
    c. Data available

Expected qualifications

Academic institutions with deep expertise in epidemiology

Geographic focus

Global

Estimated budget and duration

Up to $100k and up to three months
(We may issue multiple scoping grants to cover different population segments.)

Submission Instructions

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