DGIM Project Summary

Name of Project
Tobacco Biomarkers in South Asian Tobacco Users

Investigator(s)
Dr. Elisa Tong (PI) Dr. Arnab Mukherjea (Co-PI) Dr. Alka Kanaya (DGIM PI) Dr. Urmimala Sarkar (SFGH PI)
elisa.tong@ucdm.edu arnab.mukherjea@ucsf.edu alka.kanaya@ucsf.edu usarkar@medsfgh.ucsf.edu

Research question(s)
The 4 objectives of this study are to:
- Assess exposure to tobacco biomarkers by measuring salivary cotinine and urinary NNAL in guthka users
- Determine the presence, if any, of salivary cotinine and urinary NNAL in paan masala users
- Compare the levels of salivary cotinine and urinary NNAL found in study participants to those found in smokers and conventional smokeless tobacco products
- Explore if the provision of biomarker levels to South Asian tobacco product users influences attitudes on cessation

Brief Background/Significance
South Asians are known to use a distinct class of tobacco products—predominantly smokeless—in the native Indian subcontinent (Gupta & Ray 2003). Many of these tobacco products are commonly used by community members in the United States, including California (McCarthy et al. 2005). Two of these products are known as guthka and paan masala. Guthka is a combined concoction of tobacco and betel nut, manufactured with other additives, many of which are carcinogenic. Paan masala is almost identical to guthka, with the optional omission of tobacco. The most popular brand of guthka—RMD Manikchand—and its paan masala counterpart—Pan Parag—are readily available in South Asian ethnic enclaves and are known to be popular among community members for social and cultural reasons (Mukherjea et al. 2011). Use of these products is surmised to be responsible for disparities in tobacco-related disease (e.g. oral and pharyngeal cancer) among South Asians, both in the native region and in Diasporic countries (Reddy & Gupta 2004; Changrani & Gany 2005; Csikar et al. 2012).

Tobacco exposure is traditionally measured through tobacco biomarkers cotinine, a nicotine metabolite measuring short-term exposure over the past 2-3 days, and N-oxide, 4-(methylnitrosamino)-1-(3-pyridyl N-oxide)-1-butanol (NNAL), a tobacco-specific carcinogen measuring exposure over the past 2 months. Salivary cotinine and urinary NNAL measured in cigarette smokers are comparable to those found in mainstream smokeless tobacco users, with the latter group exhibiting slightly higher levels of these carcinogens. These studies used conventional smokeless tobacco products popular in the United States (Hecht et al. 2007).

To the best of our knowledge, no study has assessed human exposure of tobacco biomarkers (salivary cotinine or urinary NNAL) for guthka and paan masala users, although direct toxicological analysis of these products indicates high concentration of TSNAs (IARC). This will be the first study to examine tobacco biomarkers related to culturally-specific tobacco use (guthka or paan masala) among South Asians in California. The purpose of assessing biomarkers among paan masala users is to verify that this product is indeed free of tobacco and if not, the level of cotinine and NNAL present in users of this popular product. This preliminary data will provide a foundation for a larger-scale population-level study to biologically assess cancer risks among South Asians who use culturally-specific products found in ethnic enclaves and compare them to those found in cigarette smokers and conventional smokeless product users. Findings will also provide formative data which may elucidate a foundation for an innovative intervention targeting use of these and other culturally-specific products by South Asians in the United States. This information will help enable the development, implementation, and evaluation of a more comprehensive strategy which reframes cancer risk in this community and has potential to reduce the burden of tobacco-related disease among South Asians in California and other densely-populated areas of the United States.

Inclusion/exclusion criteria (list)
- Identification as South Asian (individuals with origins in Bangladesh, India, Pakistan and/or Sri Lanka)
- Only English-speaking participants
- Past month use of either paan masala or guthka
- Aged 18+ years (adults)
- Non-pregnant women
- Exclusion of those who have smoked cigarettes in the past month or are regularly exposed to cigarette smoke
Method of contact/recruitment (be specific)

We will recruit South Asians in the greater Sacramento area and the San Francisco Bay Area through recruitment flyers disseminated at Shifa Community Clinic (an official UC Davis School of Medicine affiliate), UCSF, SFGH, local clinics and health programs serving predominantly South Asians (e.g. the South Asian Heart Center at El Camino Hospital in Mountain View, CA) or the general South Asian community with affiliated organizations (email flyer). We will also ask local providers with patients who might meet the inclusion criteria to contact study personnel. Interested participants may contact Dr. Mukherjea to undergo screening questions to determine eligibility.

Benefits/burden for participants (clearly identify potential for harm)

Potential benefits to individual subjects include provision of TSNA levels and comparison to those of mainstream tobacco users (e.g. heavy smokers). This information may influence users of these products to reduce or cease use, thus conferring a direct health benefit.

More broadly, the information gleaned by subjects may also be disseminated to family and community members and perhaps serve as a catalyst for reduction or cessation of use among South Asians who did not participate in this study. Absent any current intervention, study subjects may serve as conduits of information to the larger South Asian community in the local area and beyond.

The expected risks related to participating in this study are considered to be minimal. The only anticipated risk is heightened concern about a specific subject’s physical health related to interpretation of biomarker results. To mitigate this concern, Dr. Mukherjea will be equipped to provide information about seeking resources—educational or clinical—to assist those wishing to obtain assistance in changing behavior related to product use. For instance, subjects may be recommended that they seek counseling or pharmacological aids through UCSF’s numerous cessation resources. Provision of educational materials will also be offered to those wishing to receive it.

The only other potential risk may be social in nature in that specific subjects might be stigmatized within the community if their product use was made public. Subjects will be assured that the highest standards of confidentiality will be maintained by approved key personnel and that any information linking specific results to the subject will be destroyed after the completion of this pilot study. The protocols employed in this study to keep identifiable information separate from the data collected serve as strong controls for any breach of confidentiality.

Any benefits or burden to DGIM practitioners?

There are no direct benefits for DGIM practitioners outside of potential participation in a follow-up study. The burden is negligible insofar that it entails providing study information to patients who might meet eligibility criteria.

Timeline for recruitment (projected start and stop dates)

Recruitment has begun and is expected to be completed in September 2013. The entire study ends in December 2014.

Funding source

Asian American Network for Cancer Awareness, Research, and Training (National Cancer Institute)

Potential for DGIM collaborators? (We encourage DGIM resident and fellow involvement in particular)

We welcome potential collaboration from DGIM investigators interested in tobacco-related disparities and willing to participate in data collection, management, analysis, and dissemination of findings.

Do you agree to notify us when recruitment is completed?

Yes

Date form completed

June 6, 2013