CALIFORNIA ENVIRONMENTAL CONTAMINANT BIOMONITORING PROGRAM

(BIOMONITORING CALIFORNIA)

SCIENTIFIC GUIDANCE PANEL MEETING

CONVENED VIA WEBINAR BY: OFFICE OF ENVIRONMENTAL HEALTH

HAZARD ASSESSMENT

CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY

STATE OF CALIFORNIA

THURSDAY, NOVEMBER 12, 2020

10:01 A.M.

JAMES F. PETERS, CSR
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APPEARANCES

PANEL MEMBERS:

Megan R. Schwarzman, MD, MPH, Chair

Carl Cranor, PhD, MSL

Oliver Fiehn, PhD

Eunha Hoh, PhD, MSES

Ulrike Luderer, MD, PhD

Thomas McKone, PhD

Penelope (Jenny) Quintana, PhD, MPH

Veena Singla, PhD

José R. Suárez, MD, PhD, MPH

OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT:

Lauren Zeise, PhD, Director

Carl DeNigris, JD, Senior Staff Counsel

Sara Hoover, MS, Chief, Safer Alternatives Assessment and Biomonitoring Section, Reproductive and Cancer Hazard Assessment Branch

Susan Hurley, MPH, Research Scientist II, Safer Alternatives Assessment and Biomonitoring Section, Reproductive and Cancer Hazard Assessment Branch

Stephanie Jarmul, MPH, Senior Environmental Scientist, Safer Alternatives Assessment and Biomonitoring Section, Reproductive and Cancer Hazard Assessment Branch

M. Elizabeth Marder, PhD, Senior Environmental Scientist, Cancer Toxicology and Epidemiology Section, Reproductive and Cancer Hazard Assessment Branch

APPEARANCES CONTINUED

OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT:

Julia Varshavsky, PhD, MPH, Research Scientist III, Safer Alternatives Assessment and Biomonitoring Section, Reproductive and Cancer Hazard Assessment Branch

Marley Zalay, MPH, Senior Environmental Scientist, Safer Alternatives Assessment and Biomonitoring Section, Reproductive and Cancer Hazard Assessment Branch

CALIFORNIA DEPARTMENT OF PUBLIC HEALTH:

Kathleen Attfield, ScD, Research Scientist III, Exposure Assessment Section, Environmental Health Investigations Branch

Jennifer Mann, PhD, Research Scientist IV, Exposure Assessment Section, Environmental Health Investigations Branch

Zhong-Min Wang, PhD, Research Scientist, Outdoor Air Quality Section, Environmental Health Laboratory

Nerissa Wu, PhD, Chief, Exposure Assessment Section, Environmental Health Investigations Branch

CALIFORNIA DEPARTMENT OF TOXIC SUBSTANCES CONTROL:

Topher Buck, Senior Environmental Scientist, Safer Consumer Products Branch

PRESENTERS:

Amanda Cosser, MPH, Biomonitoring New Hampshire Program, New Hampshire Public Health Laboratories

Rachel Long, MSPH, Michigan Department of Health and Human Services

Jessica Nelson, PhD, Minnesota Biomonitoring, Minnesota Department of Health

APPEARANCES CONTINUED

PRESENTERS:

Brian Wells, PhD, California Health Interview Survey(CHIS), University of California, Los Angeles, Center for Health Policy Research

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PROCEEDINGS

DIRECTOR ZEISE: Good morning, everyone. I would like to welcome the Panel and audience to this meeting of the Scientific Guidance Panel for the California Environmental Contaminant Biomonitoring Program, which we also call Biomonitoring California. So thank you all for participating and sharing your expertise.

The SGP last met on July 14, 2020. And I'll just give a brief recap. So, first the Program provided updates, the Panel discussed aspects of the California Regional Exposure Study and planning for the air pollution biomonitoring studies under AB 617, focusing on disadvantaged communities, which we'll hear more about later on today.

The remainder of the meeting was focused on non-targeted analysis, abbreviated NTA, and included presentations by the Program's laboratories and five distinguished guest speakers. The main goal of this session was to identify next steps for Biomonitoring California in the area of NTA. And some key recommendations for the Program were to:

Design an NTA pilot project in a specific population, such as a disadvantaged community, a refugee group, or another group relevant to California's unique population;

Apply NTA to examine the cumulative burden of chemicals and non-chemical stressors in heavily impacted communities to help inform policy decisions;

Use NTA proactively to identify emerging chemicals including regrettable substitutions and chemicals with no toxicity information;

And finally, ensure that we keep Biomonitoring California's main -- major priorities and participants' needs in mind when designing NTA projects.

So a summary of the input from July's meeting, along with the complete transcript is posted on the July SGP meeting page on biomonitoring.ca.gov.

So since we're meeting virtually today, I'd like to have the SGP members introduce themselves. I'll call on each member and if you could unmute yourself and say your name and affiliation, please. So starting with Carl Cranor.

PANEL MEMBER CRANOR: Carl Cranor, the University of California, Riverside. I'm in both the Department of Philosophy and I have a faculty appointment in environmental toxicology.

DIRECTOR ZEISE: Thank you, Carl.

Oliver Fiehn.

PANEL MEMBER FIEHN: My name is Oliver Fiehn at UC Davis. And I'm involved in the Genome Center

specifically for non-targeted chemical analyses.

DIRECTOR ZEISE: Okay. Thanks.

Eunha.

PANEL MEMBER HOH: I'm Eunha Hoh. I'm in School of Public Health in Division of Environmental Health in San Diego State University.

DIRECTOR ZEISE: Ulrike. Thank you.

PANEL MEMBER LUDERER: Hi. I'm Ulrike Luderer. I'm a professor in the Center for Occupational and Environmental Health at the University of California, Irvine.

DIRECTOR ZEISE: Thank you. Tom McKone.

PANEL MEMBER McKONE: Hi. Tom McKone. I'm a Professor Emeritus at the University of California, Berkeley and also retired from Lawrence Berkeley National Laboratory, where I remain as an affiliate.

DIRECTOR ZEISE: Thank you.

José.

PANEL MEMBER SUÁREZ: I am José Suárez. I am Associate Professor in Herbert Wertheim School of Public Health and Human Longevity and the University of California, San Diego.

DIRECTOR ZEISE: Thank you.

And, Veena.

PANEL MEMBER SINGLA: Good morning. Veena

Singla. I'm a Senior Scientist with the Natural Resources Defense Council based in San Francisco.

DIRECTOR ZEISE: Okay. Thank you.

And then, Meg.

I'm Meg Schwarzman

CHAIRPERSON SCHWARZMAN: Good morning. I'm Meg Schwarzman. I'm a physician and environmental health scientist in the School of Public Health at UC Berkeley.

DIRECTOR ZEISE: Okay. Well, thank you, and welcome, Panel and again appreciate you taking the time and sharing your expertise today.

And with that, I'll turn the meeting over to Meg, our meeting Chair, who will provide more details about the meeting and get us started. So thank you.

CHAIRPERSON SCHWARZMAN: Thanks so much, Lauren. And welcome to everybody and the Panelist -- Panelists, and the staff who have made this complex meeting format workable. I wanted to announce the goals for today's meeting. We are going to start by hearing an update about the planning for the AB 6-1-7, 617, biomonitoring studies and have a chance to provide input into that. The primary goal of that item about providing input to the AB 617 studies is to really weigh in with the -- with the Program on options for biomarkers of exposure and effect and also the proposed intervention study design.

The second goal -- the second thing we'll do is receive a general Program update and provide input in response to that.

We will then turn to the major topic of the meeting, which is to -- delving into the challenges involved in conducting biomonitoring surveillance studies in the state. So we'll hear an overview of the issues and presentations by guest speakers from UCLA and other states' biomonitoring programs in New Hampshire, Michigan, and Minnesota. And the main goal for the Panel will be to provide input to the Program -- to our State Program to form the design of our own statewide surveillance, all in the context of the current COVID-19 emergency and the resource limitations.

And the last two items of the day will be discussion of topics for the 2021 SGP meetings and an open public comment period.

So I want to briefly cover how we'll handle participation and discussion in this webinar format. So during the question periods that follow each talk, we ask that the speakers who presented remain unmuted with their webcams on, so that they can respond to questions from the Panel and from the audience.

If SGP Panel members want to speak or ask a question, you can just raise your hand physically, not

electronically, and I will call you at the appropriate time. Then you can unmute yourself and ask your question or provide your comment. Attendees of the webinar who have questions or comments during the question periods following each talk, you can submit them via the question feature of the GoToWebinar platform or by email, as the cover slide shows, at -- the address is biomonitor@oehha - O-E-H-H-A - .ca.gov. And keep your comments, if you wouldn't mind, focused on the item under discussion. And we will read your comments allowed, paraphrasing them as necessary.

During the open public comment periods, both in the morning and the afternoon, and the discussion session that occurs in the afternoon, webinar attendees are also invited to speak, not just provide written comments. If you wish to speak, please use the raised hand or question feature in GoToWebinar, the platform itself, and we'll call on you at the right moment.

So to start with our first agenda item, which is update on the AB 617 biomonitoring studies. I want to introduce Susan Hurley and Julia Varshavsky. Susan and Julia are both Research Scientists in the Safer Alternatives Assessment and Biomonitoring Section of the Office of Environmental Health Hazard Assessment. Susan and Julia will be providing an update on OEHHA's

activities under Assembly Bill 617.

(Thereupon a slide presentation.)

MS. HURLEY: Okay. So I hope everybody can hear me and see my screen. I will assume so unless I hear otherwise.

So thank you, Meg.

MS. ZALAY: Can you just --

MS. HURLEY: Yes.

MS. ZALAY: -- move that into slideshow.

MS. HURLEY: Oh, yes. Sorry.

MS. ZALAY: Okay. Thank you.

MS. HURLEY: There, is that better?

MS. ZALAY: Yes. Thanks.

MS. HURLEY: Okay. Thanks.

Okay. Thank you, Meg and good morning, everyone. Although Julia and I will be doing most of the talking today, this presentation really represents a team effort with contributions from Marley Zalay and others in the Biomonitoring Section here at OEHHA, all of whom are also here today.

So I'll be starting with some background and a summary of the literature on air pollution biomonitoring. And then I'll be handing it over to Julia, who will be talking about some of our ideas for potential study designs.

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MS. HURLEY: So I know some of you are very familiar with AB 617, but for those of you who aren't, here is just a little bit of background. It was passed in 2017 with the goal of reducing emissions of air pollutants in communities affected by a high cumulative exposure burden. In response, the California Air Resources Board created the Community Air Protection Program to fulfill the aims of the legislation. And so now, OEHHA, in collaboration with the University of California, is designing targeted biomonitoring studies in selected AB 617 communities. And the objectives of these studies are three-fold.

One is to complement and validate ongoing air monitoring. The second is to increase our understanding of exposures and potential health risks faced by the residents in these communities. And the last is to evaluate specific emission exposure reduction measures.

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MS. HURLEY: So there are currently 13 AB 617 communities throughout the state. The primary air pollutants of concern include the criteria air pollutants, PAHs, VOCs, metals and pesticides. A number of these communities have developed or are in the process of developing emission reduction plan -- plans that involve a

number of strategies. And I just want to call your attention to this last strategy, which is the installation of air filtration, because it's actually quite popular. It's being embraced by many AB 617 communities. And you'll be hearing a little bit more about this strategy later in the talk.

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MS. HURLEY: I'd also like to highlight the community air monitoring that's being done in AB 617 communities to characterize local sources of exposure. The locations of the local monitors have been chosen with input from community members to reflect their concerns about exposures.

So we're hoping to use these data to help identify an area for biomonitoring that has exceptionally high exposure levels. Also the pairing of the biomonitoring data that we collect with these hyperlocal air monitoring data should improve our ability to interpret our findings and also enhance the value of our study to the community.

So these data which will include measurements of PM2.5 and VOCs also provide really an exceptional opportunity to reduce exposure misclassification that often hampers the success of air pollution biomonitoring, as I'll discuss a little bit later in my talk.

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MS. HURLEY: I should also note up front that in designing our study, we're working with some practical constraints in terms of resources. Our current contract with UC is sufficient to conduct one targeted biomonitoring study. We've got some contract funds that can be redirected to UC labs for the biomarker analyses. And then, you know, as long as COVID-19 is with us, there are some practical constraints with respect to participant contact, which might affect our study design in terms of recruitment, and outreach, and sample collection, et cetera. So one consequence of these constraints is that we are limiting our focus to urinary biomarkers only.

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MS. HURLEY: So considering the con -- the practical constraints and also the exposure concerns across AB 617 communities, the options that we're considering for biomarkers of exposure include urinary hydroxy metabolites of PAHs and also stable metabolites of VOCs.

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MS. HURLEY: We also have been exploring a number of measures of biologic effect, including measures of mutagenicity and oxidative stress. Oxidative stress is of particular interest because of its central role in the

path of physiology of many of the cardiovascular and pulmonary health outcomes that have been linked to air pollution. There is evidence linking these measures of effect to both air pollution as well as health outcomes, such as cardiovascular disease, respiratory diseases like asthma, and metabolic disorders such as diabetes.

So this list is currently under development. We're continuing our research and evaluating the feasibility, such as laboratory capability and costs.

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MS. HURLEY: Now, there are some well-recognized challenges in biomonitoring for air pollution that really are both a function of the complexities in air pollution exposure assessment, and also the limitations of the urinary biomarkers themselves.

So probably first and foremost, the interpretation of PAH and VOC biomarkers is complicated by the fact that there are many different exposures; ambient air pollution isn't the only source. And for PAHs, for example, diet and smoking are considered the primary exposure sources outside of occupational settings.

Another important issue is the short biologic half-lives of these urinary biomarkers. This makes their measured levels particularly sensitive to acute exposures, so that -- you know, a study that relies on these

biomarkers must be really carefully designed to make sure that the sample collection is timed to capture the appropriate window of exposure.

And while this makes it more challenging to apply these biomarkers to evaluate long-term exposures, they are actually particularly well-suited for the evaluation of short-term changes in air pollution. The other thing that should be noted is that the substantial spatial and temporal variation in air pollution levels poses a further challenge. Season and meteorology are factors that can significantly affect local air pollutant levels. And for PAHs, they can affect the partitioning between gas and particle phases.

And it's also important to recognize that regional ambient measures of air pollution do not necessarily capture hyperlocal exposures that can be very high, can extend over a small -- and extend over a very small geographic area, maybe only even a block or two.

So the use of regional air monitoring data to assign individual exposures at a given time and for a specific location can be problematic and result in substantial misclassification of exposure. We're fortunate that the community air monitoring offered under AB 617 can help at least somewhat address this issue.

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MS. HURLEY: So despite these challenges, our review of the literature has found evidence for the successful use of urinary PAH and VOC biomarkers to characterize air pollution exposures. Specifically, there's a fairly large body of literature that demonstrates that urinary PAH and VOC biomarkers are correlated with ambient air levels of selected pollutants, including PAHs and particulate matter, such as PM2.5 and black carbon.

Correlations have also been shown with NO2. And there's also a fairly substantial body of literature linking these urinary biomarkers to GIS-based measures of traffic density.

Let's see. These biomarkers have also been used to characterize exposure profiles for given communities, so, for example, those heavily impacted by traffic or proximity to a known industrial emissions site. There's also an emerging literature demonstrating a link between some of these urinary PAH and VOC metabolites with the biomarkers of effect that I had previously mentioned. And perhaps the most convincing evidence for the viability of these biomarkers comes from studies aimed at detecting changes in exposure within individuals who have experienced a recent change in their air pollution exposure, so -- either due to an intervention study, or

travel to and from areas with high and low air pollution, or a measured pre- and post-shift in occupational studies.

So now what I'd like to do is just share a few examples to illustrate how these -- some successful approaches using a lot -- these -- these biomarkers.

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MS. HURLEY: So this first example demonstrates the use of urinary PAH metabolites to characterize changing air pollution exposures associated with travel between LA and Beijing. So what this study found was that while in Beijing, the participants had significantly elevated urinary levels of metabolites of pyrene, phenanthrene and fluorene. These differences corresponded to PM2.5 levels that in the LA area where about one-fifth of those measured in Beijing during the study period.

And it's also important to note that this study was conducted only among non-smokers and they required an 8-hour fast prior to urine collection to try to account or remove some of the influence of diet.

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MS. HURLEY: This next study, this is another example of the use of biomarkers to capture short-term changes in air pollution exposures within individuals.

So it measured 1-OHP, a metabolite of pyrene, in traffic policemen before the start of their work week and

then again six days later at the end of their work week. And what they found was that 1-OHP, a metabolite of pyrene, was nearly doubled after several consecutive days of work. They also found that levels of urinary mutagenic activity, as well as oxidative stress also increased during the same time period.

And note again that they prescribed a low-PAH diet to try to limit the influence of diet and was all -- it was conducted among non-smokers.

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MS. HURLEY: So, this example, I include as an illustration of the use of urinary PAH and VOC metabolites to evaluate the effectiveness of an intervention. So in this case, the intervention was a replacement of a wood cooking stove with a cleaner burning stove. This was among Guatemalan women.

And what they found was significant declines in metabolites of several PAH and VOC metabolites. And these declines corres -- or coincided with a 56 percent decline in -- in PM2.5 levels in the air. And then not shown in this table, the study also reported significant correlations between the air measurements of PM2.5 and all of the PAH metabolites and some of the VOC metabolites.

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MS. HURLEY: And then this next study, I've

included as a demonstration of the effectiveness or the ability for PAH metabolites to be linked to ambient air exposures, even in situations when air exposures are quite low. So this study was conducted in the Atlanta region among CDC employees. And this table here summarizes the correlations between PAH air exposures and PAH metabolites. And as you can see, the correlation coefficients are quite high, especially for naphthalene, you know, they're approaching 0.9, and another interesting findng in the study s that, although slightly attenuated, they still saw significant correlations, especially again for naphthalene, even when the participants were following a higher PAH diet.

Now a key aspect of this study was -- that probably led to its success was the modeling they did to more accurately estimate exposures -- air exposures by combining personal air monitoring measurements with time activity data to compute a total amount of PAHs inhaled over the previous 24-hour period.

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MS. HURLEY: So, in summary, there clearly are some well-recognized challenges to air pollution biomonitoring, but they're not insurmountable. We do think there is a way to design around them. We believe an intervention study is the best approach. From our

research an intervention that results in exposure reductions of about 50 percent or so should be sufficient to be detectable with our proposed panel of urinary biomarkers. Accounting for smoking and dietary sources of exposure is critical, as well as other exposures.

Ideally, air biomonitoring would be conducted at a time and in a place with high ambient exposures, so the signal doesn't get completely drowned out by these, you know, exposures from these other sources.

Let's see. Given that there's no perfect biomarker, you know, there's no silver bullet, it makes sense to measure a panel of biomarkers. And then, you know, collecting spatially and temporally appropriate measures of air pollution is really important to be able to link the biomarkers to air exposures.

So, in particular, being especially careful to design the timing of specimen and data collection that's appropriate to the short half-lives of our proposed urinary biomarkers.

So with that, I will now like to hand this off to Julia who will talk about study design options.

PANEL MEMBER FIEHN: We can't hear you.

MS. ZALAY: You might be muted, Julia.

No, we still can't hear you.

DR. VARSHAVSKY: Oh, no.

MS. HOOVER: Oh, I think we

MS. ZALAY: Now --

MS. HOOVER: I just heard you say oh, no, so --

(Laughter.)

MS. HOOVER: Oops, no. No. You went off again.

Maybe can you try it, yeah, without your headphones just try straight into the computer perhaps.

DR. VARSHAVSKY: Can you hear now?

MS. HOOVER: Yes.

DR. VARSHAVSKY: Okay. For some reason my headphones aren't working. I apologize. They do not usually do that. So let me just make sure I can -- we transfer power of the PowerPoint here. And, let's see here. Okay. Let me know if you can see my screen.

Can you hear me?

MS. ZALAY: We were looking at your desktop, but no actually, we don't see that desktop anymore.

DR. VARSHAVSKY: Okay. Can you see it now.

MS. ZALAY: Okay. Now, we can. Yes.

DR. VARSHAVSKY: Okay. Great. Sorry about this.

Okay. Here we go. So that should be good, I think.

MS. ZALAY: Yeah, and we see it in presenter mode.

DR. VARSHAVSKY: Okay.

MS. HOOVER: I'm wondering if we should have someone else present the slides for you.

DR. VARSHAVSKY: Okay. How is this?

MS. HOOVER: There you go. All right.

DR. VARSHAVSKY: Okay.

MS. HOOVER: Go for it.

DR. VARSHAVSKY: All right. So let me just move the GoToWebinar stuff here and make sure I've got what I need here.

Okay. I'm going to go. So thank you so much, Susan. And so as she nicely described, I just want to start by saying that given what we've learned from literature so far, we do realize that we really need to take a multi-pronged approach to our biomonitoring study design.

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DR. VARSHAVSKY: So what we're proposing is to design a study that would -- that using the PAH and VOC metabolites that we can measure in urine, which, as you recall, have short biological half-lives on the order of hours to days, to help us assess the effectiveness of air filtration in elder care facilities and schools that are located in highly exposed communities, which again is one of the major exposure reduction strategies that's moving forward under AB 617. And it also really lends itself

well to a targeted biomonitoring study design approach.

So what -- to do this, we would basically collect at least two samples per person, before and after installation of air filtration or exposure to filtered air. And we would aim to analyze those urine samples not only for the exposure biomarkers of interest, but also for urinary biomarkers of effect, including some of those most commonly measured -- commonly used measures of oxidative stress that Susan mentioned, as well as the mutagenicity assay.

And, you know, as you heard from some of the examples that Susan presented, this pairing of exposure and effect biomarkers is an effective approach that's been used in prior studies, to -- to ultimately enhance the ability to detect potential changes and exposure reductions. And then also by including these urinary biomarkers of effect, we can also potentially gain insight into health outcomes of interest.

So I'll also say that another key element of our approach is pairing biomonitoring measurements with air measurements. And that will sort of allow us to further enhance our ability to detect potential changes in pollution -- or in exposure by measuring key pollutants in the air. And that's really critical for interpreting our biomonitoring data in the context of multiple ambient and

non-ambient sources like diet and smoking.

And further, we would like to take both indoor and outdoor air measurements, so that we can kind of further delineate ambient from non-ambient sources. And then we also plan to distinguish sources even further by pairing this array of biomonitoring and air data with extensive questionnaire data on diet, smoking and cooking-related behaviors, as well as an activity diary that would capture additional factors like how much time was spent indoors versus outdoors the prior day and whether or not windows were shut.

And then I also just wanted to note that we're -- we're going to aim to recruit non-smokers, but we're also going to be taking additional measurements of biomarkers like cotinine and others of passive smoking exposure, so that we can even further assess the influence of exposures to secondhand smoke and -- on our -- on our exposure biomarkers of interest.

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DR. VARSHAVSKY: Now, regarding the intervention itself, most air filtration systems predominantly filter out particulate matter, while some can also capture VOCs. So we're going to be exploring opportunities to install both particle and VOC air filtration. And as you may recall, one of the most important elements of air

pollution biomonitoring is really having this sufficiently large exposure differential that you can measure. And although there's not a lot of data on this, it appears from our research to date that indoor air filtration should provide reductions in particulate matter that are sufficient to be detectible by our exposure biomarkers -- by our proposed exposure biomarkers.

So we think, you know, ultimately this intervention study holds a lot of promise.

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DR. VARSHAVSKY: And this is an illustration of our proposed design in an elder care facility where the study population would consist of both residents and staff at the facility. And we think this can also be applied to children and staff at schools as well. But the overarching picture here is that we would be -- we would be enrolling both staff and residents at an elder care facility and taking -- collecting samples during winter months when we would expect people -- peak pollution in the air, also more windows to be closed so that we could kind of better isolate that -- the effect or the intervention of interest, which is air filtration.

And for the residents who live at the facility, we would plan to collect pre- and post-intervention samples or samples before and after the installation of

air filtration, which would likely mean taking samples -- spot urine samples at the same time of day at each assessment. So, for example, the first morning void to reduce the potential influence of diet.

For staff, we would be aiming to assess cross-shift changes in exposure to the filtered air, since staff don't live at the facility. And we would then plan to take pre-shift a post-shift samples so that we could kind of measure the effect of the intervention across the work shift or the workweek. And both of these study populations have key advantages, which is to say that we're not going to be comparing them directly, but sampling both residents and staff provides different information that is -- that are both valuable.

One key advantage of sampling residents is that we might be able to control better for diet, because some facilities may have very standard meal plans, for example. And, you know, elderly residents may have a little bit more limited mobility, which might -- or which -- which means they might have more consistent exposure to the filtered air indoors.

On the other hand, the short half-life biomarkers that we're measuring really lend themselves well to the short-term cross-shift changes that we're -- that we would be evaluating with staff.

So -- and that's because exposure biomarkers with short-term half-lives kind of reflect what you've been exposed to in the last day or several days.

So samples collected before and after installation of air filtration might be capturing more than the air filtration exposure reductions of interest, because there's likely to be a longer time period between sample collection.

Another key advantage of including staff is that we would capture different demographics than -- than residents who can afford full-time care at the facility within the community.

But regardless, there is a really large range of variability in elder care facilities. And we know we're going to have to consider that variability as we design our study around a specific location and a specific study population.

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DR. VARSHAVSKY: And I know I've mentioned it, but I just want to reemphasize the importance and that -- a critical component of this study is the pairing of biomonitoring data with air data. So we pan to complement our biomarker measurements with air measurements in ideally capturing both particle and gas phase PAHs and VOCs in both the local indoor and outdoor environments of

our facility. And then pairing those with other air pollutant measurements at the community and/or regional levels.

We're also planning to work with the Environmental Health Lab at CDPH to do an ultrafine particle analysis, which uses microscopy to distinguish sources based on particle composition at the molecular level.

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DR. VARSHAVSKY: We are also interested in applying a non-targeted screening approach to VOCs, which is basically -- basically means applying an analytical method that can more broadly screen for VOCs in air. And we're exploring the possibility of measuring unmetabolized parent PAHs in urine, which would kind of expand our -- the universe of PAHs that we can measure and understand with regard to their -- the importance of their exposures in AB 617 communities.

And if we decided to pursue that, we would have to propose an expanded set of PAHs for the SB -- SGP's consideration as designated chemicals in 2021. The last thing I want to mention is that we're also hoping to apply diagnostic ratios to PAHs, which are basically a way of looking at levels of PAHs and the ratios between them to further distinguish specific sources.

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DR. VARSHAVSKY: So, in summary, the keys to our success we think for this intervention study are first selecting the selection of an appropriate intervention that will result in a sufficiently large measurable change in exposure. And that is also appropriate for these short half-life exposure biomarkers that would further help minimize interindividual variability in the metabolism of PAHs and VOCs and would sort of help control for unmeasured confounding.

Another key element is using an exposure assessment method that ideally captures again both gas phase and particle bound air pollutants, but also makes sure to measure them at an appropriate time and place, and then pairs that - those air measurements with -- with exposure and effect biomarkers. And again those collectively can increase our chance of being able to see something of value for the community. We're also doing everything we can to control for and adjust for diet and smoking.

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DR. VARSHAVSKY: And then I just want to say that in addition to our air filtration study -- intervention study, we'll be exploring collaborative opportunities to build on existing cross-sectional and longitudinal

studies, so that we can leverage other ongoing studies and potentially biobank urine samples for future use, so that would allow us to potentially compare exposure profiles within or across AB 617 communities and potentially over time, and could also provide an opportunity to examine their associations with biomarkers of effect and associated health outcomes, like asthma and lung inflammation.

So we do think there are a lot of ways that -- potential ways that biomonitoring can contribute to AB 617 efforts going forward.

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DR. VARSHAVSKY: In terms the of next steps, we'll need to identify a facility for the intervention study. We'll be evaluating the possibility of air filtration measures that are already ongoing or underway or being implemented under AB 617 to try to build on those efforts.

But if not, we would be looking to install air filtration under our own current capabilities or by working with a facility to apply for grant funding to do so.

And regardless, or either way, the most important point here is that we need to select our location wisely to really capture that hyperlocal high exposure that is

relevant for the most vulnerable members of our AB 617 community.

And we'll be continuing, of course, to further our research on biomarkers of exposure and effect. And we'll continue working with our UC and CDPH collaborators on the selection of a specific location, and, you know, the securing of funding for additional complementary measurements in air and so forth.

We'll continue to engage with community members and CARB, you know, as we pin down the specific study design and location. And then we'll also be continuing these conversations about leveraging resources for other collaborative opportunities.

So I just want to end by saying that we are really still in the planning phases of this study. We really appreciate the opportunity to solicit the feedback today from the SGP and the expertise from the SGP. And we're really looking forward to the questions and discussion period, because we're hoping that we can kind of collectively help us get from where we are so far to where we need to be.

So thank you so much for your time. And I also want to just acknowledge our collaborating institutions. And then I think we can turn it over to questions and discussion at this point.

CHAIRPERSON SCHWARZMAN: Thank you. Yes. Exactly. Thank you so much both Julia and Susan for these presentations. It's such an exciting study to hear about and potential program to develop.

So, we have 10 minutes now for clarifying questions from the Panel for either Susan or Julia from their presentations.

So, Oliver. I see Oliver's hand.

PANEL MEMBER FIEHN: Thank you. It was very interesting. Julia, I wondered why you have not considered the most important and drastic exposure to PAHs that is through wildfires? You know, like wildfires don't go away. This is not a one-time event through climate change. We have seen it this summer, weeks, and weeks, and weeks for almost all of California was blanketed in PAHs, including indoors. Many people purchased filter systems, but obviously not everybody can purchase filter systems.

And I -- I disagree with the notion that now -- nowadays would have the highest exposures in winter. Could you comment on that?

DR. VARSHAVSKY: Yeah. That's actually a really great point. So I think that one thing we've concluded is that wildfires we are going to have to grapple with. And we're kind of thinking about ways that they can impact our

study design. And things like the timing of sample collection and winter versus not winter are important considerations in doing that, but they are things that we can -- we can try to design around somewhat.

I will say that I know -- I know that, you know -- I know that wildfires aren't necessarily an emission that AB 617 is trying to target. But regardless of -- if we didn't care about that, I think that focusing on the air filtration itself as an exposure reduction strategy still helps -- still helps answer the question of whether that's an effective exposure reduction strategy regardless of the emissions source.

So that's something I've -- we've been grappling with is how much do we need -- like, you know, just because wildfires aren't an emissions source that AB 617 is trying to target, that doesn't mean necessarily that focusing on an exposure reduction strategy like air filtration -- shouldn't also be trying to capture that emission source or that exposure from that emission source.

So while I think it's a really important point that it can affect our -- the timing of our study, and, you know, we can think about sampling on days when there aren't wildfires abounding, I also think that focusing on the air filtration as an exposure mitigation strategy can

still help -- we can still help have relevance for AB 617, regardless of the wildfire factor, If that -- if that makes sense. I know I'm not being very articulate, but I don't know if anyone else wants to --

MS. HOOVER: I think that was good Julia. Let's --

CHAIRPERSON SCHWARZMAN: Go ahead.

MS. HOOVER: Sorry. Go ahead.

CHAIRPERSON SCHWARZMAN: I just want to propose that we put this as a topic. We're going to have a chance to have more discussion around this item. So I appreciate Oliver raising the question and let's flag it as a topic for further discussion later and get the rest of our clarifying questions in.

Tom had a question.

PANEL MEMBER McKONE: You have to unmute.

Julia and Susan, thank you very much. It's a really interesting program. I guess -- and this is -- I just want to bring it up now, but it will probably focus maybe in our discussions later, and that is it's -- when I look at your community map, you have -- you've set up sensors for measuring a number of pollutants. And I just wonder, in the communities that you identified, there are many -- they're very well covered by the sort of the personal -- the inexpensive personal or, you know,

sensors, you know, that you could provide -- I don't want to mention brand names because, we're like on the air so to speak. But there -- there are two companies that have good coverage that sell, you know, the $200 PM2.5 monitors.

And, you know, I have one indoors and outdoors, and I learn a lot just -- you know, it's -- and there are publications about the accuracy. Lawrence Berkeley Lab has studied them. You know, they're not going to be as accurate but they're really good for trends and they're really an excellent way of sort of ground-truthing or providing adjunct data to a small number, because you have so many of them.

I mean, in the cities you're talking about, there probably are 30, 40, 50 -- I mean, in this area around Richmond, there's many, many more as I look at.

So it's just a thought of could you enhance some of the information you get, both indoors and outdoors, and you just take advantage of all the existing low-cost sensors that people are buying?

MS. HURLEY: Yeah, we haven't actually specifically discussed that, but that's a great idea.

CHAIRPERSON SCHWARZMAN: Other clarifying questions. We have a couple more minutes allotted for Panel questions and then we'll go to public comment?

Ulrike and then I have José after.

PANEL MEMBER LUDERER: I was having a little bit of trouble unmuting there, but I was -- did it. Thank you.

Thank you for that presentation. And I think it's a very exciting study that you're proposing. One question I had is just a quick question about the urinary mutagenicity assay, is that variation of the of Ames assay that you're planning to use or what assay are you proposing to use there?

MS. HURLEY: Yes, it is -- well, it is some version of the Ames assay. Although, we're not -- we're still really just investigating that. We, you know, fairly recently came across a study that used that and linked it to -- I can't remember what it was. It -- I think it was in -- was it a policeman's study, but --

DR. VARSHAVSKY: It was a cook stove -- cook stove study.

MS. HURLEY: Oh, it was cook -- but so we've -- so, yeah, so we're still evaluating the feasibility of that and trying to figure out there may be several different ones that may -- may be better or worse. So if you know anything about that, we would love to pick your brain.

(Laughter.)

PANEL MEMBER LUDERER: Well, one other thought is if you're specifically interested in PAHs, I think there have been some studies that have looked at PAH DNA adducts in uroepithelial cells collected from urine samples. So that might be a possibility to -- you know, that looks at adducts for some of the chemicals that you're specifically interested in.

MS. HURLEY: Okay. Great.

CHAIRPERSON SCHWARZMAN: José had a question.

PANEL MEMBER SUÁREZ: Yeah. Hi. Very interesting presentations. And I think it's very interesting to start looking at interventions as well. So that was fantastic. I had some questions about the proposed study design. So it's primarily aimed at pre-post-intervention comparisons. Have you considered actually including a control group? So in interventions, control groups become very essential, those that are not receiving the intervention. Even though you may be comparing pre- and post-, typically in clinical trials what we try to do is actually also have this other control group, just because even pre-, post-intervention there may be other factors that could be influencing the levels of the PAHs.

So I see that there are two proposed groups, one would be with residents looking at air filtration

installation and the other one with staff. And then they would be assessed it seems like in the morning before going into the exposure -- to the filtered air exposures and then again after the shift, which means that I suppose in that particular scenario, you might be considering different PAHs as the latter approach, probably the VOCs that you'd want to focus or --

MS. HOOVER: José. José, this is Sara. Julia just put up a bonus slide in which -- because she has thought of such a thing as a control group, so she could just provide input on that real quickly or we could hold it for the discussion, since we're just about at public comment. But you can wrap-up your question, but I just wanted to point out --

PANEL MEMBER SUÁREZ: Right. Okay.

MS. HOOVER: -- to you that the slide changed.

PANEL MEMBER SUÁREZ: Fantastic. Yeah, it will be great to get that.

So the only point that I was trying to make is that with the point of the residents versus staff, you might be focusing on those chemicals that have the shortest half-lives, when it comes to assessing pre- and post-shifts, which would be, I suppose, a slightly different question with pre- and post-air filtration installation, right? So what are your thoughts.

DR. VARSHAVSKY: Right. Great points. I think -- so sampling residents and staff is different. I think you were -- you were just saying this, because residents you kind of have to think about before and after installation. Since they live at the facility, they're not going to be -- you're not going to be able to assess a short-term like you would for staff. So there are slightly different study designs.

But I think I -- I put up this slide just to get to your question about a comparison group or, you know, a control group. Ideally, we've thought about adding a comparison group, as resources may allow, to compare, for example, residents who live at a facility, that has received installation of air filtration compared to say residents at a facility in the same community, who -- in which air filtration hasn't yet been installed. And you could kind of compare -- or take the assessments at the same time of day for each group, the residents that live at a facility with air filtration and residents who haven't yet gotten it.

The problem with this is the comparison groups wouldn't be great. They wouldn't be perfect, because you're really comparing residents at two different facilities, so you'd really -- we'd really -- in order to implement this in an effective way, we'd have to really

make sure that our comparison group is as similar as possible to the residents who do receive the intervention.

And the, you know, ideal way to do this would be to have residents and control -- or residents at multiple facilities that you could randomly assign to the -- to the group -- the intervention group receiving the air filtration installation and to the control or comparison group. And we likely won't be able to do that realistically. Realistically, we'll be comparing residents at one facility to another. And so we could try to minimize the differences between the groups, but -- but ultimately, it would never be a perfect comparison. So, you know, that's why we didn't present this as kind of the main element of the study, but we certainly would like to add a comparison group, if we could.

CHAIRPERSON SCHWARZMAN: Thank you for taking that on.

What I'm going to suggest is that I'm keeping a list of items to return to for the discussion later. Thank you to both Julia and Susan for your presentations. It's an exciting project. And I want to turn to public comment for a moment. And we have -- following that, we have a full discussion session. So we'll return to these in a minute.

We have 10 minutes allotted for public comment.

And I want to remind attendees how to submit comments. You can submit them via the GoToWebinar question feature or by email to biomonitoring@oehha.ca.gov.

And I want to find out from Marley and from Stephanie if there are any comments we should at this point?

MS. ZALAY: Thanks, Meg. There are no questions coming in through GoToWebinar about this topic.

Thank you.

CHAIRPERSON SCHWARZMAN: And is -- are you monitoring the email too or is that Stephanie?

MS. JARMUL: Yeah. No comments have come in through the email either as of yet.

CHAIRPERSON SCHWARZMAN: Why don't we actually give it a minute in case folks were -- haven't submitted them until we gave -- provided the prompt. And then since our next topic is -- and we have 20 minutes for discussion of this study and input into the design, we'll turn back to that in just a minute, but I want to make sure we have the chance to capture any public comment that hasn't --

MS. ZALAY: There is one hand raised. And is now a good time for that, Meg?

CHAIRPERSON SCHWARZMAN: Sure. That's a

MS. ZALAY: Okay. I'm going to unmute -- your last name is Wang from CDPH. I see that you raised your

hand. So now you're self-muted. So attendees that would like to speak in the meeting -- okay. So now you -- you can unmute yourself and go ahead and share your comment.

DR. WANG: Yeah. This is Zhong-Min Wang from CDPH EHLB. My question is that for the household filter generally they do not filter out the PM2.5, PM10. Then what is this filter is going to be for? Normally, it's only filtered for large particles and does not filter VOCs, PM2.5, PM10. Then how do you want to compare? So what kind of a component are you going to compare?

MS. HOOVER: I'm going to -- this is Sara Hoover. I'm just going to chime in and maybe Marley could address it. Actually, the filters we're talking about are -- do filter to that level. Marley, do you want to comment more about the technical details of that?

MS. ZALAY: Sure. And there's -- yeah, so there's a lot of different school -- school filtration systems that are being designed, based on feasibility within different -- you know, existing HVAC systems. There's also stand-alone filtration units that can be used. And so there's a variety of different types of filtration out there. And we will be trying to pair our study around filtration that will be measuring out fine particulate matter and possibly VOCs, if -- if that is something that will be biomonitored as well.

DR. WANG: So practically, I don't think that will be easy, because if you really wanted to do that, then you have to use a HEPA Filter or really high efficiency filter, then most of the facility may not be able to do that, because the -- you know, the resistance will increase dramatically then you have to change the whole thing. So I don't know, have you considered about that?

MS. HOOVER: So this is Sara Hoover again. So thanks for the input and we'll write that down and look into it. Just to clarify, we haven't gotten to that part of the design. We are -- Marley has been in touch with -- and we're working closely with CARB. These are definitely issues that we'll consider. And we're actually -- for an elder care facility, we're really thinking about helping fund installation of appropriate filtration, including VOC filtration, which is not necessarily part of the plan in some of the CERP strategies for AB 617.

But let's move on to another question, if there is one.

DR. WANG: Yeah. So I have another question. For the --

MS. HOOVER: No. No. We need to go to somebody else. So you can email your question to the Biomonitoring California email and we will track that for later.

DR. WANG: Okay.

MS. HOOVER: So we need to move on.

MS. ZALAY: There's a question from Jessica Nelson. Are you considering biomonitoring for pesticides, which was one of the pollutants mentioned initially?

MS. HOOVER: So I -- this is Sara Hoover again. And I'll just chime in and answer that. So pesticides -- so we actually did a big sweep of all the different possibilities across the communities -- the AB 617 communities, pesticides are of concern in certain communities. I will mention, which I mentioned I think in the last meeting, that our original funding for these studies has been cut. We originally had planned to do three targeted biomonitoring studies. At the moment, we only have funding for one. So what you heard today is what we're going to be focusing on in the first study, but we definitely are aware of and are interested in potentially looking at pesticides in relevant regions.

And then I think Marley, did you want to just acknowledge I think we got another comment that we just want to acknowledge that we received and we'll -- but it's not related to this topic. Did you want to explain that?

MS. ZALAY: Do you want me to read it?

MS. HOOVER: No, just to say who it's from and we acknowledge.

MS. ZALAY: I commented to Dr. Ahimsa Sumchai's comment privately.

MS. HOOVER: Okay. Well, you can say it to the meeting. We received a comment that's not directly relevant to this topic, but we're just acknowledging that we received it and just to put it on the record that we got a comment from Dr. Sumchai and we're taking note of that.

CHAIRPERSON SCHWARZMAN: If there's no further comments that we should acknowledge, just get confirmation from that -- about that from Marley, Stephanie, Sara.

MS. ZALAY: Yes. There's no further comments at this time.

CHAIRPERSON SCHWARZMAN: Okay. In that case, I want to open the Panel discussion and input session and invite all topics for discussion about this study and about the presentations that we just heard from Julia and Susan, and note that there were two topics that we sort of shelved further discussion on. One was this issue of developing or using a control group and the other was understanding this -- these studies in the context of wildfires and/or targeting wildfire smoke exposure.

And if I could jump in on that topic with sort of a reflection and a question. My understanding -- if I understood you right, I don't remember whether this was

primarily in Julia's or Susan's presentation about aiming to hold the study during the winter when windows were more likely to be closed to sort of isolate the -- like, there's monitoring happening in indoors and monitoring happening outdoors and you want to understand the difference to see the effect of the air filtration.

It seems to me like that would actually be really useful and that in terms of, you know, we know that wildfire smoke exposures is an enormous problem in this state, but it -- I almost worry that it -- it has -- we run the risk of ignoring all the hyperlocal sources that increase exposure to disadvantaged communities, if we only think about the sort of overwhelming problem of wildfire smoke. And in non-wildfire seasons, year-round, day-in day-out, if they're exposed to local sources of pollution that other people are not exposed to and other communities are not exposed to. If we sort of open up this intervention study to wildfire smoke in a way partly by timing and by the study design, I worry that we're actually not accomplishing the goal of the AB 617 studies.

And so I just wanted to explore that idea, acknowledging Oliver's point that there's a massive problem of air pollution and particulate exposure from wildfire smoke, but see if there was more that you wanted to reflect on about kind of the specific goals of this

study in the context of exposures under AB 617.

DR. VARSHAVSKY: Was that a question for us?

CHAIRPERSON SCHWARZMAN: Just, I mean, my -- my reflection or my comment is that I think it's really important. You know, there's sort of a historical approach that can sometimes happen when talking about all kinds of exposures to sort of dismiss one type of exposure because it might be not the worst or the largest. And while I completely hear the relevance of wildfire smoke exposure and its enormous public health issue to many people in both historically disadvantaged and non-historically disadvantaged communities, as I understand it, the goal of this -- of studies conducted under AB 617 is really specifically to get at what are the -- are there elevated exposures and can we characterize, and understand, and intervene in those sources that are primarily affecting these communities that have been disproportionately affected by industrial sources, by transportation, by, you know, transportation hubs, by proximity to road traffic of all kinds and that we risk kind of missing that, which is a significant factor in addition to wildfire smoke exposure for many communities.

And so that was sort of my take on that, but I also am inviting any other reflection from Julia or Susan

about that topic.

DR. VARSHAVSKY: Yeah. I think that was really well said. I -- I think it's -- I -- what I should clarify is it is true that our mandate under AB 617 is really to assess the effectiveness of the exposure mitigation strategies that are being implemented under AB 617, which includes the air filtration and other strategies that Susan presented. So -- but at the same time, I also hate to discount the importance of this overwhelming other -- and emerging -- or already emerged emissions source that, you know, is the wildfire factor.

So we are -- we are -- we are focused on assessing the mitigation strategy itself, but there is this sort of overwhelming emission from wildfires that we are going to have to consider in how we design around or including that factor.

So, yeah, that -- I'll stop there and just see if anyone else on our team wants to add to that, but I think that point is really, really well taken.

MS. HURLEY: Well, I'll just add to that. I kind of -- I agree with what both Megan and Julia said, and I -- maybe just add to it that I think there are probably better ways of looking at the health effects of wildfire and the exposures associated with them than this -- you know, what we're proposing here. And, you know, I -- I

just -- I don't think it -- I'll just reiterate that I don't think it -- the wildfire issue necessarily fits well with the mandate of AB 617 for these biomonitoring studies.

PANEL MEMBER LUDERER: Meg, I think you might be muted, but I did have a comment

CHAIRPERSON SCHWARZMAN: Malfunction at the wrong moment, but I was trying to call on you.

PANEL MEMBER LUDERER: It's just a practical consideration as well, that in terms of planning a study like this where you want to have a pre- and post-intervention, you know, with the wildfires, it's so unpredictable that, you know, I think that would make planning a study much more complicated. And it's already going to be quite, you know, an involved and complicated study. So it's just a practical consideration.

DR. VARSHAVSKY: And, you know, speaking practically, we were thinking that we were going to have to make sure to sample on days where there was no rain, because that can change -- that can affect, for example, PAHs in the air and no wildfires. You know, that's not addressing the question around season so much, but it's addressing sort of the practicality of what days we would be trying to sample on.

CHAIRPERSON SCHWARZMAN: If there's other

comments from the Panel on this topic about the influence of wildfires and how to work around that or with it, we can do that now, and we're also -- I'd also welcome comments on any other topic related to these AB 617 studies.

Ulrike.

PANEL MEMBER LUDERER: Yeah. This is not related to wildfires, but I wanted to get back -- we had a little bit of discussion earlier about the -- the different types of exposures that the -- the intervention study is going to capture in the residents kind of versus the pre- and post-shift model for the staff. And I think there -- with the staff, the things that -- you know, that there needs to be consideration of is that the pre-shift sample is going to be reflecting their exposures during the prior 24 hours. They may live in an entirely different community with different air pollution levels. They likely are commuting to this job, and commuting is often a time during which there may be significant exposures to air pollution. So it may be relatively difficult to observe pre- and post-shift changes in your pollutants of interest, because of the -- in the staff, I think.

DR. VARSHAVSKY: Great point. And that, -- you know, those kinds of details are going to become more clearly -- it will become more clear whether or not that's

manageable. I think when we select a specific location and identify the specific study population, we'll find out, you know, when we select our location, how -- do the staff actually live within the community or not. That will be -- that will be kind of a big factor in how they are commuting, et cetera, whether or not they eat the same food as the residents. You know, there's a lot of factors there that we're going to have to consider, but those -- that's exactly right.

And so one of our strategies was going to be, you know, maybe we can take first morning -- first morning void samples of staff on Monday morning, you know, before they even -- of before they eat breakfast, but maybe even before they make their commute. And that's not necessarily going to be realistic strategy. So those kinds of things are definitely difficult details we're going to need to work out.

Thank you.

CHAIRPERSON SCHWARZMAN: I have José and then Eunha.

PANEL MEMBER SUÁREZ: Just to follow up on that question. I mean, the way to disentangle that by -- is by adding a control group. With a control group, you can easily see the change and compare the change differences within -- within that, and hence coming back to the

importance of pretty much always trying to include a control group when testing interventions.

MS. HURLEY: So I would just say that I agree that's the -- that ideally is the whole purpose of having a control group, but it is going to be really tricky to figure out how to identify an appropriate control group, because I mean just, for instance, the commuting issue. You know, if they're in a different community -- we really don't know exactly what our options are for facilities, if -- can we do more than one faciity? Are there two facilities close to each other?

So we really -- you know, and we're sort of weighing -- we're definitely still compare -- considering that comparison group, but we also have to weigh -- you know, we only have limited resources and, you know, one of the issues that we want to be able to address is the high degree of intra-individual variability. And ideally, it would be good to have a few different samples for each participant under the various, you know, exposure scenarios, but -- so we really need to -- we need -- we're exploring all these options. And I'm -- my biggest concern about the comparison group is whether or not we can really come up with a good one. I think if we can, that would be fantastic, because it would help address some of these issues.

PANEL MEMBER SUÁREZ: Yeah, I mean -- I mean, for selection of the comparison group, I mean, you can still use a screening -- all the different PAHs that you would be measuring. I guess, my -- I mean, we haven't talked a lot about the design of this, but my --

MS. HURLEY: Yeah.

PANEL MEMBER SUÁREZ: -- question is you mentioned resources. So roughly, how big of a study can you afford to do, first of all?

DR. VARSHAVSKY: Good question. I don't know, Sara, do you want me to answer that with our --

MS. HOOVER: Yeah. Please do. You can give the --

DR. VARSHAVSKY: Okay.

MS. HOOVER: We have done some preliminary, you know, research.

DR. VARSHAVSKY: We have done some preliminary power calculations. So we have assumed a 50 percent or lower reduction in particulate matter in air pollution, as reported in prior studies. You know, we saw at least like -- or something like 50 to 90 percent reductions in air pollution measurements, based on air filtration. And so assuming 50 percent or less to be a little more conservative, we've estimated that a sample size of fifty to a hundred would give us more than enough power actually

to detect potential differences within each group. And I think we are saying fifty to a hundred, because if we think about a hundred, that would give us much more than enough. And that would potentially account for things that we're not able to anticipate that may impact our power, like -- like, for example, high interindividual variability or sort of things that we may not anticipate that would decrease our power at this point.

So I hope that answers the question sufficiently. But I -- you know, based on our power calculations, a sample size of 50 would be sufficient. And we are trying to be conservative in kind of saying fifty to a hundred because of that.

MS. HOOVER: Yeah, and Julia, I'll just quickly chime in because José also asked what can we afford?

DR. VARSHAVSKY: Oh, yeah.

MS. HOOVER: And we think we can afford that. We actually are going to be able redirect some of our budget that we have already encumbered with our UC contract to a UC lab. And we are actually in discussions about that now. So we're figuring all those details out and we'll definitely be updating you all again when we -- we get further. But we really want to -- we really appreciate this input. So if you have other ideas, just sort of at the basic level of the biomarkers of the design, we'd love

to hear those in the next couple of minutes.

CHAIRPERSON SCHWARZMAN: I had that Eunha had something to add and then Veena.

PANEL MEMBER HOH: Yes.

MS. JARMUL: And then I have a question from Stephanie afterwards.

MS. HOOVER: Yeah, so we'll hold that till the very end, because we want to -- yeah. So, please continue.

PANEL MEMBER HOH: Okay. So my comment is more like the -- you know, the survey questions, you know, that you're going to collect, which seems to me it's very important. And then based on my previous study, and then my current work with other people that the smoker -- you know, tobacco smoke, it's -- you already identified that. That's one of the sources of the PAHs. But one thing that I want to assure that, you know, not only does secondhand smoke, but in the behaviors is also highly related. So the -- for example, like secondhand smoke, like a person who's smoke inside, a person who smoke outside, if there is a difference, you know, in terms of exposure? And also, that we study quite a bit of lot in the thirdhand smoke, which is like the tobacco smoke residue at home, which also affects the PAH exposure as well.

So maybe that -- you know, we have a -- I just

share that, you know, the resource that the -- currently, we have a thirdhand smoke consortium and there is a thirdhand smoke resource center. That could provide, you know, good kind of examples of questions, you know, to -- to assess the exposure, you know, the -- not only just active smoking, but secondhand smoke and thirdhand smoke. You know, how can -- you can measure that exposure from that sources.

DR. VARSHAVSKY: That sounds like a great resource, so we'll definitely follow up with you on that. We also -- you know, in addition to the survey questions being as optimal as they can be, you know, to address all of the things that we need to address, you know, we are still figuring out what our capabilities are lab-wise to kind of assess for the more -- or include more sensitive biomarkers of second or thirdhand smoking in our -- in our analysis, so that we can also account for it that way. But we are -- are aware that, you know, the more sensitive we can get, the better at tracking second and then thirdhand we'll get to.

CHAIRPERSON SCHWARZMAN: Thanks, Julia. I want to make sure that we get Veena's questions in or comment.

PANEL MEMBER SINGLA: Thank you, Meg. Thank you, Julia and Susan for the great presentations.

I had a couple comments and one question. So

just a comment on the comparison group issue is that it seems like if there was a facility with two separate buildings at the same site, that might be an ideal comparison group. Although, I think it's -- there's already many challenges of finding participating sites, so, you know, another one to add on top. But I think that that could be a very good comparison group.

And a comment on the type of air filtration system. I think, you know, there's pros and cons to it, but I do feel like to the extent the system that's used in the intervention is similar to other -- other systems being installed and buildings already under the California programs. It would make it most informative to what impacts we might actually be having.

But I can -- I can also see the value in looking at, you know, more -- a system that does more. But anyway, that's just -- just my inclination, because it can -- it can be more generalizable to what's going into buildings.

And then my last comment and question is just around COVID and this study, because, you know, I think elder care facilities have been very much in the news regarding COVID. And air pollution exposures and COVID outcomes have also been very much in the news. So I think there's kind of multiple factors intersecting with this

study, so -- but I just -- I think it will be really important to communicate really clearly with the participants about what this study is and is not going to be about, because I think it's --

MS. HURLEY: Correct.

PANEL MEMBER SINGLA: -- correct me if I'm wrong, there's nothing about COVID in relation to this study.

MS. HURLEY: Yeah.

CHAIRPERSON SCHWARZMAN: I wanted to raise that issue too. And we're out of time for this topic discussion, so I'll just kind of lodge it that that was one of the things that I perked up my ears about when you talked about doing this in an elder care facility is that -- and schools, is there's certainly work to develop a standard within California to do air filtration systems that will remove Coronavirus from the air. And so figuring out the overlap between the kind of system you might use and what is being recommended for reducing the spread of SARS-CoV-2 I think would be an important consideration that you're maybe already accounting for, but just to tag that onto Veena's comment.

MS. HOOVER: Hey, Meg, I just want to note for Stephanie Holm and Dr. Sumchai we received your questions and comments, and we will take those into account. And if you want to speak, there will be more time for public

comment at the end of the day in the open public comment period. But right now, we'll go ahead and move on.

CHAIRPERSON SCHWARZMAN: Great. Thank you, Julia and Susan for those really excellent presentations.

And I want to move on to our Program update and overview of biomonitoring surveillance issues. So, for that, I'm going to introduce Nerissa Wu, who is Acting Chief of the Environmental Health Investigations Branch at the California Department of Public Health. And she's overall lead for Biomonitoring California.

And Nerissa is going to provide our Program update now. And we'll have 15 minutes for Panel and audience questions following her presentation.

(Thereupon a slide presentation.)

DR. WU: Hi, everyone. This is Nerissa. Just making sure you can all hear me.

(Heads nod.)

DR. WU: Okay. Now, let me scoot over to my slides. Sorry.

This reminds me of the days when you'd show up and your slides wouldn't advance because your project was in backwards or something.

(Laughter.)

DR. WU: Okay. So what do you see on your screen now? Do you see my slides?

MS. HOOVER: Yeah, your slides but not with slide show.

DR. MARDER: The PowerPoint program version.

MS. HOOVER: If you just start your slide show that should do it.

DR. WU: Yeah. I'm trying to -- you know, how I got the panelists to show up and now I can't get them to go away. So here we go. All right.

DR. MARDER: Perfect.

DR. WU: So good morning, everyone. Good to see you all. I am really excited for today's discussion. I am really excited to have our friends from other State programs in particular here for today's meeting to talk a little bit about surveillance.

I'm going to spend a little time on Program updates --

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DR. WU: -- starting with staff transitions that I want to mention. We've had a couple people leave the Program. Christopher Ranque, our PFAS analyst from DTSC, and Lissah Johnson from our metals team at EHLB have both left the Program. So I just want to thank them both for all of their work. We also have a new Senior Environmental Scientist, Stephanie Jarmul, who's joined OEHHA and you've heard her on the line helping facilitate

today's meeting. So, welcome, Stephanie.

And Duyen Kauffman who you all know is so valuable to so many aspects of the Program. She's thankfully not leaving Biomonitoring California, but she has moved back over to CDPH. And we are very happy to have her back.

So our work at CDPH continues to be quite impacted by COVID-19. Our staff are in high demand for their epi and data management skills, anything from generating and tracking statistics to overseeing investigations, or monitoring the health of State workers deployed to the field. And we don't know how long staff redirections will continue, but it's likely that it will go on for some time and continue to impact our ability to move forward with biomonitoring.

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DR. WU: So within biomonitoring our focus has been on the CARE study. And as you know, we did have to discontinue CARE-3, which is San Diego and Orange County, in March, because, of COVID-19.

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DR. WU: We've been working on analysis and interpretation of data. CARE-3 metal analyses are just being finalized at the lab. And so we'll be starting our calls out to participants with elevated levels of lead,

arsenic, mercury, or cadmium anytime now. And we have an expectation of getting results out to participants within one year of sample collection. And we are anticipating that we'll be able to make that deadline for CARE-3 despite our COVID duties and the impact of COVID on our -- on our own staff condition.

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DR. WU: CARE-2 summary data is now up on the web and we're continuing with statistical analysis and hope to have some kind of public presentation perhaps online -- I'm not sure what just happened there -- at some point. And we're continuing to analyze CARE-LA data again with the goals of getting a publication or a project report out.

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DR. WU: But the focus for today's meeting is surveillance and our approach to surveillance for the future. And in the past we've talked in broad terms about our limited budget and how that limits what we can do for surveillance, given the lack of supplemental funding. Today, we're going to talk in a little more detail about some of the challenges of surveillance work and some of the potential options for the Program.

There is a lot to unpack with this topic. There are lots of moving pieces. And as I go through my talk,

there will be pieces that you've heard before at previous meetings, but I'm trying to present a comprehensive collection of issues together. Things that impact our Program, so that we can consider them all in our discussion.

And some of the pieces to consider, include things like the challenges that all public health surveillance face and some of the challenges that are particular to biomonitoring, things like sample collection and management.

And we'll talk about some of our Program priorities, what we hope to get out of surveillance work. There are logistic issues to consider, what can we do, given our staff, and budget limits, and data issues. How can we collect data that is generalizable and useful for our purposes given all of the things I've mentioned above.

So, of course, all of these factors are quite intertwined when you're designing any kind of study, including statewide surveillance. You have to find a balance between the ideal study and your very real limitations. So we hope this ensuing discussion with you and with our experts that we have assembled here, you can help us think about the relative value of different aspects of surveillance, what should we be prioritizing, what are trade-offs we can make, and how do we move

forward.

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DR. WU: So just a reminder that surveillance is spelled out explicitly. It's mandated as part of our legislation. And part of the original vision for this Program included a goal of a representative sample of Californians so that we could establish trends in the levels of Californian's bodies over time and assess the effectiveness of public health efforts and regulatory programs.

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DR. WU: Population-based surveillance at the State level is also one of CDC's goals for State biomonitoring programs. And you see this in reports and funding announcements. But beyond what's spelled out in legislation or in CDC's prioritization, surveillance has always been one of our primary goals, because of what we can learn from it and how important it is to our mission.

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DR. WU: I want to highlight the contrast between community-based studies and surveillance and some of the differences in goals and methods. They're both important to understanding exposure in our state. But community-focused studies are about looking at how a particular group, either an occupation, or a community

group, or some cultural group, how they might be disproportionately affected. So it's more about looking at elevated exposures. The goal of surveillance is to look at the population as a whole, how does it compare to other populations or how does it change over time.

So surveillance is more about understanding the mean, the overall exposure picture. And again, both of these are really important. And, in fact, surveillance data is critical to understanding and interpreting community-based studies.

You can do community-based surveillance. For example, you could look at changes over time and in a particular community, but our legislation calls for representation over California's demographics. And it explicitly prioritizes surveillance over community-based studies.

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DR. WU: So surveillance is the ongoing systematic collection, analysis and dissemination of data and there are many different examples of surveillance, which everyone is familiar with, particularly in the realm of infectious disease or assessments of how behavioral factors change over time. But regardless of the particular health focus, there are a number of attributes that characterize surveillance and these are things that

we've tried to incorporate into CARE.

So representativeness, of course, we want to be -- we want to be generating data that's generalizable to our population and that's a very big part of study design. There's the usefulness of your data. We want to collect data that can be used to improve public health, so we've selected analytes like metals that have a very clear public health consequence, and for which we can provide information on how to reduce exposures.

We want our data to be compatible, so the data that's collected can be combined or compared with data collected by other surveillance systems. And for the CARE Study, this means being able to compare region to region, as well as being able to compare our data to NHANES or data from other states.

Your protocol needs to be acceptable. Will people participate in the surveillance? And this is a big issue for biomonitoring, because we're asking participants not only for their time and information, but also for biological samples. And this can discourage participation.

Surveillance also needs to be flexible, because as you want to get out in the field year after year or on a regular basis, you need to be able to adapt to changing needs, so things like budgets that fluctuate or changing

social norms, like the switch from land-lines to cell phones.

So the original intent of CARE was to be modular, to be adaptable to changing budget scenarios. And finally, your study needs to be sustainable. It needs to be stable, so that data can be collected in an ongoing consistent manner. And this is one of the issues that we've encountered, our ability to sustain the CARE study year after year.

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DR. WU: So in addition to our goals understanding California-specific exposures, there are other values that have guided our Program and our prioritization over the year. Environmental justice has always been a very strong value of the Program. We want to identify communities that are disproportionately impacted, so that we can target exposures for reduction.

We are a statewide Program, so we're created to serve the entire state. And one of the challenges of California is the size of the state. Getting to all parts of the state to do field work is very difficult. But it's not only an obligation, it's also something that makes us a better Program, helps us get our message out to different parts of the state, helps us learn about different communities and priorities, and also helps us

determine if there are differences in California by geography.

And finally, this is right to know principle. This one of the founding principles of the Program. We really want to get our information out to people where it can make an impact. And results return is explicitly mandated in our legislation. But in addition, dissemination of information takes place during recruitment, in participant interaction or in community meetings, it's a big part of who we are as a Program.

Trying to get information on chemical exposure, because participation in a study might actually be somebody's first interaction with public health, it might be the first time they thought about chemical exposure and health. So those are important interactions to have.

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DR. WU: So our history with surveillance goes back to the beginning of the Program. The initial design of Biomonitoring California was to conduct Cal-HANES, which would be modeled after NHANES. And this was estimated to cost about $12 million in 2007, which is an amount the Program never received. So we did conduct three other studies towards our goal of surveillance.

There's a Biomonitoring Exposure Study, or BEST, for which participants were recruited from Kaiser patients

living in the Central Valley. So the thought was that this was a model that could be used across the state.

We conducted the Measuring Analytes in Maternal Archive Samples, or MAMAS, for which we used samples from the State's prenatal screening program. And then there's CARE, which I've been mentioning, which is what we've done for the past few years, region-by-region coverage of the state.

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DR. WU: And just a reminder of CARE's protocol. Divide the state into eight regions and monitor in one region per year. We recruit three to five hundred participants per region we've been biomonitoring all participants for metals and PFASs with the potential to include additional panels, such as 1-nitropyrene or environmental phenols as resources allow.

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DR. WU: So each one of these studies, BEST, MAMAS and CARE, each one of them have added to our understanding of chemical exposure. But in addition they've also provided useful information to us on what's possible, what works, what doesn't work, and what can we hope to achieve in future studies.

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DR. WU: So there are a number of lessons

learned. And these are not big surprises. These are things we've discussed at some -- to some length in our meetings. But based on prior studies, particularly CARE, we have a little more specificity with which we can discuss these points.

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DR. WU: So recruitment, of course, is one of the big challenges we face. But our experiences in CARE give a sense of the response rates we could expect from a card -- a letter or some kind of communication sent out to the public. We sent out 65,000 postcards to households in randomly selected postal codes. And we got a 0.4 percent response rate. This is a response rate, not a participation rate. Not everyone who responded to the postcard ended up participating or completing the study. This is just people who were interested enough to get in touch with us.

And this is illustrative of how difficult it is to connect with a target population and it's something that's seen in many different studies, that it's increasingly difficult to get people to respond. The experience also demonstrates that we could get people through mailing. It would require many more postcards at this response rate or alternatively -- alternatively, we could try to boost the response rate by increasing our

incentive, or by sending a follow-up letter, or doing some other outreach measures. But all of these strategies would raise the cost of recruitment.

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DR. WU: There's also the cost of field work. This doesn't even include lab work, which is a whole other conversation. With our experiences in CARE, we now have better numbers about what it costs to set up and manage field offices. And some of these are at quite remote locations. This includes travel, bringing in short-term contract staff to manage field work, a phlebotomist to take blood samples. There's sample management and storage in the field. And there are participant incentives to draw participants in.

So field work is not only very expensive, but some of these things are also difficult to purchase with State budgets. State dollars tend to be fiscal year bound and purchasing and contracting through State infrastructure can be very, very slow.

Another thing to consider is that all facets of study design are very interrelated. So you could try to limit your time in the field, because it's so expensive, but then you really need to invest in efficient recruitment, because limiting your time in the field makes it harder for participants to get to you and to complete

the study. And that might impact your participant rate, particularly in difficult to recruit demographics.

Another thing to keep in mind as we consider field work is that so many things are out of our control. I mean, this year is a great example of that. Delays always have consequence for your bottom line, so we put a lot of effort into choreographing the process from participant interventions to sample collection to try to minimize our field time and our field costs. But any deviation to that schedule has implications for the cost of field work.

In the case of CARE-3, we were somewhat delayed because of difficulties recruiting staff. But there are other issues that come up, there's weather, the wildfires, and, of course, COVID, and everything impacts your timeline.

My point for this is just that we were able to make CARE-LA and CARE-2 happen by packing a lot into our budgets and stretching our staff probably beyond their limits. But planning on a shoestring like this really leaves your very vulnerable to delays and problems with your timeline.

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DR. WU: Another potential for surveillance that we explored was the use of samples from a biorepository,

in this case the Genetic Disease Screening Program biobank. So there's significant advantages to using a source like this. Much less expensive to purchase samples as opposed to gathering them from participants, the process is fairly automated, so there are fewer variables to contend with, and the prescreen -- prenatal screening biobank, it only includes pregnant women who utilize the State program, so it's not universal, but it's an important demographic. It could help us look at exposures for the most important -- the most vulnerable populations.

But for analytes that might have an association with sex, for example PFAS, for which there's a gender disparity, may not be the best source of samples.

There's also very little information available on the moms. There's very little sample available and very little volume, and it's only serum. And they also don't have any control over how the samples are collected. We did find that we could not use these samples for metals analysis, because of contamination of the serum separator gel, but they are usable and there's enough of it for PFAS analysis and potentially for non-targeted analysis.

There's no participant contact, so we don't have a way to get exposure information from the sample -- the people who donated samples, there's no results return and there's no opportunity to disseminate information to the

participants themselves.

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DR. WU: And finally, there is this need for sustainable funding, again something that we have discussed in this forum. So for any kind of surveillance work, we need to be out in the field at regular intervals, just like we had planned for CARE. So this requires ongoing steady funding, both for the actual field work and to do the necessary preparations before we go out in the field. Extramural funding, while it can supplement our study plans, it fluctuates, there are often requirements or limits. So it's great to have it to supplement our Program, but it's really difficult to build a sustainable program and plan ahead for surveillance work and retain staff on a budget that's uncertain.

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DR. WU: In parallel with the feasibility issues that I've just described, we also have put a lot of thought into the issue of representativeness of our study population. And again, these things are all interrelated, because study design still has to be something that works, that fits within our budget. There are many different ways to design participant recruitment.

There's, on one hand, convenience samples, which is the quickest and least expensive method for

recruitment, but it's also most likely to result in a non-representative study population. Anyone who wants to sign up is enrolled in the study. So it's really not appropriate for surveillance.

On the other side of the spectrum, we have population-based sampling, which is the gold standard for surveillance. Random selection of participants from the overall population or study frame, so that everone has an equal chance of being selected into the study. But this approach generally requires a lot of effort to pursue selected individuals and get them to sign up to the study.

What was -- what we've done in CARE is quota sampling. This allowed us to control the proportions of our study population and have it reflect the overpopulation -- overall population in terms of sex and race. We paired quota sampling with the use of the randomly distributed postcards to try to ensure that participants were coming from many different communities. And we have protocols, like limiting the number of participants from one address to prevent bias.

So one of our questions about study design, which I'd like to have discussion about, is should we be trying to do population-based sampling? When we were starting CARE, we were concerned that the response rate would be low and that a potential for study population that did not

reflect our overall population would be high.

But one of our questions is if we went with population-base sampling and put our resources into that intensive pursuit of selected participants, we would have to cut back somewhere else? And the question is what tradeoffs are worth making in order to move us towards this population-based sampling? One of our afternoon speakers, Brian Wells from UCLA will be helping us think about this issue.

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DR. WU: So I've put all these factors together. What are things we can consider when designing our next phase of surveillance? What are the most important aspects of surveillance for us to retain, and what are we willing to drop?

There are a few options for reducing the scope of surveillance, things like reducing our geographic coverage. Maybe not getting to every county or region, but instead focusing on the subset.

We could limit the type of samples we collect. Maybe only collecting urine, but this would limit the analytes that we measure, or we could conduct field work less frequently, or include fewer participants, or we could forgo field work altogether and use banked samples.

So this is not an exhaustive list. It's also not

exclusive. The scenarios I'm going to present to you combine some of these options. These aren't the only potential options. This is just to get our brainstorming started.

So one option would be to continue the CARE study, with our quota sampling design, but reduce costs by limiting the frequency we get out into the field, maybe reducing field costs by limiting the time we're in the field and reducing the number of participants.

We could also try to move more towards convenience sampling away from our randomized postcard strategy. And this option would reduce overall costs, though we'd still have to support field work, albeit at lower costs and less frequency. But reducing costs by compressing our field time or changing our recruitment strategy would likely reduce the generalizability of the data.

And in addition the recruitment -- the reduced frequency of getting out in the field would introduce more temporal bias. And that would make it more difficult to compare data collected from different rounds of CARE.

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DR. WU: Other ideas on how to modify the CARE Study might be to pick one to two regions which are easy to get to and reduce travel costs and visit them every few

years, which would not give us data for the whole state, but we'd be able to look at temporal trends in these selected locations. Or as I mentioned earlier, we could do stuff like only collecting urine samples. People might be more willing to sign up, if it didn't involve a blood draw, but it would really limit the analytes we could look at. For example, we would not be able to look at PFAS.

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DR. WU: We could -- here's another option, we would work with an existing population or study frame such as CHIS the California Health Information Survey. For example, adding a question on the CHIS survey that identifies potential participants in a limited geographic area. Other states have used the Behavioral Risk Factor Surveillance System, or BRFSS, in the past. So we're interested to hear about some of the advantages and disadvantages of this design.

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DR. WU: Using an existing study for recruitment would reduce our upfront costs. For example, we wouldn't need to mail out a postcard, but it would require staff time to follow up with the participants and get them enrolled in the study. Then we'd have two layers of recruitment which might compound our response rate issue and might result in a more skewed population.

We'd also still have to figure out the field work piece and one of the potential advantages of working with Kaiser as we did in BEST or in other health organizations would be that if they have lab facilities, this might facilitate our field work.

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DR. WU: And finally, another option would be to conduct surveillance using GDSP samples. And this would be focused on PFASs and potentially non-targeted assessments. Huge advantages, as I described, with regard to cost and logistics. We could conduct randomized sampling of pregnant women across the state. And GDSP actually captures about 70 percent of pregnant women statewide. So that's pretty good.

And the response rate isn't a factor here. And because this wouldn't involve field work, we could conduct sampling more frequently, for example, year after year to really look at temporal trends.

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DR. WU: Of course, this would only include pregnant women who utilize the State screening program. It's a significant population, but would this be sufficient to fulfill our mandate of looking across demographics? I don't know the answer to that.

We'd also still need to find funding to support

the purchase of samples. And the samples are serum only. Again, that really restricts what we can measure. As I mentioned earlier, no opportunity to collect exposure information, such as it relates to their county of residence and no opportunity to do results return. There are other biorepositories besides GDSP, but they are unlikely to be as representative as G -- as GDSP is.

And finally, I guess one other thought that was proposed at the last meeting is that we abandon surveillance, but this really isn't an option given our legislative mandate.

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DR. WU: So I think I'm getting the time message here. I just want to leave you with a few questions that we'll bring up again in the afternoon session. How do we balance all of these challenges? What are our priorities for surveillance? Would looking at PFASs in pregnant women and getting sense of temporal trends, would that fulfill our surveillance mandate? What aspects of surveillance are most important to us? For example, is it important to cover the whole state, is it more important to get to every region, or is it more important to look at temporal trends?

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DR. WU: And which analytes do we prioritize? Is

it important to us that we are able to look at PFASs, because that necessitates serum collection or are there other analytes, which are our priority? And what is the importance of probability-based sampling? Should we be focused on moving our study to a probability-based protocol, even if this might make a study population that doesn't match on demographics?

And finally, how should we be evaluating the success of statewide surveillance? How do we know if we have achieved our goals?

So I will look forward to a discussion of these issues in the afternoon and I just want to close by acknowledging and thanking our staff.

CHAIRPERSON SCHWARZMAN: Thanks, Nerissa.

So we have 15 minutes now for questions for Nerissa from both the Panel and the audience. So I'll start by asking Marley and Stephanie, if you have questions from the audience to pass on for consideration at this point and then --

MS. JARMUL: Nothing from the email at this point.

CHAIRPERSON SCHWARZMAN: Okay. Great.

MS. ZALAY: Yeah. And there isn't anything in GoToWebinar. Thank you.

CHAIRPERSON SCHWARZMAN: So then I would invite

panelists to ask questions for Nerissa and -- about this and a reminder that we'll have a discussion session on this topic in the afternoon.

Questions from panelists?

Thank you. Ulrike.

PANEL MEMBER LUDERER: Hi. Yeah, I just have a clarifying question. Thank you for that overview and presenting all the issues and problems that we need to consider. About the GDSP, so you mentioned, are there absolutely no demographic data? Is there any information about location, what part of the state these women are located in, anything like that?

DR. WU: There is limited demographic information. So we have been able to get their gestational age of pregnancy, race, weight -- last weight, so from their last appointment, I think the age of the women and the county of residence. So I have -- it might be possible to look at water source, if we can get a little more specificity on their address. That is something that GDSP is loath to share across programs. But if one of the possibilities I've been thinking about is if we could work with them, so that they could geocode the address or maybe do the -- work with us on the actual addresses of the participants. That might be able to give us some more environmental sources, if not, their personal

exposure sources.

PANEL MEMBER LUDERER: Right, because that would also enable you to look not just at temporal trends, but obvious also at the geographic disparities or differences.

DR. WU: Yeah, that's an outstanding question for GDSP and I appreciate that, because that would allow us to look at some more interesting predictors for PFAS.

CHAIRPERSON SCHWARZMAN: Other questions for Nerissa?

Maybe everybody is hanging onto their thoughts until our discussion session this afternoon once we've heard from other State biomonitoring programs.

I guess one thing that would -- I would love to hear is just what you feel like has been most valuable about the CARE program so far -- I mean, the various CARE studies.

DR. WU: There are a number of things that have been very valuable. It was, I think, one of the most ambitious things this Program has undertaken, but it was really important to try to get to other parts of California, and that is one of the aspects of surveillance I am somewhat loathe to give up, because there -- you know, we are a statewide Program and we have really focused on the Bay Area for obvious reasons. It's much easier for us to do that. But I think there are many

priorities across the state that we want to hear of as a Program. We can't always address them. But it's important for us to be doing that kind of outreach and interaction with people across the state.

I think also CARE was a huge learning curve for us in terms of what it really means to get a field operation going. We have done community-based studies in the past and we've had very active partners. And they have been also mostly focused in the Bay Area. So this was our first attempt at really setting up a remote location. And it was -- we learned a lot from that whole process, some of which really impacts what we can do going forward.

CHAIRPERSON SCHWARZMAN: Tom.

PANEL MEMBER McKONE: Yeah. It's sort of a similar question, but on a different line, because we're facing -- I'm going to -- didn't want to bring up much about geographic versus temporal trends, because we're going to talk about that this afternoon. But I think the question, at this point, might be are there other areas or other programs in the state that might give us one or the other. For example, you know, the AB 617 talk is clearly an example of where there's some really interesting temporal analysis on some very important exposures, right.

So that -- and, I mean, that -- and are there

other, what, adjunct or complementary programs that might still give us temporal trends and the -- you know, the Biomonitoring Program really is best for geographic. I mean, I think to address that later, it might be useful to know it is geographic coverage or temporal coverage that is unique? You know, what aspects of those are -- could only be covered by this Program and what might be covered through partnerships of other efforts?

DR. WU: Well, I think one of the things to think about is the whole methodology issue, because in order to do either geographic or temporal trends, we really need to have a representative sample, something that's generalizable. And so collaborations or community-focused studies, which are very informative and very important, will not give us that same sense. I mean, how will we know how to interpret the results for that, if we don't have kind of ongoing generalizable data?

I think it's still -- it's not like you don't learn anything from it. I think if we cannot do -- if we didn't have a mandate to do surveillance and in the early days of the Program, we did focus on community studies, you do learn quite a bit and you can maybe piece together a picture of what's happening, but you really don't have generalizable data that you can use to -- to monitor those trends, either geographic or temporal.

CHAIRPERSON SCHWARZMAN: Veena, let's -- we'll have this be our last question and comment before we break for lunch.

PANEL MEMBER SINGLA: Thank you. So, two questions. One is on the BEST model, the partnering with health care. I know you mentioned that, you know, there was hope that that could be expanded. So I wondered if you could comment a little bit on the potential there. And my second question is maybe better reserved for the afternoon discussion, but I'll just say, you know, I'm wondering about techniques, like monitoring chemicals and metabolites in wastewater, which can inform on chemical exposures, but it's not direct biomonitoring. And to what extent thinking about incorporating some of those kinds of techniques that can still provide information, although it has obviously a lot of limitations that direct biomonitoring doesn't.

DR. WU: I will try to answer your second question first briefly. And then I just want to give Jennifer Mann a warning that I'm going to call on her, because Jennifer has been looking at the BEST data and have -- most likely has a better answer for this.

So the wastewater analysis is super interesting. And I think that's a great way to be looking at really kind of high level changes in exposure. But we're

biomonitoring. We're tasked with looking at it in biological media. So, I mean, it has some of the downsides of something like biobank in that we don't have participants -- we don't have an ability to talk to participants and give individual results. And I do think that we have seen that that is one of the most effective ways. I mean, we can give summary results out. But having interactions with participants who are getting their personal results back is a very unique and very impactful way to talk about chemical exposures. And that's something that that wouldn't be available to us through wastewater.

For your first question, Jennifer, are you able to unmute yourself?

DR. MANN: Let's try. I'm am unmuted. Can you hear me?

CHAIRPERSON SCHWARZMAN: Yes.

DR. WU: I can hear you.

DR. MANN: Okay. So as you know, the BEST model which we did with Northern California at Kaiser Permanente, if you include Southern California Kaiser Permanente, it actually covers a lot of California. And it would give us -- if they were interested in a partnership, if it was a partnership we could afford -- the ability to randomly select participants who had agreed

overall to participate in research studies. So there could be some issues participation by us right there. Some of the advantages that Nerissa already mentioned is that the second BEST study actually had participants come into the lab, so there wasn't the same need for a field office. And I'd like to hear more what your questions were around that model.

Could you repeat them?

PANEL MEMBER SINGLA: I think we --

MS. HOOVER: This is Sara. I'm sorry, it's -- we've got one minute to go. We don't want to make ourselves late for lunch, so why don't we hold this. It's an interesting and relevant topic for discussion. So, Meg, over to you.

CHAIRPERSON SCHWARZMAN: Great. I have it noted for our afternoon discussion and we can pick back up on it. Thank you, Jennifer, for weighing in. And thank you, Nerissa, for summarizing a bit of where the Program is and also getting us kind of started for our discussion of the questions around surveillance, biomonitoring studies in the afternoon.

So it is time to break for lunch. And we will have one hour. Everyone should return no later than 12:55, so that we can start the afternoon session right on time at 1:00 p.m. And for the Panel members, I just want

to provide this informal Bagley-Keene reminder, that you should comply as usual with Bagley-Keene requirements and refrain from discussing Panel business during lunch or the afternoon break.

And we'll see you all back in an hour -- well, at 12:55 in preparation for our 1:00 p.m. start.

Thanks very much.

(Off record: 12:00 p.m.)

(Thereupon a lunch break was taken.)

AFTERNOON SESSION

(On record: 1:00 p.m.)

CHAIRPERSON SCHWARZMAN: I think it's 1:00 o'clock and we will start the meeting again.

MS. HOOVER: Read your email and reply. Okay. I'm hanging up. Bye.

CHAIRPERSON SCHWARZMAN: So we're going to start the afternoon by hearing an overview of issues with biomonitoring surveillance studies starting with response rates for population-based studies. And then we're hearing from three State biomonitoring programs in New Hampshire, Michigan and Minnesota before we move on to a discussion session.

So just quickly before I introduce our first speaker of the afternoon. We've had a panelist join us for the afternoon session. Jenny Quintana, do you want to just introduce yourself.

MS. HOOVER: So, Meg, we just got an email from Jenny that she's having technical difficulties. I suggested that she try joining -- can you hear me?

CHAIRPERSON SCHWARZMAN: Okay.

MS. HOOVER: Okay -- joining --

CHAIRPERSON SCHWARZMAN: (inaudible)

MS. HOOVER: There she is. She's here. Okay. Go for it, introduce yourself, Jenny.

PANEL MEMBER QUINTANA: Hi, I'm Jenny or Penelope Quintana from the school of Public Health at San Diego State University.

CHAIRPERSON SCHWARZMAN: Great. Thank you for joining us this afternoon.

So I want to introduce your first speaker for the afternoon. Brian Wells is the survey methodologist for California Health -- I'm sorry, there's something happening with my screen. Just one sec -- for California Health Interview Survey, CHIS and that's at the UCLA Center for Health Policy research, where his primary role has been to develop, oversee and evaluate the redesign of CHIS sample and data collection, changing it from a random digit dial telephone survey to an address-based sample mixed-mode survey.

Brian's previous work in academia and government has focused on sample design, questionnaire development, statistical analysis and non-response evaluation.

He obtained his doctorate from the University of Michigan, Program and Survey Methodology, where his research focused on biomeasure collection in longitudinal surveys. Brian will present on response rates for population-based surveys.

Thanks, Brian.

DR. WELLS: Thank you, Meg. I appreciate that

very much. Hello everyone.

Good afternoon.

(Thereupon a slide presentation.)

DR. WELLS: I'm going to try to share my screen now.

MS. HOOVER: And sorry. This is Sara again. Just a reminder for all Panel members to pause your webcams. You hover over your picture and you get the pause button.

DR. WELLS: Okay. I just lost my slides.

Can you all see my slides?

DR. MARDER: We can. You have -- we are seeing your display mode.

DR. WELLS: I'm tying to move the -- yeah. All right. That will have to do.

Okay. So everyone can see that okay?

DR. MARDER: Yes. Thank you.

DR. WELLS: Fantastic. Okay.

Well, I was -- I was invited today and I'm grateful for the invitation to really talk about population-based surveys, giving you a couple of examples and really focusing on response rates and representation in those surveys. And I'll draw from a couple of examples.

As a background as a survey methodologist, my

perspective is a little bit different from, I think, everyone else's here who is attending today. And hoping to just provide additional perspective as -- as we have looked at from the survey methodology way of thinking, in terms of thinking about these issues, especially in relation to collection of biomeasures.

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DR. WELLS: A general disclaimer about my -- my role of -- this is my -- my personal opinions and doesn't reflect necessarily UCLA and the University of California.

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DR. WELLS: I don't think that this needs a lot of work or a lot of discussion here, given what has already been discussed today. But for those who are maybe less familiar, getting through -- a couple of these definitions that I think have a little bit of confusion, especially for those coming in from a survey methodology background into this space.

So obviously, biomonitoring is dealing with the -- assesses the human exposure to environmental chemicals, usually through some kind of measurement like blood, urine or saliva. The survey field has really focused in on using the term "biomeasures" to refer to -- collectively to a large group of anthropomorphic measures, physical performance measures and biological materials,

like blood, urine, saliva.

That the biomarkers are really the biological indicators of a particular process, event or condition generally through an assay. And so something I do to help, as I've communicated this to others who are not familiar with this space is we biomonitor by observing biomarkers from biomeasures.

So from my perspective in the survey methodology field, you know, biomeasure collection really focuses in on, you know, our -- the biomeasures we choose to collect are determined by the biomarkers that we're actually interested in obtaining. And there have been mainly three major approaches in survey research as part of a population-based survey in order to obtain biomeasure samples.

So first is through medically-trained nurses or phlebotomists. This can be done in-home with a nurse coming to a respondent's home. This can be done at a clinic or through some other location.

A classic example of this is NHANES, National Health and Nutrition Examination Survey, which we are probably all very familiar with. Obviously, they have their mobile clinic. We'll make some references to that here in the future as well.

The second approach is using non-medically

trained interviewers. This is where the interviewer who is conducting a -- usually a face-to-face survey will also collect the biomeasure specimens. This obviously has to be limited to minimally invasive collections. Usually, dry blood spot assays or saliva catches, or things that they can help instruct the respondent to participate in.

A great example of this is the National Social Life, Health, and Aging Project, or -- which has done a number of collections using non-medically trained interviewers to collect this information. And the last that's most commonly used as well is self-administered mail back. Again, this is -- also requires minimally invasive collections, because you are relying on the respondent to follow instructions that you provide, that they can do something themselves, and then return to the researchers, or to a lab to be analyzed as part of this study.

An example of this from a larger study is the Health and Retirement Study's 2003 Diabetes Study, where they did a follow-up mail interview -- or mail survey, excuse me, with -- with respondents age 50 plus with diabetes and then asked them to send back a sample.

So these are just a couple of examples. And the primary ways that we have considered in population-based research how to conduct biomeasure collection as part of

this process.

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DR. WELLS: Obviously, the goal of population-based research is to produce findings that are generalizable to a target population and can be used for population health surveillance. And obviously, the most common way we do this is through surveys to obtain from a sample or a random subset of the population. But obviously, representation is a big concern for this particular idea.

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DR. WELLS: And so one of the frameworks that we use in dealing with the question of representation is looking at what we call the total survey error paradigm, or TSE. The -- what you have there on the right there is just a basic description of it -- or basic kind of flowchart of what we look at. And really what it comes down to is we have two different types of error sources. We have measurement and we have representation.

Measurement really focuses on the constructs or the questions and responses, and things related to that, that we are trying to get at and through that process. And then the representation component deals everything from the population that we're interested in all the way down to the respondents of that population. And all the

kind of the things that happen that we lose people from that population as we get to our final set.

The big thing we have to remember, and I think this has been touched on earlier as well in the morning session is that really all surveys have error and our job is really to minimize it in the best ways possible.

Obviously, as we're focusing on representation, I want to focus on the right-hand side of this particular flowchart. And focus in on where we're seeing the sources of error, which may be -- may be influencing if we -- population-based research for surveillance.

So the first sources from -- going from our target population, who we're really interested in surveying, and getting to a frame that is actually able to capture that and when the sampling frame is incomplete, we have coverage error.

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DR. WELLS: The most common problem of this being obviously undercoverage of not getting at particular -- a particular group of people.

Two of the largest and population-based research, in terms of frames is random-digit dialing. This is all your classic telephone surveys over the last 40 years. Obviously, the undercoverage problem with that is that there are people without telephones. As we have gone

through a lot of changes in the last, especially 10, 20 years with the increase of cellular phones, there are land-line frames for random-digit dialing. There are cell phone considerations as well. And so we can always miss out on a particular group, even though the number of people who have a cell phone is rising.

Another example is also address-based sampling. So this is using something like the United States Postal Service computerized delivery system file, which has basically every mailable address in the United States, but we also know there are many people who do not have an address. Those who are homeless, very transient individuals, it may be hard to reach them and will result in us having some problems with coverage.

We think, in general, that the coverage is not as much of a concern, especially as we've made massive improvements in terms of being able to get at these populations, especially with the United States Postal Service, the CBF, which has almost a hundred percent coverage in some particular areas. And so that -- this is becoming less of a concern, but may still be a concern, if we're not using these particular methods that I'm describing here.

The second area that we focus on is sampling error. And this is how we determine the sample for the

survey, based on the sampling frame that we have used. This is where you get into those spaces of are you doing a simple random sale, or an SRS? Are you doing a cluster design, stratified, some kind of complex design, or are you doing something different altogether. What this really does for us as survey methodologists is allows us to quantify the variability in estimates.

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DR. WELLS: We want to be able to say with good confidence that we are confident in the variability that we're seeing in a particular variable or outcome. And so depending on the -- how our design works will depend on if those variances go up, or if they get larger, or if they get smaller.

And obviously, this is a space where non-probability designs, or convenience samples, and other methods are a concern, because we do not -- we don't have a good ability to quantify that variability, for purposes of error estimation.

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DR. WELLS: The final one, and I think it's the one probably most people think about is really our non-response error. And that's of the sample that we do select, who doesn't respond, who does not respond to our invitation to participate.

Many of you may use the term "self-selection bias" as part of this. And that is certainly an aspect or a dimension of non-response error.

We often classify non-response error into two types, contact or cooperation. So there's the ability to actually contact and find a sample member. And then there is also the ability to actually get those to cooperate or participate in the study itself. And we run into different problems and probability methods in order to make that happen.

Non-response error is most commonly measured through response rates. And obviously that, as has been mentioned earlier, is a big concern. And we will talk a bit about that here momentarily.

I think the caveat I want to start with -- or the idea I want to start with, anyway, is that low response rates does not necessarily equal non-response bias, which is obviously our biggest concern is we're concerned that our sample will be biased.

And I want to explain a little bit why that -- that idea kind of holds some water and something we --

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DR. WELLS: -- should consider as we consider what we can do about it. So I apologize for the mathematical formulas here, but this is the standard

mathematical definition for non-response bias is used in most survey methodology texts on the subject.

Basically, the bias for a particular outcome, Y, is essentially one minus the response rate and then it's the difference between the population value of the respondents and the population value of the non-respondents.

And so the question is what has more of an effect on bias, the response rate itself or how different the non-respondents are from the respondents?

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DR. WELLS: To give an example to give an illustration of this, this is taken from a classic textbook and survey methodology from Groves and Couper. If we assumed some kind of mean of say 0.5 -- this could be a proportion, this could be a mean of some concentration of some material, if we look at the blue line -- there's the blue line here that is very close to that non-response bias of zero. At a high response -- non-response rate -- at a response rate - excuse me - of like say 95 percent, big differences between the respondents and non-respondents really result in very small non-response bias. We can feel much more assured if we have that high response rate, that there's not a lot of bias that we can measure.

But if you really focus on all those lines as we go from say 95 to 70 percent response rate, to 50, and then even to 30, the closer we are to that 0.5 or to the actual value of the respondents, you know, the response rate makes very little difference, in terms of creating that non-response bias. It is really when the differences are very large that we really start to see those differences there.

And so obviously this is a concern for why -- you know, having high response rates is good. But if we're doing a good job at getting those respondents and non-respondents to be very similar, then we can be less worried about bias. And obviously, bias is variable dependent. You know, if we only had one outcome, we'd have a really good measure. But unfortunately in most surveys, we have - excuse me - dozens, if not hundreds, of measures that we have to look at. And so while one particular outcome may be biased based off this evaluation, there may be a hundred more that are not.

So in terms of thinking about these response rates and representation, a lot of work that has been done looking at this has found that there -- the correlation between response rates and non-response bias is relatively weak, which is some -- something reassuring for us as we -- as we go through this.

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And generally, it is assumed that response rates would need be to be increased substantially to really lower the average non-response bias. And obviously that's a problem to -- we're good at increasing it in little bits. It's hard to increase it those large jumps that we would hope to do.

So part of the takeaway I want to make sure everyone understands is that response rates, while they are important and they are the most common metric that we use, they're only one part of this -- of this equation. And there's obviously a lot of extra work that has to go into evaluating things like non-response bias, but we should be wary when it's the only measure -- or the only metric that we use when evaluating these types of studies.

So another thing that many of my colleagues have tried to put forward is that, you know, saying that because they're a low response rate is not adequate and that we shouldn't use that kind of data is very misleading. It undermines the work that we are trying to accomplish. We've seen examples of this in recent weeks related to other things that, you know, oh, it doesn't have a good response rate, so we can't -- we can't trust it.

Unfortunately, there are a lot of difficulties

with that. And I'll show some examples of why this is obviously a growing problem for every type of survey that's there.

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DR. WELLS: So here's just a couple of examples. I've picked a number of examples. Some of them are just basic population-based surveys, some of them are surveillance and other of them actually have a lot of that biomeasure collection component.

So here I'm just highlighting about four different studies. So the first is the California Health Interview Survey, the survey that I've worked on over the last three and a half years. In 2019, you know, we were -- we go for a target sample size of 20,000 adults in California. We received a final response rate of 10.8. That's based off of a stratified address-based sample. And we collect using web and telephone.

As we look at others like the California Behavioral Risk Factor Surveillance Survey, or the BRFSS, you know, they're trying to get 10,000 adults in California. They have a 20 percent response rate using random-digit dialing on telephone.

As we move to a more national level, the National Health Interview Survey, which CHIS is originally based off of, in 2018, they were trying to get 30,000 across the

United States and they saw a 64 percent household response rate, but they use a multi-stage cluster sample and they focus on face-to-face surveys.

And then the NHANES, as we kind of briefly mentioned, goes for about 5,000 for a two-year cycle. And they've seen it decrease as well, where their current interview response rate is 51.9 percent and their examination rate, which is at their mobile exam center is about 48.9 percent. And they use a very similar multi-stage cluster sample face-to-face.

While I didn't want to go through too many examples, many of you probably have seen or hear reports from places like Pew Research Center or Gallup and another -- many other survey agencies have reported that there are -- for a lot of studies that you hear about on the news or that are shared have response rates consistently below ten percent. But again, we still kind of trust them as sources.

Obviously, comparing some of these can be very dangerous. I'll talk a little bit about that in a moment.

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DR. WELLS: I just wanted to highlight some specifics just to give some context. So with the NHANES, as an example, talked about some of these details already, but you can see that over the last 20 years, the response

rates start at around 82 percent and has consistently been dropping more drastically in the last ten years down from about 82 percent down to about 52 percent.

And the examination rate, which was up in -- near 80, has also now dropped. So, you know, thinking about 30 percentage points over the last 20 years has been the drop. You know, NHANES has some advantages that we have to consider. We have to consider every aspect of a design. We're going to talk more about that in a moment.

But NHANES has national sponsorship. You know, obviously, works with CDC, but they also utilize very large incentives, both for the interview as well as for the mobile examination center visit. And so they have -- there's lots of good incentives to kind of increase that response rate. That's certainly very helpful for that.

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DR. WELLS: As a contrast, something like the California Health Interview Survey, which I have partici -- I have worked on, you know, we have a different design. We classically had a random-digit dial telephone. And as was mentioned in my introduction, we've recently been working on redesigning it. And in 2019, we did implement meant that. And we saw, with the decline that we were having, up from about 60 percent screener response rate, so that's just seeing if they are eligible, you

know, dropping all the way down to eight percent in 2017-2018.

Obviously, we had probably very similar concerns to some of you in some of your projects in terms of who we're getting and how those response rates were dropping. But by making active changes to our design, we were able to bump those back up, both for the screener and for the adult response rates and hopefully starting to reverse the trend that we've been seeing over the last 20 years.

Obviously, we don't have national sponsorship. We have a university sponsorship. UCLA does hold some good weight within the state, but, you know, it's nothing like the federal government or other entities that may have kind of a -- what they need, anyway to get your -- get your attention and get you to participate.

We also don't offer any incentives besides a $2 pre-incentive. That very first mailing has a $2 incentive. So we're asking a lot for a very little and we're grateful for the, you know, 20,000 plus households every year, who on basically $2, are willing to participate as part of this study.

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DR. WELLS: We have to be very careful though, as I was mentioning. You know, we're comparing essentially apples and oranges. We have a standard kind of

international standard for calculating important response rates from the American Association for Public Opinion Research, or AAPOR. But because every design is different, comparing one to another isn't really fair and it's not really equivalent in any way. So again apples to oranges, NHANES to CHIS is we're really comparing two very different things, so they shouldn't technically be compared, because their designs are very different. And those different study attributes really change how people are contacted and how they cooperate as part of the study.

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DR. WELLS: With that, I want to bring together one last framework for us to consider as we go through this. And this is the framework for survey cooperation. And this is really where we start to focus on what can we do, what steps can we take? But we have to understand the dynamics of how these things are working together.

This framework is primarily -- that I'm sharing is primarily used for face-to-face surveys. But the general framework really does apply. And I'll explain kind of those applications as we go through this.

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DR. WELLS: As we look at this, I want to focus first on the things that are kind of out of researcher control, so -- and in some cases they are out of control

right now.

The first aspect there is really the social environment. What kind of climate are we in as we're taking surveys. Obviously, we've talked about there's a lot of resistance now, a lot of reluctance to participate in research, especially when you're not -- you don't feel like you're, you know, kind of recompensed for your time. We've had a large increase over the last couple of years in distrust or discrediting claims, which means people are much more -- are much less likely to participate. And obviously, the newest problem that we've run into in the past year is COVID-19 with restrictions, both in being able to -- how we're able to contact or interact with individuals, fear about leaving or participating in particular studies.

And so the climate has really not been ideal, and it continues to get worse as time goes on, and as our society continues to change.

Obviously, one of those social factors is also neighborhood characteristics. Obviously, some areas may be disproportionately affected by something. We saw examples of that - excuse me - this morning in some of -- some of the work that we have previously discussed. And so those factor may have big influences on participation and cooperation.

Obviously, we also have household characteristics, sociodemographics, psychological predisposition, things that we kind of would expect would have an impact.

Now, these are things that we cannot control. We have to kind of react to a lot of these things. And so focusing on what's under control or what we can have under our control, you know, obviously, the topics of the surveys that we focus on, the modes in which we contact and have them participate we have control over. We can also control how -- who we bring into the study. Also, it involves incentives and other design aspects that we have control over.

Interviewers, where applicable. You know, this could also for certain biomonitoring studies could involve nurses, or phlebotomists or other researchers working as part of the study. But this also can be -- you can think of this in terms of kind of self-administered or other web-based studies that this is really instrument interface, you know, how well is it designed? If we don't design our interface well, then people aren't going to be willing to participate. And so we have a lot of factors that we can work on. And again, we'll focus a little bit on what we can do specifically in surveillance studies.

But eventually all of these components come

together into that interaction and makes that final decision for them whether or not to decide to cooperate or to refuse to participate in the study.

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DR. WELLS: Something that was conveyed to me and that was really important as we think about it is who is often not responding to surveys generally. And there are a number of groups that are often the culprits, in terms of who we're missing out on, regardless of what study it is and what efforts we put forward.

We miss out on a lot of young adults, 18 to 29 specifically probably due to their transitional states of living, of, marriage, and college, and all these different things. We often miss out on low income or low socioeconomic status households, limited English proficient speakers. You know, obviously, California is a very diverse state with a lot of people who do not speak English as their first language or who do not speak English at all. And it can be very hard, if you don't have methods in place to help them to participate.

CHIS has taken great steps, for example, in terms of doing the survey in six different languages in order to get at those groups to allow them the opportunity to participate despite those barriers.

Those -- we found that those who are less

socially connected or politically active are less likely to respond. Obviously, there are a number of racial and ethnic minorities who do not respond as well. But really, a lot of these factors can depend on the survey and what steps are taken to address those.

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DR. WELLS: One think I needed to note --

MS. JARMUL Sorry, Brian, I think you might be muted.

DR. MARDER: Or possibly disconnected.

CHAIRPERSON SCHWARZMAN: Brian, I don't know if you can hear us, but we can't hear you.

DR. MARDER: I think it's likely his headphone became disconnected. Someone might want to message him.

CHAIRPERSON SCHWARZMAN: Okay.

DR. WELLS: Okay.

DR. MARDER: There we go.

DR. WELLS: All right. I don't know much we missed, but I'm just going to keep going, because I know -- I know we're running low on time here.

So we have a number of sources we can get for these population totals. Generally, we use things like age, gender, race and ethnicity as common weighting dimensions to weight to bring the population to be representative, but there are a number of others.

MS. HOOVER: Hey, Brian. I'm sorry. We just lost your sound for a little bit but you're back.

DR. WELLS: Okay. Great. So one of the biggest benefits from weighting is that it reduces biases due to all of the things that we talked about before in terms of representation, that's coverage, that's sampling and the non-response.

These reductions can be maximized when we know that they're correlated with both response to the survey, so who is choosing to respond, and the actual outcomes we're interested in. In this case, for a lot of cases, it's the biomarkers that we're interested in.

We've seen a number of examples where two very different samples can produce very similar estimates when weighted to populations using equivalent methods. And so weighting can -- can do some good, but also have to warn, it's not a silver bullet, it's not a magic wand. Waiting doesn't just fix everything, but it can do a lot of good in terms of reducing biases that we may see.

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DR. WELLS: Just as an example very quickly for CHIS, we use both ACS and California's Department of Finance projections. And we use things for age, gender, race and ethnicity, education, county and region, housing tenure and number of adults, to try to make sure that we

get as representative of sample as possible.

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DR. WELLS: Weighting is very common in studies with population studies for -- with biomeasures NHANES, the Health and Retirement Study, which also does that collection also has weights that they use specifically for the biomeasures that are collected. Another example that I worked on was also the University of Michigan Dioxin Exposure Study, which dealt with a Dow Chemical spill up in Central Michigan, which again they also produced weights both for -- not only just the full sample but also for the biomeasure component. And so this is very common for a lot of population-based surveys that do this collection.

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DR. WELLS: So with the two minutes I have left, I just want to focus a little bit on just a handful. This is really just a -- we're barely scratching the surface here, but just some of ideas as we think about some of the Trade-Offs of the Possible or what I want to call kind of the T.O.P.s. here of what we can do. And these are just five very simple examples that I want to kind of illustrate.

So the first are the type of biomeasures that we're interested in. This was something that was alluded

to earlier this morning during the morning session as well, is that we have some flexibility -- some flexibility. And obviously this applies to any type of study is what kind of measures we want to be able to get.

There are some big benefits from using minimally invasive methods. It allows us for more mode flexibility, what modes we can contact or do the surveys in. It can result in reductions in costs for study staff, nurses, phlebotomists, and also for travel as people are not only respondents having to travel to a location, but study staff having to travel as well. So this can be really beneficial. But that means that we are not allowed to have the full suite of things that we want to look at.

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DR. WELLS: Examples earlier this morning of, you know, what if we just did urine samples? Well, there's things that we're going to miss with that. And so we have to think, you know, is the -- what we can benefit from, what we can gain, will that really outweigh some of the things that we're going to lose out on, the typi -- the outcomes we can maybe get.

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DR. WELLS: For sample -- for sample design, you know, obviously as we've just -- I've spent a lot of time talking about today, population-based samples allow us to

select phone number or addresses with known probabilities, which allows us to do weighting, et cetera.

But there are concerns about low sample sizes, poor response rates, is it representative enough. And so we have to kind of weigh those things of, you know, what good can come with the bad. You know, could we do a follow on on existing study design? That can be really good, in case it helps us with screening or identifying specific individuals. But we can suffer limitations if that design is not ideal.

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DR. WELLS: Non-probability or convenience can be easier to implement, but we may not have confidence in the variability of those estimates, the impact of self-selection bias on those in particular.

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DR. WELLS: Mode I think is relatively straightforward, but, you know -- you know, what -- what could we do with things like mail, or web, or telephone?

And then the final one of the five here is just incentives, is that we know that incentives improve things. Pre-incentives can even be more effective than promised incentives in some cases, depending on the amount.

But we have to balance the final sample sizes,

what does the budget say that we can do for incentives. And pre-incentives can be a very big upfront cost and there can be some loss there.

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DR. WELLS: Location and travel I think -- I think we kind of know this pretty well.

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DR. WELLS: But just as a conclusion, we really have to fight with the idea of we can't let perfect be the enemy of the good. Low response rates are not desirable, but that doesn't mean that it's not of value and it's not -- and that it's not inadequate.

We accept the errors and we do our best to control what we can. And by adopting good principles of design, we can make big steps in terms of bridging that and short -- shrinking - excuse me - the gap between respondents and non-respondents.

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DR. WELLS: I just wanted to point to a resource from the CDC on probability built -- population-based biomonitoring studies that they provided. So with that, I will -- I will end my comments.

CHAIRPERSON SCHWARZMAN: Thank you so much for that overview, Brian. It's really helpful -- sorry I will turn on my -- stop this pause -- sort of background and

overview as set up for our discussion this afternoon. We have some time for questions from the Panel. And then questions from the audience before we move on to our speakers who will be talking about State biomonitoring programs.

So questions from the Panel for Brian?

Jenny.

PANEL MEMBER QUINTANA: Hi, Brian. That was really a great overview. And you had a lot to cover in a short time. So I was wondering if you could comment on kind of the pluses and minuses of community -- community-engaged research, where you really work with community groups to help recruit, especially some of the participants that are harder to reach. And if you have any comments about that.

Thank you.

DR. WELLS: Absolutely. You know, obviously community-based outreach really works well for very specific populations and very specific areas. You know, if you are having issues in a particular, you know, area, or jurisdiction, or with a particular group, you can certainly can take advantage of those.

Part of -- there's a lot of obviously logistical problems getting buy-in from those particular groups or areas. And so I think that there's a long history of very

mixed results. I think that -- the -- in my experience, a lot of that has been -- while it's -- it creates goodwill, it doesn't always necessarily translate into improved response rates or improved participation.

So it's a little bit of a mixed bag, I think. And I -- but I definitely think that there are particular studies, especially that are focusing on a more focused area. California is very hard, because it is so large. But, you know, focusing on a specific area when you're doing kind of smaller scale or very area focused study, that that can be very effective in bringing together a group or a population together to participate.

I can say from CHIS's experience we have done in the past some outreach, especially in the early years of CHIS really trying to focus in, but we haven't found it as effective, because there is that random component. That's the other -- that's the other hard thing I think with population-based studies is, you know, you're randomly selecting maybe one of a thousand in a community, and -- but you're talking to all thousand people, right?

And so the community may be engaged, but if you get that one person who isn't, well, that doesn't really work out so well. So again, it works well for studies where it's much more concentrated, it's much more -- where your focus is much more, I think, specific and focused.

Thank you.

PANEL MEMBER QUINTANA: Thank you. And actually, I had a quick follow-up if that's okay, Meg?

CHAIRPERSON SCHWARZMAN: (Nods head.)

PANEL MEMBER QUINTANA: You talked about telephones, but nowadays cell phones are much more common. And I'm just curious, have you been texting? And I'm just curious, how you make that transition from telephones to cell phones, or how you're allowed to blend them, or how that works? I'm just curious.

Thank you.

DR. WELLS: Yeah. Great question. So in your first regard to texting, there are a number of studies that are implementing texting as part of their protocol in contact. There are some concerns about some legal considerations about who you're allowed to text. But, you know, the transition to cell phones has been -- has been going on for most studies for the last 15 years. For example, CHIS was a dual frame, meaning that we had half landline and half cell phone for a long time or various proportions of those two groups.

So contacting cell phones is not so much of the issue. Obviously, there are new barriers with cell phones, which makes them more difficult. Obviously, I'm sure many of you, as having cell phones, that you have

maybe a spam blocker on your phone, so it says potential spam when a call comes in.

Plenty of studies, legitimate studies are flagged as spam, including CDC-funded studies that you would think would be immune to that, but they're not. They are flagged as spam, because it's not based off of say, well, I'm a survey. I'm legitimate. It based off of, oh, this number keeps calling me, so I'm flagging this as spam.

So there's a number of new barriers and hurdles with cell phones, which is why some studies are considering moving away. It's becoming a very expensive avenue. And obviously landlines are really starting to die out. And so telephone is in an interesting transitional phase, I think, in terms of the work that it's done. It's been a great boon of the last 40 years for survey research, but the landscape has changed a lot in recent years.

PANEL MEMBER QUINTANA: Thank you.

CHAIRPERSON SCHWARZMAN: Other questions from the Panel?

Do we have questions from the audience, Marley or Stephanie.

MS. JARMUL: Nothing from the email as of now.

MS. ZALAY: Yeah, no questions.

CHAIRPERSON SCHWARZMAN: And any staff that wants

to ask a question.

MS. ZALAY: Kathleen Attfield.

CHAIRPERSON SCHWARZMAN: Okay great

MS. ZALAY: Go ahead, Kathleen.

DR. ATTFIELD: And sorry, I realize I didn't plug in my headphones before noting that I had question. So hopefully you can hear me okay.

My question for you Brian is sort of what advice you have for our programs in evaluating our response bias, because some of those factors that you note about, you know, known response issues and low SES, we also have gender, which I saw you didn't note actually, age, race, like those can very much be associated with various environmental chemicals we know. So sort of your advice on thinking about that.

And then I also wondered if you might say a little bit about how over time your program has looked at response bias since you've had such severe declines as of late.

DR. WELLS: Absolutely.

DR. ATTFIELD: Thank you.

DR. WELLS: Yeah. So in the first thing, you know, obviously the ideal is being able to do non -- non-response bias analyses. You know, basically looking at people who didn't respond and through additional means

getting them to participate to see if they are different in some meaningful way. That's -- obviously, that's kind of a gold standard to be able do. This is what a number of federal studies have to do as well, you know, to verify that that non-response bias is not a problem or that it is less of a problem, I should say.

And so that's kind of the ideal. That has obviously -- that has large cost considerations, a lot of non-response bias or non-response follow-up studies can be expensive. Usually, you have much higher incentives and have to cut some corners in order to able to get at those people. But that's really, you know, as funding is available to do that, that's a wonderful way.

Obviously, comparing to other sources of data that you can rely on, obviously, part of the work that we're trying to do is getting data that isn't available. You know, we -- generally, in survey research, you know, we have multiple sources for certain types of data. So, you know, if you wanted to look at say insurance, for example, you know, ACS covers, a portion of that, CHIS covers a portion of that. There are, you know -- you can look at how Medicaid within the state is working, so you have sources that you could look at. So comparing to gold standards, if they are available or to other resources to see, you know, are you keeping at pace with them is

another great way to be able to do that. So those would be two potential things to consider in adding again what is available to you.

In relation to what we've done for CHIS, we've had a number of non-response studies in the past in work that we've done. About ten years ago, we did a study where we recontacted people face-to-face in Los Angeles County and looked to see if those who did not respond had different attributes, and found a couple differences here and there, but on the whole found a lot of it was very similar. And so we felt very assured at that point.

As part of this redesign that we just implemented, we actually did a very -- tried to be a very thorough study and see if we could disentangle different sources of error as part of that.

Also, again referring to gold standards and other studies that we could compare to to see does this match with this other source of data? And so we were able to do that for a number. And so as part of our study, we've -- we have felt confident in a majority of our variables that is less of an issue as part of that. But there is a lot of time and effort that has to go into those types of studies to be able to make that judgment related to that.

So you know for us, you know, we were concerned in the directions it was going and we feel reassured that

we are kind of correcting that path of getting too far away from truth, so to speak.

So thank you.

CHAIRPERSON SCHWARZMAN: All right. That's perfect timing for us to move on to our next speaker. This is the first of our three guests who will be speaking about their state biomonitoring programs.

Thank you so much, Brian, for that presentation and your willingness to take questions.

I want to introduce -- sorry, I just flipped my screen. I want to introduce Amanda Cosser, who is the administrator and lead epidemiologist for Biomonitoring New Hampshire Program at the New Hampshire Public Health Laboratories, where she has been for 14 years.

Since 2015, she's worked with her team on both targeted and surveillance projects and is excited to continue leading their second consecutive biomonitoring cooperative agreement with the CDC National Center for Environmental Health.

Amanda has experienced many facets of public health laboratory science during her career, and credits that experience with helping her cultivate the many relationships that are necessary for a successful biomonitoring program.

Thanks for being with us, Amanda.

(Thereupon a slide presentation.)

MS. COSSER: Sure. No problem. Can you hear me and see my slides okay?

CHAIRPERSON SCHWARZMAN: Yes.

MS. COSSER: Yes. Great.

Okay. So thank you for inviting me to join you all today. The last time I attended one of your meetings was in November 2015 as part of the CDC biomonitoring grantees' meeting and I had only been in my position for a couple of weeks at that time. So today I'm excited to be back here to share with you what my team and I have learned since then.

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MS. COSSER: I just realized the presenter pictures are off to the side here. Let's see. Okay.

So today, I'm going to give some background on New Hampshire and the two studies Biomonitoring New Hampshire completed with the previous 2014-2019 CDC Biomonitoring Cooperative Agreement, because they have impacted our program in many ways as well as influence how we plan to conduct our second statewide surveillance study.

New Hampshire is small in geographic size, but it has a combination of cities, suburban and rural areas. We're a largely White non-Hispanic slightly older

population with a higher median household income and fewer persons living in poverty than the U.S.

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MS. COSSER: Okay. But just because we're a geographically small state does not make it easy to conduct biomonitoring studies. We're also a very small team with only five funded positions, two epidemiologists and three toxicologists with one vacant toxicologist position at this time.

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MS. COSSER: So the lessons learned from our first study helped us formulate how we would accomplish our 2019 surveillance study. The targeted arsenic and uranium study was a long study with a multi-year recruitment for a relatively small geographic area, just 28 cities and towns within three counties that were very close to where our public health laboratory is located in Concord.

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MS. COSSER: Our analytes of interest were arsenic and uranium. We tested urine specimens and water samples from people with private well water as a primary source of household water. We also recruited a small comparison population from the City of Concord who were on a municipal water system. Our program had an

unfortunately late start to this project as hiring was delayed due to a State government budget continuing resolute -- continuing resolution that lasted until October 2015. So the targeted arsenic and uranium study was officially launched in August of 2016 and participants were recruited until September of 2018 for a total of 566 participants from 293 households.

This was a very time-intensive study. Informed consent was obtained in person followed by administration of an exposure questionnaire and education on how to collect the urine specimens and household water samples.

Each meeting took one to two hours depending on the number of participants per household. Much epi time was spent scheduling these meetings reserving public meeting space, traveling and then post-interview transcription of the exposure questionnaire data into Epi Info, since we couldn't rely on having Internet access at all of our public meeting spaces.

Epi Info is a survey platform created by the CDC, but it is not intended for something so complex with so much logic. We are grateful to receive assistance from the New Hampshire Environmental Public Health's Tracking Program for our participant interviews. But there simply was not enough funding to support the necessary staff to accomplish this project in a more reasonable time frame.

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MS. COSSER: This picture is of all 566 of our targeted arsenic and uranium reporting packets. Each one of these represents at least two hours of staff preparation and interview time. And although the in-person meetings were successful at educating residents about environmental exposures and increasing knowledge of biomonitoring, they simply would not be possible for a New Hampshire surveillance project.

As we are deep in recruitment for this study, we realized we wouldn't be able to do this across the state, and so we started looking at ways to achieve informed consent, complete exposure questionnaires, and have specimens collected remotely. We began thinking about our partners and who we might turn to for advice and assistance.

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MS. COSSER: But before we reached out to them, we finalized our clinical and environmental test panels for the 2019 New Hampshire Tracking and Assessment of Chemical Exposures or TrACE Study. Our panel included 50 biomonitoring analytes in whole blood, serum and urine, and hundreds of chemicals and quality indicators in water, which allowed for much paired clinical and environmental data.

We worked closely with the New Hampshire Department of Environmental Services Drinking Water and Groundwater Bureau, the New Hampshire Environmental Public Health Tracking Program and the New Hampshire Public Health Laboratory's Water Analysis Lab to secure funding and staff for testing and sampling.

Since not of all of -- since not all of the clinical matrices could be self-collected, like in our previous study, we knew we would need assistance. We kept our New Hampshire Laboratory Response Network partners up to date with our study since the first Cooperative Agreement by presenting at their quarterly meetings and we quickly decided to solicit their help. We reached out to the lab directors at the 26 acute care hospitals across the state.

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MS. COSSER: We confirmed with the lab directors that their staff and facilities would be able to meet certain collection guidelines and offered on-site trainings. Over the years, our lab has developed a strong relationship with the New Hampshire Chapter -- or the New Hampshire and Vermont Chapter of the Clinical Laboratory Management Association and the leaders in New Hampshire were eager to help us accomplish our goals, offering to help review collection kit materials and meet with us in

person.

We were able to secure 31 collection sites across the state with many of the satellite facilities not shown on this map. We also added funding to our New Hampshire Public Health Lab's private courier contract for specimen transport to our lab and enlisted the help of a lab assistant.

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MS. COSSER: We mailed specimen collection kits to participants who had completed the study enrollment process. This picture shows our lot screen materials, including specimen collection tubes and urine cup, transfer pipettes, long-term storage, cryovials and a stagnant water collection bottle for lead and copper testing.

The advantages of hospital specimen collection were experienced phlebotomists, safe processing, aliquoting, freezing and storage within a specified time frame following our guidance, which was based off the CDC sampling guidelines, as well as the positive perception from our participants that could come from working with a reputable member of their community. The disadvantage to this was some materials were wasted due to loss to follow up. About 10 percent of our kits were lost, but we felt that was minimal and didn't really impact our budget.

We considered screening other materials like needles, but we didn't feel comfortable sending them through the mail directly to our participants.

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MS. COSSER: Lessons learned as far as our incredible water incentive. The TrACE Study was often referred to as the water study by our participants. And we oversampled private well users in our state. We learned we need more emphasis on biomonitoring component of the study, even though we are very happy being able to offer this water panel, and to limit enrollment based on water source.

This picture is of two New Hampshire Department of Environmental Services water samplers collecting raw, private well water for us. The sampling team were very engaged professionals and we received nothing but positive feedback from our participants on their experiences with them. However, they became the face of our program instead of the epi staff.

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MS. COSSER: Long before we reached the collection planning stage, we had laid the groundwork for recruitment. We decided in 2016 that we would use the Behavioral Risk Factor Surveillance System Survey and added questions to the 2018, and also the 2017 survey. We

contributed $10,000 per year to the New Hampshire BRFSS program for this opportunity.

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MS. COSSER: During the targeted arsenic and uranium study, many epi hours were spent contacting interested participants, qualifying them for the study and scheduling the in-person interviews. We decided a more efficient use of our time would be to contract with the University of New Hampshire Survey Center for participant qualification and directing qualified participants to a website for enrollment.

UNH provided assistance with drafting the interest solicitation and qualification script, and used industry standard practices of eight calls on different days of the week in different times of day.

We secured contact information from about 3,600 New Hampshire residents from the two BRFSS cycles and about 3,100 calls were completed. Some of the phone numbers were out of service or might have been transcribed wrong. We also ran out of time and money actually to finish eight attempts with all the remaining numbers, but at least everyone was contacted at least once.

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MS. COSSER: The in-person interviews were off the table for our surveillance study. And we knew from

our arsenic and uranium experience that we needed a better survey platform than CDC's Epi Info. And so we asked our value partners what they use for questionnaire software. The Association of Public Health Laboratories, and another program within our division responded with Qualtrics, which APHL described as the Gold Standard for questionnaire software and the product to use if you had your choice of any system.

Qualtrics is proprietary cloud-based software, with data stored on their secure servers, but owned by your program. It was successfully vetted by our very strict Department of Information Technology and we contracted with them.

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MS. COSSER: So other lessons learned, our electronic signature policy. So we learned from our Institutional Review Board that that process wasn't quite perfect for our state. We are allowed to have electronic signatures, for signing informed consents or other legal documents, but now we have to add this check box to any of our online form until we roll out the program DocuSign.

So instead of having to meet with the person, you know, face-to-face and confirm their identity using a legal form such as a driver's license, they simply type their name into this box and then they add the date and

they check this box here just saying that they are who they are saying they are.

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MS. COSSER: So various restrictions regarding TrACE enrollment. So we did monitor our enrollment, you know, throughout the process based on New Hampshire Census data from 2010 and we tried to limit enrollment here and there. But really, we couldn't stop enrollment for a demographic until the specimens were received at the public health lab.

So we -- there were multiple steps for potential loss to follow up. So after that University of New Hampshire phone call, people might not go online and complete our survey, and then they might not take their specimen collection kit once it's been received by them at their home and actually go to the hospital site for their specimen collection. So in the end, although we had about 3,600 contacts from the two BRFSS cycles, we were only able to enroll 336 people.

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MS. COSSER: As far as sample size consideration for our surveillance study, we worked with the New Hampshire Department of Public Health Services, health data statistician who recommended just a general sample size calculator for us and we determined we wanted to

recruit about 400 people for our surveillance study. This is what would work for us as far as the time frame that we had left, which was actually only four months to being able to conduct this study and with the funds we had available. So we knew we wouldn't be able to stratify by these various demographics.

But after consulting with CDC, there were no requirements that we had to be able to do that. We just needed to design a study that would work best for our program. And so we moved forward with the goal of recruiting 400 people.

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MS. COSSER: So data analysis and sample size lessons learned. You know, our recruitment goals were not met for some counties or some age groups. The buckets start to get kind of small sometimes. You know, for some of these biomonitoring analytes, we did have some really high exposures. But to be able to connect them with, you know, a possible environmental exposure, compare it to the water data, the bucket started to get really small as we broke it down. And so perhaps if we had a larger sample size, we'd be abe to do some of that more confidently, but it made it a little bit difficult for us.

Other major issues we realized as we were doing data analysis was what to compare to for a reference

population. You know, all along our idea was just to use NHANES, but New Hampshire's population is a little different from NHANES. You know, we're largely non-Hispanic White, 93 percent of us here. And we -- using that as our reference population, especially on our clinical report, so not just in the summary report where we can, you know, draw their attention to other populations that might better fit some of our participants, but to use it in a clinical report where you want to put just the one reference population that doesn't quite, you know, represent all of our participants in our study.

Also, comparison -- comparing to NHANES, we found that there was a large issue when method limit of detections differed between our program and CDC's. So for our lab, some of our LODs are a lot lower. And so when we were to compare to NHANES and just look for significant -- you know, a difference between our two groups, it was really affected by the LODs. And so we struggled with that and how to actually analyze the data and then put that into context for our participants. So we're still working through those details.

And then similarly outliers, how do we -- you know, we represent the data. We showed geo means and we showed 95th percentiles, but some of the outliers there

like really skewed the 95th percentile results and how to, you know, communicate that with our -- to our participants how to put these findings into context for them and like what is this really showing them is something that we struggle with doing and we're still working through.

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MS. COSSER: Okay. So for our 2024 TrACE study, so we're still a few years out from this one, we decided that, you know, we're going to take all of these lessons into consideration as well as the new CDC guidance on not using the BRFSS for recruitment. We're evaluating how we're going to conduct this recruitment now, possibly using three-stage cluster sampling based on census tract, randomly recruiting using the University of New Hampshire Survey Study or other USPS random mailers and talking with other states to learn about their procedures, as well as considering what would be necessary to allow the placement of our data into the National Environmental Public Health Tracking portal. So there are certain requirements that they're going to be asking of us and we want to make sure we check those boxes.

We're considering implementing better or multiple incentives to encourage study completion. We're in the final stages of contracting with a mobile specimen collection company to go collect those specimens from our

participants. So they'll be going in-home. They're going to do the scheduling of the appointments. They're going to go to their homes at, you know, evenings, daytime, weekends, whatnot to collect their specimens. They're going to package. They're going to do the preliminary processing for us, freeze them if we need them frozen, transport them back to our lab or mail them to us.

From this process, we learned how incredible price negotiation can be, even as, you know, a State government entity, reducing the cost of this service from $200 to $75 per collection. We want to put this final contract that we're creating as a resource for the National Biomonitoring Network.

And we're going to continue with remote recruitment, electronic informed consent, and our online exposure questionnaires, because they've been successful. And so we would like to do that for all of our future studies.

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MS. COSSER: So our entire program has been a learning process. We conduct an investigation, reflect on what we've learned, keep what worked, and then try something new. We do our best to share these lessons with the National Biomonitoring Network, and from -- or for others, you know, like you guys in Biomonitoring

California. So we're appreciative of the opportunity to speak with you today and we look forward to continuing our relationship with you.

Thank you.

CHAIRPERSON SCHWARZMAN: Thank you so much, Amanda. We have just a few minutes for clarifying questions before we move on to our next speaker and then we'll do all the discussion together.

MS. COSSER: Sure.

CHAIRPERSON SCHWARZMAN: Clarifying questions from the Panel? And if you're in the audience and have a clarifying question, you can email that or raise your hand through the GoToWebinar and our -- the staff will keep an eye on that in a moment. We'll come to you after the Panel.

I can see I suddenly lost my view of all the panelists. Anyone with a clarify question for Amanda?

Anything from -- oh, there's Oliver. Sure.

PANEL MEMBER FIEHN: I may have missed it. How were the chemicals chosen that are monitored?

MS. COSSER: Yeah, sure. We actually wrote them into our cooperative agreement years ago. So you guys have your Scientific Guidance Panel and we have a Technical Advisory Committee. And so as we were drafting our proposal for the 2014-2019 cooperative agreement we

met with our Technical Advisory Committee and, you know, just listened to their concerns, their thoughts on what they would want us to look for in -- you know, in our state as well as we felt, you know, what would be feasible for our lab to bring on here.

We actually -- there was -- I can't even remember now what we decided to remove from our panel, but because PFAS became such a hot topic in our state, we have a couple of local investigations here at the Pease Tradeport in Newington, as well as some exposures in southern New Hampshire that we removed one panel of chemicals and added PFAS.

CHAIRPERSON SCHWARZMAN: Eunha.

PANEL MEMBER HOH: Thanks for your presentation. It's just curiosity is that do you collaborate or do you have any kind of leverage funding, you know, for your current biomonitoring study?

MS. COSSER: So current, as in right now?

PANEL MEMBER HOH: (Nods head.).

MS. COSSER: Right now we've received the 2019 to 2024 CDC biomonitoring cooperative agreement --

PANEL MEMBER HOH: Um-hmm, yes.

MS. COSSER: -- but we don't have any state funding for our program. We lean heavily on our partnerships with other programs within the Division of

Public Health Services and the Department of Environmental Services. A lot of our studies have paired data with water testing and we do not pay for that. The CDC does not support environmental testing. So we've been able to get mini grants from DES or from the New Hampshire Environmental Public Health Tracking Program for that.

CHAIRPERSON SCHWARZMAN: I want to check in and see if there are clarifying questions for Amanda from the audience?

MS. ZALAY: There's a question from Kathleen Attfield. I'll read the question. Were there differing response rates by demographics? And secondly, was the initial BRFSS sample representative overall New Hampshire?

MS. COSSER: So we don't have the information on what the original sample actually looked like, the demographics. You know, all we have are our -- the responses to our questions, which were pretty basic. They were on one of the previous slides, would you be interested in learning more and some high level contact information. So we don't really know what we -- who we could have recruited overall.

CHAIRPERSON SCHWARZMAN: Okay. Amanda, thank you so much for the presentation. We'll look forward to having you back for the discussion.

And meanwhile, I want to introduce the next

speaker, who is Rachel Long, an environmental epidemiologist at the Michigan Department of Health and Human Services. She was the lead epidemiologist for Michigan's first exposure assessment of perfluoroalkyl and polyfluoroalkyl substances. She's also lead epidemiologist for the Michigan Chemical Exposure Monitoring Project, which is funded by the CDC's State biomonitoring capacity building cooperative agreement.

Thanks, Rachel.

(Thereupon a slide presentation.)

MS. LONG: Thank you. Thanks very much for having me. Can you all hear me and see my slides?

MS. HOOVER: Yes.

MS. LONG: Okay. Thank you.

Okay. Thank you again very much for giving me the opportunity to speak about our biomonitoring projects. Again, my name is Rachel Long and I'm with Michigan Department of Health and Human Services or MDHHS.

MDHHS was awarded CDC's cooperative agreement to expand our state's biomonitoring capacity in 2019, which is enabling us to embark for the first time on statewide biomonitoring surveillance.

MDHHS has done numerous biomonitoring studies throughout the State over the past several decades, but these were all focused on specific sites of contamination

and on limited analytes of concern at these sites.

So the CDC cooperative agreement funding enables us to expand to statewide surveillance and is funding two new projects. I'll be speaking about one of those today, the Michigan Chemical Exposure Monitoring project or MiChEM.

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MS. LONG: Michigan has some unique characteristics that make biomonitoring surveillance a priority for public health here. We have a legacy of industrial activity. We rank fifth among states in terms of superfund sites. Over a million Michigan residents engage in hunting and fishing annually. And past biomonitoring studies in Michigan have shown associations between consumption of sport-caught fish from certain Michigan water bodies and elevated exposure to persistent pollutants.

2.6 million people in Michigan rely on private drinking water wells as their home drinking water source. This is the third largest number of people on private drinking water wells among U.S. states. And these wells are typically not tested after construction for contaminants.

So our main objective for MiChEM is to establish reference exposure levels for certain chemicals of concern

using a statewide representative sample of non-institutionalized Michigan adults.

In addition to establishing these reference exposure levels, we plan to use the biomonitoring data collected to identify subpopulations with elevated exposures and identify potential exposure sources and use these data to help us better address and mitigate exposures in Michigan.

In addition to our target population of adult non-institutionalized Michigan residents, we're also aiming to generate reliable estimates for low-income adults to assess potential disparities in exposure based on socioeconomic status.

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MS. LONG: On this slide are the analyte panels we are measuring in MiChEM and I'll provide a little context for why some of these were selected. So we're measuring a panel of 39 PFAS. State agencies in Michigan have identified over 100 sites of PFAS contamination in the state. And in Michigan we just analyzed and reported out some initial data from our first PFAS exposure assessment. This was a site-based assessment. And having reference values for PFAS for Michigan adults will be a useful tool and useful data to which we can compare estimates from contaminated sites.

We're measuring 100 PCBs. They're a legacy contaminant at multiple sites in Michigan, including several Superfund sites. We're measuring 18 organochlorine pesticides historically used in Michigan. We're testing a suite of heavy metals. And we are speciating urinary arsenic and blood mercury. Arsenic is of particular concern in Michigan, because there are areas of the state with elevated arsenic in groundwater.

We're measuring 10 PBDEs and PBB congener 153. PBB-153 is of particular interest because of a contamination incident that occurred in Michigan in the 1970s.

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MS. LONG: We have been using simulations to estimate the total sample size and the number of primary sampling units that we will need to achieve less than 25 percent relative error for geometric means for our chemicals of interest.

Census tracts are our primary sampling unit and we aim to recruit from 54 census tracts between 2021 and 2023, recruiting from about 18 census tracts each calendar year. We aim to recruit about 20 adults per tract giving us a total of about 1,080 adults recruited over three years. The numbers on this slide are approximate. We're still finalizing our sample size, taking into account

logistics and funding.

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MS. LONG: Our first stage of sampling will be an unequal probability sample of census tracts within four geographic strata. Those strata are shown on the map on the left here. Our second stage of sampling is a simple random sample of households within selected census tracts. And our third stage is a simple random sample of one adult per selected household.

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MS. LONG: Our geographic strata are based on Michigan's Prosperity Regions. Prosperity Regions are groups of counties that were created during the last administration by the Regional Prosperity Initiative. This initiative encourages development of regional economies, streamlines alignment of State agencies and delivery of State services.

Many State agencies report data by prosperity region. MDHHS reports other public health surveillance data by Prosperity Region or groups of Prosperity Regions. For MiChEM, we've grouped the 10 Prosperity Regions into four geographic strata, the north, central, south and metro Detroit regions. Geographic coverage is a priority for us for this first cycle of MiChEM.

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MS. LONG: The unequal probability sampling of census tracts will be based on the proportion of adults in each tract who meet our low income definition. The probability of a tract selection will be directly proportional to the percent of adults in that tract that are low income. The map on the right shows the percent of adults in each of Michigan's census tracts who are low income.

And in the chart on the left, the green bars represent the proportion of tracts in our sampling frame in each of three categories, so tracts in which 40 percent of adults are low income, tracts in which 40 to 60 percent of adults are low income, and tracts in which over 60 percent of adults are low income.

And the blue bars represent our sample in each of those categories when we -- when we take this oversampling approach. So when we select tracts with their probability of selection being proportional to the percent of adults in that tract who are low income, we end up about doubling the proportion of tracts in our sample relative to the sampling frame in this category of the tracts with the highest proportion of low-income adults.

And it is our expectation that this oversample of areas with a higher proportion of low-income adults will help us get reliable estimates for this subgroup.

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MS. LONG: This slide shows an overview of our second- and third-stage sampling and recruitment approach. So community outreach will be conducted in all selected tracts to raise awareness about the project. Households will be selected via a simple random sample in each tract. And project invitations will be sent to selected households.

This invitation will request that recipients provide a census of interested adults in the household. This can be done online or by calling us at MDHHS. And one adult per household from the census will be selected to proceed to data collection. And data collection involves taking an exposure survey and providing blood and urine specimens at our department's mobile clinic.

Participants who complete data collection will receive a gift card worth up to $65 to thank them for their time and effort.

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MS. LONG: This slide shows in more detail how recruitment will be rolled out in each census tract. We know from other surveys and public health surveillance efforts in Michigan that response rates varied greatly throughout the state. And indeed, it seems like one of the major challenges of planning biomonitoring

surveillance is anticipating and planning for response rates.

So we're rolling out recruitment in two phases, with phase one giving us a sense of response rate in a given tract, so that in phase two, we can calibrate our resources to reach the target number of adults that we are trying to get in each tract.

So on this slide, I'll go through a hypothetical example illustrating this. This is a case where we're trying to recruit 20 adults per tract. In phase one, we'll go into recruitment assuming an optimistic response rate of 10 percent. And by response rate here, I mean, completion rate, so the rate at which people complete all data collection steps.

So because we want 20 adults from this tract and we're assuming a 10 percent response rate, we'll take a simple random sample of 200 households in this tract. Those households will receive the project invitation. And in this hypothetical example, 20 percent of adults -- oh, my.

Can you still see the slides?

MS. ZALAY: Yes, we can.

MS. HOOVER: Yes.

MS. LONG: Okay. Thanks.

Twenty percent of adults will take the census and

will therefore be invited to proceed with data collection. We'll send reminders to the adults to encourage them to complete data collection. And in this hypothetical example, one out of those 20 adults will complete all data collection. That gives us effectively a 0.5 percent response rate from phase one.

So since we're trying to get 20 adults from this tract and we had a 0.5 percent response rate in phase one, we know we need to recruit 19 more adults. And therefore, we will randomly select 3,800 households without replacement from the same tract. Those households will receive a project invitation. In this hypothetical example, if the response rate from phase one holds for this step, 380 households will respond to the census and we'll select one adult from each household for 380 adults that we'll proceed with data collection.

Those adults will get reminders to encourage them to participate. And if the same response rates from phase one hold, 19 adults will complete data collection in phase two. This example is completely hypothetical and we, of course, don't know what our response rates will be, but we hope that doing it in this phased approach will help us better allocate our scarce resources.

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MS. LONG: For more details on the project

invitation, what this will include will be notification that the household has been selected, instructions on how to complete the census of interested adults and the exposure survey - again, this can be online or by phone - and instructions on how to make their clinic appointment and what to expect at the mobile clinic.

We also plan to resend -- send a variety of reminders to selected households and adults. So for houses that don't respond readily to our request for the census of adults in their household, we will send reminders by mail. And for households that have completed the census or that have had adults complete the exposure survey, we will have collected additional contact information and can then send them reminders via a text, email or phone -- phone call.

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MS. LONG: In terms of data collection, our exposure survey includes questions on water source, smoking, pregnancy and childbirth, and demographics. And by letting participants choose the modality, we hope that we'll be opening up participation to a wider audience and reach all Michigan residents.

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MS. LONG: Data collection at our mobile clinic looks something like this. So the mobile clinic will be

parked at locations in or near our selected census tracts at the time that recruitment is recurring in those tracts. At the mobile clinic, we will ask that participants take a short clinic survey. This survey addresses safety. So at this time, it includes COVID-19 screening questions, questions related to the safety of the blood draw, and also factors that can affect exposure levels in the short term, such as recent fish consumption.

Our mobile clinic is equipped with exam rooms and phlebotomy chairs for collection of the blood specimens, a restroom for collection of urine specimens, and a lab area, where our specimens will be processed and stored before they are shipped to our public health laboratory.

We're very fortunate that our department has allocated funding for this mobile clinic outside of the funds provided by the CDC State cooperative agreement for use for biomonitoring and other environmental health initiatives.

We're in the process of purchasing this mobile clinic and we expect it to arrive in spring of 2021.

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MS. LONG: So we plan to roll out our recruitment in one tract in spring of 2021 after our mobile clinic is available to test out our processes, and then proceed with recruitment in the remaining 17 tracts for that year,

staggering recruitment in those tracts throughout the year.

The start date is also subject to change. We've experienced some delays due to COVID and other barriers, but this is our projected timeline.

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MS. LONG: So thank you again for having me. And I very much look forward to speaking with the rest of the panel about the challenges of planning biomonitoring surveillance. This is again our first time doing biomonitoring surveillance on a statewide scale. And I'm very interested in talking about how to plan and design these projects to be sustainable financially and in a way that maximally benefits public health.

So thank you.

CHAIRPERSON SCHWARZMAN: Thank you so much, Rachel. Again, we have a few minutes for clarifying questions for Rachel first from the Panel and then from the audience, if there are any.

Panelists can just raise a hand and I will check in with staff about audience questions in a minute.

Ulrike.

PANEL MEMBER LUDERER: Thank you very much for your presentation. The question that I have, so you said that this -- that it's going to be 18 tracts per year kind

of over three years. Is the plan that you would continue to do this on a rolling basis, so that it would sample kind of every three years, get a representative sample?

MS. LONG: That's -- that is our long-term ambition. Of course, that depends on funding and what resources are available to us, but yes, we would like to repeatedly generate three-year estimates for our chemicals of interest.

CHAIRPERSON SCHWARZMAN: Other questions for Rachel?

Marley or Stephanie, are there any questions from the audience that we should pass on to Rachel before we move on to our last speaker in this series.

MS. ZALAY: Yeah. Nerissa Wu has a question. Would you like to ask now, Nerissa?

DR. WU: Sure. Hi, Rachel. Thanks so much for that presentation. I had a question about the scheduling of the different census tracts, whether you would be trying to finish up in one census tract or would the -- would the mobile unit be going between census tracts and there would be some calculation of how long it would take participants to finish up and get back to you or will there be a time limit within which participants have to respond to you or they lose their chance, because your mobile unit has gone off somewhere else? How are you --

how are you figuring that out?

MS. LONG: Yeah, so the participants will have a limited window in which to make appointments at our mobile clinic since it is mobile. We investigated some options for stationary specimen collection sites and have found that between COVID and other factors, that the mobile clinic, which again we're very fortunate to have, is probably going to be our best bet for this project.

So we plan for the mobile clinic to have stops in each tract twice. So once in phase one and once in phase two. We're anticipating lower numbers of people responding to our invitation in phase one. And so therefore, the clinic will be stationed in those tracts for its phase one period on -- for a shorter time. But if anyone from phase one, you know, is just slow to respond, but we hear from them later, they can, of course, come and make an appointment at the mobile clinic when the mobile clinic is back in their area for phase two.

And as for the exact timing of those periods where the mobile clinic is going to be stationed in each tract, we're still figuring that out. We're balancing the use of this mobile clinic for this project along with our other biomonitoring surveillance project that was funded by this cooperative agreement, which is a targeted investigation into PFAS exposure in firefighters.

So, you know, we're still planning out the logistics, but we hope that we're -- we will be able to provide ample opportunity for participants in each tract to provide their specimens.

DR. WU: Great. Thank you.

MS. LONG: Thanks.

CHAIRPERSON SCHWARZMAN: We're about at time to start our next presentation, but I just wanted to make sure there isn't anything else from the audience.

Thank you, Rachel. And we'll look forward to having you join the discussion again after our final presentation.

MS. LONG: Thank you.

CHAIRPERSON SCHWARZMAN: So I want to introduce our final speaker discussing state programs. Jessica Nelson is the Program Director and an epidemiologist with the Minnesota - sorry - Biomonitoring at the Minnesota Department of Health. She works on design, coordination and analysis of biomonitoring projects and has been the principal investigator for the Healthy Rural and Urban Kids, Minnesota FEET, and PFAS studies. Jessica received her PhD and MPH in environmental health from Boston University's School of Public Health, where her research involved the epidemiologic analysis of biomonitoring data.

Thank you for joining us, Jessica.

(Thereupon a slide presentation.)

DR. NELSON: Thank you. Can folks hear me and see my slides?

CHAIRPERSON SCHWARZMAN: Yes, we can.

DR. NELSON: Great. Yeah. So I, too, really appreciate the chance to participate and share a perspective from Minnesota. I'm an epidemiologist and Director with our Program. But I am actually a native Californian, so I just wanted to give a little shout-out to Ukiah where I'm from.

I'm going to start with some background on our program. And like you in California, we started with a State law.

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DR. NELSON: Ours was in 2007 and was a little different from yours. So our law actually directed the Department of Health to conduct a pilot biomonitoring program. It laid out -- so these are four projects. It laid out the chemicals in three of those projects. It also created our Scientific Advisory Panel which guides our work. And then based on every -- all those lessons learned from the pilots we were to develop recommendations for and then ultimately to implement an ongoing program for our state.

It also explicitly integrated biomonitoring with

environmental health tracking, which is -- I think is unique and our two groups sit together in the same unit today. But the law really didn't give specifics on the overarching goals of the biomonitoring program with definitions and things like we heard about from your law.

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DR. NELSON: So to develop these, we actually engaged in a multi-phased strategic planning process. I want to share a little bit about this background. It involved our advisory panel, but also a pretty wide range of different stakeholder groups. And the first phase involved coming up with vision and goals because that wasn't in the law in an explicit way.

So these were the three main purposes that we agreed on through this process. You can see that it doesn't name surveillance explicitly. It alludes to the idea tracking over time, you know, being a key one, looking at differences between subpopulations, but it didn't give clear definitions and it doesn't say how we should do this.

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DR. NELSON: So our next phase, our phase two of this process was to explore strategies for how to implement those goals. And we developed this model with these three distinct approaches to biomonitoring. You

know, folks have probably seen a different version of this. And, you know, we recognize that really a comprehensive State program that could address all those goals I just showed would have all three of these pieces, so statewide population exposure tracking, targeted tracking that focuses on subgroups that may be more vulnerable, and then the special investigations in specific communities.

Discussions with our advisory panel and an awareness of budget constraints, which actually was thanks in part to work that your Program did earlier on, led our panel to recommend that a targeted population exposure tracking approach made the most sense as a way to continue. It's still in the ongoing surveillance systematic tracking category, but in this more targeted fashion.

And the panel concluded that it shared and could achieve many of the goals of the statewide tracking, but do so at a lower cost, and then to be scalable as resources allowed.

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DR. NELSON: Phase three of our planning, this was like in 2010, 2011 this is when I actually joined the program, was around exploring and getting feedback from a pretty wide array of stakeholders about what -- what the

most important target populations are for biomonitoring in our state. And here is what we heard from them.

So to focus on people and communities most vulnerable to effects of chemicals especially lower levels of chemicals, we see in the environment and on those least able to modify their environment and avoid exposure. So they named children, really the younger the better, pregnant women, women of child-bearing age, and disadvantaged communities, including communities of color, lower income communities, agricultural and rural communities and environmental justice communities were some of the ones named most frequently.

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DR. NELSON: So since coming up with that plan and that process, you know, it's been eight or nine years, truthfully, we haven't been able to fully implement this targeted surveillance approach. We didn't -- our original funding amount was decreased and we are -- we've been subject to two years State funding cycles, which makes planning for surveillance very difficult. But we have done a number of important projects focused more on specific communities with these target populations that we got feedback on involved. We actually did a clinic-based project in pregnant women. I was thinking about that a little bit in the discussion about the BEST program you

guys have done.

But the thing I wanted to emphasize here is that for all of these we think a lot about recruitment methods and how to get a population-based sample to the extent that we can. So this idea of having the larger sampling frame that you're working from and then being able to quantify at the end, you know, assessing participation rates, looking at other factors to determine if the results we have are at least generalizable to this sort of smaller subpopulation that we were trying to represent.

And the example that I wanted to share is our PFAS biomonitoring work which has been done in a community east of our Twin Cities metro area that was an affected community from water exposures. We did random recruitment using utility water billing records. So we randomly selected those addresses, mailed a household survey, offered participation to eligible individuals enumerated in that survey. And the participation rates have been strong. I think it was 65 percent for our first project. And we've actually been able to follow that group over time.

So that takes us to the present.

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DR. NELSON: And I'm excited to say that with the help of a CDC cooperative agreement that we got last

summer, summer of 2019, we finally are on the cusp of realizing the targeted surveillance approach with our new Healthy Kids Minnesota Program. So this will be a statewide surveillance program focused on younger kids, preschool aged kids. And child environmental health and health equity are sort of central here. We'll be dividing the state into five regions, which you can see here, recruiting from one non-Twin Cities metro and one metro region each year.

We're going to start in Southeast Minnesota and in Minneapolis, although recruitment was delayed for a year by COVID-19 and we'll have to see how things go next spring. But a key piece is that we partner with local public health and counties, with school districts and with tribal nations whose staff actually do our recruitment.

And then as far as how it works on the ground, we're using a successful model from a project -- a pilot project we did in 2018 called Healthy Rural and Urban Kids. So this recruited the same age group of kids from two specific communities in our state. And we recruit kids through an existing program in Minnesota called Early Childhood Screening. And this is really key to our plan. So I'll say a little bit more about it.

So this is a universal pre-kindergarten screening program. All kids have to go through it before they start

kindergarten. And the purpose is to identify developmental issues early, so we can intervene before they're actually coming to the classroom. So it's hearing, vision, other kinds of developmental screenings.

But at the appointment that the families are already coming to, we can kind of add on the biomonitoring. The staff introduced the project to them. They do informed consent and conduct the interview with the family. In most cases, there's a fair amount of waiting around time by the family, so it works well. And then the child actually gives the urine sample at that same visit.

And we -- we were pretty amazed by the participation rates we saw in both the rural and the urban settings and really credit this to the staff of these programs who know their communities. They work in them every day. They really have the trust of the families coming into these programs.

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DR. NELSON: So here's a little bit more about our regions and the population sizes. I know this is very different from what you're facing in California, but just to give you a sense of kind of -- this is total population, not kid population, but just to give you a sense for what they look like.

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DR. NELSON: The details of our sampling plan are here. So our -- we're considering this a three-stage plan. The first stage is region, but we'll be getting to all of these regions, so we consider this to be sampling with certainty.

The secondary stage is a sample of counties in that region to kind of represent the larger region. And when we, you know, wrote our proposal, kind of thought about this theoretically, we thought we would do a random sample of the counties who administered these early childhood screening programs in the region. But when we actually have to come put this into practice in Southeast Minnesota in particular, the complexities have become clear.

So we are going to actually use a three-tiered approach. We want to be sure we include larger population centers, mid-sized population centers, and rural parts of these regions and counties. They could be having very different exposures from one another.

From there, we'll do our best to choose the counties randomly. But again, kind of the practical -- practicalities have become more obvious as we've gotten deeper into it. So other factors are also important, interest by the local partner, geographic coverage across

the region, demographic coverage, and then we do always want to have a heath equity lens. But with all these steps we can kind of compare the demographics probably using U.S. census data of our sample to the -- to the next level up.

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DR. NELSON: The third level then is the actual kids who are coming in for their screening. And this is going to depend a little bit on the specific locations. So in some of the smaller areas, we'll probably offer participation to all families. But in the bigger ones, like Minneapolis Public School District, it will be a much smaller subset of the -- of the overall number of kids coming through.

But there -- we're going to space recruitment over a six-month window. There will be a target number of kids per county per month. And our plan is just to have our partners recruit up to that point and then stop recruitment for the month. We think we'll be oversampling. We have to figure out those details.

But a key piece is, you know, related to Brian Wells' talk earlier. We have this larger sampling frame, so we can calculate the participation rates and then hopefully working with our partners we can get a pretty good sense for the characterization of families who did

not choose to participate and get a better idea of their refusals.

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DR. NELSON: So next I kind of wanted to end by just reflecting on a few different areas of trade-offs that our program has made. The first is around this targeted approach, you know, of this -- of kids, but not even just kids, of very particular subset of age kids versus a larger statewide population. So on the pro side, we can focus on a key group of concern for different reasons of vulnerability. And really probably the big one for us has been that it was more feasible economically and logistic -- logistically.

It's of a kind scaled back approach. We're still building capacity. We can expand in the future as -- as it makes sense. We can also tailor our outreach. I mean, we've all heard a lot and thought a lot about how important results communication is. In this case, you know, we know it's to parents of young children, so that -- that makes it a little more specific. But we're not getting estimates for the full state population that we can compare to NHANES or, you know, compare to other programs.

We -- I imagine we'll be missing important exposures and disparities in other age groups related to

occupation, personal care product use, things like that. And we are only doing urine sample. So we've just been talking a lot about that. I won't say much more. We will not be doing PFAS, which is disappointing, because it's an important compound in our state as well.

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DR. NELSON: The next trade-off - try to go quickly through these - is just recruiting through an existing infrastructure. For us, it's these EC -- early childhood screening programs versus a new infrastructure for biomonitoring. Again, a lot of it came down to economics and viability. This is a more efficient approach.

But I do think, as I talked about in the example from our pilot project, that it can lead to more successful recruitment because these are known programs. They have trust in the community. And another key thing is that the relationship building with partners is really a critical component here for us. So for us it's local public health and school districts. In addition to all the help and, you know, guidance they provide in planning and implementing, they're also a really important audience for our findings. And they have definitely higher levels of buy-in, you know, for being involved all the way through. And then they -- they are important advocates

for our program down the road.

But on the con side, we don't have as much control. They have their existing program that we, you know, kind of need to work our efforts into their flow. And it is -- it's not a perfect sampling plan. We're doing our best to achieve, you know, as close to population-based sampling as we can. There may be some selection bias. We know these local programs vary. It's not totally consistent. So I think being pragmatic and being open about the limitations, quantifying them like we were hearing about earlier, and finding ways to communicate them are really important.

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DR. NELSON: The last trade-off is just this regional versus statewide approach. So, you know, we're taking a regional approach. And one -- and a few things I wanted to mention. We've heard from our local partners that they really want to know information about their area. I don't think they would be satisfied with just a statewide estimate.

It also gives us the -- a better ability to really develop these connections and relationships and do community outreach in these smaller areas. And an important part of our new grant is to pair this with broader environmental health outreach, especially in some

parts of the state that we often aren't reaching.

But it is a longer time window for the statewide estimate, especially since it's a five-year window. We're planning to do this with weighting, but we need to think a little more about the utility of that estimate. The time trends just get more challenging because chemical use patterns are changing.

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DR. NELSON: So here are a few takeaways. And I'll just say to conclude that on the question of whether or not these trade-offs have made sense for our program. I think they have and that our approach has enabled us to keep going in a scaled-back version, but we'll have to see about a lot of them. As others have talked about, our program has been going for some time, but we're still learning and building capacity, COVID-19 has just thrown us a huge curve ball on a lot of fronts.

So especially for surveillance, we're just getting going, figuring out ways to maximize those pros, to address the cons that I discussed. But it does feel like with this approach we're building a foundation to expand out as new partners and new resources are available.

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DR. NELSON: So many different acknowledgments to

make with these projects as we know. It's a very wide-ranging team.

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DR. NELSON: And I thank you for your time and look forward to the discussion. Thanks.

CHAIRPERSON SCHWARZMAN: Great. Thank you so much, Jessica. We're going to have -- we have five minutes or so for questions -- specific clarification points for Jessica and then we're going to take a break and open the discussion.

Tom.

PANEL MEMBER McKONE: I've got to remember that mute button.

Thank you, Jessica. That was very good. I guess this kind of a question about in a state like Minnesota, where you've got a very high concentration in like Minneapolis/Saint Paul of racial, economic, lifestyle, heterogeneity vary -- you know, a lot of variability there.

DR. NELSON: Yeah.

PANEL MEMBER McKONE: And then even though the outlying regions on the map, I mean they do look more diverse, but I think they tend to be more heterogeneous, right?

DR. NELSON: Um-hmm.

PANEL MEMBER McKONE: Then you've got this really significant one. So can you get enough samples -- I mean, given the constraints on the number of samples you get, how do you -- how do you manage getting representative samples in all the regions, but also having enough resources to capture the variability that's likely to be in the urban area. You know and again, it's kind of a -- I think there's kind of a tension there right, between --

DR. NELSON: Yeah.

PANEL MEMBER McKONE: -- making sure you oversample, where there's a lot of variability, but not to the point where you so under sample the outlying regions. You might get a good State representation, but then you fail to meet your goals and get representative samples in each of those regions.

DR. NELSON: Yeah it's great question. And I think just sort of an ongoing tension that we'll keep having to balance. A few thoughts are that's a piece -- I think another strong advantage of working with a local partner who really knows the communities they serve and who can advise us on some of those trade-offs of like oversampling versus not. And I think it's also a strength of the regional model. I mean, certainly when you think about trying to get the one statewide estimate and still cover all those different areas of diversity, you know,

the challenges there are pretty clear, so I wouldn't say it's something we've solved. We're aware of it. Kind of trying to work on different methods, but really relying on our partners.

And just thinking about like languages and all that kind of stuff, you know, they have those staff available because they're -- they're doing that every day for the populations they serve.

And interestingly, in Minnesota, some of those demographics are really changing. There are some areas of sort of the non-metro that are, you know, increasing a lot in diversity. So we're learning a lot about shifting demographic patterns in our state, but I think it's a point well made and just, you know, one that as a field we'll have to keep considering. And, you know, I do think this idea of being clear about what the trade-offs are and why you're -- why you're making them one way or the other is just always so valuable to come back to.

CHAIRPERSON SCHWARZMAN: Thanks.

Carl.

PANEL MEMBER CRANOR: Yes. Thank you. Thank you for the presentation. This is maybe the opposite of Tom's question. Can you speak to gaps in the -- what you're possibly detecting? And I ask that question, because if you have children from a household, their contamination,

as it were, is likely to represent a good bit of the household. If they were newborns, of course, it would represent contamination of the mother.

DR. NELSON: Um-hmm.

PANEL MEMBER CRANOR: And we all -- we know that -- or at least my -- my view is, if we can protect the children, we can protect a lot of the rest of us as well. So you may -- you indeed miss some and you miss some because of -- you're testing only urine. If you could use urine and blood, how worried would you be about what you're missing for the general population?

DR. NELSON: Yeah. I mean, as I stated, that -- that was one of the sort of painful trade-offs we did have to make with that targeted approach. And I would agree I think we are concerned. I mean I mentioned occupational exposures, especially as one, increasing concern about personal care products, and various chemicals, and those sorts of exposures.

We certainly -- I think, ideally our program's vision would be to kind of have this as our ongoing surveillance piece, but to use possibly our State funds to continue to do some of these sort of special community investigations as exposures are -- exposure concerns are raised. But again, those are more reactive studies, instead of the idea Nerissa was mentioning of surveillance

of really being the baseline that helps you identify where some of those concerning differences might be.

So I -- you know I hope we can supplement to some degree, like I said, with more community focused work that will -- that will be compatible and go along with the surveillance, but I am concerned about that. And it was just sort of a choice we had to make, you know, that focus on, as you said, given the developmental life stage of children, the fact that they may have more, you know, intake per body weight than adults do, those are all compelling reasons to choose that group.

And it just sort of felt like for our program and the size of our program, we had to narrow it down. But they are always painful decisions to make. All -- all those trade-offs I mentioned are difficult painful decisions. And probably that's what we'll be talking about in our discussion as well.

PANEL MEMBER CRANOR: Thank you.

CHAIRPERSON SCHWARZMAN: We need to break now.

PANEL MEMBER CRANOR: You may mean less than the --

CHAIRPERSON SCHWARZMAN: I'm sorry.

PANEL MEMBER CRANOR: Thank you.

CHAIRPERSON SCHWARZMAN: I'm so sorry. Let's pick this up. I'll put you first on the list for after

the break. But we need to break, I think, partly for the transcriber.

So I have a question for Sara, do you -- should -- are -- should we take an entire 15-minute break from now or should we reconvene at 3:00.

MS. HOOVER: Why don't we try to reconvene at 3:00.

CHAIRPERSON SCHWARZMAN: Okay. Then a quick break and we'll come back together at 3:00 and continue the discussion.

(Off record: 2:49 p.m.)

(Thereupon a recess was taken.)

(On record: 3:00 p.m.)

CHAIRPERSON SCHWARZMAN: I have that it's three o'clock, so I'd like to restart the meeting, assuming that Nerissa is present.

DR. WU: I am.

CHAIRPERSON SCHWARZMAN: Great. Okay. Then I'd like to start the next session as intended. And since it's a discussion session that Nerissa is just going to introduce, that I want to keep in mind that I think Carl had another point to make, and -- but we can roll this all into the discussion session that's coming.

So I want to reintroduce Nerissa, Acting Chief of the Environmental Health Investigations Branch at the

California Department of Public Health and overall lead for Biomonitoring California, because she's going to provide a brief introduction to the afternoon discussion session. So we have a few minutes now and then we will open it up to general discussion.

(Thereupon a slide presentation.)

DR. WU: Okay. And are you seeing my slides again?

CHAIRPERSON SCHWARZMAN: Yes.

DR. WU: Okay. So welcome back, everyone. And thank you to all the afternoon speakers. That was really, really excellent, super informative.

Each state -- it's so interesting to hear about each state's programs, because each state, of course, is unique, but we all face similar issues trying to balance all of these different challenges. So I want to come back to the questions that I had posed this morning, but now with this additional context of what we've heard from our after -- afternoon speakers.

So what are our priorities for surveillance? We've heard about trade-offs made by other states. And I want to refocus the discussion on how should California move forward. I really appreciated Jessica's description of the trade-offs, sometimes painful decisions, about making -- about focusing on a particular demographic, but

with a similar targeted approach, such as working through GDSP to fulfill our legislative mandate. Would that be something that's acceptable in the state of California or as our legislation says, do we need to address a fuller -- cover the full demographic of California?

What aspects of surveillance are most important for us to retain? All states are making trade-offs in terms of how often you create a statewide estimate, but -- and California might be a little more complicated, just because we are so large and it might take us a really long time to get around the state. But how do we decide which one of these aspects is most important?

I'd also like to hear from the Panel prioritization where there are choices to make regarding analytes that we really want to focus on. Do we -- can we continue to do all media and our priorities of metals and PFASs, or are there choices to make there based on prioritization of different interests in the state.

And for Brian, I hope Brian is still here, I do want to get back to Kathleen's question about what do you advise us to do in terms of probability sampling versus sticking with our quota sampling, particularly about how to evaluate non-response bias?

We can compare demographics of our population versus the census, but, you know, demographics do have

some bearing on environmental exposures. But there are lots of other variabilities in exposure as determined by things like occupation or rural versus urban. And what that variability is in exposure, I'm not sure how we would go about capturing that.

So I want to just repose these questions back out to the group. I know there were a number of questions out in the queue from this morning as well as the afternoon talks, but I'd like you to keep an eye on these -- these different questions and help us answer some of them.

CHAIRPERSON SCHWARZMAN: So, Nerissa, sorry. I was just taking a couple notes on your questions. Are you going to keep the discussion questions up during our conversation or do folks also have access to this information on the website.

DR. WU: I can leave it up, if that's helpful to you. I think it is in the slides that were posted earlier. I understand there might be more follow-up questions for -- for Dr. Wells or for our other panelists. So, Sara, would you like me to keep my slides up?

MS. HOOVER: Yea, that was the idea. And then --

DR. WU: Okay.

MS. HOOVER: I think there's a couple, right? So, Meg, you can feel free to say, okay, switch to -- switch to the other questions as appropriate.

CHAIRPERSON SCHWARZMAN: I have some thoughts on this discussion, but I want to first circle back and see if we need to get some last questions tended to from our -- from our previous question session.

So, Carl, did you have something else that you didn't get answered?

PANEL MEMBER CRANOR: No, I don't think so. I -- I just raised the question of whether the kind of sampling that was done in Minnesota might be better than you would think abstractly simply because children are a mirror or a window into a lot of the world around them. And that may produce a wider range of results than you might think. So I appreciated the things that got left out. But I was very interested in that. That's all I had.

CHAIRPERSON SCHWARZMAN: Okay. Thank you. I think I'm also supposed to do a reminder about how to participate during this discussion session. So just like we have been, Panel members should raise their hands, if you want to speak. And I'll make a queue as necessary. Guest speakers and Program staff, anybody who wants to speak should just turn on your webcam and raise your hand, like Panel members do, and I'll spot you.

For attendees who want to speak during the discussion session, you can alert us using the question function or the raise hand feature of GoToWebinar. And we

will collect your names and call on you at the appropriate time when you can unmute yourself and ask your question or provide a comment.

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So Marley and Stephanie are there things that you want to turn back to from previous question sessions or shall we dive into the discussion?

MS. ZALAY: There was a question from Kathleen Attfield for Jessica. The question is did you administer any type of exposure questionnaire?

DR. NELSON: Hi. Yeah. Thanks. We definitely did. That's -- that's actually a pretty high priority in the different biomonitoring projects we've done. So for Healthy Kids, it was about a 15-minute interview that the recruiters actually administered to the parents in person. So it asked about a range of exposure -- demographics and exposure predictors for the analytes we were measuring.

CHAIRPERSON SCHWARZMAN: Thank you for that. Anything else we need to capture, Marley?

I have one comment or question then from José.

PANEL MEMBER SUÁREZ: Yeah. Hi. This is a question for Jessica as well. So the only Biomonitoring Program currently existing is the early childhood screening program, is that right?

DR. NELSON: We actually have one other area of ongoing work at this time, which is around urine mercury. Actually, I mentioned another kind of community-specific project we did in pregnant women and babies. And it was focused on heavy metals. And we had some concerning findings, particularly around urine mercury and the use of skin lightening products, which I know is a -- something California has been addressing and talking a lot about.

So some follow up to that. It was called our MN FEET study has resulted in some clinic-based urine screening projects in prenatal populations, but also in some broader populations. So that, at this time, is our other ongoing work. We have some sort of smaller kind of targeted follow-up work we'd like to do from the Healthy Rural and Urban Kids 2018 project. But due to mostly staff capacity limitations, especially right now with the COVID-19 response, we haven't been able to pursue those.

So, yeah, it's our -- the kind of rollout of our new kids program, as well as these ongoing projects focused on urine mercury screening and skin lightening

product use.

PANEL MEMBER SUÁREZ: And in the future, how do you see these -- the biomonitoring going forward? Are there changes that you're envisioning? I saw that you have some of the target populations. Are you going to continue going to other -- some of the other target populations?

DR. NELSON: Well, for right now, you know, we've really kind of settled on this target population of younger kids for our statewide surveillance. It's a -- it's a good question about the bigger picture. I mean, I think I would imagine, you know, doing that for a handful of years, maybe trying to, you know, make our rounds around the State, see how that surveillance approach works, assess it by all the different ways we've been talking about, and then depending on resources and capacity, see does it make sense to expand that.

I mean, the -- the sampling method we're using for that is pretty specific to this age group of kids, so we couldn't use that same approach for other populations, unless we wanted to add on -- you know, we've talked about, you could -- you could include the family potentially when you recruit a child. There's ways that that could be expanded. But right now, we're, you know, doing our best to roll this program out and we'll keep a

focus on urine mercury, as well as some of these other kind of smaller targeted follow-up projects based on past findings. I hope that helps.

PANEL MEMBER SUÁREZ: Thank you.

CHAIRPERSON SCHWARZMAN: I wanted to turn -- thank you, Jessica, for that. I wanted to turn to Nerissa's question about the priorities of surveillance and just kind of jump start that conversation with a couple of thoughts that I was having. That it strikes me, as I was thinking about it, that the priority in surveillance completely depends on the goal, like what you're trying to learn with the information. And I currently have a couple of research projects going on where I'm really trying to find out the impact of public policy and public health policy. And for that, what we've really struggled with is finding data that are comparable over time. And that feels like the -- the sort of Holy Grail.

There's very few opportunities to find consistent data sets that are collected in a systematic way and ongoing over time, that they become comparable over time and we can track how things have changed, you know, in response to lots of things, but including in response to public policy, in response to market changes, and advocacy efforts, and community interventions, and all kinds of

things like that.

So I've had as a priority being able to look at changes over time and have been very frustrated with the paucity of data that one can mine for that in biomonitoring, but also in environmental data and other ways of understanding exposure or estimating exposure.

But, of course, something that we've heard about a lot today and that we hear about that is often a goal of biomonitoring studies is to identify high risk populations, identify populations that have particular exposures, that, you know, then merit intervention, or help identify high risk groups that, you know, we didn't know about. We just heard about the mercury and urine, pointing to skin lightening creams, which, of course, is an issue in California as well. Arsenic has come up in California among some high exposures. Biomonitoring staff could give a bunch of other examples, I'm sure.

And I guess I've just been reflecting and I would be curious to hear, you know, Nerissa how you feel about whether this characterization I'm about to give is true. But I feel like with the CARE study -- so the thing that's keeping everybody from generating data that's comprehensive and comparable over time is money. It's always the limitation, right, because everybody knows how to design -- the great data collection methods that would

do that purpose, but nobody has enough -- big enough budget to do it and so it's always this question of trade-offs.

And I feel like in California with the CARE study that has been under such budgetary pressure, in a sense, we chose geography, you know, going from one region to another. And in doing so, we gave up the temporal comparisons, because it's going to take so long to get around the state, that we can't make comparisons over time, unless we get like 20 years out and can finally get back to one of the regions that we started in.

And because it's been so attenuated, in a way, I feel like we've also lost the geologic -- geographical comparability that we opted for -- or we opted for some geographical diversity anyway, but then we're not able to compare across geographical regions, because it's taken so much time.

And none of this is to implicate the Biomonitoring Program, because this just the -- what has happened with the realities of the budget that you've been working under.

But I just wanted to -- that's what I've been thinking about a little bit is sometimes in a way, we don't get to choose, that by choosing one priority, we jeopardize another, and then that jeopardizes the priority

we were trying to elevate.

And I guess my frame for thinking about this is, first, like the goal of the information, and we want all of the information. But are we trying to understand changes over time, are we trying to identify high-risk populations, what is the priority, what is the public health impact priority, I think, knowing that we have, you know, slim resources to distribute to support all of this, and that to back up from there -- from the goal to figure out which -- which to elevate, you know, high potential exposure populations, or particular geographical regions, or to do something that allows more comparison over time.

That's how I've been thinking about it. And so I just wanted to frame that. And I'd be curious, Nerissa, if you have any reaction to how I portrayed the -- what we've given up through the CARE study's minimal, you know, budget or if you think more of that has been preserved than I'm portraying.

DR. WU: Well, it is all so difficult. I think that is -- I think one of the risks we run with CARE is that we couldn't make a choice, that we want to do everything. And by not choosing, I think you're right, but somehow we spread ourselves too thin trying -- in all directions and we run the risk of -- of ending up not getting robust data in one direction or another.

That's not to say that CARE wasn't robust and the data aren't useful, but I -- you know, as I was referring to before, you know, we've -- we've made it work somehow for a couple of regions, but -- but not without a pretty big cost to ourselves as a staff. And it, you know, worked almost by luck. And we're seeing now that it doesn't always work that way.

So that was what I was trying to get at with one of my options that maybe for -- maybe we can do CARE, but pick an area like Sacramento or the Bay Area where it's easier for us to get to, and then we really get to know that region, so we can do very frequent sampling and get at that temporal and even maybe get at more of the disparity questions, because we'll be repeatedly sampling in an area. It's a hard choice to make. And I guess that's what I'm turning around to you. I mean, is that -- is that appropriate, as a State program, to make that kind of decision? Is one geographic region adequate to represent across the state? Is that appropriate for us to do? We are a statewide program and we're saying we're not going to go to all these other communities, which have their own individual concerns and exposures that we should be learning about as well.

CHAIRPERSON SCHWARZMAN: Thank you for that, Nerissa. And I would -- just one quick thought I had in

response is that, obviously, the Program has to make choices now because of budget and can't fulfill the legislative mandate, because you haven't been given the budget to do it, in my view at least. I don't know that that's how you would portray it.

But I guess I would say that, you know, this one version that you just threw out, for example, right now, of like repeatedly sampling a single geographic region that's easier and less expensive for the Program to access, that that wouldn't be -- there's no sense that -- in no sense would you be representing that as your understanding of a representative sample of the state, right?

It -- that -- that represents a choice that the Program has to make, not that you're interpreting that choice as oh, no, no, we're studying the whole state, and this is a representative sample, and we're going to fill in the Bay Area or we're going to fill in Sacramento for the rest of the state.

So anyway, I just wanted to make that distinction, that there's some hard choices that have to be made, but I think, you know, we're not asking you to then portray those as accomplishing something it isn't accomplishing.

So I will turn it over to other folks who want to

advance the discussion. I have Tom, and then Veena, and then Jenny.

PANEL MEMBER McKONE: Yeah. So I'll weigh in just to say I think this is a very difficult question about priorities. And I tend to kind of agree with Meg and others that -- and I think, you know, when we set out on this Program, I mean, there was -- there's a number of dimensions we're interested in. You know, spatial and temporal and spatial. We -- and I -- to me, I still think we were very much concerned about time trends, that is what's happening? Are things going up, going down? And then also seeing differences in economic, ethnic, racial, whatever classes, you know, to basically look at diversity issues, community variation, which you can actually get -- I think, you can get some of that in -- there's a lot of overlap in how that plays out. It's different in different parts of the state, but mainly it's different between rural and urban, I mean, to -- first order.

But I was -- I was just wondering if there -- I think we should try to give preference to temporal trends. I'm a little uncomfortable saying, well, let's just reduce it down to one population. I'm just wondering if there aren't ways that we could fold in, you know, not -- not a high-powered study from every region of California, but maybe do a fairly focused study on at least a rural and a

urban community and then try to fill in, either with opportunity samples or with just some very quick samples in different places to just sort of ground truth what's happening in other areas with our -- with our core, sort of our anchor study sites.

So we could have an anchor study site, you know, I would like to say the Bay Area, but I also would suggest we should have something for a non-urban type region a non-urban population, and then try to fill in with opportunity samples. Like some of the AB 617 sampling is not complete, but it might actually help us see how different these different communities are in different parts of the state relative to our core communities.

Just -- I'm just thinking out loud, as -- but kind of a thought about how to move this ahead and focus on temporal without totally losing all of the geographical elements of the survey -- or surveillance.

CHAIRPERSON SCHWARZMAN: I wonder if you might add into that not just the trade off between temporal and geographic, but by limiting geographic and focusing on temporal, maybe that also still allows the opportunity to look for highly exposed populations, sort of subpopulations, subgroups within a geographical region might apply elsewhere in the state as well.

PANEL MEMBER McKONE: Yes. Thanks. I mean, I

was going to move in that dimension too, but kind of got --

CHAIRPERSON SCHWARZMAN: I couldn't have said it --

PANEL MEMBER McKONE: First-year approach. So, yeah, thank you.

CHAIRPERSON SCHWARZMAN: -- recommendation.

Veena is up next.

PANEL MEMBER SINGLA: Thank you to Brian and the presenters from the State Biomonitoring programs. Really, really informative presentations. And I appreciated Jessica's presentation kind of speaking about their stakeholder process that helped them identify priorities, that informed their thinking, in terms of what stakeholders would place high on the priority list and vulnerable population, children. I think that's, you know, helped them ended up determine where they were going to focus.

And I wonder if it might be helpful for the Program to think about something like that here, also, to inform this question. And I think I recall maybe a couple of years ago the Program doing some interviews or listening sessions with environmental justice groups in the State. And I wondered if there was anything informative on this question in terms of priorities that

could be gleaned from those interviews?

DR. WU: In response to your question, we did do listening sessions around the state, when we were starting out CARE to try to identify what were priority pollutants and priority issues around the state. So it was fairly narrowly focused on this question of, you know, what -- what are your concerns and how does that tie into biomonitoring?

And we did hear a wide range. We heard -- almost everyone had concerns about air pollution and drinking water quality. There's quite a bit of concern about pesticides, and then there's -- there are a number of other issues. We actually have a report on those listening sessions. I think that is coming out somewhat soon.

But, yeah, that is -- it's always great to check back with stakeholders. I think that would be a really great idea. It is not without considerable effort though to convene a panel like that. And I guess the question is, you know, if that is an appropriate step to take at this point, then our Program resources would go there as opposed to getting out in the field to do biomonitoring. So it might be an appropriate time to take that pause, but it is also -- it is not without cost to the Program.

CHAIRPERSON SCHWARZMAN: One of the things that I

remember from the Panel meet -- the SGP meeting that we had around that time of those listening sessions was a request from communities, sort of an expression of fatigue over being studied and a desire to have action.

And that -- that's hard when you're a Program that studies. But one of the things I remember that sort of fueling the conversation about intervention studies, because that's a nice way of bringing those two needs together, and sort of matching what's being requested by a community with what this program actually does.

And so in that way, I think it's really -- what you're designing for the AB 617 studies is a really excellent response to that and obviously not as good a match for a surveillance study.

I had Jenny next on the list.

PANEL MEMBER QUINTANA: Hi. I had a couple of comments. One was that an obvious way to save money is to try and use samples that are being collected by someone else, because I think the strengths of California Biomonitoring really are in the amazing work done by the labs and the ability to detect so many different analytes. And so we've talked about this in the past and had issues with certain samples that are collected.

I know Jose Ricardo, in particular, has had experience with long-running health studies and using

archived samples. But I just want to kind of bring up should we think about a way to use samples being collected by someone else, because that really does save a lot of money and maybe making more explicit partnerships with ongoing long-running studies or something like that. That was my first comment.

I did -- I was concerned with CARE studies having -- really having a lot of educated people and not really representing the population just in San Diego. And I really want to see if we could have a way to try to get more of a sample that reflects our whole state.

And the second thing I wanted to say just a long thing actually, but -- is really thinking about what makes California special and what makes California information different than what we get from NHANES?

So if there's nationwide trends in something, that shouldn't be our focus, because NHANES will already tell us that. If it's pollutants that NHANES measures and there are nationwide trends, then that shouldn't be our focus in my mind.

What we should think about is what are we doing that would provide different information? For example, are there new analytes not measured in NHANES at CDC, how is California different? And it's different in a sense that it grows a lot of produce for example. So the kind

of -- even though people are concerned about pesticides nationwide, the kind of pesticides they use here are quite different than a place that's only growing corn, for example.

And traffic, we talked about traffic already earlier today. Immigrants and refugees, California is very different in that from a lot of states. And also environmental justice being a focus. California should be very proud of having AB 617 and really putting the resources behind environmental justice initiatives. The State is really a leader in that sense, and perhaps we should also make California Biomonitoring part of the environmental justice efforts more explicitly.

And then I also wanted to echo Tom's comment about rural versus urban. California is such a big state, there's air pollution exposures down here at the border, burning trash, plastic trash from Tijuana down here that's not going to be reflected in other parts of the state. There's rural uses of pesticides. There's people on water wells in the Central Valley and people on big water projects out drinking the same tap water in other areas. So it's a lot of diversity across the state, but -- so I guess those are some questions to have.

But if I had to choose, I would choose to save my resources by analyzing existing samples, whether they're

new partnerships or other ones. And then try to keep that temporal aspect if it's a long-running study. And I'm just thinking the California Teachers Study, or something like that, some kind of large study. They don't always collect biospecimens in a way that could be used by us, because they're different tubes or not metal free or whatever, but I guess I'll end there.

Thank you.

CHAIRPERSON SCHWARZMAN: Go ahead, Eunha. And then I have Ulrike next.

PANEL MEMBER HOH: I think I agree with many of the panelists' comments that I think it should be -- we should probably target and be very selective, but how we can select analytes, how we can select the reasons. Something that I think is so far the CARE study, you know, if those data shows that there is not much difference for certain analytes, based on the reasons, I mean, those chemicals do not need to be constantly measured covering whole state, you know.

But in the -- if we see really big difference, you know, for certain analytes in certain region or certain demographic, you know, based on the what -- based on the study so far, based on the results so far, you know, that has to be probably continuously analyzed it using some -- you know, covering the whole geographic

population, maybe like Jenny said that something like currently available or some other kind of a resource already, collected samples, or continuously collecting samples programs, you know.

So I think that's probably like maybe using some, you know, current -- so far the collected data and even literature. And I think it's important to select what analytes have to be focused on geographically more -- more based or certain analytes doesn't have to cover whole geographical basis.

CHAIRPERSON SCHWARZMAN: Thank you.

Ulrike.

PANEL MEMBER LUDERER: Yeah. I really also agree with what Jenny said about the -- I think that a lot of given limited resources using samples that have already been collected really makes sense. And I wanted to come back to one of the things that was talked about early on today, which is the Genetic Disease Screening Program.

So I understand that there are limitations that, you know, only serum is collected, not urine, metals can't be measured, but it does -- and also it's only pregnant women. However, it is pregnant women from all over California. It's ongoing. It would give us the ability to look at temporal trends, but also to look at geographic differences. So, to me, it seems like that -- you know,

those samples might be -- you know, given that we can't really do what we want to do, which is, you know, surveillance of a representative sample of the entire state, you know, on an ongoing basis.

But this -- you know, it gets pretty close for pregnant women and kind of hearken back to the -- you know, the -- the -- for example, the choice in Minnesota to use children between the age of three and five as kind of -- you know, to focus on a particular group that's a potentially vulnerable population. I just wanted to throw that out there as that might be a good approach to take. And it might be possible, depending on how detailed the geographic information that you can get. I think Nerissa mentioned it might be possible to get addresses. One could potentially identify particularly vulnerable populations, you know, based on the measured exposures, you know, within a geographic area and then potentially that could be used to develop maybe other targeted types of studies. So those are just some thoughts that I had.

Thanks.

CHAIRPERSON SCHWARZMAN: José.

PANEL MEMBER SUÁREZ: So just as a follow-up. When thinking about CARE, for example, just for me to understand, what proportion of the budget is allocated towards participant recruitment, and the processing

collection of biospecimens, et cetera?

DR. WU: On the processing of biospecimens, do you mean the analyses?

PANEL MEMBER SUÁREZ: Oh, sorry. No, not the analyses. I meant just the like venipunctures or sample collection and storage of those.

DR. WU: Well, I can say that for CARE-LA and CARE-2 our field presence probably cost us about a hundred thousand dollars per region. And that's not including in-kind costs or laboratory support of any kind. And there were probably unquantified in-kind donations just from, you know, working with the lab and with things we were able to leverage from within our Program.

That is -- I mean, it doesn't -- like in the context of a budget that is not very much money, but one of the things that is true about the Biomonitoring budget is we only have staff paid for. There is no operating expense money in our budget and so we have been reliant on CDC and other extramural funding to cover those costs.

PANEL MEMBER SUÁREZ: So what's the total -- so you said about a hundred thousand or so per site.

DR. WU: Um-hmm.

PANEL MEMBER SUÁREZ: What's the total budget for the -- per site?

DR. WU: That's hard to answer, because I -- it's

really -- you know, we're using a lot of our staff time, both at the lab and our epi staff. And so I'd have to give that some more thought. But it does consume our staff pretty much year-round on a constant basis to get those regions up and running, both the planning and then the actual, you know, participant recruitment and management of those field sites and then, of course, the analyses afterwards. And I would also say that running of CARE with the staff that we have now, it consumed more than a hundred percent, which meant that we weren't able to do things like analyze the data and get that ready for publication.

And, you know, it's -- that's what I was referring to in one of my slides, I mean we're planning for over a hundred percent of our capacity, and so it's not really sustainable in a staff management point of view either. You do it, because we really wanted to get this done, but we're so easily derailed, because we are -- we're stretching people -- we're stretching people too much. So I can't give you a number assessment, but it does consume our entire staff to get those regions operational.

PANEL MEMBER SUÁREZ: Thank you. Yeah, I mean, what I'm trying to get at is given the known amount that -- in dollars that needs to be reduced, what would

be -- what would be some of the more straightforward ways to save money, right? So the ones somebody once proposed are tacking on -- kind of relieving the whole participant recruitment piece and collection of biospecimens through other existing programs within the State or partnering with other institutions, be those HMO, or academic units, or whatnot, and whether that, of course, makes sense given how the Biomonitoring Programs have been structured over time.

But it's -- I mean, that's one of the ways to do it. The other one is, of course, reducing the number of target chemicals. And that's the other point that Jenny made, which is an interesting one. How much more are we providing beyond -- like information are we providing beyond NHANES or what could we actually start trading off and perhaps relying on NHANES information for some of these things and then prioritizing other things? So I guess there are slightly complex ways to look at cost cuts ultimately.

DR. WU: Yeah. I mean, I think those two different scenarios are quite different. So if you -- if we worked with a Kaiser or a health management organization, we would be able to reduce our field cost, because we wouldn't have to have, you know, phlebotomy and sample management. On the other hand, our staff would

have to be very involved with following up and enrolling participants. And that's -- that is an enormous effort.

If we went with a biobank kind of scenario, that is -- is much simpler. I mean you are just selecting samples and, you know, there's some administrative effort, but there's not a lot you have to do on the sample selection and procurement side of things.

The biobank samples and -- when we're talking specifically about GDSP, they're only serum, but we could do PFAS work. And I guess I would say that we don't know what our difference are -- differences are from NHANES until we look at them. And we certainly have run into analytes where we don't know if the difference is because we're in California or if we have a particular cohort. And until we have a California-wide baseline, we really can't determine that.

But with serum, we could do PFAS, we could do non-targeted screening, because some of the -- some of the complications of returning non-targeted assessment results to participants, they go away when you're doing biobank samples. You don't return those results. So that might get away from the kind of thought that maybe we don't need to be doing NHANES -- repeating NHANES work.

I am unaware of biobanks that are -- that are representative that have more than serum, that have blood,

serum and urine. I know there's some private biorepositories that collect samples for medical research, but they're not representative.

And so, I mean, actually that's a question maybe I'll turn around to the Panel, if you're aware of other biorepositories that we could look into that would get at -- that would be similar to biobank that would have other media available?

CHAIRPERSON SCHWARZMAN: Ulrike, do you have another comment or an answer to Nerissa's question?

PANEL MEMBER LUDERER: This is -- it's sort of a question to Nerissa's question, which is the Program a while ago worked with the newborn -- the blood spots from the screening -- the Newborn Screening Program. I mean, that -- would that be a possibility? I know it's a very small sample, but there were some promising results presented to the Panel about that some time ago.

DR. WU: Yeah. I guess maybe one of the -- I don't know if the lab folks are on and they could speak to the methodologies available to us for newborn blood spots. I guess I also have questions about how they're collected and what they might be exposed to. There's less control over that than there is over a prenatal serum sample. But certainly that does cover 90 percent of newborns. And so it's -- it's a great cross-section of the population. So,

yeah, I think both of those -- both of those banks of samples have potential.

CHAIRPERSON SCHWARZMAN: Yeah, go ahead, Jessica.

DR. NELSON: I just wanted to add that we've done a little bit with newborn blood spots here in Minnesota, mainly around mercury. And we had some really mixed results. I think it's a pretty -- and there may be lab folks who could say more. But in our experience, we had paired cord blood and newborn blood spot samples and kind of concluded that it's -- it's still very in the kind of developmental stage about how reliable those blood spot estimates would be, at least for that one analyte, just to throw that in there.

DR. WU: Interesting.

CHAIRPERSON SCHWARZMAN: I think, Jenny had her hand up. Did you have a comment here, Jenny?

PANEL MEMBER QUINTANA: Yeah. I guess you've been talking about kind of population-based existing samples. But there could also be a role for existing -- other existing samples. And I mentioned the California Teachers Study, just because that's all I can think of at the moment.

But I don't know, does UCSD - I'll say Ricardo - have a Million Genomes Project, or whatever it is, where they're collecting blood or something from people. And

there's other projects going on. And the advantage -- even though you might give up geographic variation, you might have extremely well characterized people in the study with lots of information about them.

So I was just wondering if we perhaps should just kind of think about those kind of things as well, even though obviously it's great to have a -- 90 percent of all the people in the state participating in a program would be ideal.

PANEL MEMBER SUÁREZ: Just as a brief --

CHAIRPERSON SCHWARZMAN: Oh, sorry. Go ahead José.

PANEL MEMBER SUÁREZ: I don't know if that was a question which was specifically directed to me, Jenny. But a couple of things that do come to mind, at least from the UCSD side, and one of them is the milk biobank, which is actually nationwide and there's a big proportion of the participants too are within California, so that could be one of those.

There's another project which is interesting with Los Angeles. There is also a placenta bank that has been growing pretty substantially since it's -- it's been growing -- the program has been doing really well. And so, you know, with all these things kind of coming back to generalizability or how representative the samples are,

that's something that would need to be, of course, discussed and analyzed depending on the case. But I'm sure that there -- there are a lot of different biorepositories throughout this state that may have some sort of a representative way to characterize exposure of the population about which I think should be something worth looking deeper into.

When I came, I was looking -- of course, there's the -- the partnership that existed between -- with Kaiser in Central Valley, which I think -- I guess that would be my question back to California Biomonitoring, how did that partnership work? Was it a pretty straightforward process, you know, with the caveat that, of course, people enrolled -- people that do have health insurance are not representative of the whole population, you know? They can (inaudible) --

MS. HOOVER: Actually -- sorry, José, I just want to chime in before we go too much further down that road, we have two comments that have been waiting from Amanda and from Kathleen. So Meg, I just wanted to make you aware of that. José, go ahead and finish up what you were trying to say.

PANEL MEMBER SUÁREZ: That was it. That was the last question.

MS. HOOVER: Okay. Well timed then. Why don't

we hear from Amanda and Kathleen.

CHAIRPERSON SCHWARZMAN: (inaudible) Sara, that José was posing a question. Did you -- is there a --

DR. WU: Yeah. It was a question about Project BEST and how -- how that partnership worked and whether it's something that could be expanded?

Jennifer, do you want to respond to that? This is sort of a continuation of what you started to say this morning.

DR. MANN: Yeah. I think there's a lot of promise with BEST. I don't know what the expenses were like for doing BEST. It wasn't free for sure, but there were a lot of advantages from the field office perspective and also they did more of a quota sample in my mind, but we could do a probability sample. We'd still be stuck with some sort of regional look. They did focus on Central Valley, but they also could have focused on the Bay Area, and there's also Kaiser in Southern California.

And they themselves have done a lot of reports using CHIS data comparing their population to other insured populations and uninsured populations. And they do fairly well. They're more -- they have a higher rate of employment. They're missing people from the lower SES extremes, so it's not a perfect representation of California, but it's not horrible.

CHAIRPERSON SCHWARZMAN: Thank you for that.

Let's go to Kathleen.

DR. ATTFIELD: Hello. I was just going to pose a reminder that with some -- with banked samples and using the like GDSP samples, we're probably losing the ability to ask any exposure questions from those samples. And, you know, again, those weighing of priorities of what we want to learn from the particular samples we have.

Thank you.

CHAIRPERSON SCHWARZMAN: Thanks for that.

Marley, do you have another question from the audience?

MS. ZALAY: Yeah. There's a question from or -- and a comment from Amanda. I'm wondering, Amanda, if you want to just verbally state it or would you like me to read...

MS. COSSER: Yeah, sure. Sure, I can just read it. So, Nerissa, this won't help you right now, but I just wanted to give you a little food for thought. So our statewide surveillance project we actually added a question to our informed consent saying, you know, check this box, sign here if you agree to have your samples stored for future studies. And we were explicit. We said that their results would not be returned to them. But now we have this repository basically everyone said yes that

we could store their remaining specimens, so whole blood, serum and urine for any future studies. That we haven't decided what we would do with them or if we would allow other -- others to come to us.

Like the Dartmouth Toxic Metals Superfund Research Program, like they were a little interested in what they could potentially do with our specimens as they work on their next grant application. So we haven't thought through the details of how we would vet an outside entity testing our specimens.

But it was just a thought. So, you know, you'd only be able to capture the exposure questionnaire. You know, ask those questions based on what is known what you're thinking about looking at. You know, but in the future, you wouldn't be able to have those specific questions for those specimens, but you would at least have the specimens to be able to do the surveillance on. Depending on the time frame and what you're looking for, you know, some analytes are only stable for so long even when they're, you know, frozen at a very low temperature.

But it was just a thought as you're like working on your planning phase, perhaps you could write something like that into your informed consent where you'd be able to store the specimens. So as other questions arose, you could then go back to them.

DR. WU: Hey, Amanda, thanks for that. We actually do have that on our informed consent and a very high percentage of participants opt into that donation. A few of them ask for us to destroy their samples right after the primary -- the primary analyses are done. So we do have quite a large repository in our freezers of samples collected, not only through CARE, but through our previous studies that have been conducted since 2009.

One of the issues for us with going back in time to look at new analytes is that we are obligated to return results, if we have individual results available to us. And that poses questions for, you know, our participants, what will participants do with this information if 10, 15 years later they get these results based on their sample collected in 2015. Is that helpful to participants? Is it potentially stressful to them?

There's also an effort that would be -- that I think we should undertake to confirm if participants are still at the addresses we have. So it isn't without some difficulty that we would be able to do that. And we'd want to think through I think the -- kind of the participant ethics of going back retrospectively to look at their samples.

We do have the samples and we have thought a little bit about pooling samples and maybe looking at

demographics over time or exposure in larger demographic pools over time.

But even that hasn't been spelled out in our informed consent. So that's something that we've kind of been thinking about for going forward.

MS. COSSER: Is there any way to go to your government and to talk about that about the reporting back feature and changing that?

DR. WU: You can open legislation, but that is a difficult and -- I mean, once it's open, there are lots of things that can be edited out of it, so I think it's a dicey proposition.

MS. COSSER: Sure.

MS. HOOVER: Yeah. And this is Sara. I mean, we have a really firm commitment to that, so that's not something that we would propose to change, at least not in my view. It's one of our key aspects that we're very proud of in terms of transparency.

CHAIRPERSON SCHWARZMAN: We have time for maybe one other comment or question.

Veena.

PANEL MEMBER SINGLA: Yes. I just wanted to raise the wastewater monitoring aspect again. I know we talked about it a little in the morning, that it's not only a biological sample, but it certainly does contain

biological samples. You can measure urinary metabolites in wastewater, and, you know, there's -- all of the different approaches we've been discussing have various pros and cons. And I would say the strengths of that approach is the ability to get large geographic coverage and a fair level of geographic resolution, depending on how the wastewater systems are set up, and to be able to look at the temporal trends moving -- moving forward to be able to identify emerging concerns, which I know this is -- that is something the Panel has expressed concerns about in the past.

So anyway, just wanted to raise it again, because I think in terms of costs and what you can -- the kind of information you can get out of it, there's aspects that make it worth considering.

CHAIRPERSON SCHWARZMAN: We do have just a couple more minutes, literally before we move on to the final session, if there's any final comments. A reminder that the last thing of the day is an open public comment session. If -- so -- so keep those for later.

And José.

PANEL MEMBER SUÁREZ: Just -- I just thought of one more potential source, which would be pretty representative, which is the All of Us Study, which is a really large nationwide study. And we have multiple sites

across the state that are collecting multiple biospecimens as well.

Besides that, I think it would be useful, I think, for us as a Panel to -- maybe to receive a few different scenarios from the Biomonitoring Program as to what are the different cuts that need to be done to the Program, knowing that, you know, this much of the budget needs to be cut, which means, you know, if you're starting to go down savings or -- yeah, trying to save money through not recruiting participants versus through reducing the number of chemicals that are being assessed, or the frequency of when all of these things are done, I think it would be informative, because right now, at least for me, it is not clear how much of the budget needs to be saved, in other words, how much of the Program needs to be cut.

And so I know it may be easier -- it may not necessarily be easy to come up with something like that. But at least having some scenarios of something that we could be a little bit better informed, as to what we would be recommending.

MS. HOOVER: This is Sara and I'll let Nerissa comment. But I think what Nerissa was trying to convey is actually it's not a -- you know, it's more a question of what do you want us to prioritize? That's what we'd

really like to hear. That's what the discussion session questions are focused on. And that's because we -- we pour in so much in-kind work that we don't have to cut, so it's a little bit more complicated than just analyzing a budget.

But Nerissa, maybe you want to chime in after me and see if you have -- you know, of the discussion questions, are there things you'd like the Panel to just quickly run through and weigh in on. I suspect we'll have a little bit of spare time in the next half hour, so I think we can go over a bit.

DR. WU: Okay.

CHAIRPERSON SCHWARZMAN: If I could jump in and echo something that José said, because what I heard was a little bit different than a request for like laying out the budget. And, José, you can tell me if I'm right, but, you know, I think we -- today's discussion has sort of focused on what we would recommend that the Program prioritize. And I've heard about prioritizing the ability to make comparisons over time and along the way not entirely losing the ability to identify and target some specific potentially high risk populations or those that wouldn't be captured with a geographic limitation.

But I think what I kind of heard José request was in light of that and in light of the budgetary limitations

that the Program staff understand better than we do in a concrete way, would it be possible to come back to the Panel with a couple of different scenarios that reflect the priorities that we've discussed today?

And it doesn't -- maybe without -- it doesn't have to be very specific budget numbers. But like given the resources that we have, we could go about accomplishing those priorities in these three ways, say. Is that kind of --

MS. HOOVER: Yeah. No, I heard that. And certainly I think we could try to get more specific options laid out. Nerissa did lay out some general options. And that's what I was trying to say is -- I don't know Nerissa, did you get clarity on like what are the key priorities? I'm not sure. You know, I wasn't taking detailed notes. Certainly, we have the transcript, but did you want to hear more about, you know, what are like say each Panel member's top priority in terms of these choices that we've put before them?

DR. WU: Well, I actually think Meg gave a nice synopsis of the things that have risen to the top. I mean, I will -- if SGP panelists have particular things that Meg didn't capture in her synopsis, that would be good to hear. But I think what I was looking for in this discussion would be, like if you said absolutely not, we

can't stop covering the entire state. That would be something that's very informative. But what I wanted to do from this discussion is to start narrowing down what are the scenarios we should really be focusing in on and what can we do? And now given sort of a narrower set of priorities, we can dig a little further into, you know, what are the actual costs of working with a biorepository? Are there other concerns that we have about working with biorepositories? And maybe there a different source of samples that help solve some of those things.

But it gives us a little direction where we should be putting our efforts into -- into kind of scoping out what a study might look like. So helpful. I think we'll have to revisit this topic probably a number of times.

And it's -- I mean, it is what our intention was this year. And actually assisted by COVID, we are not out in the field, so it is -- it's a good time for us to be kind of putting a pause on this and thinking through what our intentions are, what our priorities will be.

CHAIRPERSON SCHWARZMAN: Jenny.

PANEL MEMBER QUINTANA: I was just thinking about what Sara said, that she heard several very concrete suggestions, but people haven't really weighed in on them. For example, was it Tom I think that said we should have

an urban site and a rural site minimum. And so it might be interesting to kind of layout some concrete options that are being discussed and then have people weigh in whether we should think about doing that or not. We haven't also discussed which are our priority chemicals to my knowledge. And I'm sorry, I missed the morning session. But that's another issue maybe people should weigh in on what are the priority exposures or priority chemicals.

CHAIRPERSON SCHWARZMAN: I would then just step in and echo one of the things that you said, Jenny, that I think does touch on that, which is to -- without naming specific chemicals necessarily in this moment, because it's too much detail for us to go into as a group, but you asked kind of what makes California special? And I think that's a really nice screen to look through our lens to look through at the chemical list and to avoid spending our energy and resources on repeating data that will replicate what's available from NHANES.

So I just wanted to echo that point and, Sara's request for Panel members to chime in and support key priorities.

CHAIRPERSON SCHWARZMAN: Other additions to this sort of short list of priorities that's kind of rising to the top at the end of this discussion?

It sounds like it would be -- any of -- any clarity there is helpful for the Program.

Julia and then Veena.

DR. VARSHAVSKY: Hi. Thank you for the opportunity. I just wanted to lift back up what I heard Veena just say. Because the second time she brought up wastewater, it kind of clicked in my head of the value of that potentially, thinking of it as a biomonitoring -- yeah, biospecimen type of sample, but on a community level, rather than an individual level and possibly, using that to try to fill the gaps between -- or the gaps around being able to monitor the California population over time and across regions. And I just thought that that's maybe something -- a priority that's worth including in the scenarios if the regional and temporal monitoring or surveillance isn't as possible with individual level samples. I thought that was a really interesting idea.

CHAIRPERSON SCHWARZMAN: I think it's probably on everybody's mind that that's certainly something that's being used in the -- sort of from a -- from an infectious disease perspective in monitoring the spread of COVID in some communities, like college campuses. And I think they might be closer to the sort of raw sewer end than the wastewater end, but it's another place to look for models of how that kind of community level surveillance is done.

They're looking for a virus. That's different, but there might be some applicable models.

Veena, you had something else to add and then I see Oliver.

PANEL MEMBER SINGLA: Yes, I just wanted to kind of highlight from what I said previously in terms of the input from the environmental justice listening sessions, like that to the extent the priorities that emerge from those listening sessions are applicable to the questions here to consider -- to consider that input in the thinking about the priorities.

CHAIRPERSON SCHWARZMAN: Great. And Oliver had a point.

PANEL MEMBER FIEHN: Yeah. In terms of the wastewater plants, I'm not a hundred percent clear if it has been shown that it's a good source for these compounds that we're interested in, right. So I know that it's like been used, for example, for opioids. It's been used for (inaudible). It's been used for several sources. But like, you know, are there differences in PFAS? Are there differences in other types of compounds that really reflect what's going on in the community? That I don't know. I haven't seen those papers. Yeah, so...

CHAIRPERSON SCHWARZMAN: Eunha.

PANEL MEMBER HOH: I think wastewater or sewer

monitoring thing it's a really emerging area. I think Oliver comment is pretty right that -- I think the field is moving on, I think, but the current -- the current technology, current -- the evidence is sort of like it's a -- probably like a -- very in the beginning, I think, especially for those environmental contaminants, body burden, you know, biomonitoring related. So there's a lot of -- kind of things have to be figured out. Like, you know, how many people are represented there, you know, all kind of normalization stuff. So it's definitely -- it's -- the field is moving along and it's a really cool area, but I think it's something that currently the limitations are there, yeah.

CHAIRPERSON SCHWARZMAN: Is there anything sort of for the Program's sake that -- that you haven't heard kind of reflected in this final conversation that felt important to you that you would elevate as a priority for the Program in surveillance?

In that case, I think we should, Sara, with your permission, move on to your section on topics for 2021 SGP meetings.

MS. HOOVER: Yeah, sure.

CHAIRPERSON SCHWARZMAN: And I'll just say that we have at 4:15 open public comment. And so, if there are issues that are occurring to attendees that haven't been

aired yet, there's a final moment for that at the end, final 15 minutes for that.

So, with that, I want to turn it back over to Sara. Sara Hoover is the Chief of the Safer Alternatives Assessment and Biomonitoring Section at OEHHA. And she'll be discussing the possible topics for upcoming SGP meetings in 2021.

(Thereupon a slide presentation.)

MS. HOOVER: I just -- can you see my screen or not, because I --

MS. ZALAY: Yeah, we can see your screen.

MS. HOOVER: The slide show is not starting for some reason.

MS. ZALAY: Could you try clicking one more time on from beginning.

MS. HOOVER: All right. There we go. Thank you. That took like four tries.

Okay. Well, this has been a fantastic meeting. Really great. Thank you to all the guest speakers. And as per usual, in November, we turn to -- actually, I can go ahead and share my webcam too following the instructions.

We turn to possible topics for our next year. So this is just a really quick overview and we welcome comments emailed to us after the meeting, if you want to

think about it some more.

Let's see. Okay. This is not responding. There we go. So we were successfully able to set all of our 2021 meetings. We're still planning to do all of those via webinar. We'll see how things develop later next year, but that's our plan for now. So they're going to be on March 8th, July 16th, and November 8th.

--o0o--

MS. HOOVER: The March meeting topic has been set. That will, as usual, have our Program update and then we'll delve into QACs again, but this time as potential priority chemicals. We're identifying guest speakers to address some of the analytical issues, which come -- kind of come to the forefront when something is considered as a priority for measurement. We also have had quite a bit of interest from stakeholders and there will be a QAC stakeholder presentation. And then per usual, we'll have a presentation from OEHHA on our potential priority document.

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MS. HOOVER: For July -- so July and November are much more open and we welcome your thoughts. For July, some of the things we're considering would be presenting some additional analyses of data from the East Bay Diesel Exposure Project. Those analyses are still ongoing.

Julia mentioned that we might consider trying to measure a broader set of PAHs in our AB 617 study. Some of you who've have been on the Panel for a long time may recall that many years ago I brought this up to look at a broader set or even the class of PAHs, because right now we only have a small number of PAHs based on some of the PAHs that CDC measures. So that would be a possible chemical selection item.

And then we also thought it might be helpful to delve more into biomarkers of effect. This is something that we've also talked about as a Program and with the SGP for many years, but we haven't had a session on biomarkers of effect, so we thought that could be interesting and useful as we embark on the targeted biomonitoring study.

--o0o--

MS. HOOVER: For November, we're thinking about -- by then EHIB analysts will have had more time to sort of integrate the results from CARE -- the CARE Study so far across the regions. And then we thought it would be helpful to delve more into the CARE Study results for PFASs. We're also aware of other studies going on in California that could be interesting to invite guest speakers to present on.

--o0o--

MS. HOOVER: Now, the -- this slide -- what I did

for this slide was I started picking out some of the most recent concepts about chemical selection options and then I actually delved back into some of our past work, partially on the suggestion of the Safer Consumer Products program. They gave me some ideas. So I just went back through and the categories that each of these chemical groups are in, that's based on the status of what the Panel last told us.

So you may recall that neonicotinoid pesticides were already screened and the Panel did ask for a document on that. And it just has been a resource and time issue that we haven't done that yet.

We also did a preliminary screening of classes of chemicals used in UV applications. And the Panel did express interest in these two classes to go in deeper and consider them as potential designated chemicals. And then something that I've also mentioned in the past as a possibility is to potentially look at PCBs as a class. There are still some non-legacy PCBs that we do not have captured, because the only PCBs on our list are those measured by CDC.

Fragrance chemicals continue to be important and interesting. We have a couple of categories of fragrance chemicals on our designated list. I've chosen one that could potentially be brought forward as a potential

priority. And then, of course, we're wide open on preliminary screening. So I've mentioned before the concept of fluorinated compounds other than PFASs. Those still are of concern to many people in California.

Other classes of chemicals used in UV applications that we didn't already capture in our prior screening, also additional classes of fragrance chemicals. The only other thing I put on here was many, many years ago, we did a preliminary screening of alternative plasticizers. Some of those phthalate alternatives, for example, are now on the list, because CDC measures a couple of them. It might be interesting to go back and look -- look again. That was about -- I think it was about eight years ago or -- no, ten -- more than ten years ago I think that we did that screen.

So, here's some possibilities, but, of course, if you have other emerging chemicals of interest, we'd love to hear about that.

--o0o--

MS. HOOVER: And as I said, you can comment now. We have a little bit of time or you can always email possible topics to the Biomonitoring California email.

So now I'll turn it back to Meg and see if there are any comments from the Panel or the audience on these ideas.

CHAIRPERSON SCHWARZMAN: Thank you, Sara.

Panel members who want to weigh in on any of the ideas.

Oliver.

PANEL MEMBER FIEHN: I really like the idea of effects -- of studying the effects. I always wondered why we only look at levels and never on effects, so I really would like to discuss that a little bit, as much as possible, of course.

CHAIRPERSON SCHWARZMAN: As Oliver says that - and we'll go to Tom next - it occurs to me that if some of the major expenses of the studies are about recruitment and, you know, obtaining samples, then adding a biomarker of effect when you already have the -- the participants is a relatively high yield for low expense addition to a study, it seems to me.

Tom.

PANEL MEMBER McKONE: I just want to add concurrence. I think that's a great -- I perked up when I saw that also. And I thought, you know, it's the same points, we got -- you've got the bio -- you've got the blood or the urine. You've got the exposure. Why not -- why wait five years to then come up with a hypothesis about effect. You might have what you need right there to put the two together. So it's kind of a nice opportunity

we shouldn't miss. And I'd certainly like to learn more about it.

CHAIRPERSON SCHWARZMAN: Jenny.

PANEL MEMBER QUINTANA: At the risk of being against this chorus, I actually would like to speak against measuring effects, because the amount of careful epidemiology you have to do when you're measuring an effect that has multiple sources is a much higher level of questionnaire work that you have to do.

I mean, for example, we're studying thirdhand smoke, and tobacco residue, and house dust and kids exposed to that. And we were just discussing this issue recently, because the people have lots of sources of exposure, which might lead to an effect like let's say oxidative damage in DNA or something. And I think that -- I would vote for staying on the exposure side, which is extremely valuable in my mind just to throw that out there.

MS. HOOVER: Thank you. Thank you, Jenny. I'm just going to chime back in and clarify one thing. With AB 617 and with our multiple funding sources for that, we're actually running our biomonitoring study under the purview of Biomonitoring California, which is an exposure-only program. We have additional funding and we have sort of a robust hypothesis that some of these

biomarkers of effect, along with biomarkers of exposure for air pollutants, are very valuable. So that's really the context of that discussion. It's not a wide-open consideration of biomarkers of effect for Biomonitoring California studies in general. So that was what -- that's what the July focus would be.

We have talked about this in the past with the Panel. And it was pretty much urged to keep the focus on exposure as -- as Jenny has reiterated. So just wanted to clarify what that July topic was.

PANEL MEMBER QUINTANA: Well, thank you. That's what I get for missing the morning session. Sorry.

CHAIRPERSON SCHWARZMAN: Veena.

PANEL MEMBER SINGLA: Sorry to be a broken record here on the wastewater topic, but I really do think it would be helpful for the Program to understand the strengths and limitations of the approach. And I agree it's emerging, but there are people -- folks researching environmental chemicals in wastewater and sewage sludge. And I think it could be an interesting topic for a meeting for us to hear from the experts and researchers, and think about, you know, if and how such an approach might be useful to the Program.

CHAIRPERSON SCHWARZMAN: Any final comments from the Panel and we will go to public comment. So I have

Eunha and José and then we'll open up for public comment.

PANEL MEMBER HOH: I'm kind of wondering if we have to -- some sort of -- like invite some people who are running the biospecimen kind of center or biorepository centers in the -- in institutions, you know, that can kind of introduce, you know, what they're collecting, you know, what they -- you know, what -- what they're measuring. You know, probably a lot of Omics kind of stuff going on, something that we can kind of, you know, learn from what they are doing that can be, you know, a good idea to have a partnership, you know, with them.

CHAIRPERSON SCHWARZMAN: And, José.

PANEL MEMBER SUÁREZ: My comment is about biomonitoring, in addition to what could be another potential addition. And coming back to the agricultural side, which California is, of course, one of the core states in the nation, especially wintertime, is measuring the most commonly used pesticide worldwide and in this country, which we're not measuring, which is glyphosate. So there are a lot of health concerns with glyphosate, some issues with potential carcinogenicity, more and more reports.

And it's something that, at least based on the U.S. Geological Survey data, the latest they have is 2017 is that sure enough we are using it in California quite a

bit. So that would be another thought.

MS. HOOVER: José, this is Sara. I just want to clarify, so glyphosate is on our list. So you're talking about discussing possible studies around glyphosate, is that your proposal for a topic?

PANEL MEMBER SUÁREZ: No. Well, I didn't see it as a list I guess on the website. Is it --

MS. HOOVER: It's on. Yeah, it's been listed.

PANEL MEMBER SUÁREZ: I looked for it, but I couldn't find it, but I trust you.

MS. HOOVER: Oh, I'll send it to you.

PANEL MEMBER SUÁREZ: Okay.

MS. HOOVER: Yeah. We did the entire class of organophosphorus pesticides of which glyphosate is one member.

PANEL MEMBER SUÁREZ: Hmm-um, no, glyphosate is not an organophosphate.

MS. HOOVER: I didn't say phosphate. I didn't say phosphate -- organophosphorus. So we specifically broadened the class to be able to capture glyphosate. I'll pull up the document and send it to you.

PANEL MEMBER SUÁREZ: Got it. Thank you.

CHAIRPERSON SCHWARZMAN: Was your question, José, about designating it or prioritizing it or about designing studies around it?

PANEL MEMBER SUÁREZ: No, for designating and prioritizing, but if it's been already added, I wasn't aware of that.

CHAIRPERSON SCHWARZMAN: Great. Okay.

All right. In that case, we will wrap-up this discussion and move on to our final public comment period. It's an open public comment period. And you can feel free to address any topic from -- that's relevant to Biomonitoring California. As a reminder, attendees can submit written comments or questions via GoToWebinar question feature or by email to biomonitoring@oehha.ca.gov. And you can also raise your hand or indicate that you have a question.

So, Marley and Stephanie, do we have any questions at this point?

MS. ZALAY: Yes. This is Marley Zalay. There's a question from Topher Buck at DTSC for Sara. Would Sara please say more about possible biomonitoring for non-PFAS fluorinated chemicals? What classes or types of chemicals or specific chemicals might be included in such a study?

MS. HOOVER: Sure. So to clarify, I wasn't talking about a study. I'm talking about looking at exactly that question, which is to look at -- so, you know, we have the entire class of PFASs, which is a type of fluorinated compounds, but there are other fluorinated

compounds of interest, and we talked about those in a prior meeting. And Eunha has looked at at least one of those. So the solvent -- let's see, it's parachlorobenzotrifluoride, is that right, Eunha?

PANEL MEMBER HOH: Yes.

MS. HOOVER: Yeah. Thank you. Okay. I just wanted to make sure. It's a solvent. It's widely used. It's of concern. It's not a PFAS. So this is something that we would do, what we call, our preliminary screening on, which is actually to look at what categories of fluorinated compounds might be of interest and of concern in the environment.

MS. ZALAY: And this is Marley Zalay again. There's a question from Jessica Nelson addressed to Brian Wells. Jessica, did you want to verbally state this question or would you like me to read it?

DR. NELSON: Sure. Yeah, I can state it. I just -- I just really appreciated your presentation, Dr. Wells. It was really informative for, I think, things a lot of us are thinking about on the surveillance front. Not to put you on the spot, but I just was wondering if, you know, you had any reflections on biomonitoring surveillance, different approaches that have been discussed to population-based sampling today. And a specific question I had was you said looking at metrics

other than just response rates when thinking about representativeness. If you could elaborate on what some of those other metrics are and kind of what you meant by that? I'd appreciate it. I could also follow up with you later, if it's too much for today.

DR. WELLS: Yeah, I understand.

Just briefly, I guess, you know, in terms of other indicators. One that has become relatively popular, however, and does require a bit more information is something called R indicators. It is a metric used, you know, what a lot of people call responsive design, which basically looks to see, you know, how was the balance on particular attributes of the population, whether it be gender, age, race, ethnicity, and how it's balancing compared to the actual population.

But that requires having information about that. And so there's -- not every circumstance can use that, but that's a -- one that's becoming increasingly popular and increasingly well liked, just because it is actually specifically targeted at let's get those gender, and age, and race in line with what the -- what we see and what we expect to see in the population. So that is an example of another indicator related to response that's gaining in popularity amongst survey methodologists.

In reference to your general question, I've been

absorbing a lot today. I don't know that I can process all. But if anyone has further questions, I'm always happy to discuss offline.

Thank you.

CHAIRPERSON SCHWARZMAN: Go ahead, José.

PANEL MEMBER SUÁREZ: Thank you. I just briefly wanted to go back to the discussion about the intervention study that's being planned and bring back this -- the discussion about having a control group.

So just some additional thoughts in that regard. So really depending on what would be the objective of this particular study, it may or may not be necessary to have a control group. So if this study is aimed at more -- being more of a feasibility study, whether the -- this particular intervention can be deployed or done, then under those cases, it may be fine to not have a control study. But if the whole point of the study is to find whether the intervention works or not, in that case, I would really urge California Biomonitoring to consider really adding a control group to be actually able to -- to see if this intervention was successful.

CHAIRPERSON SCHWARZMAN: Any other final comments, questions or contributions before we adjourn the meeting?

And I'll do one last check-in with Marley to see

if there's anything else that we should consider.

MS. ZALAY: No other questions.

CHAIRPERSON SCHWARZMAN: Okay. Then in that case, I will do my couple of announcements. That a transcript of this meeting will be posted on the Biomonitoring California website when it's available. The next SGP meeting is on Monday, March 8th, 2021 and will be held also as a virtual meeting.

I want to thank the Panelists and all the presenters today, the attendees, and as always the Program staff, for your work on the Program and also for all the work it is to make this meeting possible. And with that, I will adjourn the meeting.

Thank you.

(Thereupon the California Environmental Contaminant Biomonitoring Program, Scientific Guidance Panel meeting adjourned at 4:28 p.m.)

CERTIFICATE OF REPORTER

I, JAMES F. PETERS, a Certified Shorthand Reporter of the State of California, do hereby certify:

That I am a disinterested person herein; that the foregoing California Environmental Contamination Biomonitoring Program Scientific Guidance Panel meeting was reported in shorthand by me, James F. Peters, a Certified Shorthand Reporter of the State of California, and thereafter transcribed under my direction, by computer-assisted transcription.

I further certify that I am not of counsel or attorney for any of the parties to said meeting nor in any way interested in the outcome of said meeting.

IN WITNESS WHEREOF, I have hereunto set my hand this 2nd day of December, 2020.

JAMES F. PETERS, CSR
Certified Shorthand Reporter
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