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Randomized Trial Study to Determine the Impact of Interventions on Children with Asthma

Additional submitted attachment is included below.

RAMBOLL

ENVIRONMENT
& HEALTH

California Energy Commission
Docket Unit, MS-4
Docket No. 19-ERDD-01
1516 Ninth Street
Sacramento, California 95814-5512

Sent via email to docket@energy.ca.gov

Comments on the upcoming solicitation for research and the CEC Workshop – "Randomized Trial Study to Determine the Impact of Gas Stove Interventions on Children with Asthma" Docket No. 19-ERDD-01

Date March 16, 2021

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Honorable Commissioners and Staff:

Thank you for providing an opportunity to comment on the proposed upcoming solicitation. I am an epidemiologist with Ramboll Environment & Health. I have the following comments on the goals and scope of the Grant Funding Opportunity (GFO) that was presented in the CEC Workshop and the accompanying materials (Notice of Staff Workshop March 2, 2021 with the Appendix).

Comments on the Research Goals

The stated research goals are:

1. Empirically quantify impact of gas stove electrification on children with asthma in California.
2. Conduct a randomized trial study to determine the impact of replacing gas stoves with electric stoves.

I support these goals. A well-designed randomized controlled intervention study may help address questions regarding possible associations between indoor air quality and childhood asthma.

Comments regarding questions 1-4

Question 1: This GFO prioritizes under-resourced communities, specifically disadvantaged communities and vulnerable populations, as the treatment group.

a. Which geographic regions, if any, should be prioritized as initial targets for this research?
b. Aside from geography, what factors should be considered when determining which communities should be selected as the treatment groups?

c. Are there other research study areas or programs that could inform or be leveraged to fulfill the goals and requirements of this research effort?

I support prioritizing under-resourced communities, specifically disadvantaged communities and vulnerable populations as the treatment (intervention) group. With respect to 1b, the same community or communities should be used as the population source of the treatment and the control groups. Random allocation to intervention groups helps avoid selection bias (for example, from differences in unknown or unrecognized baseline factors that are associated with the exposure and outcome) that may systematically overestimate or underestimate risk of the outcome. Ideally, such a study would be double-blinded, meaning the study participants do not know whether the intervention group to which they were randomly allocated is the intervention hypothesized to show an effect, while the researchers who measure the health effect do not know which intervention group the study participants were allocated. A well-designed study minimizes the opportunity for systematic bias to arise after random allocation of study participants has occurred.

With respect to Question 1c, I understand that the initial source of the funding for this project is from an Electric Program Investment Charge (EPIC) program. It might be useful to also include similar sources of funding from gas companies that can be used for a comparison intervention such as retrofitting cooking ventilation or exhaust hood on gas stoves. Such an intervention would serve two purposes: 1) the results can be used to understand the potential costs and benefits associated with different interventions to improve asthma; 2) it could potentially increase the sample size by offering additional funding; and 3) it may retain study subjects. In the absence of such another large intervention, it may be difficult to enroll and retain study subjects. Study subjects who are not randomized to the replacement of a gas stove with an electric stove may decide they are not interested in participating. Furthermore, diversifying the funding source may remove design or interpretation bias, or the perception of such bias, by including multiple stakeholder groups.

Question 2: Should the study include children in single family and/or multi-family homes?
There are several ways that including children in family and/or multi-family homes may influence study results: 1) smaller kitchens may be associated with higher combustion-related exposures due to less space to dilute exposures; 2) disadvantaged communities and vulnerable populations may be more likely to live in multi-family houses (and these factors may also correlate with socioeconomic factors that are related to determinants of health and asthma); and 3) multifamily homes may be more likely to be situated where outdoor ambient pollution levels are higher (greater potential for infiltration). It may be simpler to study only children who live in multifamily homes, and minimize bias that may be introduced if researchers included both single family homes and multi-family homes.

Question 3: Previous Randomized Controlled Trial studies have indicated that large sample sizes are needed to make robust conclusions and optimally inform public health standards. What sample size would be desirable for the proposed randomized trials and how many subjects should be included to obtain meaningful results?

I agree with comments made by Dr. Ann Harvey and Dr. John Balmes during the workshop. There are many sources of indoor pollutants (for example, environmental tobacco smoke) and allergens (for example, dust mites, pollen, pet dander, mold spores, cockroaches) that trigger asthma. The factors that influence asthma are many, and although replacement of a gas stove with an electric stove may

result in a reduction in NO_2 concentrations, it does not necessarily follow that changes in asthma symptoms will be seen. Because any small changes in NO_2 concentrations are unlikely to have a large impact on an asthmatic population, a large sample size will be required to distinguish what is likely to be a small signal (or a small effect) from background noise. (Generally, the smaller the effect, the larger the sample size that is needed to show a statistically significant effect, assuming there is a true difference between the treatment and control group).[1] Further, NO_2 concentrations are lower now than in the past because gas-fed pilot lights have been replaced with electronic ignitions, and gas stoves and ranges are more efficient. For example, Paulin et al. (2014) reported that average NO_2 concentration was 19.7 ppb (at baseline) and had decreased to 9.7 ppb on average 3 months after the intervention. It is not clear whether improvements with asthma will be seen with these small changes in absolute measurements at relatively low concentrations.

How large a sample size is required to answer the research question will depend in part on the actual comparisons to be made regarding the measured outcomes. There are a range of possible measurable outcomes for asthma, such as severity of asthma (using an asthma index), number of wheezing episodes, number of days with symptoms, use of rescue medication, and visits to emergency room. The GFO/Request for Proposal (RFP) should ask for the researchers to specify which health outcomes will be measured and to provide sample size calculations as part of the proposal / study protocol. As a rough estimate, I expect a sample size of one hundred may be able to show changes in pollutant concentrations; however, a much larger sample size (perhaps on the order of one thousand to several thousand) will be required to see changes in asthma symptoms from pre- to post-intervention and when the treatment group is compared to the control group (assuming there is an actual relationship between low concentrations of NO_2 and asthma severity). (Note: Belanger et al. (2013) included 1,342 children in a study of household NO_2 exposure and asthma severity that reported higher risks of asthma severity with increased NO_2 exposure).

Question 4: The proposed funding for this GFO is $1 million. Is this funding amount sufficient to support a meaningful study? If not, are there partnerships that could provide additional support?

Under the assumption that the research question is intended to evaluate the effects on asthma symptoms from changes in concentrations of NO_2 and $PM_{2.5}$, $1 million will not likely provide adequate funding for conducting such a study. As stated previously, a larger sample size will be required to evaluate what are likely to be small changes in asthma impacts in relation to changes in NO_2 and/or $PM_{2.5}$ concentrations, even if the changes in the pollutant concentrations are statistically significant. Beyond the cost of stove replacement, there will be significant personnel time for developing a study protocol, ensuring protection of human subjects in research studies, recruiting study participants, sampling for indoor pollutants (before and after interventions and perhaps seasonally), and measuring outcomes over a period of follow up sufficient to show improvements related to the intervention.

Potential partnerships that could help provide funding and/or in-kind contributions include air filter manufacturers, gas appliance manufacturers, or natural gas research and development programs.

[1] By convention, studies of human populations typically use a type I error rate of 5% (meaning no more than a 5% chance of detecting a difference between study groups when a difference does not actually exist) and statistical power of 80% (which in turn sets the risk of a type II error at 20%, meaning no more than 20% chance of failing to detect a difference when a difference actually exists).

Additional comments related to the forthcoming RFP

Currently, the GFO does not discuss how the proposed research will be used to evaluate the relative impacts on asthma from electric stoves compared to other interventions that may be less costly but show similar impacts on asthma. One of the research goals could be expanded, or a research goal added, that formally addresses the relative costs in addition to the relative health benefits of various options for improving indoor air quality (installation of air purifiers, gas stove ventilation/exhaust retrofits, induction stoves, electric coil stoves) and how these options potentially impact disadvantaged communities (for example, higher or lower bills from gas or electric, and how costs associated with improvements may be passed on to renters).

If the Appendix that was attached to the Staff Workshop Notice is used to form the basis of the rationale for the RFP, I suggest adding a reference to the global study of asthma in approximately 250,000 children conducted by Wong et al. (2013) that reported no association between gas cooking and asthma.[2] Wong et al. (2013) reported odds ratio (OR) for current symptoms of severe asthma below 1.0 (meaning no association between gas cooking and asthma). The OR was 0.97 (95% Confidence Interval (CI) 0.87–1.09) for children 6–7 years old and the OR was 0.97 (95% CI 0.89–1.07) for children 13-14 years old when compared to electric cooking only. For asthma (ever), the OR was 0.94 (95% CI 0.88–1.02) for children 6–7 years old and the OR was 0.99 (95% CI 0.93–1.05) for children 13-14 years old. These results provide further evidence that the proposed research is needed in order to resolve the apparent discrepancy between these results by Wong et al. (2013) and the results reported by Lin et al. (2013) that are currently cited in the Appendix. However, as the Appendix is currently written, it sounds as if there is a clear expectation that there will be an observable and significant improvement in asthma in relation to changes in pollutant concentrations from replacing gas stoves with electric stoves. If that were indeed the case, the proposed research would not be needed.

Finally, the CEC should consider convening a scientific advisory panel comprised of those with relevant scientific expertise to help them evaluate proposals and research designs. Individuals with relevant expertise and experience can be drawn from those with expertise in epidemiology, research sampling design, pulmonary medicine, exposure science, toxicology, data management, and statistical analysis.

I am happy to discuss any of these comments further with the CEC staff.

Yours sincerely,

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[2] Wong GWK, Brunekreef B, Ellwood P, Anderson HR, Asher MI, Crane J, Lai CKW, for the ISAAC Phase Three Study Group. 2013. Cooking fuels and prevalence of asthma: a global analysis of phase three of the International Study of Asthma and Allergies in Childhood (ISAAC). Lancet Respiratory Medicine, 1:386–394.